





Financiación de Estados Unidos para la Investigación en Salud: El Programa de los National Institutes of Health (NIH) y otras iniciativas internacionales.

Universitat Politècnica de València, 15 de Junio de 2017



Índice:

- 1.- El Programa NIH: Descripción, presupuesto y tipos de convocatorias. Características, requisitos y documentación. Ejemplo práctico.
- 2.- Gestión y justificación del Programa NIH.
- 3.- Otras convocatorias internacionales de interés en el ámbito Salud.



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- 2.- Gestión y justificación del Programa NIH.

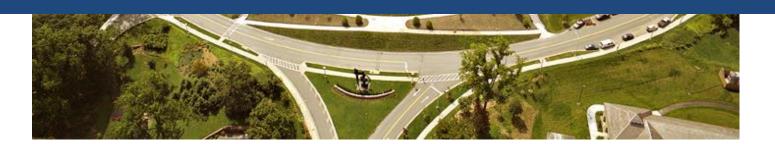
3.- Otras convocatorias internacionales de interés en el ámbito Salud.







MAYOR ENTIDAD DE FINANCIACIÓN DE PROYECTOS CIENTÍFICO-TECNOLÓGICOS A NIVEL MUNDIAL.







NCI



NEI

National Eye Institute



NHLBI

National Heart, Lung, and Blood Institute



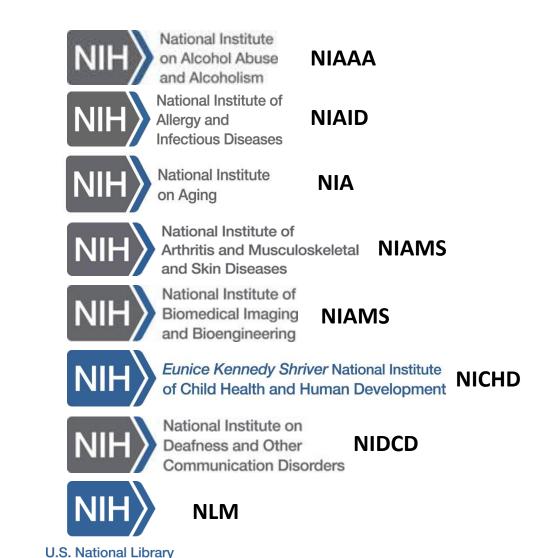
NIDDK

National Institute of Diabetes and Digestive and Kidney Diseases



NHGRI

of Medicine









FINANCIACION TOTAL POR AÑOS

Fiscal Year	Application Type	NIH Institutes / Centers	Activity Code	Number of Applications Reviewed	Number of Applications Awarded	Success Rate ²	Total Funding ³
2012	FY Total	All Institutes	Total	51.313	9.032	17,6%	\$3.811.804.254
2013	FY Total	All Institutes	Total	49.581	8.310	16,8%	\$3 513 047 712
2014	FY Total	All Institutes	Total	51.073	9.241	18,1%	\$4.494.169.749
2015	FY Total	All Institutes	Total	52.190	9.540	18,3%	\$4.300.145.614
2016	FY Total	All Institutes	Total	54.220	10.372	19,1%	\$5.025.523.010







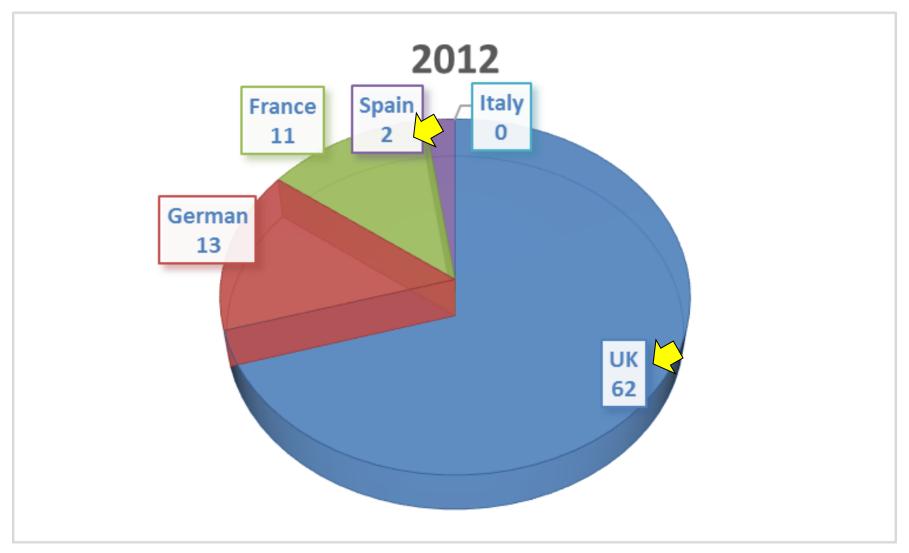
FINANCIACION NON-US (FOREIGN) TOTAL POR AÑOS

Fiscal Year	NIH Centres	Number of Applications Awarded	Total Funding
2012	All institutes	534	226.564.007 USD
2013	All institutes	480	232.230.209 USD
2014	All institutes	481	181.501.478 USD
2015	All institutes	481	193.005.186 USD
2016	All institutes	471	189.259.184 USD
2017	All institutes	209	73.355.467 USD

ESPAÑA COMO SOLICITANTE??

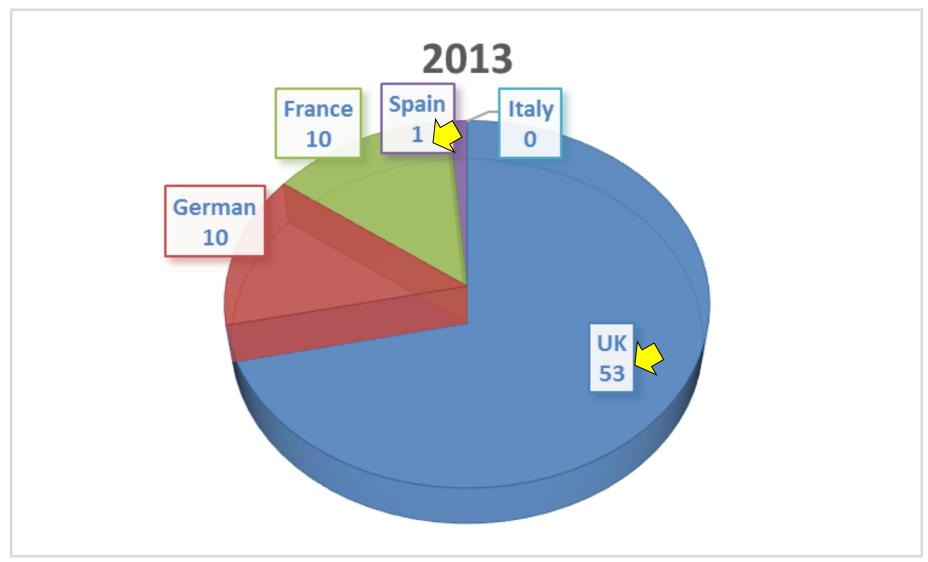






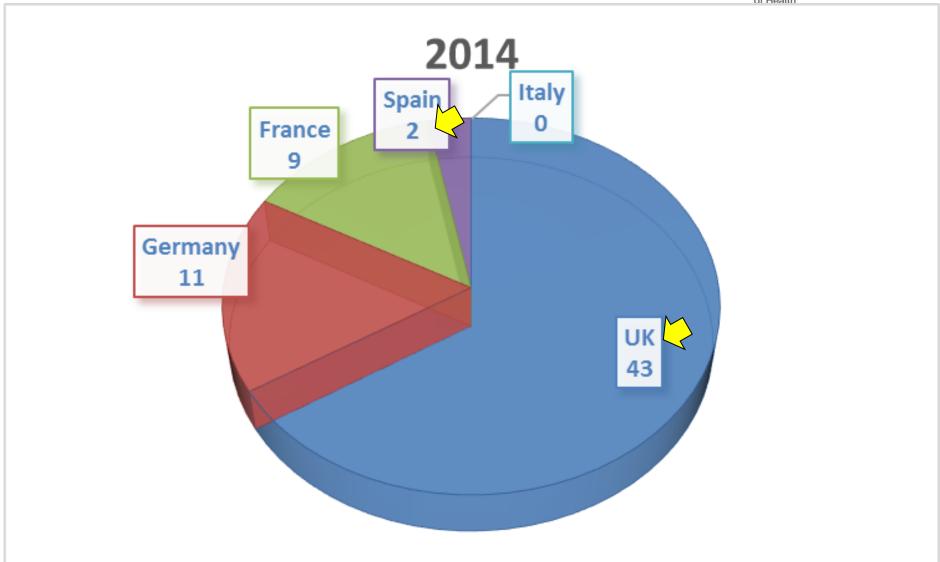










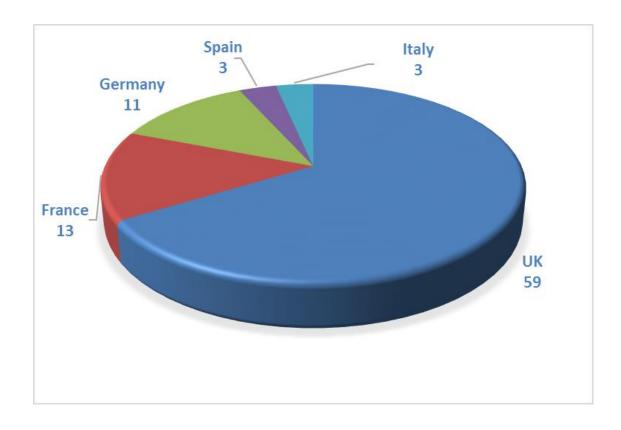


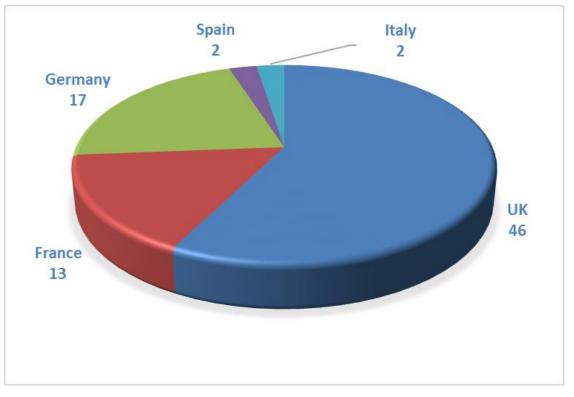




2015

2016





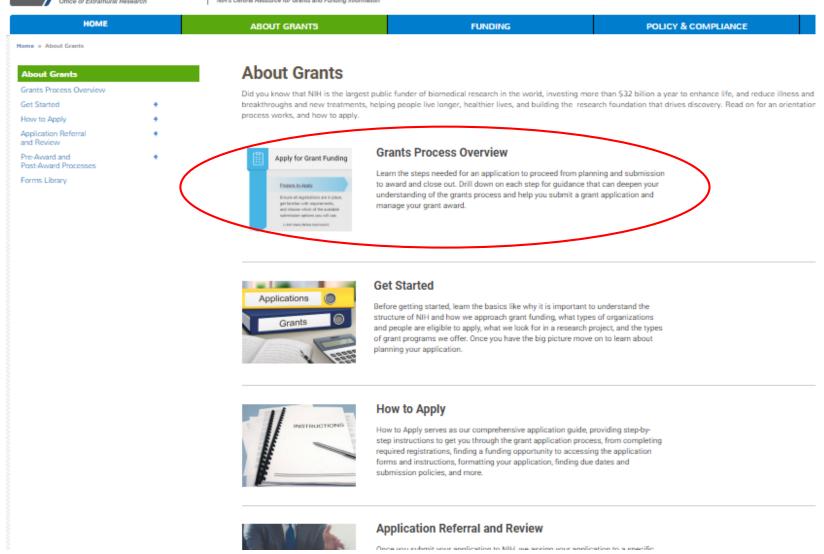






Grants & Funding

NNFs Central Recourse for Grants and Funding Information



Fuente: https://grants.nih.gov/grants/about_grants.htm.









Fuente: https://grants.nih.gov/grants/grants_process.htm.





Tipos de Grants:

RESEARCH GRANTS (R series)

NON U.S. ELEGIBILITY



FINANCIACIÓN

CAREER DEVELOPMENT AWARDS (K series)

RESEARCH TRAINING & FELLOWSHIPS (T&F series)

PROGRAM PROJECT/CENTER GRANTS (P series)





R01: NIH Research Project Grant Program (R01)

- Se utiliza para financiar un proyecto específico de investigación, es una **subvención**.
- No hay límite específico de presupuesto.
- Se requiere permiso si se va a solicitar \$500K o más (costes directos) en un año.
- En general es para proyectos entre **3-5 años**.
- Se requieren **resultados preliminares** contundentes.

R03: NIH Small Grant Program (R03)

- Subvención limitada a un **período corto de tiempo** para apoyar tipos de proyectos como:
- estudios piloto o de factibilidad, ejecución de datos preliminares, análisis secundarios de datos existentes, proyectos de investigación cortos, desarrollo de una nueva tecnología, etc.
- Hay límite de presupuesto hasta \$ 50.000 por año (Máximo \$ 100.000).
- Máxima duración del proyecto son 2 años.
- No es renovable.
- No se requieren resultados preliminares.





R21: NIH Exploratory/Developmental Research Grant Award (R21)

- La subvención R21 pretende fomentar **nuevos proyectos de investigación exploratorios y de desarrollo**.
- La viabilidad de una nueva área de investigación o de un nuevo sistema experimental que tiene el potencial de mejorar la salud.
 - Uso único e innovador de una metodología existente para explorar un área científica nueva.

Estos estudios pueden implicar un riesgo considerable, pero puede dar lugar a un gran avance en un área en particular.

- Máxima duración del proyecto son **2 años**.
- El presupuesto total no puede exceder los **\$275.000**. En un año el presupuesto máximo debe ser \$200.000.
- No se requieren resultados preliminares porque en esta convocatoria se asume un cierto riesgo, pero se

valora muy positivamente que se presenten estos resultados preliminares aunque no sean muy contundentes.





CONVOCATORIAS "PARENT CALLS"



R01: https://grants.nih.gov/grants/guide/pa-files/PA-16-160.html

R21: https://grants.nih.gov/grants/guide/pa-files/PA-16-161.html

R03: https://grants.nih.gov/grants/guide/pa-files/PA-16-162.html

EXPIRAN EN EL AÑO 2019

Con 3 fechas límite/año Ro1: 5 febrero, 5 junio y 5 octubre.

R21 y R03: 16 febrero, 16 junio y 16 octubre.





Department of Health and Human Services Part 1. Overview Information

Participating Organization(s)	National Invatutes of Health (NIH)
Components of Participating Organizations	National Cancer Institute (NCI) National Eye Institute (NEI) National Heart, Lung, and Blood Institute (NHLBI) National Human Genome Research Institute (NHGRI) National Institute on Aging (NIA) National Institute on Alcohol Abuse and Alcoholism (NIAAA) National Institute of Allergy and Infectious Diseases (NIAID) National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) National Institute of Biomedical Imaging and Bioengineering (NIBIB) Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) National Institute on Deafness and Other Communication Disorders (NIDCD)
	National Institute of Deathal and Craniofacial Research (NIDCR) National Institute of Deathal and Craniofacial Research (NIDCR) National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) National Institute on Drug Abuse (NIDA) National Institute of Environmental Health Sciences (NIEHS) National Institute of General Medical Sciences (NIGMS) National Institute of Mental Health (NIMH) National Institute of Neurological Disorders and Stroke (NINDS) National Institute of Nursing Research (NINR) National Institute on Minority Health and Health Disparities (NIMHD) National Library of Medicine (NLM) National Center for Complementary and Integrative Health (NCCIH) Division of Program Coordination, Planning and Strategic Initiatives, Office of Research Infrastructure Programs (ORIP)
	Note: Not all NIH Institutes and Centers (ICs) participate in Parent Announcements. Applicants should carefully note which ICs participate in this announcement and view their respective areas of research interest at the R01 IC-Specific Scientific Interests and Contact website. ICs that do not participate in this announcement will not consider applications for funding.
Funding Opportunity Title	NIH Research Project Grant (Parent R01)
Activity Code	R01 Research Project Grant
Announcement Type	Reissue of PA-13-302





BÚSQUEDA DE CONVOCATORIAS ESPECÍFICAS NIH



POR PALABRAS CLAVE/DISCIPLINA/ENFERMEDAD

POR EJEMPLO



CANCER



http://grants.nih.gov/funding/index.htm





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(for unsolicited applications)



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Related Resources:

NIH Funding Strategies

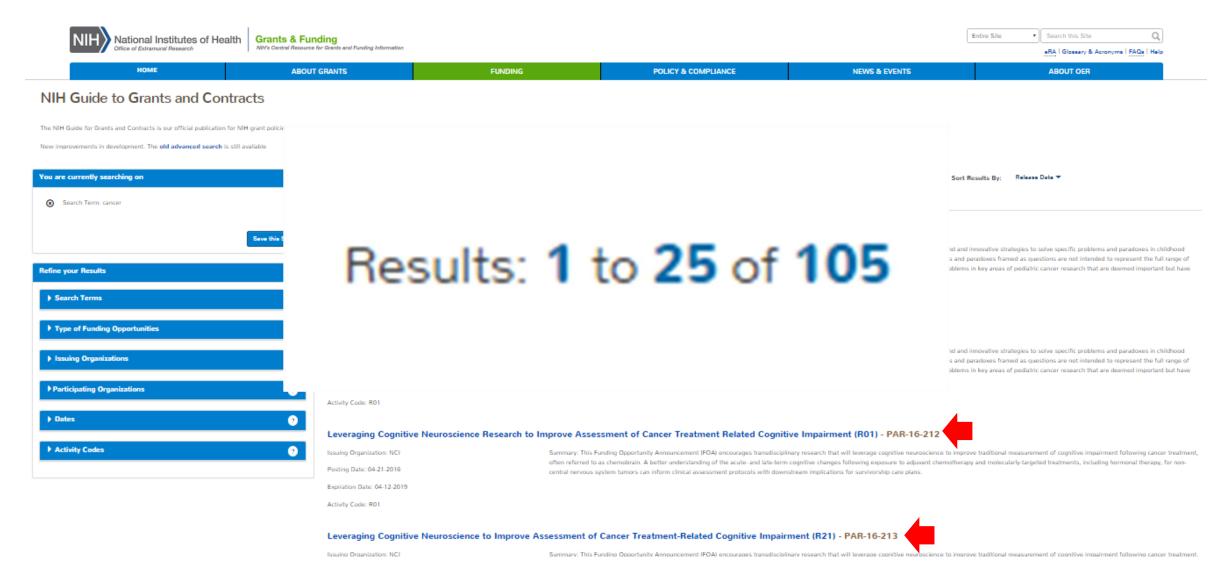
Types of Grant Programs

Find and Understand Funding Opportunity Announcements



http://grants.nih.gov/funding/index.htm









R01: Early-life Factors and Cancer Development Later in Life. PA-15-126. http://grants.nih.gov/grants/guide/pa-files/PA-15-126.html

R21: Early-life Factors and Cancer Development Later in Life. PA-15-125. http://grants.nih.gov/grants/guide/pa-files/PA-15-125.html

R03: Early-life Factors and Cancer Development Later in Life. PA-15-124. http://grants.nih.gov/grants/guide/pa-files/PA-15-124.html



La convocatoria termina en el año 2018.

Tres fechas límite anuales:

R01: 5 febrero, 5 junio y 5 octubre R21 y R03: 16 febrero, 16 junio y 16 octubre. The purpose of this Funding Opportunity Announcement (FOA) is to stimulate research focused on the role of early-life factors in cancer development later in

life. Given that current emerging evidence from limited research indicates a potentially important role for early-life events and exposures in cancer development, it is necessary to better understand 1) the early-life (maternal-paternal, in utero, birth and infancy, puberty and adolescence, and teenage and young adult years) factors that are associated with later cancer development; 2) how early-life factors mediate biological processes relevant to carcinogenesis; and 3) whether predictive markers for cancer risk based on what happens biologically at early-life can be measured and developed for use in cancer prevention strategies. Markers that predict malignancy or pre-malignant conditions would allow assessment of early-life exposures with relevant outcomes without having to wait 50 years for cancer development. Ultimately, a better mechanistic understanding of how early-life events and exposures contribute to the etiology of cancer later in life will allow for the development of effective interventions during pregnancy or early **life** that may have a profound impact on cancer prevention.

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)				
Components of Participating Organizations	National Cancer Institute (NCI) Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) National Institute of Environmental Health Sciences (NIEHS)				
Funding Opportunity Title	Early-life Factors and Cancer Development Later in Life (R01)				
Activity Code	R01 Research Project Grant				
Announcement Type	New				
Related Notices	None				
Funding Opportunity Announcement (FOA) Number	PA-15-126				
Companion Funding Opportunity	PA-15-125, R21 Exploratory/Developmental Grant PA-15-124, R03 Small Grant Program				
Number of Applications	See Section III. 3. Additional Information on Eligibility.				
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.393; 93.113; 93.865				
Funding Opportunity Purpose	The purpose of this Funding Opportunity Announcement (FOA) is to stimulate research focused on the role of ear factors in cancer development later in life. Given that current emerging evidence from limited research indicates potentially important role for early-life events and exposures in cancer development, it is necessary to better				

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Key Dates

Posted Date	February 26, 2015				
Open Date (Earliest Submission Date)	May 5, 2015				
Letter of Intent Due Date(s)	Not Applicable				
Application Due Date(s)	Standard dates apply, by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on these dates.				
	Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.				
AID'S Application Due Date(s)	Standard AIDS dates apply, by 5:00 PM local time of applicant organization. All types of AIDS and AIDS-related applications allowed for this funding opportunity announcement are due on these dates.				
	Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.				
Scientific Merit Review	Standard dates apply				
Advisory Council Review	Standard dates apply				
Earliest Start Date	Standard dates apply				
Expiration Date	January 8, 2018				
Due Dates for E.O. 12372	Not Applicable				

Table of Contents

Part 1. Overview Information

Part 2. Full Text of the Announcement

Section I. Funding Opportunity Description

Section II. Award Information

Section III. Eligibility Information

Section IV. Application and Submission Information

Section V. Application Review Information

Section VI. Award Administration Information

Section VII. Agency Contacts Section VIII. Other Information

Part 2. Full Text of Section I. Funding Opportunity

Purpose

The purpose of this Funding Opportunity Announceme emerging evidence from limited research indicates a p

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Ultimately, a better mechanistic understanding of how interventions during pregnancy or early life that may h

Background

Most of the epidemiology research conducted to date consequences for cancer development later in life.

- There is good evidence that prenatal exposure vagina, and breast in the daughters of the wom
- Other evidence shows that early menarche has period is critical in the etiology of this disease.
- Size at birth (i.e., birth weight and length) also
- In addition to early growth, having been breast
- Other in utero and early-life factors have been I have been associated with several adult malign almost all invasive cervical cancer cases world
- A single acute exposure to radiation to those w elevated risk of malignancies decades later.

Table of Contents

Part 1. Overview Information

Part 2. Full Text of the Announcement

Section I. Funding Opportunity Description

Section II. Award Information

Section III. Eligibility Information

Section IV. Application and Submission Information

Section V. Application Review Information

Section VI. Award Administration Information

Section VII. Agency Contacts

Section VIII. Other Information

Animal studies have also provided support to link early-me exposures with cancer development. The Agout mouse model was used to demonstrate that material declared epigenetic modifications and phenotypic changes in the off-spring that are potentially linked to cancer.

NIH Efforts

Table of Contents

Part 1. Overview Information

Part 2. Full Text of the Announcement

Section I. Funding Opportunity Description

Section II. Award Information

Section III. Eligibility Information

Section IV. Application and Submission Information

Section V. Application Review Information

Section VI. Award Administration Information

Section VII. Agency Contacts Section VIII. Other Information

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Table of Contents

Part 1. Overview Information

Part 2. Full Text of the Announcement

Section I. Funding Opportunity Description

Section II. Award Information

Section III. Eligibility Information

Section IV. Application and Submission Information

Section V. Application Review Information

Section VI. Award Administration Information

Section VII. Agency Contacts

Section VIII. Other Information

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NIH Efforts

Section III. Eligibility Information 1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- · Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- · Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- · Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are** eligible to apply.

Foreign components, as defined in the NIH Grants Policy Statement, **are** allowed.

- · Indian/Native American Tribal Governments (Federally Recognized)
- · Indian/Native American Tribal Governments (Other than Federally Recognized)
- · Eligible Agencies of the Federal Government
- · U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- · Faith-based or Community-based Organizations
- · Regional Organizations
- Non-domestic (non-0.3.) Entitles (Foreign Institutions)

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) are eligible to apply. Non-domestic (non-U.S.) components of U.S. Organizations are eligible to apply. Foreign components, as defined in the NIH Grants Policy Statement, are allowed.

Required Registrations

Applicant Organizations





BÚSQUEDA DE CONVOCATORIAS ESPECÍFICAS NIH



POR PALABRAS CLAVE/DISCIPLINA/ENFERMEDAD

POR EJEMPLO



BRAIN DISORDERS



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New improvements in development. The old advanced search is still available



Results: 1 to 25 of 173

Release Date 🔻

neasures for use in clinical trials for individuals with intellectual atments for these populations. This FOA will focus ongoing led in the FOA Preclinical Research on Model Organisms to

R-16-215

sms of neurodevelopmental disorders. Applications submitted to fectively translate to human clinical trials for individuals with signed for safety, toxicity, and efficacy prediction or to perform an atments and therapeutic compounds in order to move promising

new drug therapies into clinical trials. Potential applicants may also be interested in the FOA PAR-16-216, Outcome Measures For Use In Treatment Trials of Individuals with Intellectual and Developmental Disabilities.

Program for Extramural/Intramural Alcohol Research Collaborations (U01) - PAR-16-214

ram for Extramural/Intramural Alcohol Research Collaborations (UU1) - PAK-10-214

Issuing Organization: NIAAA

Posting Date: 04-22-2016

Expiration Date: 05-08-2019

Activity Code: U01

Summary: The purpose of this funding opportunity is to encourage collaboration between alcohol researchers in the extramural community and those within the NIAAA intramural research program. The objective of this Funding Opportunity Announcement is to bring together the research expertise that, as a functioning collaborative unit, will address key alcohol-based research questions that would not otherwise be possible by the same individuals working towards similar goals in isolation. The goal of the research proposed by the collaborating investigators should address questions that advance the alcohol research field with respect to issues surrounding alcohol use disorders including dependence and the effects of alcohol on health. The NIH Intramural Scientist will be a tenured or tenure-track scientist from the NIAAA Intramural Research Program, with whom the PD/PI has made prior contact for the collaborative project.

Leveraging Cognitive Neuroscience Research to Improve Assessment of Cancer Treatment Related Cognitive Impairment (R01) - PAR-16-212







http://grants.nih.gov/grants/oer.htm

MRI-Based Neuroimaging Datasets from Diverse Sources	010	relaced	1141 111	2015			
Molecular and Cellular Substrates of Complex Brain Disorders (R01)	PAR-14-309	Related	NIMH	08-04- 2014	09-05- 2014	09-08- 2017	R01
Molecular and Cellular Substrates of Complex Brain Disorders (R21)	PAR-14-310	Related	NIMH	08-04- 2014	09-16- 2014	09-08- 2017	R21
Notice of Correction to PAR-14-153 "Temporal Dynamics of Neurophysiological Patterns as Potential Targets for Treating Cognitive Deficits in Brain Disorders (R01)"	NOT-MH-14- 013	Related	NIMH	03-14- 2014			
Temporal Dynamics of Neurophysiological Patterns as Potential Targets for Treating Cognitive Deficits in Brain Disorders (R01)	PAR-14-153	Related	NIMH	03-14- 2014	05-05- 2014	05-08- 2017	R01
Temporal Dynamics of Neurophysiological Patterns as Potential Targets for Treating Cognitive Deficits in Brain Disorders (R21)	PAR-14-158	Related	NIMH	03-14- 2014	05-16- 2014	05-08- 2017	R21
Notice of Informational Conference Calls for Prospective Applicants to NIH BRAIN Initiative Funding Opportunity Announcements	NOT-NS-14- 005	Related	NINDS	01-06- 2014			





R01: Molecular and Cellular Substrates of Complex Brain Disorders. PAR-14-309. http://grants.nih.gov/grants/guide/pa-files/PAR-14-309.html

R21: Molecular and Cellular Substrates of Complex Brain Disorders. PAR-14-310. http://grants.nih.gov/grants/guide/pa-files/PAR-14-310.html

This Funding Opportunity Announcement (FOA) encourages research grant applications directed toward the discovery of the impact of alterations associated with complex brain disorders on the fundamental cellular and molecular substrates of neuronal function.



La convocatoria termina en el año 2017.

Tres fechas límite anuales:

R01: 5 febrero, 5 junio y 5 octubre

R21: 16 febrero, 16 junio y 16 octubre.

Department of Health and Human Services Part 1. Overview Information

	•				
Participating Organization(s)	National Institutes of Health (NIH)				
Components of Participating Organizations	National Institute of Mental Health (NIMH)				
Funding Opportunity Title	Molecular and Cellular Substrates of Complex Brain Disorders (R01)				
Activity Code	R01 Research Project Grant				
Announcement Type	Reissue of PAR-11-299				
Related Notices	None				
Funding Opportunity Announcement (FOA) Number	PAR-14-309				
Companion Funding Opportunity	PAR-14-310, R21 Exploratory/Developmental Grant				
Number of Applications	See Section III. 3. Additional Information on Eligibility.				
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.242				
Funding Opportunity Purpose	This Funding Opportunity Announcement (FOA) encourages research grant applications directed toward the discovery of the impact of alterations associated with complex brain disorders on the fundamental cellular and molecular substrates of neuronal function.				
Key Dates					
Posted Date	August 4, 2014				
Open Date (Earliest Submission Date)	September 5, 2014				
Letter of Intent Due Date(s)	Not Applicable				
Application Due Date(s)	Standard dates apply, by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for				

this funding opportunity announcement are due on these dates.

Table of Contents

Part 1. Overview Information

Part 2. Full Text of the Announcement

Section I. Funding Opportunity Description

Section II. Award Information

Section III. Eligibility Information

Section IV. Application and Submission Information

Section V. Application Review Information

Section VI. Award Administration Information

Section VII. Agency Contacts Section VIII. Other Information

Part 2. Full Text of should Section I. Funding Opportuging

Disorders of complex brain function such as sonizoph neuroscience. Impairments in complex brain function developing effective treatments has been slow since t with the recent emergence of potential disease-associ assay technologies, neuroscientists are now poised to perspective of hypothesis testing for disease relevance contribute to disorders of complex brain functions.

To facilitate progress towards understanding the biologoprocesses act at the basic molecular, cellular, and circ third messengers, neuromodulators, neurotrophins and neuron-glia communication; oxidative, immunological adynamics such as excitatory/inhibitory balance or progressions.

This funding opportunity encourages the submission of understanding the biological mechanisms behind putat disorders. Applications submitted to this FOA should mechanisms at the molecular, cellular and circuit leve disorder). Rather, applicants are encouraged to addre

Examples of relevant research include, but are not lim

- Studies aimed at exploring the molecular, cellul pathways associated with brain disorders.
- · Investigations of epigenetic or environmental fa
- Exploratory studies including innovative in vitro disorders and/or to identify novel potential treat
- Optimization and implementation of novel cell-b associated alterations in cell processes.
- Studies to identify the functions of molecules lir neuroimmune/neuroinflammatory, environmenta
- Development/optimization of new biological tool to complex brain disorders.

Applications submitted to this FOA should propose wo

Table of Contents

Part 1. Overview Information

Part 2. Full Text of the Announcement

Section I. Funding Opportunity Description

Section II. Award Information

Section III. Eligibility Information

Section IV. Application and Submission Information

Section V. Application Review Information

Section VI. Award Administration Information

Section VII. Agency Contacts

Section VIII. Other Information

the mission of NIMH (see: http://www.nimh.nih.gov/about/strategic-planning-reports/nimh-strategic-plan-2008.pdf). Projects with a primary focus on behavioral measures, pharmacology or drug discovery, modeling mental disorder symptoms, human subjects or clinical populations (except for generation of iPS cells) and the neural substrates of neurodegenerative disorders are not appropriate for support under this announcement. The NIMH has high interest in applications that incorporate the longitudinal trajectory of highest all harvest into the constituent attack of the developing





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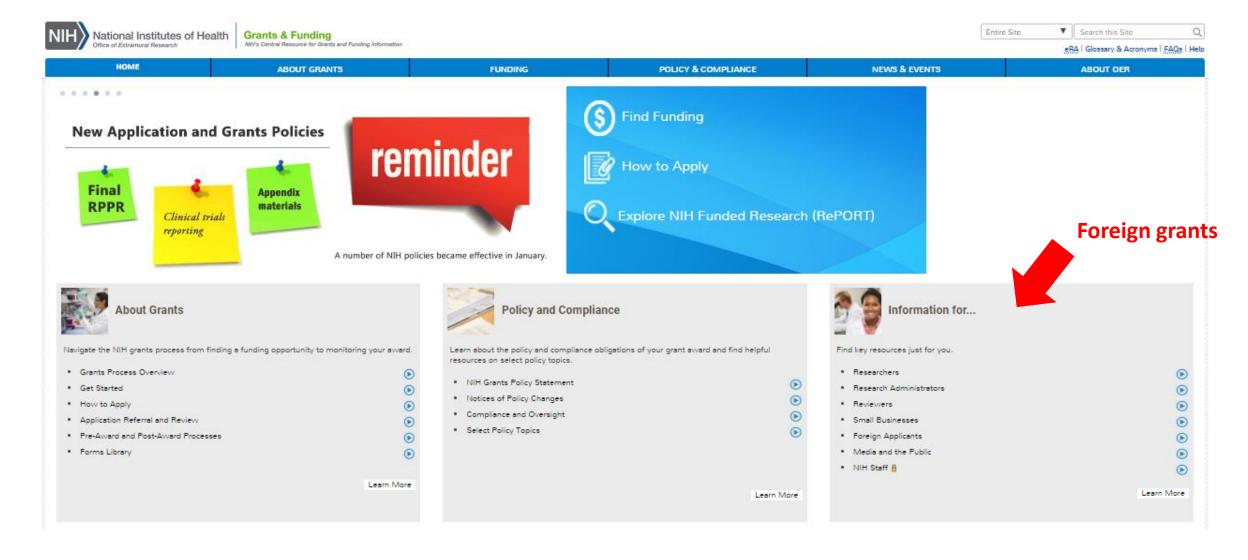








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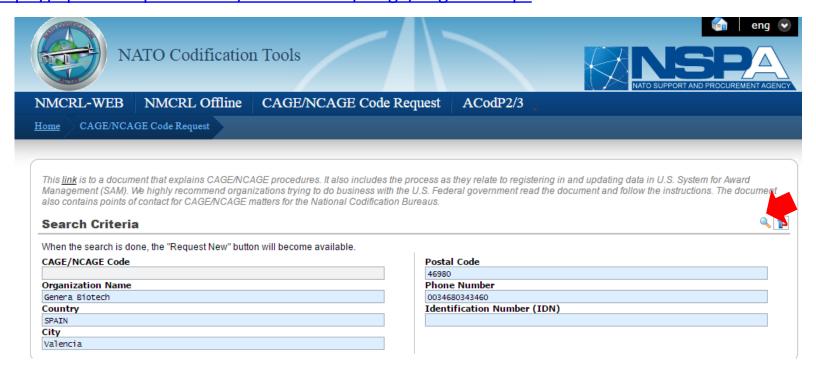


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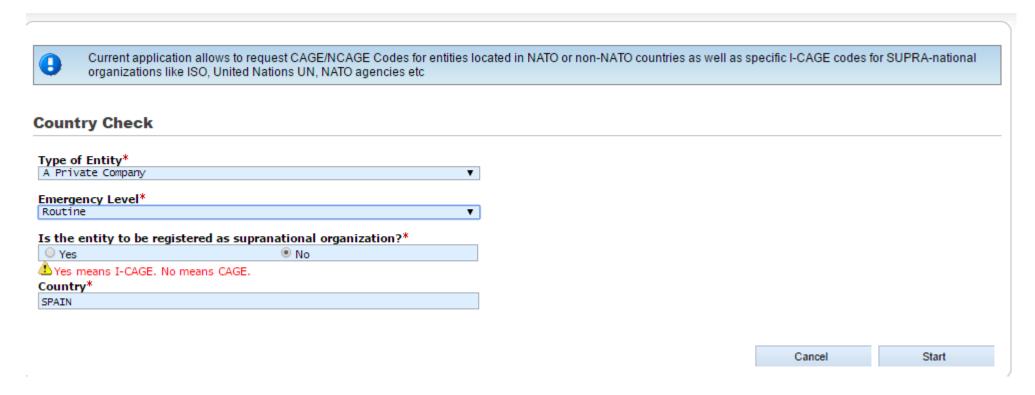






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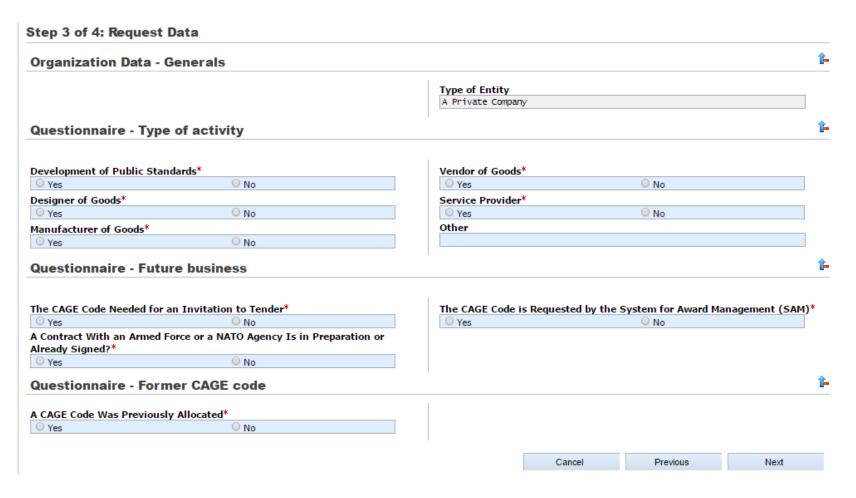






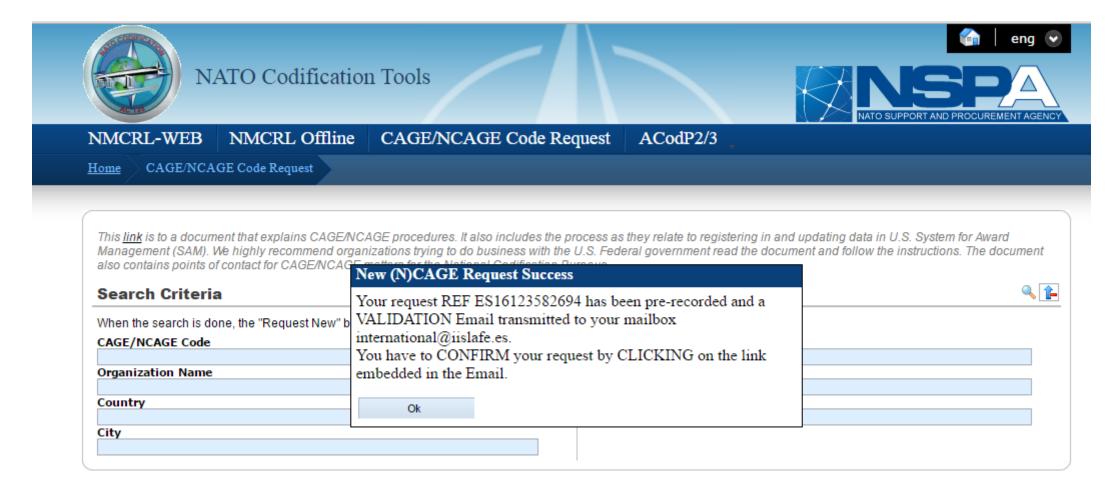
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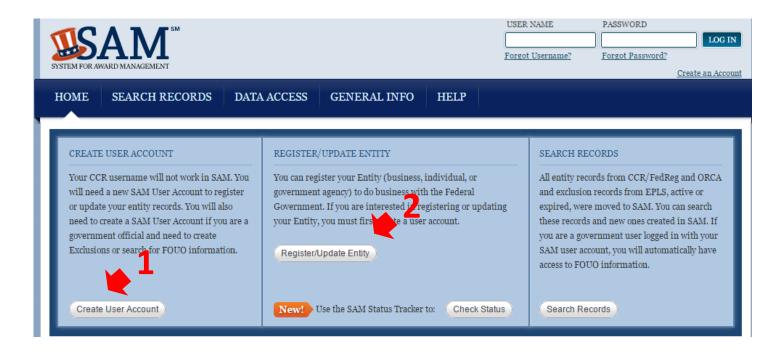


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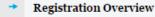
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Core Data

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Points of Contact

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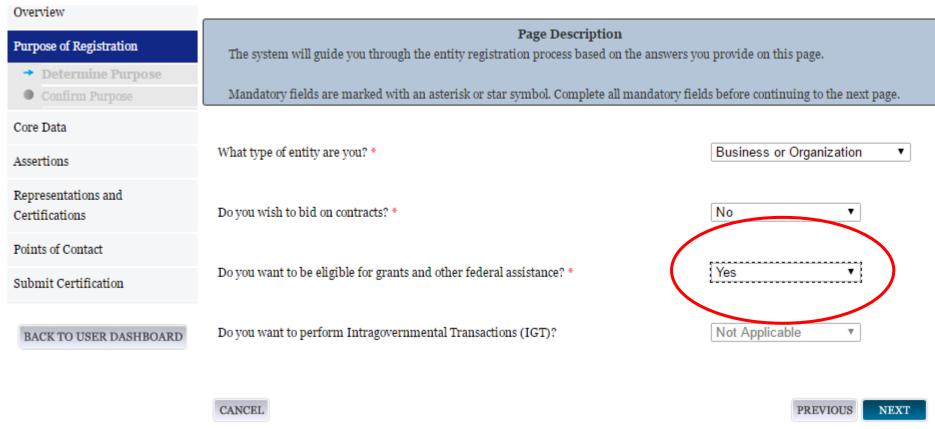
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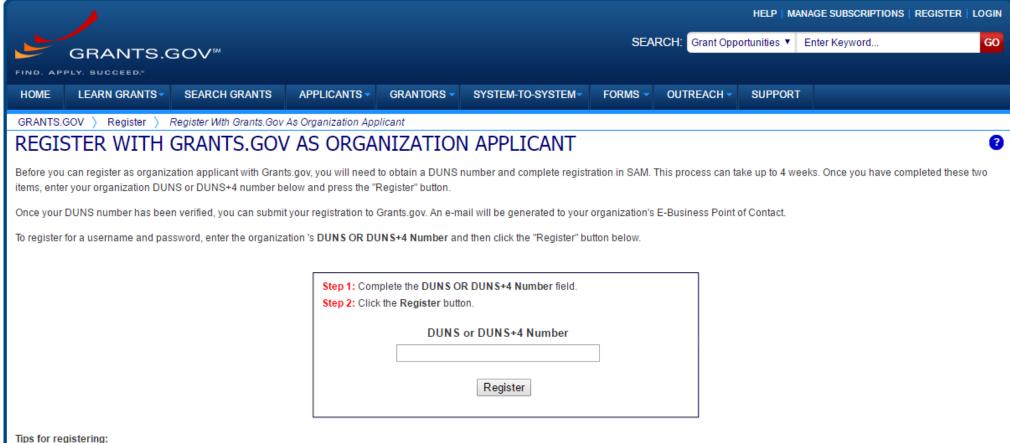
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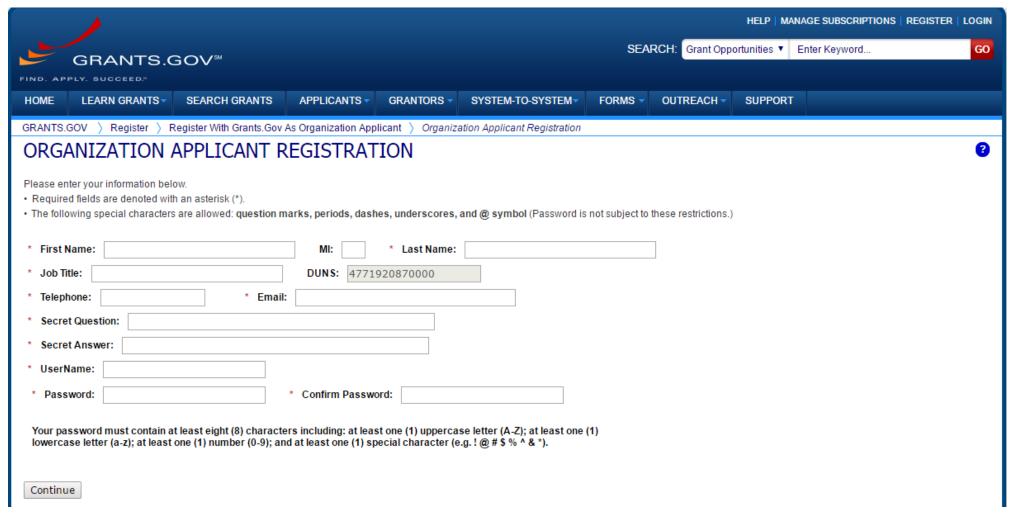


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- Registering with Grants.gov is a simple process. Guidance on this process is included in the tutorial, user guide and Help section of this site. Please click on the Applicant tab for further assistance.











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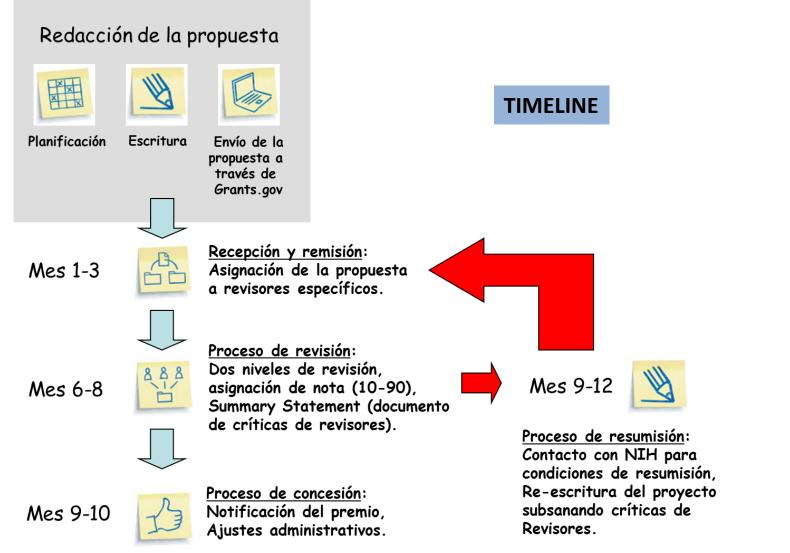


APLICACIÓN NIH





Dr. Ana Ma Blanco







DOCUMENTOS solicitud NIH:

☐ Research strategy (6 o 12 páginas)
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☐ Specific aims (1 página)
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SF424 (R&R) Application Guide

http://grants.nih.gov/grants/funding/424/index.htm#inst

PHS SF424 (R&R) Forms Version C Application Guide

TABLE OF CONTENTS

P	AKI I	I. INST	RUCTIONS FOR PREPARING AND SUBMITTING AN APPLICATION
1.	Fore	word	1
	1.1	Applica	tion Guide Format3
	1.2	NIH Ex	tramural Research and Research Training Programs4
	1.3	Researc	ch Grant Activity Codes and Program Guidelines4
	1.4	Interact	ions with PHS Staff5
	1.5	Grants 1	Policy Statements8
	1.6	Referen	ces8
	1.7	Authori	zation
		1.7.1	Collection of Personal Demographic Data
	1.8	Paperw	ork Burden10
2.	Proc	cess for A	Application Submission via Grants.gov11
2.	Proc 2.1		Application Submission via Grants.gov
2.		Overvie	
2.	2.1	Overvie	sw
2.	2.1	Overvie Registra	ew
2.	2.1	Overvie Registra 2.2.1 2.2.2	11
2.	2.1 2.2	Overvie Registra 2.2.1 2.2.2	11
2.	2.1 2.2	Overvie Registra 2.2.1 2.2.2 Softwar	11
2.	2.1 2.2	Overvie Registra 2.2.1 2.2.2 Softwar 2.3.1	11
2.	2.1 2.2 2.3	Overvie Registra 2.2.1 2.2.2 Softwar 2.3.1 2.3.2 2.3.3	11





EJEMPLO RESEARCH STRATEGY R21 (6 pages)

RESEARCH STRATEGY

Pfindpai Investigator/Program Director (Last, first, middle); McCune, Joseph, M.

RESEARCH STRATEGY (a) SIGNIFICANCE The developing human immune system faces a balancing act that must be carefully timed. On the one hand, it must tolerate the presence of the surrounding mother and her non-inherited maternal alloanisance (Nilma) or otherwise risk the potential of engaging a fatal "graft vs. host" disease. On the other hand, novel antigens must be recognized as foreign when encountered after birth, triggering a vigorous adaptive immune response (e.g., with cytolytic T cells and neutralizing antigens) against them. Otherwise, the newborn will be susceptible to diseases caused by multiple infectious agents.

In ongoing experiments, we have obtained preliminary data (see below) indicating that this switch from a fetaltype to an adult-type immune response is dependent upon the stage-specific appearance of distinct multilineage hematopoletic stem/progenitor cells (HSPC). Thus, in utero, hematopolesis in the first and second trimester is largely sustained by a fetal-type HSPC that gives rise to tolerogenic Tregs; later (and perhaps as early as the third frimester), an adult-type HSPC instead gives rise to immunoreactive T cells. The timing of this switch coincides with birth and normally allows the newborn to move from a stance of tolerance to one of active defence against all foreign antigens. In this manner, the "immune privileged" aspect of mammalian pregnancy is preserved while the ability of the newborn to fight infections is also permitted.

Nonetheless, infection remains a leading cause of death and morbidity in newborns. Not only are neonates susceptible to more severe forms of disease caused by human pathogens such as herpes simplex virus 1, respiratory syncytial virus, Bordetella pertussis and Staphylococcus aureus), they are also subject to serious infection by microbial entities that are commensal flora in adults. For example, even after implementation of intensive screening and prevention practices, the estimated rate of Group B Streptococal sepsis in the first week of life is 0.34 per 1000 live births, resulting in 60-70 deaths per year. In addition to the immediate impact of neonatal illness and death, the long-term disability resulting from these infections represents a profound public health burden. Premature Infants, in particular, are predisposed to more severe infections from all pathogens and can also succumb to fatal infection by microbes that infrequently cause severe disease in adults, such as Staphylococcus epidermidis.9 Compared with adults and older children, newborns produce less, and generally less effective, antibody in response to most immunizations. They are also less able to generate T cells that mediate effective antimicrobial responses. 10-15 Together, these deliciencies render the neonate a vulnerable target for a host of invading pathogens.

If the switch to an "adult-type" immune system is incomplete or overly slow after birth, two other problems may also arise. First, the neonate may respond less well to immunizations provided during the first months of life, either generating low levels of an effective response or polarized features of a non-effective response. Secondly, those neonates that are most likely to develop atopic disorders after birth are also those who are most likely to generate suboptimal (and/or strong Th2-type) response to vaccination. 21,26 Since fetal Tregs may suppress Thi-type (or other) immune responses to vaccines in a manner that is different than adult Tregs, we speculate that strong Th2 polarization of childhood responses to vaccines may in part be due to a higher than normal proportion of fetal Treds at birth

In the studies of this proposal, we hypothesize that the immune system "layering" that is necessary for effective In utero development and postnatal protection of the human fetus occurs at a dissimilar pace in different easing some at birth to less effective immune responses to childhood immunizations.

(b) INNOVATION Previous experiments have demonstrated that similar "layering" of the immune system can occur in avian and must e models. 1-3 In these species, however, the timing and/or anatomic constraints are ectively different to particular, the murine immune system develops at a markedly different pace than does the human immune system, e.g., with very few Tregs detectable until three days after birth²⁷ as compared to the late 1st trimester in the human. This study is innovative in two respects: this is the first time that human immune system layering has been studied in utero and at birth; in addition, we have identified and validated a set of genes that are uniquely expressed in fetal or adult T cells, allowing us to quantitatively and qualitatively study the kinetics of the two populations as a function of time. The proposed research has the potential to improve prevention (through improved vaccine strategies) and treatment of neonatal infection (by providing a better understanding of normal human fetal immune development), and should teach us how the developmental state of the fetus and newborn affects their ability to respond to pathogens or vaccines.

APPROACH

(c) RESEARCH PLAN We propose to test the hypothesis that the immune system of the human newborn is comprised of two distinct rematopoletic lineages, one derived from a multilineage HSPC that resides in the that liver and bone marrow, and another from an HSPC that begins to function later in pregnancy and that supplants the fetal lineage thereafter. The former lineage is endowed with tolerogenic T cells that allow the fetus to co-exist with the mother (including her NIMA and other foreign antigens circulating with her); the latter lineage is instead comprised of T cells that are more likely to develop effector functions against novel antigens. The basis for this hypothesis is found by recedent in axian and much enodels as well as by way largely unpublished Preliminary Data:

The human fetus can mount a vigorous mmune response to exogenous antigens. Although the human fetal and neonatal adaptive immune systems are often described as "immature" (i.e., dysfunctional or

ineffective at mounting a response to antigenic challenge), there is substantial evidence that immune responses can develop at or before birth in species such as sheep and nonhuman primates (but, Interestingly, not mice) (reviewed in refs.16 and 28). To determine whether human fetal T cells are responsive against alloantigens, fetal (~20 q.w.) lymphocytes from spleen or lymph node (LN) were labeled with carboxyfluorescein succinimidyl ester (CFSE) and co-cultured with Irradiated antigen-presenting cells (APCs) that had been isolated from the peripheral blood of a single healthy adult donor. After five days substantive proliferative responses were observed for both CD4* and CD8* fetal T cells (Fig. 1). This finding raised the question: if fetal T cells respond so vigorously to alloantigens in vitro, do they not also respond to NIMA expressed by maternal cells that have moved into fetal LNs In

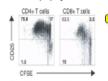


Figure 1. Representative plot of CD4+ and CD8+ proliferation after stimulation with allogeneic APCs from an unrelated donor for 5 days

The human fetal immune response to exogenous antigens can be actively suppressed by antigenspecific Tregs. We recently demonstrated that human fetal secondary lymphoid tissues contain significantly

Figure 2. Comparison of field T_{ring} cell suppression spansal acrologous, maternal, or unrelated APCs determined based on the following calculation: % Suppression = 1-(%CFSEon (total LM

higher frequencies of CD4 CD25 Ngh Tregs than those of adults. Because Tregs have been shown to regulate maternal immunity to fetal alloantigens,29 we reasoned that fetal Tregs might also play a role in suppressing fetal immune responses against invading maternal cells. To test this hypothesis, fetal LN cultures were either depleted or "mockdepleted of Tregs before stimulation with self (autologous), maternal, or unrelated allogeneic APCs. Depletion of Tregs resulted in a highly significant increase in proliferation of CD4* and CD8* T cells responding to autologous or maternal APCs, but only a

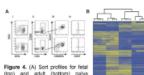
slight (yet statistically significant) Increase in proliferation of those responding to unrelated APCs (Fig. 2).

These data indicate that fetal T cells are not inherently deficient at responding to maternal alloantigens; rather, they are actively suppressed by fetal Treqs.

The frequency of Tregs in peripheral lymphoid organs changes markedly during the course of gestation, falling from ~15-20% of total CD4" T cells at 12-20 q.w. to ~3-7% at birth. 50 To test the hypothesis that such a change in frequency reflects a greater propensity of fetal naive CD4* and CD8* T cells to differentiate into Tregs in response to stimulation, fetal LN cells were depleted of CD25^{high} Treqs and stimulated *In vitro*. After a five-day primary mixed lymphocyte reaction (MLR), a significant fraction of fetal, but not adult, CD4" and CD8" T cells had divided and upregulated FoxP3 expression to high levels (Fig. 3A, B).



Principal Investigator/Program Director (Last, first, middle): McCune, Joseph, M.



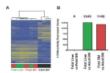
(top) and adult (bottom) naïve CD4+ T cells (panels ii/iv) or CD25+ Treg cells (panel ii). (B) top 500 differentially expressed genes and clustering



Fetal Tregs are derived from a fetal-specific lineage of T cells. The above studies revealed profound differences In function between fetal and adult T cells that had otherwise indistinguishable phenotypes. To determine whether such differences are intrinsic to the T cell lineages found during these stages of ontogeny, CD4°CD25^{high} Tregs and CD4*CD45RA*CCR7*CD27* naïve T cells from fetal and adult samples were sorted with a FACSDIVA (Fig. 4A). Microarray analysis (Fig. 4B) Identified thousands of genes whose expression levels in adult and fetal CD4* naïve T cell populations differed significantly (P<0.05) and in a highly consistent manner between donors, including NOG, GZMA, and RGS1 were highly expressed (20-55 fold greater) by fetal cells whereas NAP1L2, NR3C2, and SYT4A were highly expressed by adult cells.

Fetal and adult HSPCs give rise to distinct populations of T cells. In avian and mouse models, there is

strong evidence that fetal HSPCs give rise to unique subsets of lymphocytes that cannot be generated from adult HSPCs and that A Immune system "layering" occurs during ontogeny.2,3 To test whether a similar situation exists in humans, we performed a series of experiments In which fetal HSPCs from fetal liver and BM (18-22 q.w.) and adult BM samples were injected directly into the human Thy/Liv organ of the SCIDhu Thy/Liv mouse.31 Following a 7-8 week maturation period, we were able to identify mature thymocyte populations derived from each HSPC population, based on the expression of a unique HLA type (typically HLA-A2 or A3) expressed by the donor (source of HSPCs) but not by the recipient thymic implant. *** We isolated mature CD3*CD4*CD8*CD25* figure 6. (A) Classistic of the bug difference of thymic cytes from thymic implants injected with fetal liver, fetal BM, or object of the bug difference microarray analysis on each population (Fig. 5A). We found that both HSPC populations from fetal liver and BM gave rise to identical hymocylw population populations of CD4" thymocytes on the basis of gene expression, with no differentially-expressed genes between them (Fig. 5B). By contrast, adult BM-derived HSPCs gave rise to CD4* thymocytes that showed



number of DE genes (>2-fold difference expression difference and p<0.05) for each

substantial differences in gene expression patterns compared to each population of fetal HSPC-derived thymocytes (Fig. 5B: 1243 and 1162 differentially-expressed genes versus fetal liver and fetal BM, respectively). These data are consistent with the hypothesis that the developmental stage of HSPCs is in part responsible for the differences seen in peripheral T cell compartments in the fetus and adult, and that layering occurs during the ontogeny of the human immune system.

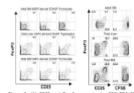


Figure 6. (A) CD25 and Foxp3 expression by CD3+CD4+CD6 thymocytes from adult BM, felol liver, or letal BM (3 SCID-ha thymic implents/group). (B) Expression of CD25 and Foig3 (left) and proliferation (CFSE-cilution, right) following stimulation of

Fetal HSPC-derived T cells show an enhanced ability to generate Tregs during thymic maturation and upon exposure to foreign antigens in vitro. CD4*CD25*Foxp3* Tregs can be generated during thymic maturation or following activation of peripheral T cells. Some evidence indicates that Treas may arise from a committed progenitor that is distinct from conventional T cell precursors.30 We observed that fetal HSPCderived thymocyte populations contained significantly greater frequencies of Tregs than those derived from adult HSPCs (Fig. 6A). In accordance with what we observed in peripheral fetal and adult T cell populations, we also noted that fetal HSPCderived thymocytes were highly responsive to stimulation with allogeneic APCs and showed a propensity to differentiate into FoxP3* Tregs (Fig. 6B).

In sum, the above Preliminary Data Indicate that the fetal





Principal Investigator/Program Director (Last, first, middle): McCune, Joseph, M.

Immune system is derived from a HSPC that gives rise to tolerogenic Tregs while the adult HSPC is more likely to give rise to immunoreactive T effector cells. At this point, we have very tittle information about the relation balance of these two compartments at birth. It is also not clear whether and to what extent variations in this balance may impact upon the response of the neonatal immune system to novel antigens, including those associated with routine vaccines or with environmental allergens. The experiments of this proposal are designed to explore these questions.

Specific Alm 1. To determine the normal range of fetal to adult T cells in the umbilical cord blood of neonates at birth

Hypothesis. Physic refing of the human immune system during ontogeny leads to a normal range in the ratio of retail to a merype T cells at the time of birth, with some neonates born with a more tolerogenic immune system t

Rationale. A din the above Preliminary Data, the human fetal immune system is poised to generate a tolerogenic This Tresponse upon stimulation, an attribute that is conferred by an HSPC that resides within the fetal liver and bohe marrow. After birth, bone marrow-derived HSPC give rise instead to immunoreacitive T cells with a reduced propensity to generate Treps. Teleologically, such 'layering' of the immune system would appear to be consistent with, and possibly necessary for, maintenance of the semi-allogeneic state of pregnancy and, reciprocally, for the generation of an active immune response against foreign (e.g., infectious agents) after birth. Similar stage-specific waves of distinct hematopoletic progenitors have also been described in avian and murine models. ¹⁹ A key question that remains unanswered is the foliowing: there inter-individual variation in the rate at which the fetal-type hematopoletic system is replaced by the adult-type system over time? In this Alm, we propose to determine whether and to what extent such variability may exist at the time of birth. Given known transcripts that uniquely identify tolerogenic fetal T cells (T_P) and immunoreactive adult T cells (T_R), the normal range of these two T cell subpopulations in the umbilical cord blood will be determined.

Experimental Approach. Co when the phenotypic, transcriptional, and functional analyses will be carried out on umbilical cord blood (UC) mothonuclear cells from a total of 200 normal full-term deliveries. Over a national control blood (UC) mothonuclear cells from a total of 200 normal full-term deliveries. Over a national control blood Bank of the UCSF Clinical and Translational Sciences institute (see attached letter from Dr. William Baike), 75 will be obtained on a collaborative basis from Dr. Elizabeth Shpall of the University of Texas M.D. Anderson Cancer Center (see attached letter), and 50 will be obtained as part of a prospective study to be carried out with Dr. Shannon Thype of the Child Health Center at SFGH (see attached letter). Initial studies will focus on naive T cells obtained by a combination of flool hypastogue gradient enrichment and FACS sorting; excess cells will be viably cryopreserved in liquid nitrogen for future experiments that may interrogate other subpopulations of cells. The following assays will be carried out:

- Phenotypic analysis of T cell populations. The frequency of various T cell populations in the cord blood will be analyzed using standard markers of nalive CD4* T cells (CD45RA*CD27*CCR7*), memoryleffector T cells (CD4*CD45RO*CD95*HLA-DR*), and Tregs (CD4*CD25**a**FoxP3*CD127**a**).5 Absolute numbers will be quantified using TRUcount tubes (BD).
- be quantified using if Robount tubes (BD). 2. Transcriptional analysis of naive T cell populations. Phenotypically-pure naïve CD4* T cells will be obtained by sort purification on a FACSAria (BD) and subjected to qRT-PCR assay to detect transcripts transcript specific to cell-type T cell to quantified and T cell to quantified T cells (e.g., NAP1L2, NR3C2, and SY74A; T_{A}) as well as transcripts for house-keeping genes that are equivalently expressed in fetal and adult naïve T cells (e.g., the β chain of the T cell receptor or HPRT; denoted by T_{A}). Each transcript will be quantifiated in replicate and three standardized ratios of fetal/adult T cell transcripts (F/A-T) will be calculated based on the formula (T_{A}/T_{A}) ($(T_{A}/T_{A}) = (T_{A}/T_{A})$, and the mean of these ratios will be used to represent the fetal/adult T cell T cell T cell to this will be used to represent the fetal/adult T cell T and T cell T and T cell T c

of proliferation. After six days of stimulation, the cells will be harvested and each T cell subpopulation will

Research Strategy

Page 31

Principal Investigator/Program Director (Last, first, middle): McCune, Joseph, M.

be measured for proliferation (CFSE dilution) and for Treg differentiation (FoxP3 upreguiation) by flow cytometry. Standard types of cytokine response (Th1, Th2, Th17, and Th22) will be measured by cytokine production after six days of differentiation in vitro by carrying out intracellular cytokine flow cytometry (CFC) for the following cytokines: IL-2, INF-y, TNF-x, IL-4, IL-17, and IL-22. To test whether cord blood Tregs are better able to suppress Th1 vs. Th2 responses, CD4* naīve T cells will be sort-purified from a healthy adult (or cord blood) donor and cultured under Th1 or Th2 conditions in the presence of antl-CD3/antl-CD28. Th1 and Th2 polarization will be measured by cytokine production after six days of differentiation in vitro. These cells will subsequently be labeled with CFSE and cultured in the presence of antl-CD3/CD28. Suppression of Tn1 or Th2 cells will be measured by inhibition of proliferation (by CFSE dilution) and suppression of cytokine secretipn (by cytokine flow cytometry) after a six-day culture period.

Interpretation of Results. The ments described in this Aim extend observations that we have made in human fetal and adult samples that, at learning the ments are samples of human cord blood. We anticipate that, at term, there will be a normative lange of fetal- and adult-type Tregs and HSPGs in cord blood, representing variable kinetics by which layering of immune system ontogeny proceeds in different individuals. The relative frequency of fetal versus adult T Cell-specific transcripts, (T_P/T_A) bill be taken as a measurement of the actual fetal/adult T Cell ratio (T_P/T_A) . Thus, we will make the assumption that $T_P/T_A = T_P/T_A$. In those cases in which the fetal/adult T Cell ratio (T_P/T_A) is high, it is predictable that cord blood naive T Cells will be more likely to uprequilate FoxP3 upon stimulation and that a predominant belerogenic response to antigen will ensue.

Potential Problems and Alternative Approaches. Given the problems of the prob

Specific Aim 2. To determine whether those full-term neonates with a high ratio of fetal/adult T cells are more likely to generate a Th2-polarized immune response to routine childhood immunizations. Hypothesis, infants with a high ratio of fetal/adult T cells will generate predominant Th2 responses to routine childhood vaccinations.

Rationale. In human neonates, T cell responses are often characterized by deficient Thi responses, ¹⁶⁻¹⁹ a reduced capacity to induce T coll memory. ²⁰ a high frequency of IgE and IgG4 production, ²¹ a skewed This response, ²⁰⁻¹⁹ and even the induction of hyporesponsiveness. ²⁰ Such responsiveness to routhin childhood vaccines has been found to vary within populations, possibly as a result of genetic and/or environmental actors ²⁰⁻²⁰⁻²⁰ and is in part magnified by the formulation of vaccines with the Tra-polarizing adjuvant, alum. ²⁰ in addition, those neonates that are most likely to develop atopic disorders after birth are also those who are most likely to generate suboptimal (and/or strong Th2-type) response to vaccination. ^{21,20-20} Since fetal Tregs may suppress Th1-type (or other) immune responses to vaccines in a manner that is different than adult Tregs, we speculate that strong Th2 polarization of childhood responses to vaccines may in part be due to a higher than normal proportion of fetal T cells at birth.

Recombinant Hepatitis B (HepB) vaccine is routinely given at birth in the United States and provides an ideal opportunity to investigate an in vivo response to antigenic stimulation in the newborn. The immune response to HepB vaccine is well studied and is characterized by a meager (10%) seroconversion rate with the first dose at birth. "Subsequent vaccine doses are then observed to yield a substantial antibody response." The primary neonatal CD4* T cell response to HepB vaccine is characterized by both Th1 and Th2 cytokine production; interestingly, however, the HepB-specific memory CD4* recall response consists of robust Th2 cytokine production at one year of age."

Experimental Approach. The experiments of this Aim will be carried out under the auspices of a study that has been approved by the UCSF Committee on Human Research protocol (H6325-26775. The effects of regulatory T cells on the development of the pediatric immune system; McCune PI). In a prospective study design, 50 pregnant women will be enrolled prior to delivery. Exclusion criteria will include previous/current

h Strategy Pr

Principal Investigator/Program Director (Last, first, middle); McCune, Joseph, M.

HepB infection (HepBsAg"), other immunomodulatory infections detected by prenatal screening (HepC, HIV), or plans for the use of cord blood for alternative purposes (e.g., banking). With assistance from collaborators in the SFGH Child Health Center (see attached letter of collaboration from Dr. Shannon Thyne), cord blood will be obtained from these deliveries and each of the 50 infants will be followed with blood draws at 6 and 12 months. In all cases, infants will have received routine childhood immunizations, including those against HepB at birth, 1-2, and 6-12 months of age. UCB and infant peripheral blood will be processed by flool hypaque and concurrent purification of CD4" cells by negative selection (RosetteSep, StemCell). These cells will be tested for the following parameters over time:

- 1. The fraction of T_E vs. T_A in the umbilical cord blood. This will be carried out using the qRT-PCR-based approach described in Aim 1 to determine the ratio of fetal/adult T cells (T_F/T_A).
- 2. Analysis of the cellular immune response against HepB vaccine. Established flow cytometric assays will be used to assess the fraction of CD4*CD25**PFoXP3**CD127*** Tregs among CD3**CD4** T cells af each time point. These fractions will be converted to absolute numbers using TruCount tube (BD) analysis of whole blood counts prior to CD4** cell isolation, as described.** In addition to quantitative phenotyping, the ability of circulating Tregs to suppress the proliferation of HepB-specific responder CD4**CD25** T cells will be assessed using well-established methods.**Air.4** UCB or peripheral mononuclear cells that have been depleted of CD25** cells (or mock depleted) will be attimulated with (1) polyclonal activators (cross-linking antibodies against CD3 and CD28), (2) solible HepB antigen, and (3) peptides corresponding to HepB. Cytokine production in CD4** cells will be assessed by CFC, as described above in Alm 1, to determine whether antigen-specific stimulation yields a response that is predominantly Thi or Th2 in type.
- Levels of circulating Immunoglobulin (Iq) isotypes generated against HepB vaccine. Established ELISAs
 will be used to quantitate circulating levels of vaccine-induced IgG1, IgG2, IgG3, IgG4, and IgE relative to
 total Iq.

Interpretation of Results. This study will relate the ratio of fetal to adult naive T cells ($T_{\rm e}/T_{\rm e}$) to a number of immune parameters associated with routine childhood immunizations. In particular, it will be of interest to know whether a high $T_{\rm e}/T_{\rm e}$ ratio is associated with a higher propensity towards a less effective "immalure" response (e.g., a Th2-predominant cytokine response to vaccine antigens and the predominance of less-mature, antigen-specific IgG1, [1963, and IgE compared to IgG2], Infants will be studied both cross-sarbure, and see anticepaste that the $T_{\rm e}/T_{\rm e}$ ratio and measures of immaturity (especially a bias towards a Th2 response) will decrease with age in tandem. The ability of Tregs to suppress antigen-specific responses against HepB will also be measured. Given the hypothesis that $T_{\rm e}$ in the newborn generate tolerance to antigens they encounter by becoming Tregs, more robust HepB-specific Treg suppression would be expected in those children with a higher $T_{\rm e}/T_{\rm e}$ ratio.

Statistical Analysis. These data will be analyzed in consultation with biostatisticians in the Biostatistics Consultation Service, associated with the UCSF CTS (see attached letter of support from Dr. Peter Bacchetti). The sample size that has been chosen will detect a 35% difference in cytokine production, with a study power of 0.8 and significance level of 0.05. The statistical approach will use an ANCOVA-type linear model approach for each outcome variable. Some data may be longitudinal as well as cross-sectional and we will include random effects to account for within-subject correlation. We will explore approaches threat age as continuous, in particular, the Laifd-Ware repeated measures model. If the measures exhibit strong skewness or outlying values, we will attempt to transform the outcome (e.g., log-transformation) to mitigate these issues. If this is not adequate, we will compare the groups using non-parametric (e.g., rank based) methods.

Potential Ptitalis and Alternative Approaches. The primary challenge in this study is that of recruiting and retaining 50 patients over an 18-month period. Given the experience of our collaborator, Dr. Shannon Thyne, we believe that this goal is attainable. The Birth Center at SFGH delivers 1250-1300 infants yearly, all of whom are under the care of the Division of Neonatology, in which Dr. Burt (an MD investigator in the PI's lab who will be working on this study) is an attending physician. He will therefore have the ability to recruit patients (under our CHR-approved protocol) as they are admitted to the hospital in labor. Furthermore, in previous studies carried out through the Birth Center, members of the McCune lab have successfully recruited similar numbers of patients in a period of approximately one year. Approximately 80% of infants born at SFG freelive their primary care in the Child Health Center at SFGH. If by three months of recruitment, we are not meeting expected goals, this study will be extended to the Birth Center at UCSF, which has a similar delivery rate and where we also have CHR approval to recruit.

Research Strategy Page 33





EJEMPLO BIOGRAPHICAL SKETCH (Max 5 pages)

ONE No. 0925-0001 (0002 (Rev. 09112 approved Through 6/51 (2015).

BIOGRAPHICAL SKETCH

Provide the following information for the Senionikey personnel and other significant contributors.

Follow this format for each person. BO NOT EXCEED TWE PAGES.

NAME: Hunt, Morgan Casey

eRA COMMONS USER NAME (credential, e.g., agency login): buotino

POBITION TITLE: Associate Professor of Psychology

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, Include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

INSTITUTION AND LOCATION	DEGREE (If applicable)	Completion Date MM/YYYY	FIELD OF STUDY
University of California, Berkeley	B.8	05/1990	Psychology
University of Vermont	Ph.D.	05/1996	Experimental Psychology
University of California, Berkeley	Postdoctoral	08/1998	Public Health and Epidemiology

A. Personal Statement



I have the expertise, leadership, training, expertise and motivation necessary to successfully carry out the proposed research project. I have a broad background in psychology, with specific training and expertise in ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. My research includes neuropsychological changes associated with addiction. As Pi or co-investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track. participants over time as documented in the following publications. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work. During 2005-2006 my career was disrupted due to family obligations. However, upon returning to the field I immediately resumed my research projects and collaborations and successfully competed for NIH support.

- 1. Megyle, R.J. & Hunt, M.C. (2004). Independent living, physical disability and substance abuse among the elderly, Psychology and Aging, 23(4), 10-22.
- 2. Hunt, M.C., Jensen, J.L. & Crenshaw, W. (2007). Substance abuse and mental health among communitydwelling elderly. International Journal of Gerlatric Psychiatry, 24(9), 1124-1135.
- 3. Hunt, M.C., Wiechelt, S.A. & Megyle, R. (2008). Predicting the substance-abuse treatment needs of an aging population. American Journal of Public Health, 45(2), 236-245, PMCID: PMC9162292 Hunt, M.C., Newlo, D.B. & Eishbeig, D. (2009). Brain imaging in methamphetamine abusers across the life-span. Gerontology, 46(3), 122-145.

B. Positions and Honors



POSITIONS & HONORS

Positions and Employment Fellow, Division of Intramural Research, National Institute of Drug Abuse, Bethesda, MD

2000-2002 Lecturer, Department of Psychology, Middlebury College, Middlebury, VT Consultant, Coastal Psychological Services, San Francisco, CA 2002-2005 Assistant Professor, Department of Psychology, Washington University, St. Louis, MO

Associate Professor, Department of Psychology, Washington University, St. Louis, MO 2007-

Other Experience and Professional Memberships

Member, American Psychological Association 1998-Member, Gerantological, Society of America 1998-Member, American Gerlatrics Society

2000-Associate Editor, Psychology and Aging 2003-Board of Advisors, Senior Services of Eastern Missouri

2003-05 NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer

2007-11 NIH Risk, Adult Addictions Study Section, members

Honors

2003 Outstanding Young Faculty Award, Washington University, St. Louis, MO 2004 Excellence in Teaching, Washington University, St. Louis, MO

2009 Award for Best in Interdisciplinary Ethnography, International Ethnographic Society

C. Contribution to Science



- 1. My early publications directly addressed the fact that substance abuse is often overlooked in older adults. However, because many older adults were raised during an era of increased drug and alcohol use, there are reasons to believe that this will become an increasing issue as the population ages. These publications found that older adults appear in a variety of primary care settings or seek mental health providers to deal with emerging addiction problems. These publications document this emerging problem but guide primary care providers and geriatric mental health providers to recognize symptoms, assess the nature of the problem and apply the necessary interventions. By providing evidence and simple clinical approaches, this body of work has changed the standards of care for addicted older adults and will continue to provide assistance in relevant medical settings well into the future. I served as the primary Investigator or co-investigator in all of these studies.
 - a. Gruczynski, J., Shaff, B.M., Merryle, R., & Hunt, M.C. (2002). Community based participatory research with late-life addicts. American Journal of Alcohol and Drug Abuse, 15(3), 222-238. b. Shaft, B.M., Hunt, M.C., Megryle, R., & Ventud, R. (2003). Policy implications of genetic
 - transmission of alcohol and drug abuse in female nonusers. International Journal of Drug Policy,
 - c. Hunt, M.C., Marks, A.E., Shaft, B.M., Merryle, R., & Jensen, J.L. (2004). Early-life family and community characteristics and late-life substance abuse. Journal of Applied Gerontology, 28(2),26-
 - d. Hunt, M.C., Marks, A.E., Ventud, R., Crenshaw, W. & Ratonian, A. (2007). Community-based intervention strategies for reducing alcohol and drug abuse in the elderly. Addiction, 104(9), 1436-1606 PMCID: PMC9000292
- 2. In addition to the contributions described above, with a team of collaborators, I directly documented the effectiveness of various intervention models for older substance abusers and demonstrated the importance of social support networks. These studies emphasized contextual factors in the etiniony and maintenance of addictive disorders and the disruptive potential of networks in substance abuse treatment. This body of work also discusses the prevalence of alcohol, amphetamine, and opioid abuse in older adults and how networking approaches can be used to mitigate the effects of these disorders.
 - a. Hunt, M.C., Megyje, R. & Jensen, J.L. (2005). The effect of social support networks on morbidity among elderly substance abusers. Journal of the American Gerlatrics Society, 57(4), 15-23.
 - b. Hunt, M.C., Pour, B., Marks, A.E., Mercyle, R. & Jensen, J.L. (2005). Aging out of methadone treatment. American Journal of Alcohol and Drug Abuse, 15(6), 134-149.

- c. Meryle, R. & Hunt, M.C. (2007). Randomized clinical trial of cotinine in older nicotine addicts. Age and Ageing, 38(2), 9-23. PMCID: PMC9002364
- 3. Methadone maintenance has been used to treat narcotics addicts for many years but I led research that has shown that over the long-term, those in methadone treatment view themselves negatively and they oradually begin to view treatment as an intrusion into normal life. Elderly narcotics users were shown in carefully constructed ethnographic studies to be especially responsive to tailored social support networks that allow them to eventually reduce their maintenance doses and move into other forms of therapy. These studies also demonstrate the policy and commercial implications associated with these findings.
 - Hunt, M.C. & Jensen, J.L. (2003). Morbidity among elderly substance abusers. Journal of the Gerlatrics, 60(4), 45-61.
 - b. Hunt, M.C. & Pour, B. (2004). Methadone treatment and personal assessment. Journal Drug
 - c. Metryle, R. & Hunt, M.C. (2005). The use of various nicotine delivery systems by older nicotine addicts. Journal of Ageing, 54(1), 24-41. PMCID: PMC9112304
 - d. Hunt, M.C., Jensen, J.L. & Megryle, R. (2008). The aging addict: ethnographic profiles of the elderly drug user. NY, NY: W. W. Norton & Company.

Complete List of Published Work in MyBibliography:

//www.nobl.nim.nih.gov/sites/mvn ions/public/1PaT7IEFIAJBtGMRDdWFmIWAO/?cort=d

D. Recearch Support



RESEARCH SUPPORT

Ongoing Research Support

R01 DA942367 Hunt (PI)

09/01/08-08/31/16 Health trajectories and behavioral interventions among older substance abusers

The goal of this study is to compare the effects of two substance abuse interventions on health outcomes in an urban population of older opiate addicts.

Role: PI

R01 MH922731 Metryle (PI) 12/15/07-11/30/15

Physical disability, depression and substance abuse in the elderly

The goal of this study is to identify disability and depression trajectories and demographic factors associated with substance abuse in an independently-living elderly population.

Role: Co-Investigator

Faculty Resources Grant, Washington University

08/15/09-08/14/15

Oplate Addiction Database

The goal of this project is to create an integrated database of demographic, social and biomedical information for homeless opiate abusers in two urban Missouri locations, using a number of state and local data sources.

Completed Research Support

R21 AA998075 Hunt (PI) 01/01/11-12/31/13

Community-based intervention for alcohol abuse

The goal of this project was to assess a community-based strategy for reducing alcohol abuse among older individuals.

Role: PI





EJEMPLO BUDGET

Next Period ORGANIZATIONAL DUNS: 4771920870000 Enter name of Organization: RESEARCH FOUNDATION OF HOSPITAL LA FE Budget Type: Project Subaward/Consortium Budget Period: 1 Start Date: 07/01/2016 End Date: 06/30/2017 A. Senior/Key Person SENIOR/KEY PERSONNEL Months Requested Fringe	mber: 4040-0001) Date: 6/30/2016
Budget Type: Project Subaward/Consortium Budget Period: 1 Start Date: 07/01/2016 End Date: 06/30/2017 A. Senior/Key Person SENIOR/KEY PERSONNEL Months Requested Fringe	
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F. Other Direct Costs OTHER DIRECT COSTS	Funds Requested (\$)
Materials and Supplies	2,500.00
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	3,000.00
7. Alterations and Renovations	
8.	
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10.	
Total Other Direct Coets	5,500.00
G. Direct Costs	Funds Requested (\$)
Total Direct Costs (A thru F)	8,000.00
H. Indirect Costs INDIRECT COSTS	
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BÚSQUEDA DE LA APLICACIÓN TELEMÁTICA

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)
Components of Participating Organizations	National Cancer Institute (NCI)
Funding Opportunity Title	NCI Small Grants Program for Cancer Research (NCI Omnibus R03)
Activity Code	R03 Small Grant Program
Announcement Type	Reissue of PAR-12-144
Related Notices	NOT-OD-16-004 - NIH & AHR Q Announce Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications (November 18, 2015) NOT-OD-16-006 - Simplification of the Vertebrate Animals Section of NIH Grant Applications and Contract Proposals (November 18, 2015) NOT-OD-16-011 - Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications (November 18, 2015) June 4, 2014 - Notice NOT-14-074 supersedes instructions in Section III.3 regarding applications that are essentially the same.
Funding Opportunity Announcement (FOA) Number	PAR-14-007
Companion Funding Opportunity	PAR-15-340, R21 Exploratory/Developmental Grant PAR-13-146, R21 Exploratory/Developmental Grant
Number of Applications	See Section III. 3. Additional Information on Eligibility.
Catalog of Federal Domestic Assistance (CFDA) Number(s)	93.393, 93.394, 93.395, 93.396, 93.399
Funding Opportunity Purpose	This funding opportunity announcement (FOA), issued by the National Cancer Institute (NCI), of the National Institutes of Health (NIH) supports small research projects on cancer that can be carried out in a short period of time with limited resources. The R03 grant mechanism supports different types of projects including pilot and feasibility studies; secondary analysis of existing data; small, self-contained research projects; development of research methodology; and development of new research technology.





BÚSQUEDA DE LA APLICACIÓN TELEMÁTICA

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants must download the SF424 (R&R) application package associated with this funding opportunity using the "Apply for Grant Electronically" button in this FOA or following the directions provided at Grants.gov.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed in this funding opportunity announcement to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit Frequently Asked Questions - Application Guide, Electronic Submission of Grant Applications.

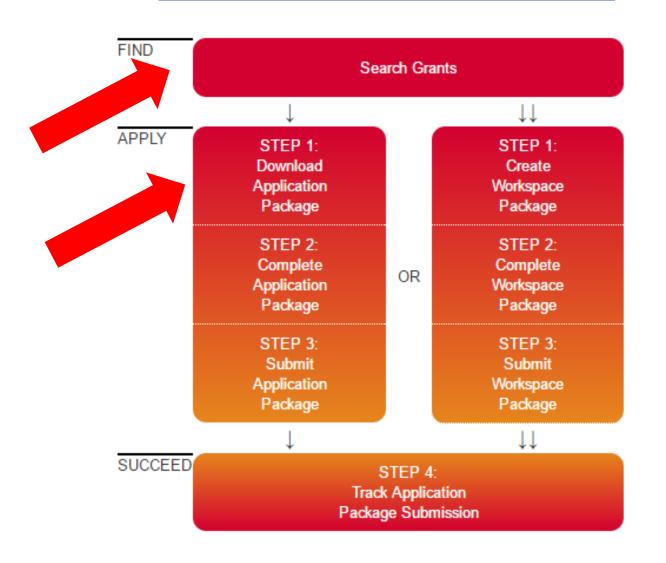


APPLICANTS: APPLY FOR GRANTS





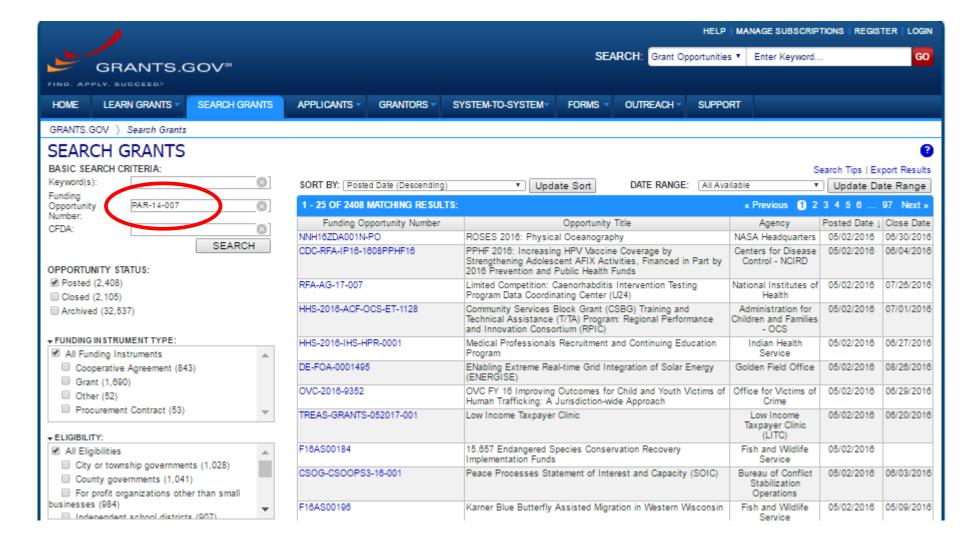
BÚSQUEDA DE LA APLICACIÓN TELEMÁTICA







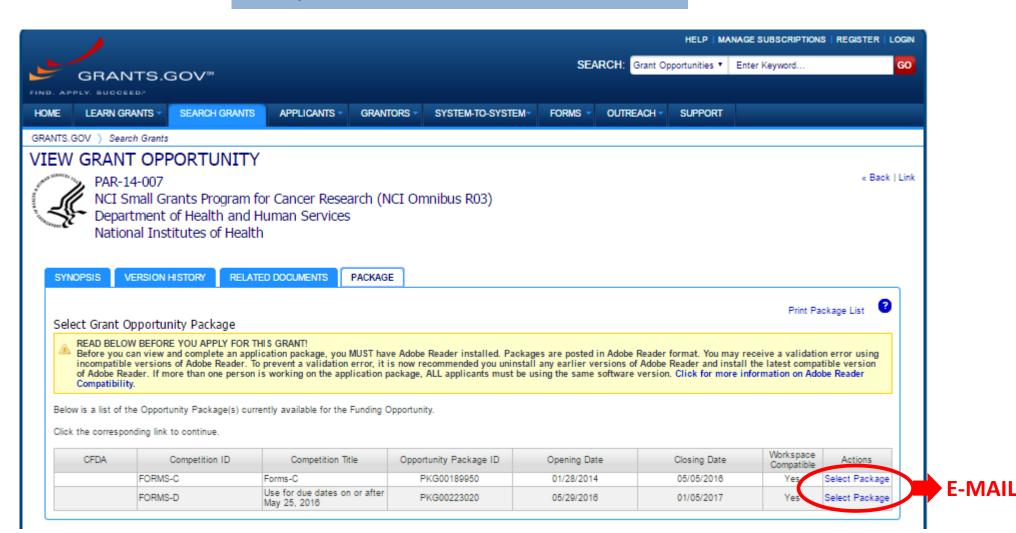
BÚSQUEDA DE LA APLICACIÓN TELEMÁTICA







BÚSQUEDA DE LA APLICACIÓN TELEMÁTICA







BÚSQUEDA DE LA APLICACIÓN TELEMÁTICA

Option 1: Download Instructions and Package

Download Instructions and Package by clicking the appropriate button below Instructions will open directly in your browser and can be saved to your computer. Packages must be saved directly to your computer. You do not need Internet access to read the Instructions or the Package once you save them to your computer.

Download Instructions »

Download Package »

Option 2: Create a Grants.gov Workspace

Login to create a Workspace, where your organization's applicants can download, complete, and upload individual forms of an opportunity package.

Learn more about Workspaces »

Login for Workspace Features »

Application Guide: FORMS-D

http://grants.nih.gov/grants/How-to-Apply-Application-Guide.htm





Grant Application Package





NCI Small Grants Program for Cancer Research (NCI Omnib Mandatory

DOCUMENTOS solicitud NIH:

	SF424 (R & R)
	PHS 398 Cover Page Supplement
	Research And Related Other Project Information
	Project/Performance Site Location(s)
	Research and Related Senior/Key Person Profile (Expanded)
	PHS 398 Research Plan
Optiona	I
X	Research & Related Budget
	R & R Subaward Budget Attachment(s) Form 5 YR 30 ATT
	PHS 398 Modular Budget
×	PHS 398 Inclusion Enrollment Report
×	PHS Assignment Request Form

If the Federal funding opportunity listed is not the opportunity for which you want to apply, close this application package by clicking on the "Cancel" button at the top of this screen. You will then need to locate the correct Federal funding opportunity, download its application and then apply.



EJEMPLO PRÁCTICO





Select Forms to Complete				
Mandatory	Save & Submit Check Package for Errors			
SF424 (R & R)				
PHS 398 Research Plan				
PHS 398 Cover Page Supplement				
Research and Related Senior/Key Perso	on Profile (Expanded)			
Research And Related Other Project Inf	<u>ormation</u>			
Project/Performance Site Location(s)				



Usuario y contraseña AOR en Grants.Gov



Required Application Instructions

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise (in this FOA or in a Notice from the NIH Guide for Grants and Contracts). Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. Applications that do not comply with these instructions may be delayed or not accepted for review.

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You must use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.

Apply Online Using ASSIST

- Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons to track your application. Check with your institutional officials regarding availability.
- Go to Grants.gov to download an application package to complete the application forms offline or create a Workspace to complete the forms online; submit your application to Grants.gov; and track your application in eRA Commons.

Learn more about the various submission options.







Home > Apply for Grants > Confirmation

Confirmation

Thank you for submitting your grant application package via Grants.gov. Your application is currently being processed by the Grants.gov system. Once your submission has been processed, Grants.gov will send email messages to advise you of the progress of your application through the system. Over the next 24 to 48 hours, you should receive two emails. The first will confirm receipt of your application by the Grants.gov system, and the second will indicate that the application has either been successfully validated by the system prior to transmission to the grantor agency or has been rejected due to errors.



Índice:

1.- El Programa NIH: Descripción, presupuesto y tipos de convocatorias. Características, requisitos y documentación. Ejemplo práctico.

2.- Gestión y justificación del Programa NIH.

3.- Otras convocatorias internacionales de interés en el ámbito Salud.







- **1) Submission Receipt:** An e-mail is sent indicating your application has been received by Grants.gov and is currently being validated.
- **2) Submission Validation Receipt:** An e-mail is sent indicating your application has been received and validated by Grants.gov and is being prepared for Grantor agency retrieval.
- **3) Grantor Agency Retrieval Receipt:** An e-mail is sent indicating your application has been retrieved by the Grantor agency.
- **4) Agency Tracking Number Assignment for Application:** An e-mail is sent indicating your application has been assigned an Agency Tracking Number. In Grants.gov, a status of Agency Tracking Number Assigned also indicates that NIH has processed the application without identifying any errors and an assembled application image is available in eRA Commons for viewing.



Chequear status en eRA Commons y Grants.gov













Home Admin Institution Profile Personal Profile Status ASSIST Prior Approval RPPR xTrain xTRACT Admin Supp eRA Partners Non-Research

Welcome to the Commons

Welcome

I Institution: RESEARCH FOUNDATION OF/HOSPITAL LA FE

Roles: Pl

eRA Service Desk

- Hours: Mon-Fri, 7AM-8PM EDT/EST
- Web:

http://grants.nih.gov/support

Toll-free: 866-504-9552
 Phone: 301-402-7469

Contact initiated outside of business hours via Web or voice mail will be returned the next business day. · 🕕 System Information Message

All systems are currently available.

Commons allows you to perform the following activities below based on the privileges associated with this profile:

- Administration Allows you to assign a delegate to perform system and accounts maintenance more...
- Institution Profile Enables you to view and update institution information more...
- Personal Profile Allows you to update your personal information. Please periodically review your profile to
 ensure accuracy of information submitted more...
- Status Allows you to check the status of grants and applications that have been submitted more...
- RPPR Allows you to review the information needed to complete a progress report. See <u>RPPR Information</u> and Submitting Progress Reports.
- xTrain Enables you in a Trainee or SO role to confirm the information that you have submitted for a Trainee
 role type more...
- Internet Assisted Review (IAR) Allows reviewer to submit critiques and preliminary scores for applications
 they are reviewing more...

What's New

- New in RPPR
- New Service Desk System

Commons Resources

- · Frequently Asked Questions
- · Latest Release Notes
- Commons Login Tutorial
- Commons Support Page
- eRA Training
- User Guides
- · Grantee Organization Registration
- eRA Website
- Applying Electronically

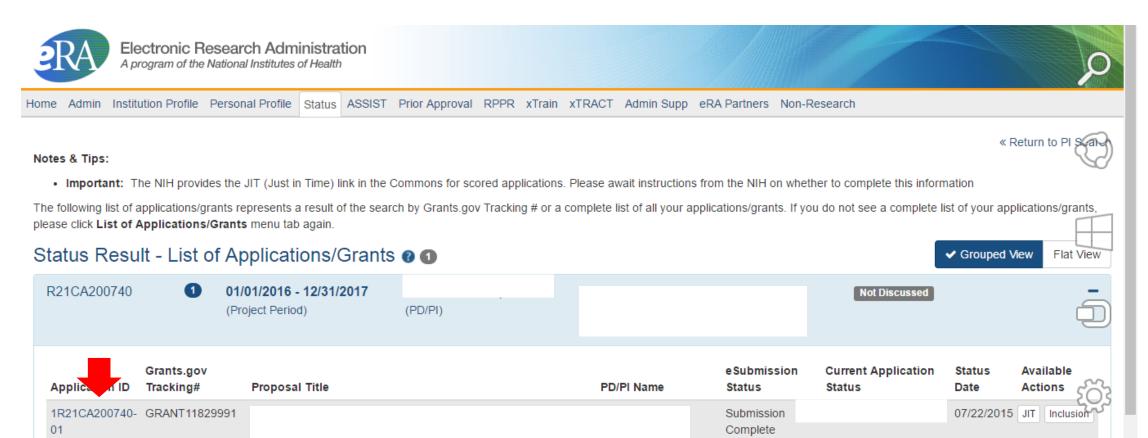
Additional Links

- eRA Contacts
- RePORT

Dr. Ana Ma Blanco











Contacts

Administration: Scientific Review Administrator(SRO))

Name: MEEKER, TIMOTHY C Phone: 240-276-6464

Email: meekert@mail.nih.gov



Administration: Program Official(PO)

Name: Kondapaka, Sudhir B Phone: 240-276-5365

Email: kondapas@mail.nih.qov

Latest Update

Application Source: Grants.gov FOA: [PAR13-146] - NCI

EXPLORATORY/DEVELOPMENTAL RESEARCH GRANT

PROGRAM (NCI OMNIBUS R21)

eRA Service Desk

Hours: Mon-Fri, 7AM-8PM EDIT/EST

Web: http://grants.nih.gov/support

Toll-free: 866-504-9552 Phone: 301-402-7469

Contact initiated outside of business hours via Web or voice

mail will be returned the next business day.

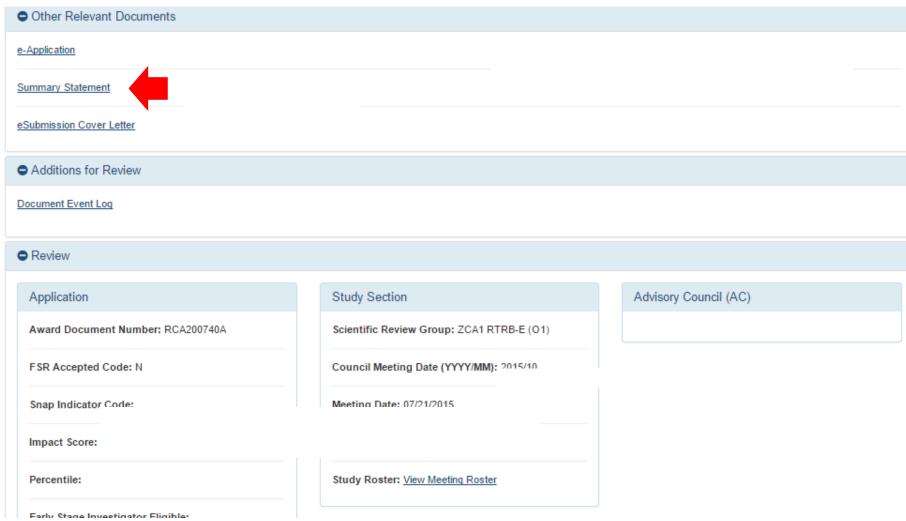
Status Information @



ri name:	ин Арр. ю. эт 1000	Application ID: 1 R21 CA200740-01
● Status		
Status: Scientific Review Group review completed:	10-90 Priority Score	
Last Status Update Date: 07/22/2015		
PI Name:	Institution Name: RESEARCH FOUNDATION OF THE HOSPITAL LA FE	NIH Appl. ID: 9011000
	Department Name:	
Proposal Receipt Date: 02/06/2015	Proposal Title:	
	late:	
Application Source: Grants.gov	eApplication Status: Submission Complete	
FOA: [PAR13-146] - NCI EXPLORATORY/DEVELOPMENTAL RESEARCH GRANT PROGRAM (NCI OMNIBUS R21)		



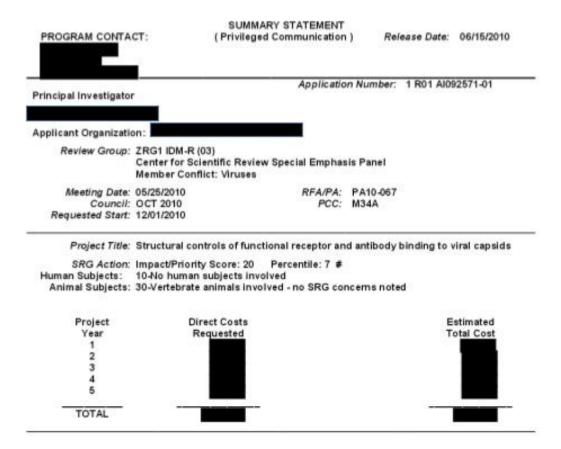








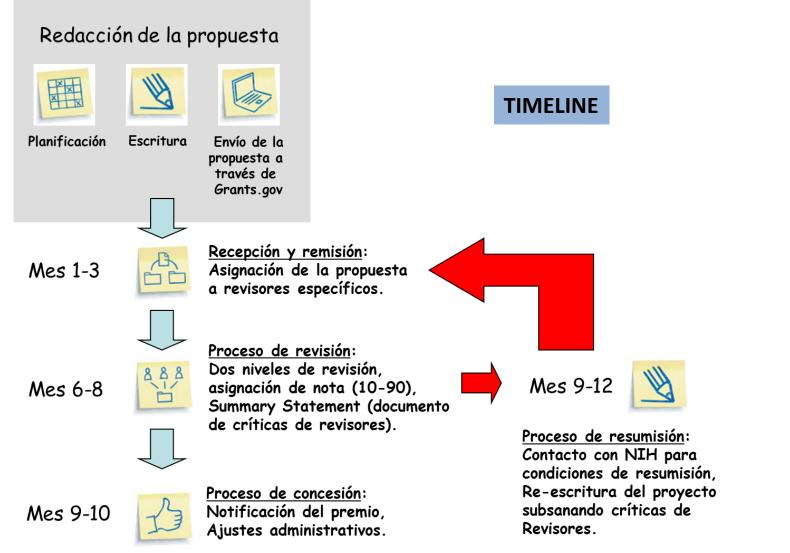
Summary statement example







Dr. Ana Ma Blanco







JUSTIFICACIÓN NIH







- 1) Preliminary Review by the NIH Institute or Center (IC): Once an application has scored well in peer review and is being considered for funding, the IC reviews the application for a number of other considerations, including alignment with NIH's funding principles, review of the project budget, assessment of the applicant's management systems, determination of applicant eligibility, and compliance with public policy requirements.
- 2) Collection of Just in Time (JIT) Information: After NIH releases priority scores, NIH sends an e-mail requesting Just-in-Time (JIT) information for grants within the competitive range for possible funding. This notification, sent to the PD/PI, is NOT a Notice of Award, nor should it be construed as an indicator of possible award. JIT information requested include:
 - other support
 - certification of Institutional Review Board (IRB) approval
 - certification of Institutional Animal Care and Use Committee (IACUC) approval
 - human subjects training certification for all key personnel

JIT information must be submitted for NIH review and evaluation prior to making an award.







- 3) Negotiation of Competing Award: Initial peer review recommendations, Overlaps, Level of effort: Program and grants management, Budget/programmatic modification.
- **4) Award Process:** Notice of Award (NoA), the legal document issued to notify the grantee that an award has been made and that funds may be requested from the designated HHS payment system or office.
- **5) Accepting the Award:** The grantee accepts an NIH award and its associated terms and conditions by drawing or requesting funds from the Payment Management System or upon the endorsement of a check from the US Treasury for foreign awardees.





Federal Award Date: 05/19/2017

Notice of Award

SMALL BUSINESS INNOVATION RESEARCH PROG

Department of Health and Human Services

National Institutes of Health



NIH

NATIONAL INSTITUTE OF MENTAL HEALTH

Grant Number: 2R44MH093334-06A1

FAIN: R44MH093334

Principal Investigator(s): Gregory John Gage, PHD Nº beca

Fecha de expedición más reciente

FAIN: Nº identificación de adjudicación federal.

Project Title: Backyard Brains: Bringing Neurophysiology Into Secondary Schools

Dr. Gage, Gregory John

CEO

308 1/2 S. State Street

Ste 35

Ann Arbor, MI 481042432

Periodo presupuestal.

Period Of Performance:

Budget Period: 05/19/2017 - 04/30/2018

Award e-mailed to: hello@backyardbrains

Project Period: 05/19/2017 - 04/30/2020

Dear Business Official:

Periodo del proyecto.

Cantidad concedida.

The National Institutes of Health hereby awards a grant in the amount of \$784,021 (See "Award Calculation" in Section I and "Terms and Conditions" in Section III) to Backyard Brains in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 15 USC 638 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

NoA





IMPORTANTE: Certificaciones y seguros tras el NoA



- ✓ Se debe seguir las políticas de becas NIH: Grants Policy Statement.

 https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf
- ✓ Se debe seguir los Terms and conditions del NoA.
- ✓ Code of Federal Regulations 45 CFR 46.
- ✓ Informe anual ORI (conductas inadecuadas en la investigación): 42CFR 93, Subpart C. http://www.ori.dhhs.gov
- ✓ OLAW: Garantía para uso de animales laboratorio. http://grants.nih.gov/grants/olaw/
- ✓ FWA: Garantía para uso de sujetos humanos. http://www.hhs.gov/ohrp
- ✓ IRB: comité de ética en USA.

IMPORTANTE: tan pronto como un investigador gaste \$1 dólar, se da por hecho que se acepta la ayuda.









- ✓ INFORMES (eRA Commons):
 - ✓ RPPR (Research Performance Progress Report)
 - ✓ FFR (Financial Reporting, SF 245)
 - ✓ Política Open Access http://publicaccess.nih.gov







IMPORTANTE: Certificaciones y seguros tras el NoA

APLICACIONES Y FORMULARIOS	FECHA DE ENTREGA	
Informe de avances en el desempeño de la investigación (RPPR)	60 días antes de la fecha de inicio del siguiente presupuesto (anualmente)	
Informe financiero federal FFR SF425 (anual)	90 días después de que termine el trimestre natural en el que termine el periodo de presupuesto (anualmente)	
Informe financiero federal FINAL	120 días después de la fecha de finalización del periodo del proyecto	
ORI	Anualmente	
Aprobación IRN	Se renueva anualmente	
Garantía FWA	Se renueva cada 3 años	
Garantía OLAW	Se renueva cada 5 años	







✓ Research Performance Progress Report (RPPR): anualmente a través de eRA Commons.

Accomplishments

What were the major goals and objectives of the project?

What was accomplished under these goals?

What opportunities for training and professional development did the project provided?

How were the results disseminated to communities of interest?

What do you plan to do during the next reporting period to accomplish the goals and objectives?

Products

publications, conference papers, and presentations

website(s) or other Internet site(s)

technologies or techniques

inventions, patent applications, and/or licenses

other products, such as data or databases, physical collections, audio or video products, software, models, educational aids or curricula, instruments or equipment, research material, interventions (e.g., clinical or educational), or new business creation.

Participants and Other Collaborating Organizations

Impact

Changes/Problems

Changes in approach and reasons for change

Actual or anticipated problems or delays and actions or plans to resolve them

Changes that have a significant impact on expenditures

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Budgetary Information





✓ Financial Reporting FFR (Institutional Requirement): anualmente a través de eRA Commons

FEDERAL FINANCIAL REPORT (Follow form instructions)

	ncy and Organiz port is Submitted				entifying Number Assigne use FFR Attachment)	d by Federal i	Agency	Page 1	of
									page
Recipient Or	rganization (Nam	e and complete address inclu	ding Zip code)						
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. DUNS NUT	nber	40. EIN			r or Identifying Number , use FFR Attachment)		port Type	Basis of Acc	ounting
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Project/Gran			lan atom po	Wasah			Period End	Date	
From: (Mon	th, Day, Year)		To: (Month, Da	iy, Year)		(Month,	Day, Year)		
). Transacti	ions							Cumulative	
lse lines a-c	for single or ma	ultiple grant reporting)							
oderal Cash	(To report mul	Itiple grants, also use FFR A	Hachment):						
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	sbursements								
	Hand (line a min	nus b)							
lse lines d-o	for single grant	t reporting)							
ederal Expe	nditures and Ur	nobligated Balance:							
d. Total Fe	deral funds author	orized							
e. Federal:	share of expendi	tures							
f. Federal:	share of unliquid	ated obligations							
g. Total Fe	deral share (sum	of lines e and f)							
		ederal funds (line d minus g)							
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	t share of expen								
		to be provided (line i minus j)						
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	eral program ino								
		ed in accordance with the ded							
		ed in accordance with the addi ome (line I minus line m or line							
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expense									
,				g. Totals:					
. Remarks:	Attach any expla	anations deemed necessary or	Information requ		al sponsoring agency in c	ompliance wit	h governing i	egislation:	
Certification	on: By signing	this report. I certify to the h	est of my knowl	edge and be	lief that the report is tru	e complete	and accurate	and the expendi	turos

REPORTING





✓ Financial Reporting (Institutional Requirement): anualmente a través de eRA Commons

Federal Expenditures and Unobligated Balance:			
d. Total Federal funds authorized			
e. Federal share of expenditures			
f. Federal share of unliquidated obligations			
g. Total Federal share (sum of lines e and f)			
h. Unobligated balance of Federal funds (line d minus g)			

10d. Enter the total (cumulative) authorized award amount for the budget period covered by this report.

(ex. Year 1 authorized amount-\$200,000, Year 2 authorized amount-\$200,000 =Total Federal funds authorized-\$400,000)

10e. Enter the amount (cumulative) of expended funds.

(Ex. Year 1 expenditures- \$150,000 Year 2 expenditures- \$150,000 = Federal share of expenditures- \$300,000)

10f. Enter the amount (cumulative) of unexpended obligation as of the reporting period (FFR) end date. Unliquidated obligations are expenses that have been incurred but have not been paid out as of the end of the reporting period.

10g. Enter the (cumulative) sum of lines (10e + 10f). This will equal the total federal funds spent and obligated as of the reporting period date.

(Ex. 10e- \$300,000 + 10f- \$50,000 = Totals Federal Share- \$350,000)

10h. Subtract line (10d - 10g) and enter the difference. This will equal the total unobligated federal funds, and would be the amount available to carryover in the following year. (ex. 10d-\$400,000 - 10g-\$350,000 = Unobligated balance-\$50,000)





✓ EJEMPLO Financial Reporting:

- ✓3-year grant
- ✓ Beneficiario recibe \$200.000/year
- ✓ El beneficiario reporta de unliquidated expenses:
 - Year 1: \$35.000
 - Year 2: \$5.000
- ✓ El beneficiario reporta Expenditures:
 - Year 1: \$150.000
 - Year 2: \$180.000
 - Year 3: \$205.000





✓ **EJEMPLO Financial Reporting:**

Federal Expenditures and Unobligated Balance:	YEAR 1
d. Total Federal funds authorized	= 200.000\$
e. Federal share of expenditures	= 150.000\$
f. Federal share of unliquidated obligations	= 150.000\$ = 35.000\$ = 185.000\$
g. Total Federal share (sum of lines e and f)	= 185.000\$
h. Unobligated balance of Federal funds (line d minus g)	= 15.000 \$

Federal Expenditures and Unobligated Balance:	YEAR 2
d. Total Federal funds authorized	= 400.000\$
e. Federal share of expenditures	= 365.000\$
f. Federal share of unliquidated obligations	= 5.000\$
g. Total Federal share (sum of lines e and f)	= 370.000\$
h. Unobligated balance of Federal funds (line d minus g)	= 30.000\$

Federal Expenditures and Unobligated Balance:	YEAR 3
d. Total Federal funds authorized	= 600.000\$
e. Federal share of expenditures	= 575.000\$
f. Federal share of unliquidated obligations	= 0\$
g. Total Federal share (sum of lines e and f)	= 575.000\$
h. Unobligated balance of Federal funds (line d minus g)	= 25.000\$





Form Approved Through 10/31/2018 OMB No. 0925-0002

√	Cierre	del	proy	ecto.
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Required closeout reports include:

Final FFR Expenditure data
Final progress report
Final Invention Statement and Certification
Final population tracking data when applicable

Department of I Final Invention St (Fo	DHHS Grant or Award No.					
A. We hereby certify that, to the best of our knowledge and belief, all inventions are listed below which were conceived and/or first actually reduced to practice during the course of work under the above-referenced DHHS grant or award for the period						
	through					
original effective date		date of termination	<u> </u>			
B. Inventions (Note: If no inventions have been made under the grant or award, insert the word "NONE" under						
NAME OF INVENTOR	TITLE	OF INVENTION	DATE REPORTED TO DHHS			
Use continuation sheet if necessary)						
	'		'			
C. Signature — This block mus	st be signed by an office	cial authorized to sign on b	pehalf of the institution.			
Name and Mailing Address of Institution						





Sistema de gestión de pagos



Payment Management System (PMS) PMS Webinar: PMS_Training@psc.hhs.gov

✓ Registro:

OMB No. 1510-0007

- Formulario de registro normalizado (SF-1199A):
- Carta bancaria internacional
- Formulario de acceso al PMS

Standard Form 1199A (EG) (Rev. June 1987)
Prescribed by Treasury
Department
Treasury Dept. Cir. 1076

DIRECT DEPOSIT SIGN-UP FORM

- . To sign up for Direct Deposit, the payee is to read the back of this form and fill in the information requested in Sections 1 and 2. Then take or mail this form to the financial institution. The financial institution will verify the information in Sections 1 and 2, and will complete Section 3. The completed form will be returned to the Government agency identified below.
- A separate form must be completed for each type of payment to be sent by Direct Deposit
- The claim number and type of payment are printed on Government checks. (See the sample check on the back of this form.) This information is also stated on beneficiary/annuitant award letters and other documents from the Government agency.
- · Payees must keep the Government agency informed of any address changes in order to receive important information about benefits and to remain

SECTION 1 (TO BE COMPLETED BY PAYEE)

	SECTION 1 (TO BE COMM EETED BY TATEE)				
Α	NAME OF PAYEE (last, first, middle initial)		D TYPE OF DEPOSITOR ACCOUNT CHECKING SAVINGS		
			F DEPOSITOR ACCOUNT NUMBER		
\vdash	1000000011 1 1 0 0 0 1000000		E DEPOSITOR ACCOUNT NUMBER		
	ADDRESS (street, route, P.O. Box, APO/FPO)				
	CITY STATE	ZIP CODE	F TYPE OF PAYMENT (Check only one)		
	▼		Social Security Fed. Salary/Mil. Civilian Pay		
⊢			Supplemental Security Income MII. Active		
	TELEPHONE NUMBER		Railroad Retirement Mil. Retire.		
	AREA CODE				
B	NAME OF PERSON(S) ENTITLED TO PAYMENT		CIVII Service Retirement (OPM) Mil. Survivor		
١.	NAME OF TERSON(S) ENTITEED TO FATMENT		VA Compensation or Pension Other		
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PAYEE/JOINT PAYEE CERTIFICATION			JOINT ACCOUNT HOLDERS' CERTIFICATION (optional)		
Los	rtify that I am entitled to the payment identified above	e and that I have	I certify that I have read and understood the back of this form.		
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my payment to be sent to the financial institution named below to be			induding the SPECIAL NOTICE TO JOINT ACCOUNT HOLDERS.		
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CIC	SNATURE	DATE	SIGNATURE DATE		
SIGNATURE		DATE	SIGNATURE		
1					

SECTION 2 (TO BE COMPLETED BY PAYEE OR FINANCIAL INSTITUTION)

GOVERNMENT AGENCY NAME	GOVERNMENT AGENCY ADDRESS

SAMPLE International Bank Letter			
(Inter	national Organizations Only)		
Information must be on the	e International Bank Letterhead with an authorized signature		

Info	ormation must be on the International Bank Letterhead with an authorized signature
TO:	HHS/Payment Management Services
DAT	E:
FRO	ví:
RE:	Currency Account Instructions - United States Dollars (USD)
	Remittances can be affected to the following account as follows:
	Beneficiary Bank Information
	Beneficiary Customer
	Beneficiary Customer A/C No Account with Institution
	Address
	Swift Code IBAN
	IDAN
	Corresponding US Bank Information Intermediary Institution in US Addites: ABA Routing # Account Number USD, if applicable
	Other pertinent information or instructions
	If you have any questions or need additional information, please feel free to contact me.
	Sincerely,
	Back Representative Elegantum
	Bank Representative Bank Address Telephone#
	Fax#

DEPARTMEN	IT OF HEALTH AND HUMAN SERVICES Program Support Center	
§ //)	gement System Access Request	
1 - CD-	ectly and in its entirety in order to be processe	d***
Please print or type		
Action(s) Requested (Select only one)		
Establish New User Access	Update Existing User Contact Information:	Current PMS Username
Change Existing User Access: Current PMS User	mame	
Change Existing Oser Access. Guiterit i Mio Oser	Halle	
Deactivate User Access: Current PMS Usernam complete sections 1, 2 and 5 below	e if not known, print or type first and last name of persor	to be deactivated and
Name of Institution/Organization		
2. Payee Identification Number(s) (PIN) if not known	, list EIN:	
Is the action requested for all accounts associated	d with this PIN(s) or EIN?	
Yes No		
Request to Establish/Change Access or Update C	Contact Information for:	
Name (Please Print)	Title	Telephone #
F-Mail Address	Mailing Address	
4. Type of access requested for user (Please comple		
A. Please check all that apply (please note inqu	uiry is included).	
Payment Requests	LOOK Transaction Report (FOTD) Assess	
	I Cash Transaction Report (FCTR) Access	
	ial Status Report (FSR) - Preparer Access ial Status Report (FSR) - Certifier Access	
rederal ciliandal Report (FFR): Financi	ai otatus Nepolt (Fort) - Gertillei Addess	





FOS vs. Auditorías

FOS (no es AUDIT)
The Mitchell Group, Inc.



Review of Administrative and Financial systems using the Foreign Organization System (FOS) review document.



- ✓ Terms & Conditions.
- ✓ Internal procedures.
- ✓ Understanding PI and NIH.
- ✓ Recommendations in COMPLIANCE.

OMB A133 Audit.



45CFR 75.501 (h)-(k): Foreign institutions

Igual o más de \$750.000/fiscal year.



- ✓ Yellow Book Audit: http://www.gao.gov/govaud/ybk01.htm
- ✓ OMB A133 Audit: https://www.whitehouse.gov/OMB/inform ation-for-agencies/circulars#numerical

https://www.niaid.nih .gov/grantscontracts/preparingforeign-organizationsystem-review







Requerimientos a las instituciones beneficiarias

Written policies&procedures

Banking Arrangements

Indirect costs

Standarized Consortium Agreements

Records management

FCOI Accounting systems

At least 2 SO

Internal control & audits

Public access

Payment Management System

Travel

Personnel





Ayuda para Monitoring and Compliance



Grants & Funding

s Central Recourse for Grants and Funding Information

Entire Site ▼ Search this Site Q

HOME ABOUT GRANTS FUNDING POLICY & COMPLIANCE NEWS & EVENTS ABOUT OER



Grants Compliance & Oversight

On This Page: . About Grants Compliance and Oversight

- · Compliance Requirements At A Glance
- NIH Compliance Activities
- Compliance Resources
- Reporting Compliance Concerns

https://grants.nih.gov/policy/compliance.htm



eRA | Glossary & Acronyms | FAQs | Hell

About Grants Compliance and Oversight

This site provides Federal requirements, guidelines and resources for the extramural community involving grants compliance. The information provided on this website is designed to assist the extramural community in understanding the recipient's responsibility for establishing and maintaining the necessary processes to monitor its compliance with Federal requirements, ensuring NIH-funded projects are conducted in accordance with the approved application and budget and the terms and conditions of award and informing NIH of any problems or concerns regarding compliance.

Division of Grants Compliance and Oversight (DGCO) at NIH

The Division of Grants Compliance and Oversight (DGCO) is the focal point to advance external compliance with policy and legislative mandates and enhance compliance oversight by recipient institutions. The DGCO also ensures and evaluates the efficient and effective management of extramural resources.

Director: Diane W. Dean

Staff:

- · Kathy Hancock, Assistant Grants Compliance Officer
- Sahar Rais, Assistant Grants Compliance Officer
- · Joel Snyderman, Assistant Grants Compliance Officer
- · Samantha Tempchin, Assistant Grants Compliance Officer

Compliance Requirements At A Glance

Recipients of NIH grant funds must comply with all applicable Federal statutes (such as those included in appropriations acts) regulations, and policies. Additionally, they must also comply with their institutional requirements. The table below summarizes the Federal administrative requirements, cost principles and audit requirements applicable to NIH grants and cooperative agreements.

	Summary of Federal Requirement References		
Recipient Type	Administrative Requirements	Cost Principles	Audit Requirements
State & Local Governments	45 CFR Part 75, Subpart C & - Pre-Federal Award Requirements and Contents of Federal Awards 575.200-575.217	45 CFR Part 75, Subpart E # See also \$75.416 and \$75.417	45 CFR Part 75, Subpart F.Ø. at 575.501 Also applicable to non-profit Hospitals
Institutions of Higher Education	AND	45 CFR Part 75, Subpart E & See also \$75.418 and \$75.419	
Non-Profits	45 CFR Part 75, Subpart D Ø − Post Federal Award Requirements \$75.300-\$75.391	45 CFR Part 75, Subpart E Ø	





CONSULTA PROYECTOS NIH CONCEDIDOS

http://report.nih.gov/nih_funding.aspx



Q Search

HOME | ABOUT RePORT | FAQs | GLOSSARY | CONTACT US

QUICK LINKS RESEARCH **ORGANIZATIONS** WORKFORCE FUNDING REPORTS LINKS & DATA **NIH FUNDING** Home > Funding **QUICK LINKS** NIH Data Book Awards by Location RTER

The NIH Data Book (NDB) provides basic summary statistics on extramural grants and contract awards, grant applications, the organizations that NIH supports, the trainees and fellows supported through NIH programs, and the national biomedical workforce More Details

Consolidates all information about NIHsupported extramural organizations in a single tool

More Details



Success Rates

Computed on a FY basis, success rates are defined by the percentage of applications funded and the total number of applications reviewed in various budget and grant activity categories.



Funding Facts

Quick access to statistics from the NIH Data Book and annual reports produced by the NIH OER's Division of Information Services. Ability to search statistics by topic, NIH IC's, funding mechanism, activity code, type of award, or fiscal year.

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AWARDS BY LOCATION



NIH DATA BOOK



FUNDING FACTS



RECOVERY ACT ON RePORT



NIH FACT SHEETS



NIH CATEGORICAL SPENDING



BIENNIAL REPORT



REPORT CATALOG



Índice:

- 1.- El Programa NIH: Descripción, presupuesto y tipos de convocatorias. Características, requisitos y documentación. Ejemplo práctico.
- 2.- Gestión y justificación del Programa NIH.

3.- Otras convocatorias internacionales de interés en el ámbito Salud.



Financiación USA: FOGARTY INTERNATIONAL CENTER.



Home

About Fogarty

Funding Opportunities

Grants Management

Global Health Resources

Fogarty Programs

News



Global health research benefits people everywhere

To protect the health and safety of Americans, Fogarty programs build scientific expertise in developing countries, ensuring there is local capacity to detect and address pandemics at their point of origin; accelerate scientific discovery; and provide national and international health leadership.

MORE

Latest News

- March / April 2017
 Global Health Matters
 newsletter
- Fogarty fact sheets

Funding News

- International Bioethics Training
 Due May 18
- ▶ Global Infectious Disease Research Training Due Jul 27
- HIV Research Training Due Aug 23
- ▶ Funding concepts:

 > Partnership Initiative
 for Health Professional
 Education and
 Research in Selected
 PEPFAR countries

 > African Association
 for Health Professions
 Education and

Making a Difference



Fogarty protects
 Americans by building pandemic response capacity in Ebola-hit
 West Africa



► Fogarty trainee heads Peru site of an NIH trial

Views of Fogarty @ 50

As we mark our 50th year, our community shares how our programs have aided careers and advanced research.

"Fogarty understands that global change starts within individual countries, and during its 50 years of existence, its unique, sustained focus on supporting people in their own countries to solve their own problems has been a critical piece of the



https://www.fic.nih.gov



Financiación USA: FOGARTY INTERNATIONAL CENTER.

Application Due Date	Fogarty Funding Opportunity (Announcement)	Affiliated Fogarty Programs (Overview)	Type of Opportunity
July 27, 2017	Global Infectious Disease Research Training Program (D43) (PAR-17-057)	Global Infectious Diseases (GID)	International Research Training Grants
July 27, 2017	Planning Grant for Global Infectious Disease Research Training Program (D71) (PAR-17-058)	Global Infectious Diseases (GID)	International Research Training Planning Grant
August 23, 2017	Infrastructure Development Training Programs for Critical HIV Research at Low- and Middle-Income Country Institutions (G11) (PAR-16-280)	Fogarty HIV Research Training	Extramural Associate Research Development Award
August 23, 2017	Planning Grant for Fogarty HIV Research Training Program for Low- and Middle-Income Country Institutions (D71) (PAR-16-281)	Fogarty HIV Research Training	International Research Training Planning Grant
August 23, 2017	Fogarty HIV Research Training Program for Low- and Middle-Income Country Institutions (D43) (PAR-16- 279)	Fogarty HIV Research Training	International Research Training Grants
August 31, 2017	Mobile Health: Technology and Outcomes in Low and Middle Income Countries (R21) (PAR-16-292)	Mobile Health (mHealth)	Exploratory/Developmental Research Grant
December 14, 2017	Emerging Global Leader Award (K43) (PAR-17-001)	Emerging Global Leader	Career Development Grant
December 14, 2017	Global Noncommunicable Diseases and Injury Across the Lifespan: Exploratory Research (R21) (PAR-16- 052)	Global Noncommunicable Diseases and Injury Research	Exploratory/Developmental Research Grant
March 7, 2018	International Research Scientist Development Award (IRSDA) (K01) (PAR-17-002)	International Research Scientist Development Award (IRSDA)	Career Development Grant
March 14, 2018	Planning for Non-Communicable Diseases and Disorders Research Training Programs in Low and Middle Income Countries (D71) (PAR-17-097)	Chronic, Noncommunicable Diseases and Disorders Research Training	International Research Training Planning Grant
May 17, 2018	International Research Ethics Education and Curriculum Development Award (R25) (PAR-16-081)	Bioethics	Education Project
		Discribing	International Research Training
May 17, 2018	International Bioethics Research Training Program (D43) (PAR-16-454)	Bioethics	Grants



Financiación USA: CDMRP.



Currently Funded Research Programs

- · Alcohol and Substance Abuse
- Amyotrophic Lateral Sclerosis
- Autism
- . Bone Marrow Failure
- Breast Cancer
- · Defense Medical Research and Development
- Duchenne Muscular Dystrophy
- Gulf War Illness
- · Joint Warfighter Medical (Coming Soon)
- Lung Cancer
- . Military Burn (Coming Soon)
- · Multiple Sclerosis
- Neurofibromatosis
- Neurotoxin Exposure Treatment Parkinson's (Coming Soon)
- · Orthotics and Prosthetics Outcomes
- Ovarian Cancer
- Peer Reviewed Alzheimer's
- · Peer Reviewed Cancer
- · Peer Reviewed Medical
- Peer Reviewed Orthopaedic
- Prostate Cancer
- · Psychological Health/Traumatic Brain Injury
- Spinal Cord Injury
- . Trauma Clinical Research Repository (Coming Soon)
- Tuberous Sclerosis Complex
- Vision

Ē News & Highlights

FY17 NFRP Funding Opportunities Now Available!

The Fiscal Year 2017 Appropriations Acts includes funding for programs managed by the DoD CDMRP

FY17/18 DMRDP Funding Opportunities Now Available!

Funding Opportunities



- Amyotrophic Lateral Sclerosis
- Autism
- · Bone Marrow Failure
- Breast Cancer
- Defense Medical Research and Development Program
- Duchenne Muscular Dystrophy
- Gulf War Illness
- Lung Cancer LUNG CANCER
- Military Burn
- Multiple Sclerosis
- Neurofibromatosis
- Ovarian Cancer
- Peer Reviewed Cancer
- Peer Reviewed Medical
- · Peer Reviewed Orthopaedic
- Prostate Cancer
- Psychological Health/Traumatic Brain Injury
- Spinal Cord Injury
- Tick-Borne Disease
- Tuberous Sclerosis Complex
- Vision





» Click on Image to View Funding Opportunities Brochure

http://cdmrp.army.mil/

Dr. Ana Ma Blanco



Financiación USA: CDMRP.



Program Announcements



FY17 Lung Cancer Research Program (LCRP)

Synopsis of FY17 LCRP Award Mechanisms 🚇 - (Adobe PDF) - provides a brief description and key elements of the award mechanism.

Mechanism	Release Date	Program Announcement/Instructions	Submission Deadline	
ncept Award	May 15, 2017	Program Announcement (A) Application Instructions (A)	Pre-Application (Letter of Intent): July 27, 2017	Submit Pre- Application
			Letter of Intent is required.	
			Application: August 10, 2017	
Career Development Award	May 15, 2017	Program Announcement (A) Application Instructions (A)	Pre-Application (Letter of Intent): September 13, 2017	Submit Pre- Application
	2017	rypication manufactoria 23	Letter of Intent is required.	Application
			Application: September 27, 2017	
ldea Development Award	May 15, 2017	Program Announcement (A) Application Instructions (A)	Pre-Application (Preproposal): June 28, 2017	Submit Pre-
			Preproposal is required; application submission is by invitation only.	Substitution (Addition
			Application: September 27, 2017	
Investigator Initiated Translational Research Award	May 15, 2017	Program Announcement 🔼 Application Instructions 🔼	Pre-Application (Preproposal): June 28, 2017	Submit Pre-
			Preproposal is required; application submission is by invitation only.	
			Application: September 27, 2017	



Financiación USA: PCORI.



http://www.pcori.org/



Research We Support





The Patient-Centered Outcomes Research Institute (PCORI) was created to fund research that will provide patients and those who care for them with the evidence-based information needed to make better-informed health and healthcare decisions. We do this by supporting studies that seek to answer questions important to patients and meaningfully involve patients and others across the healthcare community at all stages of the research process.

What is Patient-Centered Outcomes Research?

With public input and approval from our Board of Governors, we created a definition of patient-centered

What Guides Our Research?

Our National Priorities for Research and Research Agenda are the road map for the work we do. Explore our guide for funding comparative clinical effectiveness

Become a Reviewer

Learn how you can help evaluate funding applications.



Read More →

E-mail Updates



Sign up for PCORI news, events, and funding announcements.



Financiación USA: PCORI. pcori

PCORI financia investigaciones encaminadas a que los pacientes y sus cuidadores obtengan la información necesaria para tomar decisiones de salud. En concreto, se financia investigación comparativa de eficacia clínica, así como el trabajo de apoyo que puede mejorar los métodos utilizados para llevar a cabo este tipo de estudios. Esta financiación se divide en cinco programas que reflejan las prioridades de investigación.

Evaluación de las Opciones de Prevención, Diagnóstico y Tratamiento.

Mejora de los Sistemas Sanitarios.

Comunicación y Difusión de la Investigación.

Abordar las disparidades.

Acelerar la investigación metodológica y productiva centrada en el paciente.



UPCOMING OPPORTUNITIES



Assessment of Prevention Diagnosis and Treatment Options - Cycle 3 2017

Key Deadlines	Туре	Funds Available	Total Costs
LOI: October 31, 2017 Application: February 6, 2018 Merit Review: April 2018	Research Award		

Communication and Dissemination Research - Cycle 3 2017

Key Deadlines	Туре	Funds Available	Total Costs
LOI: October 31, 2017 Application: February 6, 2018 Merit Review: April 2018	Research Award		

Improving Healthcare Systems - Cycle 3 2017

Key Deadlines	Туре	Funds Available	Total Costs
LOI: October 31, 2017 Application: February 6, 2018 Merit Review: April 2018	Research Award		

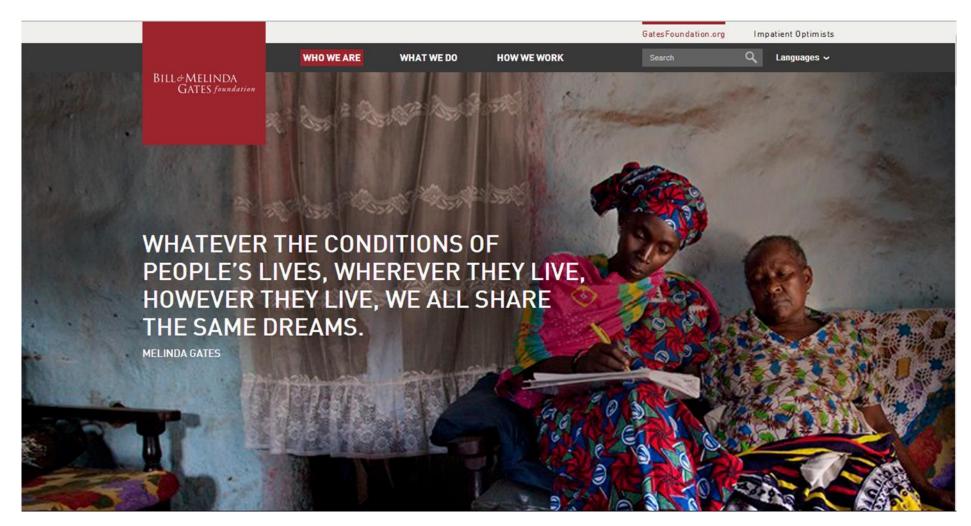
Foreign organizations and nondomestic components of organizations based in the United States may apply, as long as there is demonstrable benefit to the US healthcare system, and US efforts in the area of patient-centered research can be clearly shown.

http://www.pcori.org/funding-opportunities





http://www.gatesfoundation.org/







Esta fundación subvenciona proyectos de I+D <u>en beneficio del Tercer Mundo</u>, sobretodo apoyando la lucha contra las enfermedades infecciosas, mejoras en la agricultura y Salud-Tecnología

GRANT OPPORTUNITIES

The foundation awards the majority of its grants to U.S. 501(c)(3) organizations and other tax-exempt organizations identified by our staff. (Tax status definitions) (Glossary of terms)

Request for Proposals (RFP)

- · Grand Challenges Grant Opportunities
- · Operations Research on Improving Paper-based Information Systems for Child Health
- School Networks for Evaluating and Improving the Efficacy of Digital Courseware
- <u>Achieving Health Product Access through Market-Based Approaches</u>
- Market Manager for HIV Prevention and HIV Treatment and Diagnostics
- · Market Manager for Tuberculosis Treatment and Diagnostics
- Teacher Preparation Transformation Centers RFI
- Amplifying the Nutrition Impact of Agriculture in India RFP
- <u>Data Innovation in US Education</u>
- Accelerated Vaccine Introduction Rotavirus Vaccine Focus RFP
- Agriculture-Nutrition Impact Studies

Open Concept Memos

Qualified organizations may submit a Concept Memo for the funding area listed below:

• Global Health Grants







--- How We Work ----

OPEN CONCEPT MEMO GLOBAL HEALTH GRANTS

← BACK

Print

We accept concept memos for grants in our Global Health initiatives. These include:

- · Enteric & Diarrheal Diseases
- Malaria
- Pneumonia

Getting Started

Please follow these instructions carefully when submitting a Concept Memo to the Global Health program. **Note:** Due to tax, legal, and reporting issues, we require that all Concept Memos be submitted in English.

Step 1: Download and Complete the Concept Memo

The Concept Memo includes questions regarding the scope, outcomes, and risks of your project as well as your organization's experience regarding the proposed work.



· Concept Memo

Step 2: Submit your Concept Memo online

You must complete the online Concept Memo submission form and attach your completed Concept Memo in order for the foundation to process your request. Please do not mail a duplicate hard copy after submitting your Concept Memo online or send any additional attachments or information (videos, books, program materials, etc.)





CONCEPT MEMO: MÁX. 4 PAGES

Concept Details 1. Project Scope

PROJECT SCOPE

Describe the concept and the overall approach you will take to achieve the intended results of this project. A detailed implementation plan is not needed at this stage.

INVESTMENT **OUTCOMES**

2. Investment Outcomes

Explain what difference(s) this project will make by answering the following questions: What is the primary outcome(s) or result(s) this investment will achieve or significantly contribute to? How will you know when that result(s) has been achieved (how will the result be measured)? What are the critical outputs or intermediate outcomes that will lead to these results?

ORGANIZATIONAL FIT

3. Organizational Fit

What experience does your organization have to implement the proposed work?

RISKS/ **CHALLENGES**

4. Risks/Challenges

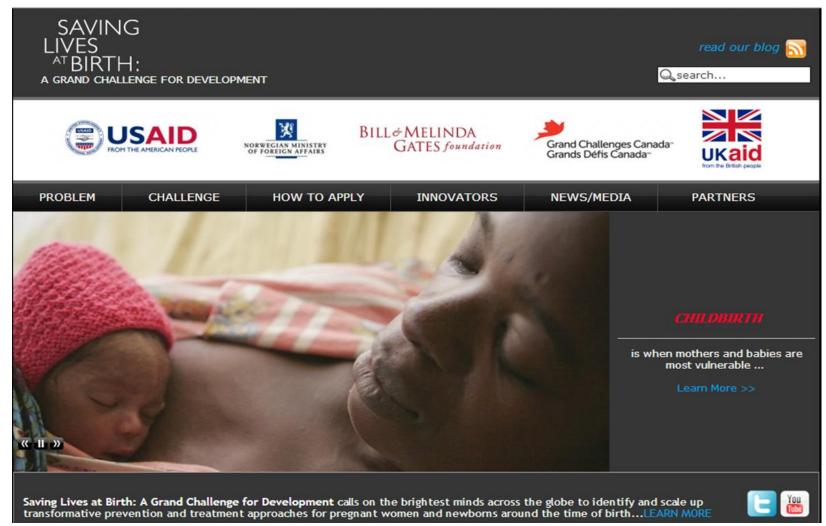
Describe your initial view of challenges to the success of this project and any early thoughts on mitigation.



Financiación internacional: Saving Lives at Birth.



http://savinglivesatbirth.net/





Financiación internacional: Saving Lives at Birth.





CIENCIA Y TECNOLOGÍAS Estas convocatorias se abren para proyectos innovadores encaminados a la **prevención y el tratamiento de las mujeres embarazadas y los recién nacidos en los países del Tercer Mundo** o subdesarrollados alrededor del momento del parto.



MEJORA DE CUIDADOS

MODALIDADES DE FINANCIACIÓN:

<u>Seed Funds/Validation Funds</u>: \$250,000 dólares/2 años, para apoyar el **desarrollo y la** validación de ideas.



MEJORA MÉTODOS COMPROMISO Y PARTICIPACIÓN POBLACIÓN

<u>Transition Funds</u>: \$2 millones dólares/4 años, para desarrollar, refinar y testar rigurosamente el impacto de soluciones integradas que evidencien una mejora en la salud muy significativa y una reducción de barreras.

ROUND 8: 2017



Futura convocatoria



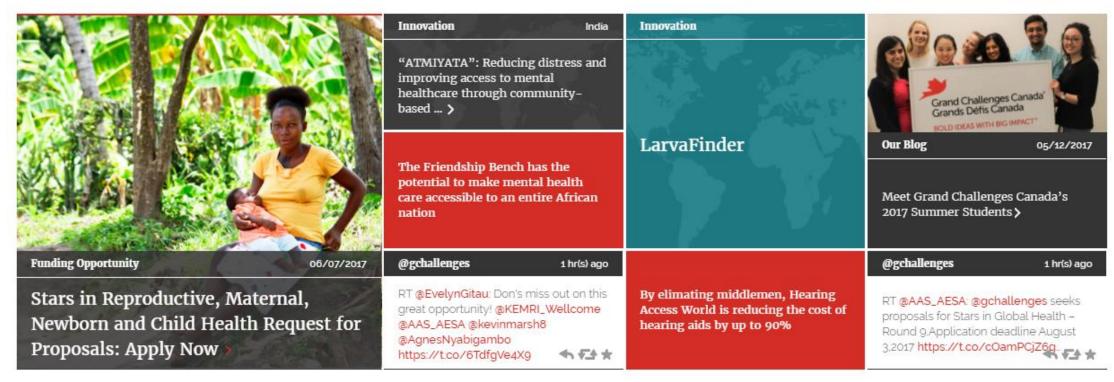
Otras fuentes de financiación internacional: Canadá.



Bold Ideas with Big Impact®

Browse our Innovations and Results





Making a Big Impact in Global Health

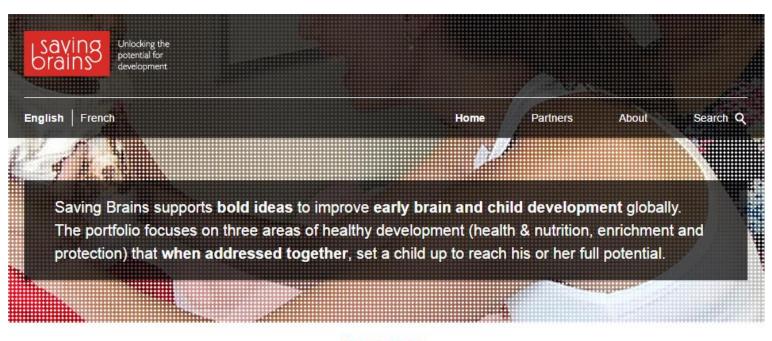
http://www.grandchallenges.ca/

Dr. Ana M^a Blanco



Otras fuentes de financiación internacional: Canadá.





Innovations















Dra. Ana María Blanco Sánchez

Oficina Internacional IIS La Fe e-mail: international@iislafe.es

+34 96 12 46617/+34 648 936 929



Information for funding applications to the National Institutes of Health (NIH): Calls eligible to non-US entities.



The NIH is the largest financing organisation and is composed of a number of institutes and centres specialised in each discipline and disease. There are worldwide calls from all of these centres either with open themes (general), or with more specific themes related to a particular illness or discipline, which are

convened by the NIH on behalf of its centres.

To differentiate the wide variety of programs related to the research it funds, the NIH uses activity codes (e.g., R01, R43, etc.), although the NIH Institutes and Centres may vary the way they use these codes. Not all centres accept applications for all types of financing programs, and they sometimes use special eligibility criteria. Additionally, non-US residents may not apply for all activity codes. Below is a list of the most relevant codes for foreign applicants within the Research Grants:

R01: NIH Research Project Grant Program (R01)

- √ Used to support a discrete, specified, circumscribed research project.
- √ No specific dollar limit.
- √ Advance permission required for \$500K or more (direct costs) in any year.
- √ Generally awarded for 3 -5 years.
- √ Strong preliminary results are required.

R03: NIH Small Grant Program (R03)

√ Provides limited funding for a short period of time to support a variety of types of projects, including: pilot or feasibility studies, collection of preliminary data, secondary analysis of existing data, small, self-contained research projects, development of new research technologies, etc.

- √ Limited to two years of funding.
- √ Direct costs generally up to \$50,000 per year (max. **\$100,000**).
- √ Not renewable.
- √ Preliminary results are not required.

R21: NIH Exploratory/Developmental Research Grant Award (R21)

V The R21 mechanism is intended to encourage exploratory and developmental research projects by providing support for the **early and conceptual stages of these projects**. These studies may involve considerable risk but may lead to a breakthrough in a particular area, or to the development of novel techniques, agents, methodologies, models, or applications that could have a major impact on a field of biomedical, behavioural, or clinical research.

√ Limited to up to **two years of funding**.



√ Combined budget for direct costs for the two year project period cannot usually exceed **\$275,000**.

V No preliminary data is generally required. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or when available, from investigator-generated data. **Preliminary data are not required for R21 applications, however, they may be included if available**.

Open NIH calls: Parent Grants (All Modalities)

R01: Research Project Grant (Parent R01)

http://grants.nih.gov/grants/guide/pa-files/PA-13-302.html

Purpose: The Research Project Grant (R01) supports a discrete, specified, circumscribed project to be performed by the named investigator(s) in areas representing the specific interests and competencies of the investigator(s). The proposed project must be related to the programmatic interests of one or more of the participating NIH Institutes and Centers (ICs) based on descriptions of their programs.

R21: NIH Exploratory/Developmental Research Grant Program (Parent R21)

http://grants.nih.gov/grants/guide/pa-files/PA-13-303.html

Purpose: The National Institutes of Health (NIH) Exploratory/Developmental Grant (R21) funding opportunity supports the development of new research activities in categorical program areas. The R21 activity code is intended to encourage exploratory and developmental research projects by providing support for the early and conceptual stages of these projects. These studies may involve considerable risk but may lead to a breakthrough in a particular area, or to the development of novel techniques, agents, methodologies, models, or applications that could have a major impact on a field of biomedical, behavioral, or clinical research.

R03: NIH Small Research Grant Program (Parent R03)

http://grants.nih.gov/grants/guide/pa-files/PA-13-304.html

Purpose: The National Institutes of Health (NIH) Investigator-Initiated Small Research Grant (R03) funding opportunity supports small research projects that can be carried out in a short period of time with limited resources. The R03 activity code supports different types of projects including pilot and feasibility studies; secondary analysis of existing data; small, self-contained research projects; development of research methodology; and development of new research technology.



Application Due Dates:

R01: June 5, 2015; October 5, 2015; February 5, 2016; June 5, 2016.

R21 and R03: June 16, 2015; October 16, 2015; February 16, 2016; June 16, 2016.

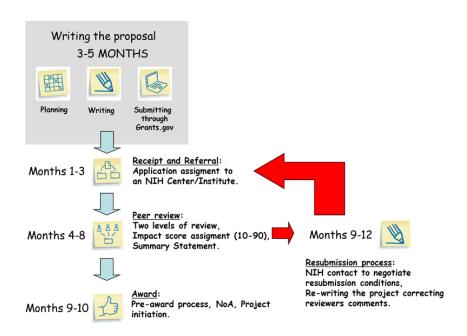


Considerations:

- The Institution or Entity must be registered in SAM.gov, grants.gov, and eRA Commons at least 8 weeks before the deadline.
- These calls allow applications from multiple Principal Investigators (PIs).
- The applications permit budget requests for salaries, materials, equipment, travel, etc. The only restriction for non U.S. residents is that the indirect costs applied for may not exceed 8% of the direct costs.
- Additional documentation must be supplied if human samples or vertebrate animals are to be used, or if the project is a clinical trial.
- It is possible to resubmit a project by addressing the reviewer's criticisms.

IMPORTANT: you must demonstrate that the project is unique and that the talent and the ability to do the research itself are uniquely available outside the U.S. Specifically, the NIH describes it this way: "whether the project presents Special Opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions in other Countries that exist and are not readily available either in the United States or augment existing U.S. resources"

TIMELINE:









Data Universal Number System (DUNS)

Purpose

A DUNS number is a unique nine-character number that identifies an organization and is required by the federal government to track how federal grant money is distributed. It is provided free of charge by the commercial company Dun & Bradstreet.

Form and Instructions

- Click on the link below to request your DUNS number: http://fedgov.dnb.com/webform/pages/CCRSearch.jsp
 - The website will first determine whether your organization already have a DUNS number. The screen will first prompt you to select the country where your company is physically located. Once you select the country, you will be prompted to enter the name of your company.
 - o If you do not see your company listed, click on Request a New DUNS number.
 - Fill out the form to request the DUNS number and click on the Submit Your Request Button at the bottom of the page.
- 2. You can also request the DUNS number over the phone.

Help

Call D&B at 1-866-705-5711 (this number may not work from abroad) Email: govt@dnb.com

Related links

- DUNS home page http://fedgov.dnb.com/webform
 - 1) Seleccionar país
 - 2) Poner Business name, street, city, phone y verification code:







BENLLOCH 9 PATERNA, ES

If you do not see your company listed above...

Search Again (try a former business address) OR

Request a New D-U-N-S Number

3) Solicitar REQUEST YOUR EXISTING DUNS NUMBER. Poner información de contacto:

^{**} If you are not able to distinguish your location from the search results please contact D&B at govt@dnb.com



D-U-N-S Number Registration > Search > Results > Your Information >		
Contact Information		
Please Complete the following information so we may process your request.		
Note: All fields are required.		
Your Information		
First Name		
Last Name		
Title		
Phone		
E-mail		
Re-Enter E-mail		
Please indicate only one category that describes the relationship you have or plan on seeking for providing goods and services under the legal business name you indicated:		
Federal Government Contractor or Vendor		
Federal Government Grantee or Applicant		
Both, Federal Government Contractor and a Federal Government Grantee		
○ U.S State Contractor or Grantee, please indicate which U.S State ▼		
Do you understand that issuance of a D-U-N-S Number may lead to D&B contacting you periodically to maintain the accuracy of your entity's information on file?		
✓ Yes		
Click here for a new image Click here to listen to audio Click here to download wav file		
Enter the verification code shown: gNnMd5		
This is to prevent automated registrations		

SUBMIT



D-U-N-S Number Retrieval Submitted

Thank you for your request for your company's existing D-U-N-S Number.

Your D-U-N-S Number will be sent to the e-mail address you provided.

If you have any questions about your D-U-N-S Number, please contact us at govt@dnb.com

Please click here to go to the search page



E-MAIL:

----- Forwarded message -----

From: <XXXXXXXXX>

Date: 2014-04-14 11:42 GMT+02:00 Subject: Requested DUNS Number

To: XXXXXXX

THIS IS AN AUTOMATED MESSAGE GENERATED BY THE D&B CCR REGISTRATION PORTAL. PLEASE DO NOT REPLY TO THIS MESSAGE.

Thank you for your request for your company's existing DUNS Number.

Your D-U-N-S Number is 467173675

for

XXXXX

CALLE XXXXXXX

PATERNA,46980

SPAIN

If you have any questions about your DUNS Number, please contact us at <u>qovt@dnb.com</u>.

International registrants can confirm DUNS by sending an e-mail to ccrhelp@dnb.com, including Company Name, D-U-N-S Number, and Physical Address, and Country.

EXAMPLE:

Dear Sir/Madam,

My name is XXXXX from XXXXX and we need that you confirm our DUNS number because we are interested in applying for FOA PAR-13-146.

D-U-N-S Number is 464693479

for

XXXXXXXXX.

CALLE XXXXXXXXXX 9

PATERNA,46980

SPAIN

Thank you very much.

Best regards,

ANSWER:



De: Govt CCR Help [mailto:govtccrhelp@dnb.com] Enviado el: martes, 22 de abril de 2014 16:50

Para: XXXXXXXXXX

Asunto: RE: Confirmation of DUNS number-international registrant [

ref:_00D306len._500a0hu6bs:ref]

Hi Ana,

The information in the DUNS you've given follows:

N
ADR_LINE CALLE XXXXXXX 9
BR_IND No
BUS_REGN_NBR B98455603
BUS_REGN_NBR_TYPE_CD Value Added Tax Registration Number (Europe)
CTRY_CD Spain
DUNS_NBR 464693479



OBTENCIÓN DEL NCAGE code:

http://www.dlis.dla.mil/Forms/Form_AC135.asp

Companies located outside the U.S.:

- 1. Register with NATO Support Agency (NSPA)
- 2. Follow the <u>step by step instructions</u> for CAGE/NCAGE/SAM Registration-Instructions for NSPA NCAGE v9 (paso 4)
- 3. Received e-mail:

De: postmaster@natolog.com

Asunto: Your NCAGE request Ref ES14056349455 Dated 25 Feb 2014

Fecha: 25 de febrero de 2014 11:20:08 GMT+1

Para: XXXXXX

Responder a: ncage@nspa.nato.int

Dear XXXXXXX,

Thank you very much for your interest in the NCAGE database.

Your NCAGE registration request is pre-recorded in our system with the following data:

click here to see your request

Your request will be activated once we have received your confirmation by clicking on the following validation link

https://eportal.nspa.nato.int/ac135public/scage/requestvalidation.aspx?requestid=04262bf7-3ea4-45e2-b50e-f4ebb58feb76

If needed you may contact the NCAGE team(<u>ncage@nspa.nato.int</u>) and refer to the following request Number ES14056349455.

- 4. Posteriormente, llamarán por teléfono del <u>Ministerio de Defensa</u> para que expliques por qué quieres solicitar el NCAGE code. Te llamará D. Rogerio Sánchez, y hay que explicarle que: SE NECESITA EL CÓDIGO NCAGE PARA PODER SOLICITAR FINANCIACIÓN PARA UN PROYECTO DE INVESTIGACIÓN A LOS NATIONAL INSTITUTES OF HEALTH.
- 5. Después te enviará un mensaje como éste (solicitando por supuesto un importe de 20 euros + IVA):

De: NATO Comercial and Goverment Entity Code <ncbspncage@oc.mde.es>

Asunto: New CAGE Request - Reference: ES14056349455

Fecha: 25 de febrero de 2014 13:04:07 GMT+1

Para: "XXXXXXXXX>



Estimado Sr. XXXXXX,

En relación con su solicitud de Ref. martes, 25 de febrero de 2014 11:35, le comunico que para la obtención del código NCAGE ha de realizar un desembolso de 20€ + IVA al amparo de la Orden DEF/182/2012 de 13 de enero, por la que se establecen los precios públicos de los servicios prestados por la Subdirección General de Inspección y Servicios Técnicos y por el Instituto Tecnológico "La Marañosa" (BOE Núm. 31 de lunes 6 de febrero de 2012). http://www.boe.es/diario_boe/txt.php?id=BOE-A-2012-1757

En cuanto recibamos su conformidad con el pago de la cantidad, procederemos a la asignación del código solicitado y posteriormente recibirá un oficio donde se le indicará el número de cuenta restringido donde ha de realizar el pago de la tasa correspondiente. Para poder asignar el citado código es imprescindible que nos haga llegar el CIF de la Fundación junto con un pantallazo de su registro DUNS al objeto de que figuren exactamente los mismos datos en ambos registros.

A la espera de sus noticias, le saluda atentamente

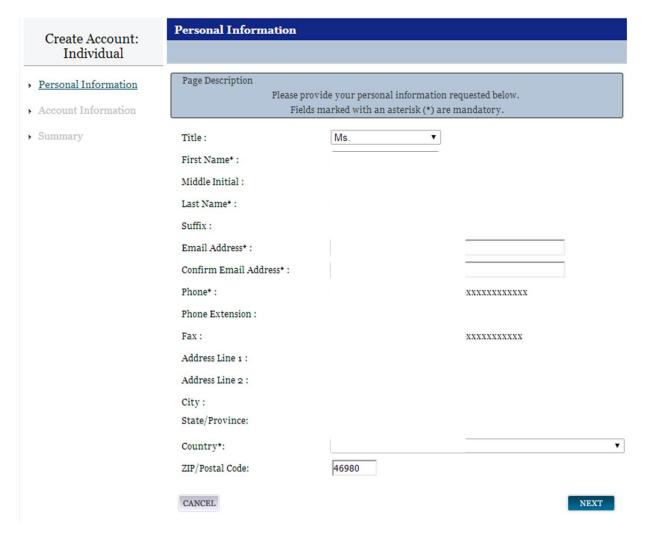
J. Rogerio Sánchez
MINISTERIO DE DEFENSA
DGAM-SDGINSERT-ARI
SPANISH NCB NCAGE
Tel. 91 2704705
Fax 91 2704653
E-Mail ncbspncage@oc.mde.es

- 6. Le envías la confirmación junto con DUNS y CIF, y te enviarán las instrucciones de cómo pagar esos 20 euros y en unos días recibes un documento en PDF con el NCAGE code "NATO Form Bpdf".
- 7. Una vez recibas el NCAGE code, continuaremos con el registro en SAM.gov.



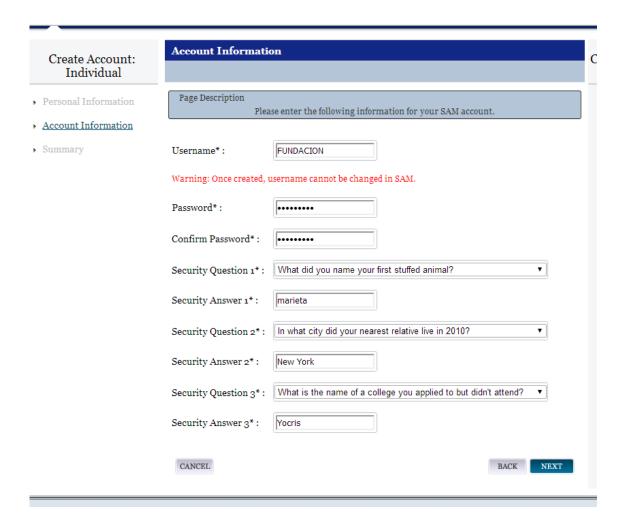
Registro en SAM.gov:

1) Individual registration.



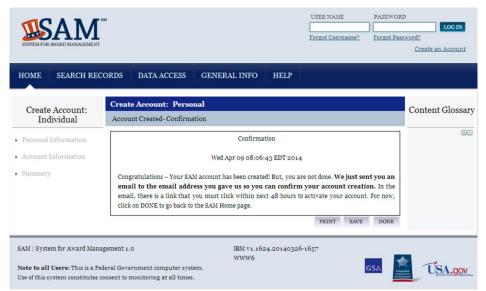


2) Account information:



- 3) Summary to check and submit.
- 4) Confirmation:





e-mail for confirmation:

From: <notification@sam.gov>

Date: 2014-04-09 14:06 GMT+02:00

Subject: ACTION REQUIRED: Activate Your New User Account in the U.S. Federal Government's

System for Award Management (SAM)

To: xxxxx

This email was sent by an automated administrator. Please do not reply to this message. Dear xxxxxxx,

Thank you for registering in the U.S. federal government's System for Award Management (SAM).

Your Username is: xxxxxx

Please note that this is only a confirmation of your Username. You must click on the link below, within 48 hours of receipt of this message, to verify your email address and complete the registration process. You may also copy and paste the URL into your browser address line to go directly to the web page.

CLICK THIS LINK to activate your account:

https://www.sam.gov/portal/public/SAM?activationCode=13CqmZ2kacVaOxf

Please note that if this is your first login attempt, the system will default to the Migrate Legacy Account page where you will be prompted to indicate whether or not you wish to transfer your role(s) held in the legacy federal government systems (CCR.gov, FedReg.gov, ORCA.gov, and EPLS.gov) to your new SAM account.

IMPORTANT: If you do not have roles to migrate from a legacy system and/or you would like a new role assigned to your account, you will need to request that a role be assigned by your Administrator in order to have access to desired system functionality.

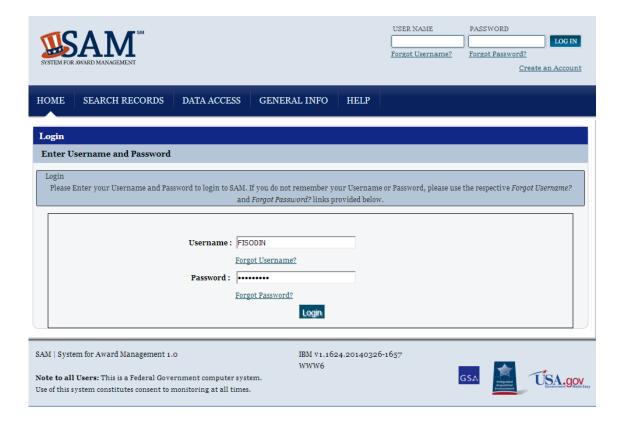


For assistance, please contact the Federal Service Desk at <u>www.fsd.gov</u> or by telephone at <u>866-606-8220</u> (toll free) or at <u>334-206-7828</u> (internationally).

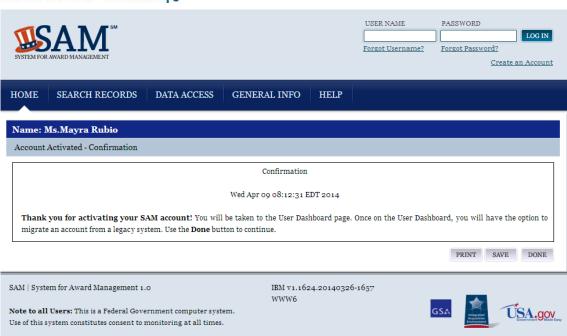
Thank you,

The System for Award Management (SAM) Administrator https://www.sam.gov/portal/public/SAM

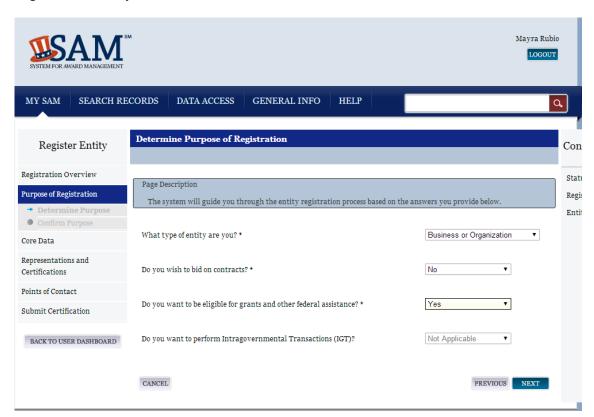
In the link:



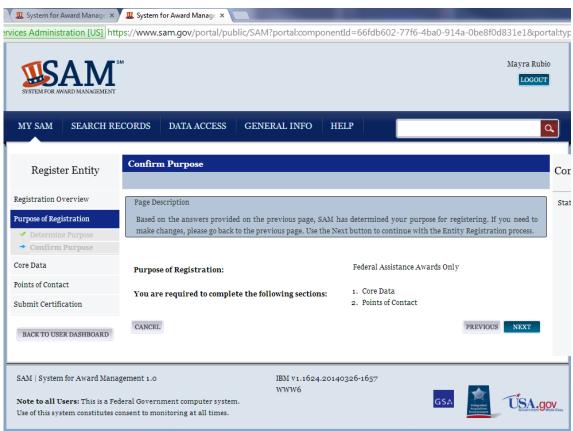




Register new entity:







RELLENAR LA INFORMACIÓN SOLICITADA PARA EL REGISTRO EN SAM.GOV:

1 Business Information:	
Business Start Date (MM/DD/YYYY):	
Fiscal Year End Close Date (MM/DD):	
Corporate URL:	

2.-Does your entity qualify as one of the following (if none are applicable, select Not Applicable from the drop-down menu)?:

- a) Not applicable.
- b) Community Development Corporation
- c) Domestic Shelter
- d) Educational Institution
- e) Foundation
- f) Hospital
- g) Veterinary hospital.

3.-Indicate the form of your business or organization? :



- a) Corporate entity, not tax exempt
- b) Corporate entity, tax exempt
- c) Partnership or Limited Liability Partnership
- d) Sole Propietorship
- e) International organization
- f) Other

4.-What is your organization's profit structure? :

- a) For-profit organization
- b) Nonprofit organization
- c) Other not for profit organization

5.-Do you accept credit cards as a method of payment? :

- a) yes
- b) no

Remittance Address:

<u>6.-Financial information:</u> CONTACTO DE LA PERSONA EN EL BANCO DE LA ENTIDAD QUE ES LA RESPONSABLE DE GESTIONAR LAS CUENTAS INTERNACIONALES.

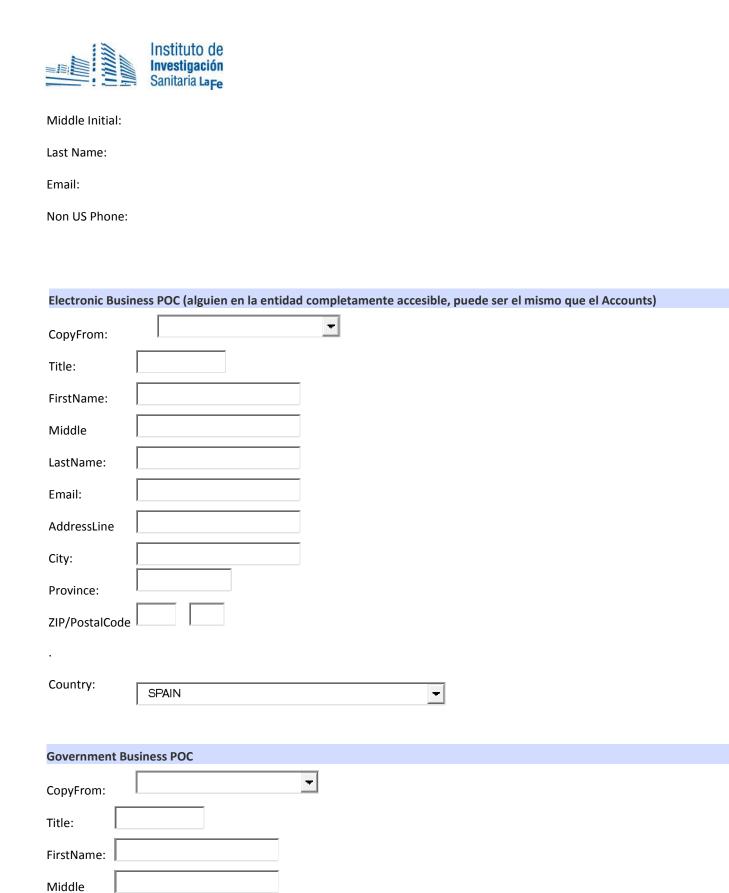
Name: Address Line 1: Address Line 2: City: State/ Province: Country: SPAIN ZIP/Postal Code:

7.-Mandatory Point of Contacts:

Accounts Receivable POC

Title:

First Name:



LastName:

Email:





REGISTRO EN eRA Commons:

1.- Entráis en esta página:

https://public.era.nih.gov/commons

- 2.- En la parte superior derecha aparece este link Register Grantee Organization. Acceder.
- 3.- Debajo aparece el link <u>Register Now</u>. Acceder.
- 4.- Rellenar los datos de la Institución (con la información del DUNS Number). Aquí tenemos que poner el nombre en inglés de la institución. Debajo tenéis que poner los datos de la persona en la institución que tiene poderes para firmar, como puede ser el CEO, Director, etc... como <u>Principal Signing Official</u>. En **Title**, poner el título que ostenta en la empresa (*NIH requires that the signing official listed on the registration request be a high ranking administrative official such as the <i>President, CEO, Executive Director, Owner , Founder/Co-Founder*), y en **Username** elegir uno. Para la sección de al lado tenéis que poner los datos de la persona que va a ser Accounts Administrator, que es conveniente poner a alguien que vaya a gestionar la solicitud. Y lo mismo como **Title**, hay que poner el puesto que ostenta en la empresa, y en **Username**, elegir uno.

Una vez rellenéis todos estos datos, cliquear **Submit**.

- 5.- A partir de aquí van a ocurrir 2 cosas:
- a) La página que aparece con los datos que habéis introducido tendréis que **imprimirla y firmarla** por las personas correspondientes a los datos que hayáis introducido. Una vez firmada por el Signing Official y el Accounts Administrator, debéis mandarla por fax al número 001-301-451-5675 (añadirle otro cero delante si utilizáis el 0 previo para llamadas al exterior). Si veis que no funciona, enviad la solicitud firmada y escaneada a la dirección e-mail <u>commons@od.nih.gov</u>, y la enviáis con este mensaje:

Dear Sir/Madam,

My name is XXX and I work in XXXX, with DUNS number XXXX in Spain. We are interested in applying for NIH funding for the development of research projects and we are in the process of registration of our organization. We followed the instructions thoroughly to register us into eRA Commons, and tried to send the fax to the register, but after numerous attempts, our request always fails.

So, we send the request to the eRA Commons registration of our organization through this message. If you are so kind, could you confirm that you can register us in this way?

Thank you very much.



Best regards,

b) El Signing Official recibirá un mail de verificación Y TENDRÁ QUE CLIQUEAR AL LINK QUE LE PROPORCIONAN PARA VERIFICAR QUE REALMENTE ES SU CORREO ELECTRÓNICO.

En este paso tendréis que estar pendientes de que la persona que designéis como Signing Official esté más o menos accesible y avisarle que si ve algunos mails de eRA notify, eRA Commons, ... que por favor siga las instrucciones, sólo tendrá que cliquear al link que le proporcionan y verificar la información que le mostrarán como correcta. O que nos re-envíe estos mails a nosotros

Además recibirá un e-mail como éste al que deberéis contestar:

De: eRA Commons Help Desk < erafpcommons@mail.nih.gov>

Data: 20 de novembre de 2013 20.57.00 GMT+1

Per a: <<u>XXXXX</u>>
Tema: XXXXXXX

Respondre a: < erafpcommons@mail.nih.gov >

When replying, type your text above this line.

Email Notification From eRA Help Desk - Ticket Closed

Ticket Number: 80230
Contact Name: XXXXXXX
CC's: (this edit only) XXXXXXX

Resolution:

Dr.XXXX and Mr. XXXX,

We are processing your registration request for XXXXXXX and the group that reviews and approves commons registrations on behalf of NIH has inquiries regarding your organization.

In order to continue processing your registration request it is necessary for the NIH to ask the following questions. Please respond to the following questions with the appropriate response,

- 1. Please describe the nature of the research and business that your organization performs?
- 2. Are the researchers employed by this organization?
- 3. Is this organization professionally responsible for the research?
- 4. What Funding Opportunity Announcement are you applying for? Please provide Announcement number.
- 5. How many people are in your organization?
- 6. Where physically is the proposed research to be conducted? Additionally, If your organization has a website please provide that website link or URL address in your response.

Please be aware that any prospective applicant organization to NIH must be able to assure they can be responsible for the administrative and scientific oversight of the work proposed in any application should an award be issued. An analysis for appropriate grantee is conducted prior to any award being issued; particularly when an organization is considered a new potential grantee.



Therefore registering in the eRA Commons does not automatically assume an organization is an appropriate grantee for NIH funding. Please see the NIH Grants Policy Statement, Section 2.3.6 Legal Implications of Applications for additional information.

Failure to respond to this e-mail may result in your registration request being delayed or denied.

Please respond as a reply to this email.

Thank you

6.- Una vez el Signing Official haga los pasos de verificación de los mails recibidos, recibirá uno último con su Username y Pasword, que os permitirá registrar a todos los demás investigadores. Este Username y Password habrá que guardarlo como dato esencial para los registros (y ya no necesitaremos más la actuación del Signing Official).

After confirmation of the registration by the signing official via a link within the approval email, the user name emails and temporary passwords are emailed to SO and AA upon the completion of the registration.

El único problema de estos registros es la persona que va a ser Signing Official, tiene que estar un poco pendiente de los mails que recibe, y que os los reenvíe.

Una vez hayamos registrado y completado en eRA Commons al Signing Official, seguiremos con los registros en eRA Commons de todo el personal investigador que va a participar en el proyecto.

<u>DATOS NECESARIOS PARA EL REGISTRO EN eRA Commons DE TODO EL PERSONAL QUE VA A PARTICIPAR EN EL PROYECTO:</u>

- a) Nombre y apellidos
- b) Posición en la entidad
- c) E-mail
- d) Fecha de nacimiento:
- e) Employments (de cada uno de vuestros empleos, tenéis que indicar lo siguiente):
 - 1) Start date/End Date (dia/mes/año).
 - 2) Title
 - 3) Employment Status (Full-time/Part-time).
 - 4) Academic Rank (Assistant professor/Associate professor, instructor, professor, other).
 - 5) Position (Assistant or Associate Dean, Chairperson of department, Director, Dean, President, Vicepresident, other).
 - 6) Primary employment? Yes/no
 - 7) Employment address: Street, phone, e-mail, city, zip code, country.
- f) Degrees/Residency (de cada uno de vuestros títulos académicos, tenéis que indicar los siguiente):
 - 1) Degree name (Bachelor/Doctor/Master in....)
 - 2) Degree completed? Yes/no



- 3) Institution
- 4) City and country
- 5) Date (or expected date) of degree: month/year
- 6) Length (number of years)
- 7) Is this your terminal research degree? Yes/No

Registro de cada participante en eRA Commons de la entidad:

 Se ingresa con Usuario y Contraseña del Signing Official de la entidad en https://commons.era.nih.gov/. LOGIN.

Electronic Research Administration RA Commons
Sponsored by National Institutes of Health Commons Login Welcome to the Commons *Required field(s) AITEXSIGNAL All systems are currently available Guidance for resumption of grant-related activities post shutdown Login Reset Forgot Password/Unlock Account? Support Related Resources Electronic Submission: Learn about the most frequent application errors at <u>Avoiding Common Errors</u>.
Electronic Application Submission: To learn about completing and submitting an electronic grant application and access helpful resources, visit the <u>Applying Electronically website</u>.

eRA Home Page: To find Commons <u>FAQs</u>. <u>User Guides</u>, training materials, and step-by-step instructions for performing tasks in Commons, visit the <u>eRA website</u>. Federated Institutions/Organizations Federal User Login Here Commons Related Resources eRA Commons Help Desk Reference Letters: To submit a reference letter when requested by an applicant, please follow this link: Submit Hours: Mon-Fri. 7AM-8PM EDT/EST Reference Letter.
 Demo Facility: <u>Demo Facility</u> allows you to try most of the capabilities of the NIH eRA Commons in a sample environment. Web: http://era.nih.gov/help/ Toll-free: 866-504-9552

- Ir a Admin: Accounts: Manage Accounts-Podemos consultar el personal asociado a la entidad con Search.
- Una vez hagamos una búsqueda, aparecerá un link CREATE ACCOUNT: tendremos que seleccionar un UserID (el username) y pondremos nombre, apellido y e-mail. En Role, seleccionaremos en la lupa qué papel va a tener el investigador y SELECT.
- SAVE.

IMPORTANTE: Una vez se vayan registrando, les irán llegando e-mails del eRA-notify y eRA Commons con contraseñas.

Mails que se reciben:

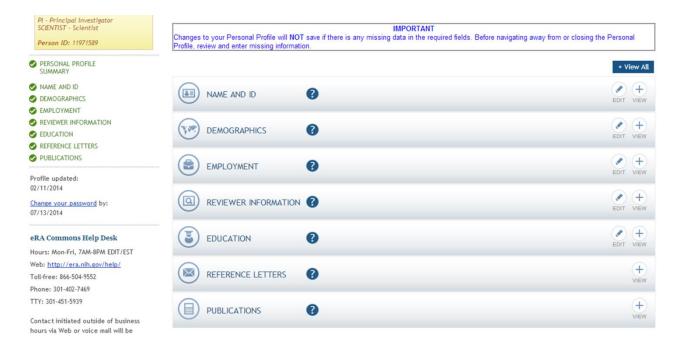
- 1.- eRA Commons Notification of Authentication Credentials and New eRA Account.
- 2.- eRA Commons: Notification of Password for New Account.

Una vez vayan recibiendo estos e-mails hay que cambiar las contraseñas, ya que las contraseñas que se reciben son temporales. Todos los datos de usuarios y contraseñas hay que tenerlos organizados.



Una vez registrados accederán a su perfil para rellenarlo en https://commons.era.nih.gov/. LOGIN.

Ir a Personal Profile: rellenar datos.



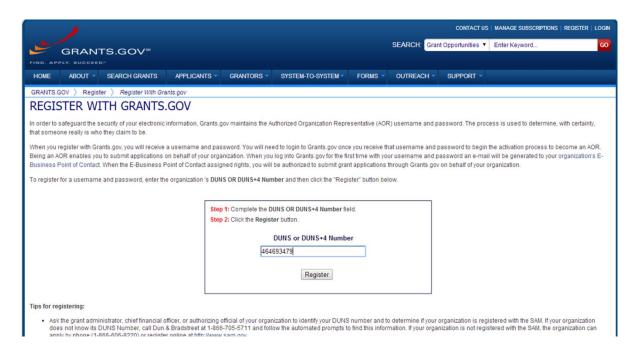


REGISTRO EN Grants.gov:

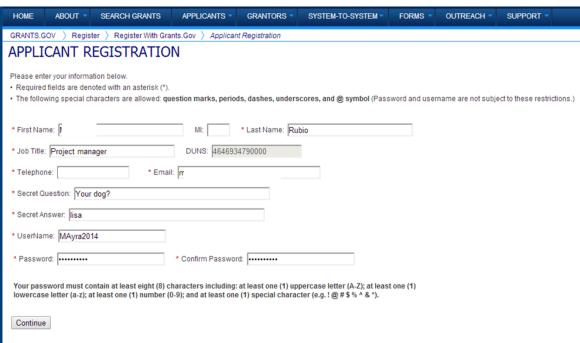
When registering with SAM establishes an **E-Business Point of Contact** (E-Business POC), who can authorize individuals within the organization to submit federal grant applications. The POC selects a special password called Marketing Partner Identification Number (**M-PIN**) that he or she uses to designate at Grants.gov at least one individual to submit grant applications for the organization. That individual is called an Authorized Organizational Representative (AOR).

The Authorized Organizational Representative (AOR):

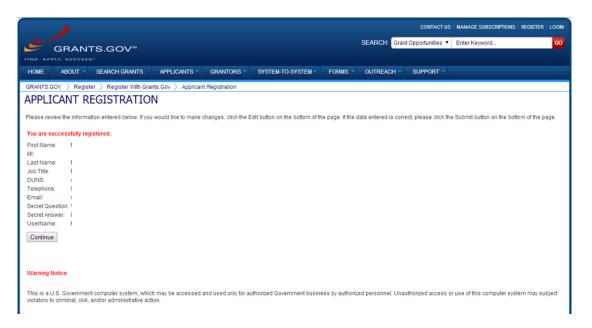
1. Registers with Operational Research Consultants (ORC), the Grants.gov credential provider (https://apply07.grants.gov/apply/OrcRegister).







Revisar información y SUBMIT.



De: DoNotReply@grants.gov [mailto:DoNotReply@grants.gov] Enviado el: lunes, 14 de abril de 2014 13:04

Para: xxxxxxxxx CC: xxxxxxxxxx

Asunto: Applicant xxxxxxxxx Requesting Grants.gov AOR Status - Action Required

Attention E-Business Point of Contact,

The following individual from your organization has registered with Grants.gov and requested to be designated as an Authorized Organization Representative (AOR) for your organization. Designating this



person as an AOR will allow them to submit grant applications to federal agencies via Grants.gov on behalf of your organization.

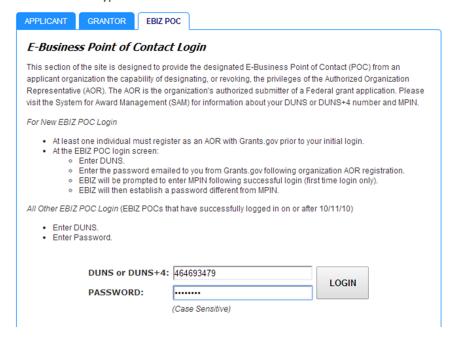
Name: xxxxxxxx

Job Title: Project manager

This user will not be able to submit an application on behalf of your organization until this designation process has been completed. As the SAM E-Biz POC, you are authorized to approve this individual as an AOR for your organization.

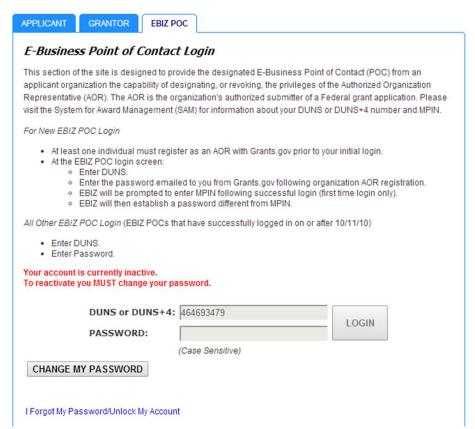
To authorize this AOR, login to the E-Business Point of Contact (E-Biz POC) section of Grants.gov at (https://apply07.grants.gov/apply/login.faces?cleanSession=1&userType=ebiz) then enter your organization's DUNS number and password.

Select Account Type:

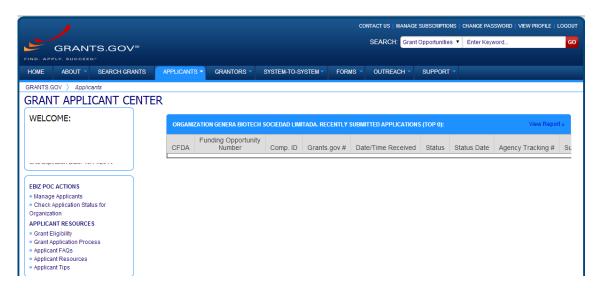


Siempre hay que cambiar la contraseña del E-Bussiness Point of Contact:



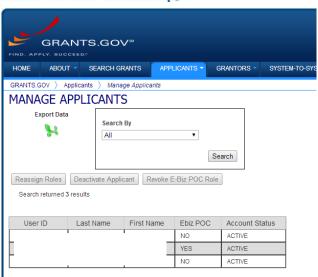


Aparece la página en grants.gov del E-bussiness PoC:



Accedo a MANAGE APPLICANTS e inserto el M-PIN: SUBMIT y luego apretó en SEARCH para que me busque todos los applicants de mi organización:





Selecciono a la persona que quiero que sea AOR y apreto REASSIGN ROLES. Selecciono Authorized Applicant y lo muevo de Remaining roles a Current roles (con la flecha a la derecha):



Y CONTINUE.

Ahora el AOR ya está aprobado y puede enviar solicitudes a los NIH, pero antes tiene que verificar que su Status es APPROVED. Iremos a la segunda parte del e-mail con las contraseñas generadas previamente:

OR

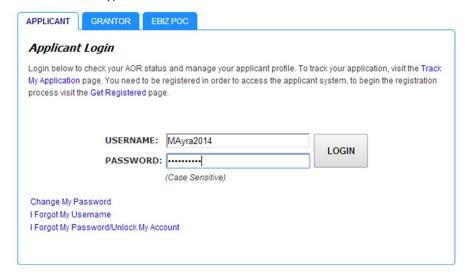
Login as an AOR at:

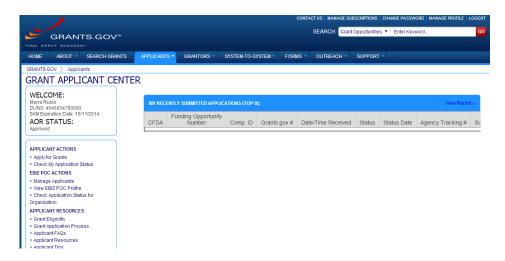
(https://apply07.grants.gov/apply/login.faces?cleanSession=1&userType=applic ant) and select manage applicants and enter your MPIN.



LOGOUT REQUEST SUCCESSFUL: You have successfully logged out of Grants.gov. Thank you.

Select Account Type:





If you determine this individual should not be assigned AOR access, do not update the user roles when you review the request in Grants.gov. You can also deactivate AORs from this section.

If you have questions regarding the E-Biz POC role assignment process, information is available on Grants.gov:

http://www.grants.gov/applicants/organization-registration.html

Thank you.

Grants.gov

If you have questions please contact the Grants.gov Contact Center:

support@grants.gov

1-800-518-4726

24 hours a day, 7 days a week. Closed on federal holidays.

PLEASE NOTE: This email is for notification purposes only. Please do not reply to this email for any purpose.



Grants.gov confirms approval by sending an email to the AOR.

From: <<u>DoNotReply@grants.gov</u>>
Date: 2014-04-14 13:28 GMT+02:00
Subject: Grants.gov AOR Authorization

To: <u>xxxxxxxxx</u>

You requested access to submit grant applications through Grants.gov on behalf of your organization. The e-Business Point of Contact for your organization (as indicated in the SAM, http://www.sam.gov) approved the request so you are now authorized to submit grant applications through Grants.gov. Your role is known as the Authorized Organizational Representative (AOR) role, which is a person authorized to submit applications on behalf of their organization. Click http://www.grants.gov/applicants/apply-for-grants.html for instructions on how to apply for grants.

Thank you. Grants.gov

If you have questions please contact the Grants.gov Contact Center:

support@grants.gov
1-800-518-4726

24 hours a day, 7 days a week. Closed on federal holidays.

PLEASE NOTE: This email is for notification purposes only. Please do not reply to this email for any purpose.







INSTRUCCIONES PARA LA CUMPLIMENTACIÓN DEL RESEARCH STRATEGY:

- El documento Research Strategy tiene un límite de páginas de **6** (para modalidades R03, R21) y **12** (para modalidades R01).
- No incluir referencias bibliográficas. Sólo la numeración correspondiente a las referencias bibliográficas por orden de aparición. El listado de referencias bibliográficas correspondientes a dicha numeración se tiene que documentar en el documento Bibliography.
- Las imágenes y figuras se incluirán sin superar el límite de 6 o 12 páginas. El tamaño máximo de las imágenes debe ser aprox. 1200 x 1500 pixels con 256 colores y en jpeg ó png.
- Contenido que debe incluir el documento:
- (a) Significance:
- 1) Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- 2) Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- 3) Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

(b) Innovation:

- 1) Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- 2) Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
- 3) Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

(c) Approach:

- 1) Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project.
- 2) Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- 3) If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
- 4) Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.
- Consideraciones:



- 1.- Dar la misma importancia a las tres secciones que componen la Research Strategy (aunque el Approach tiene que describir exhaustiva y concienzudamente la metodología a utilizar y debe ser más extenso que las otras secciones).
- 2.- Incluir resultados preliminares en la sección más adecuada. Discutir los estudios preliminares, datos y experiencia pertinente del IP.
- 3.- Plasmar en el documento la siguiente idea principal del NIH: "The project must present special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources".
- 4.- Si en el proyecto existen varios *Specific aims*, se podrá exponer en el documento las tres secciones por cada objetivo (*Innovation, Significance y Approach*), ó bien redactar las tres secciones en general para todos los objetivos de forma colectiva.
- Criterios de evaluación de los revisores:

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment



Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

INSTRUCCIONES PARA LA CUMPLIMENTACIÓN DEL ABSTRACT:

- El documento Abstract tiene un límite máximo de 30 líneas.
- Contenido que debe incluir el documento:

The Project Summary must contain a summary of the proposed activity suitable for dissemination to the public. It should be a self-contained description of the project and should contain a statement of objectives and methods to be employed. It should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate lay reader. This Summary must not include any proprietary/confidential information.

The Project Summary is meant to serve as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the agency). Describe concisely the research design and methods for achieving the stated goals.

INSTRUCCIONES PARA LA CUMPLIMENTACIÓN DEL PROJECT NARRATIVE:

- El documento *Project Narrative* tiene un límite máximo de 2-3 líneas.
- Contenido que debe incluir el documento:

This attachment will reflect the second component of the Project Summary. The second component of the Project Summary/Abstract (i.e., "Description") is Relevance. Using no more than two or three sentences, describe the **relevance of this research to public health**. In this section, be succinct and use plain language that can be understood by a general, lay audience

INSTRUCCIONES PARA LA CUMPLIMENTACIÓN DEL DOCUMENTO BIBLIOGRAPHY:

- El documento *Bibliography* no tiene límite máximo. Debe incluir las referencias bibliográficas citadas en los documentos *Research Strategy, Protection of Human Subjects, Inclusion of women and minorities, Inclusion of children, Vertebrate animals, Multiple PD/PI Leadership plan y <i>Resource Sharing Plan.*
- Contenido que debe incluir el documento:

Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations.



The references should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.

INSTRUCCIONES PARA LA CUMPLIMENTACIÓN DEL DOCUMENTO FACILITIES AND OTHER RESOURCES:

- El documento Facilities no tiene límite máximo.
- Contenido que debe incluir el documento:

This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project.

Describe how the scientific environment in which the research will be done contributes to the **probability of success** (e.g. institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements.

If there are multiple performance sites, describe the resources available at each site.

INSTRUCCIONES PARA LA CUMPLIMENTACIÓN DEL DOCUMENTO EQUIPMENT:

- El documento Equipment no tiene límite máximo.
- Contenido que debe incluir el documento:

List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities.

INSTRUCCIONES PARA LA CUMPLIMENTACIÓN DEL DOCUMENTO FOREIGN JUSTIFICATION:

- El documento *Foreign justification* no tiene límite máximo.
- Contenido que debe incluir el documento:

Describe **special resources** or characteristics of the research project (e.g., human subjects, animals, disease, equipment, and techniques), whether similar research is being done in the United States and whether there is a need for additional research in this area.



EJEMPLO PARA LA CUMPLIMENTACIÓN DEL DOCUMENTO BIOGRAPHICAL SKETCH:

OMB No. 0925-0001/0002 (Rev. 08/12 Approved Through 8/31/2015)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME:

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE:

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completi on Date MM/YYY Y	FIELD OF STUDY

NOTE: The Biographical Sketch may not exceed five pages. Follow the formats and instructions below.

A. Personal Statement

Briefly describe why you are well-suited for your role in the project described in this application. The relevant factors may include aspects of your training; your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.

B. Positions and Honors

List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.



C. Contribution to Science

Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations. Also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine.

D. Research Support

List both selected ongoing and completed research projects for the past three years (Federal or non-Federally-supported). Begin with the projects that are most relevant to the research proposed in the application. Briefly indicate the overall goals of the projects and responsibilities of the key person identified on the Biographical Sketch. Do not include number of person months or direct costs.



BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FIVE PAGES**.

NAME: Hunt, Morgan Casey

eRA COMMONS USER NAME (credential, e.g., agency login): huntmc

POSITION TITLE: Associate Professor of Psychology

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completi on Date MM/YYY Y	FIELD OF STUDY
University of California, Berkeley	B.S	05/1990	Psychology
University of Vermont	Ph.D.	05/1996	Experimental Psychology
University of California, Berkeley	Postdoctoral	08/1998	Public Health and Epidemiology

A. Personal Statement

I have the expertise, leadership, training, expertise and motivation necessary to successfully carry out the proposed research project. I have a broad background in psychology, with specific training and expertise in ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. My research includes neuropsychological changes associated with addiction. As PI or co-Investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time as documented in the following publications. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work. During 2005-2006 my career was disrupted due to family obligations. However, upon returning to the field I immediately resumed my research projects and collaborations and successfully competed for NIH support.

1. Merryle, R.J. & Hunt, M.C. (2004). Independent living, physical disability and substance abuse among the elderly. Psychology and Aging, 23(4), 10-22.



- 2. Hunt, M.C., Jensen, J.L. & Crenshaw, W. (2007). Substance abuse and mental health among community-dwelling elderly. International Journal of Geriatric Psychiatry, 24(9), 1124-1135.
- Hunt, M.C., Wiechelt, S.A. & Merryle, R. (2008). Predicting the substance-abuse treatment needs of an aging population. American Journal of Public Health, 45(2), 236-245. PMCID: PMC9162292 Hunt, M.C., Newlin, D.B. & Fishbein, D. (2009). Brain imaging in methamphetamine abusers across the life-span. Gerontology, 46(3), 122-145.

B. Positions and Honors

Positions and Employment

1998-2000 Fellow, Division of Intramural Research, National Institute of Drug

Abuse, Bethesda, MD

2000-2002 Lecturer, Department of Psychology, Middlebury College,

Middlebury, VT

2001- Consultant, Coastal Psychological Services, San Francisco, CA 2002-2005 Assistant Professor, Department of Psychology, Washington

University, St. Louis, MO

2007- Associate Professor, Department of Psychology, Washington

University, St. Louis, MO

Other Experience and Professional Memberships

1995-	Member, American Psychological Association
1998-	Member, Gerontological Society of America
1998-	Member, American Geriatrics Society
2000-	Associate Editor, Psychology and Aging
2003-	Board of Advisors, Senior Services of Eastern Missouri
2003-05 reviewer	NIH Peer Review Committee: Psychobiology of Aging, ad hoc

Honors

2007-11

2003 Outstanding Young Faculty Award, Washington University, St.

NIH Risk, Adult Addictions Study Section, members

Louis, MO

2004 Excellence in Teaching, Washington University, St. Louis, MO

2009 Award for Best in Interdisciplinary Ethnography, International

Ethnographic Society

C. Contribution to Science

1. My early publications directly addressed the fact that substance abuse is often overlooked in older adults. However, because many older adults were raised during an era of increased drug and alcohol use, there are reasons to believe that this will become an increasing issue as the population ages. These publications found that older adults appear in a variety of primary care settings or seek mental health providers to deal with emerging addiction problems. These publications document this emerging problem but guide primary care providers and geriatric mental health providers to recognize symptoms, assess the nature of the problem and apply the necessary interventions. By providing evidence and simple clinical approaches, this body of work has changed the standards of care for addicted older adults and will continue to provide



assistance in relevant medical settings well into the future. I served as the primary investigator or co-investigator in all of these studies.

- a. Gryczynski, J., Shaft, B.M., Merryle, R., & Hunt, M.C. (2002). Community based participatory research with late-life addicts. American Journal of Alcohol and Drug Abuse, 15(3), 222-238.
- b. Shaft, B.M., Hunt, M.C., Merryle, R., & Venturi, R. (2003). Policy implications of genetic transmission of alcohol and drug abuse in female nonusers. International Journal of Drug Policy, 30(5), 46-58.
- c. Hunt, M.C., Marks, A.E., Shaft, B.M., Merryle, R., & Jensen, J.L. (2004). Early-life family and community characteristics and late-life substance abuse. Journal of Applied Gerontology, 28(2),26-37.
- d. Hunt, M.C., Marks, A.E., Venturi, R., Crenshaw, W. & Ratonian, A. (2007). Community-based intervention strategies for reducing alcohol and drug abuse in the elderly. Addiction, 104(9), 1436-1606. PMCID: PMC9000292
- 2. In addition to the contributions described above, with a team of collaborators, I directly documented the effectiveness of various intervention models for older substance abusers and demonstrated the importance of social support networks. These studies emphasized contextual factors in the etiology and maintenance of addictive disorders and the disruptive potential of networks in substance abuse treatment. This body of work also discusses the prevalence of alcohol, amphetamine, and opioid abuse in older adults and how networking approaches can be used to mitigate the effects of these disorders.
 - a. Hunt, M.C., Merryle, R. & Jensen, J.L. (2005). The effect of social support networks on morbidity among elderly substance abusers. Journal of the American Geriatrics Society, 57(4), 15-23.
 - b. Hunt, M.C., Pour, B., Marks, A.E., Merryle, R. & Jensen, J.L. (2005). Aging out of methadone treatment. American Journal of Alcohol and Drug Abuse, 15(6), 134-149.
 - c. Merryle, R. & Hunt, M.C. (2007). Randomized clinical trial of cotinine in older nicotine addicts. Age and Ageing, 38(2), 9-23. PMCID: PMC9002364
- 3. Methadone maintenance has been used to treat narcotics addicts for many years but I led research that has shown that over the long-term, those in methadone treatment view themselves negatively and they gradually begin to view treatment as an intrusion into normal life. Elderly narcotics users were shown in carefully constructed ethnographic studies to be especially responsive to tailored social support networks that allow them to eventually reduce their maintenance doses and move into other forms of therapy. These studies also demonstrate the policy and commercial implications associated with these findings.
 - a. Hunt, M.C. & Jensen, J.L. (2003). Morbidity among elderly substance abusers. Journal of the Geriatrics, 60(4), 45-61.
 - b. Hunt, M.C. & Pour, B. (2004). Methadone treatment and personal assessment. Journal Drug Abuse, 45(5), 15-26.
 - c. Merryle, R. & Hunt, M.C. (2005). The use of various nicotine delivery systems by older nicotine addicts. Journal of Ageing, 54(1), 24-41. PMCID: PMC9112304
 - d. Hunt, M.C., Jensen, J.L. & Merryle, R. (2008). The aging addict: ethnographic profiles of the elderly drug user. NY, NY: W. W. Norton & Company.



Complete List of Published Work in MyBibliography: http://www.ncbi.nlm.nih.gov/sites/myncbi/collections/public/1PgT7IEFIAJBtGMRD dWFmjWAO/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support

R01 DA942367 Hunt (PI)

09/01/08-08/31/16

Health trajectories and behavioral interventions among older substance abusers

The goal of this study is to compare the effects of two substance abuse interventions on health outcomes in an urban population of older opiate addicts.

Role: PI

R01 MH922731 Merryle (PI)

12/15/07-11/30/15

Physical disability, depression and substance abuse in the elderly

The goal of this study is to identify disability and depression trajectories and demographic factors associated with substance abuse in an independently-living elderly population.

Role: Co-Investigator

Faculty Resources Grant, Washington University

08/15/09-08/14/15

Opiate Addiction Database

The goal of this project is to create an integrated database of demographic, social and biomedical information for homeless opiate abusers in two urban Missouri locations, using a number of state and local data sources.

Role: PI

Completed Research Support

R21 AA998075 Hunt (PI)

01/01/11-12/31/13

Community-based intervention for alcohol abuse

The goal of this project was to assess a community-based strategy for reducing alcohol abuse among older individuals.

Role: PI



DATOS A RELLENAR PARA LA CUMPLIMENTACIÓN DEL NON-MODULAR BUDGET:

- Para la modalidad R01, no hay límite de presupuesto, aunque si se van a solicitar más de 500,000
 USD de costes directos en un año, hay que pedir permiso justificando la necesidad. El proyecto no debe durar más de 5 años.
- Para la modalidad R21, el total de presupuesto que se puede solicitar son 275,000 USD de costes directos (más un máximo de 8% de costes indirectos). En el primer año, se puede solicitar como máximo 200,000 USD de costes directos.
- Para la modalidad R03, el total de presupuesto que se puede solicitar son 100,000 USD de costes directos (más un máximo de 8% de costes indirectos). En el primer año, se puede solicitar como máximo 50,000 USD de costes directos.
- El presupuesto se debe realizar por separado para cada anualidad.
- En el caso de Multiples PIs de diferentes instituciones, cada IP debe hacer su presupuesto por separado y para cada anualidad (Subaward budget).
- Los costes indirectos para no residentes en USA son como máximo del 8% de los costes directos.
- Los ítems para el presupuesto son los siguientes:
- a) Total Federal Funds Requested: Enter total Federal funds requested for the entire project period.
- **b)** Estimated program income: Identify any Program Income estimated for this project period if applicable.
 - * Explicación al final de este documento.
- c) Budget año 1 -año 2 por separado: (rellenar tabla en USD)

	A SENIOR/KEY PERSON (Year 1)									
	Prefi	First	Last	Suffi	Projec	Base	Calendar	Requeste	Fringe	Funds
	X	Nam	nam	X	t role	Salar	y months	d salary	benefit	requeste
		e	e			у		(\$)	s (\$)	d (\$)
1										
2										
3										

......

		A SENIOR/KEY PERSON (Year 2)								
	Prefi	First	Last	Suffi	Projec	Base	Calendar	Requeste	Fringe	Funds
	X	Nam	nam	X	t role	Salar	y months	d salary	benefit	requeste
		е	e			у		(\$)	s (\$)	d (\$)
1										
2										
3										

......



		В.	- OTHER PERSO	ONNEL (Year 1)		
Number	of	Project role	Calendary	Requested	Fringe	Funds
personnel			months	salary (\$)	benefits (\$)	requested (\$)
		Postdoctoral				
		associates				
		Graduate students				
		Undergraduate				
		students				
		Secretarial/Clerical				

		В.	- OTHER PERSO	NNEL (Year 2)		
Number	of	Project role	Calendary	Requested	Fringe	Funds
personnel			months	salary (\$)	benefits (\$)	requested (\$)
		Postdoctoral				
		associates				
		Graduate students				
		Undergraduate				
		students				
		Secretarial/Clerical				

	C L	EQUIPMENT (Year 1)
	Equipment item	Funds requested (\$)
1		
2		
3		

	C EQUIPMENT (Year 2)		
	Equipment item	Funds requested (\$)	
1			
2			
3			

D TRAVEL (Year 1)				
Travel	Funds requested (\$)			
Foreign travel costs				



D TRAVEL (Year 2)			
Travel	Funds requested (\$)		
Foreign travel costs			

	E OTHER DIRECT COSTS (Year 1)
	Funds requested (\$)
Materials and supplies	
Publication costs	
Consultant services	
ADP/Computer services	
Subaward/Consortium/Consortium Costs	
Equipment or facilities rental/User fees	

	E OTHER DIRECT COSTS (Year 2)
	Funds requested (\$)
Materials and supplies	
Publication costs	
Consultant services	
ADP/Computer services	
Subaward/Consortium/Consortium Costs	
Equipment or facilities rental/User fees	

Instrucciones:

- c.1.- Senior/Key Person: This section could include such roles as PD/PI, Postdoctoral Associates, and Other Professionals. Para cada investigador senior que se desee pedir salarios, rellenar individualmente los siguientes datos:
- Base salary (USD): Annual compensation paid by the employer for each senior/key person. Se puede dejar esto en blanco, aunque el NIH puede solicitar este valor antes del award.
- <u>Calendary months</u>: Number of months devoted to the Project for each key person.
- Requested salary (USD): Regardless of the number of months being devoted to the project, indicate only the amount of salary being requested for this budget period for each senior/key person.
- **Fringe benefits (USD):** Enter applicable fringe benefits, if any, for each senior/key person.

EL REQUESTED SALARY ES EQUIVALENTE AL SUELDO BRUTO DE UN SALARIO EN ESPAÑA, Y LOS FRINGE BENEFITS EQUIVALE A LA CUOTA EMPRESARIAL A LA SEGURIDAD SOCIAL.

c.2.- Other personnel: If Project Role is other than Post Doctoral Associates, Graduate Students, Undergraduate Students, or Secretarial/Clerical, enter the appropriate project role (for example, Engineer, IT Professional, etc.). Rellenar individualmente los siguientes datos:



- Base salary (USD): Annual compensation paid by the employer for each senior/key person. Se puede dejar esto en blanco, aunque el NIH puede solicitar este valor antes del award.
- **Calendary months:** Number of months devoted to the Project for each key person.
- Requested salary (USD): Regardless of the number of months being devoted to the project, indicate only the amount of salary being requested for this budget period for each senior/key
- **Fringe benefits (USD):** Enter applicable fringe benefits, if any,
 - **c.3.- Equipment description:** *este presupuesto debe ser + de 5,000 USD. Poner el equipamiento* necesario y los Funds Requested para cada uno.
 - **c.4.- Travel:** Funds Requested (USD).
 - c.5.- Other direct costs (USD):
- Materials and supplies: glassware, chemicals, animal costs, including an amount for each category.
- Publication costs: costs of documenting, preparing, publishing, or otherwise making available to others the findings and products of the work conducted under the award. Include supporting information.
- **Consultant services:** List the total costs for all consultant services. Identify each consultant, the services he/she will perform, total number of days, travel costs, and the total estimated costs.
- ADP/Computer Services: Including computer-based retrieval of scientific, technical and education information.
- Subaward/Consortium/Contractual Costs: This line item should include both direct and indirect costs for all subaward/consortium organizations. Contractual costs for support services, such as the laboratory testing of biological materials, clinical services, or data processing, are occasionally sufficiently high to warrant a categorical breakdown of costs. When this is the case, provide detailed information as part of the budget justification.
- **Equipment or Facility Rental/User Fees**
- <u>Other</u>

* PROGRAM INCOME

- 1.- Program Income. Gross income earned by the applicant organization that is directly generated by a supported activity or earned as a result of the award. The NIH Grants Policy Statement contains a detailed explanation of program income, the ways in which it may be generated and accounted for, and the various options for its use and disposition.
- Examples of program income include:
- Fees earned from services performed under the grant, such as those resulting from laboratory drug testing;
- Rental or usage fees, such as those earned from fees charged for use of computer equipment purchased with grant funds;
- Third party patient reimbursement for hospital or other medical services, such as insurance payments for patients when such reimbursement occurs because of the grant-supported activity;



- Funds generated by the sale of commodities, such as tissue cultures, cell lines, or research animals;
- Patent or copyright royalties (exempt from reporting requirements); and
- Registration fees generated from grant-supported conferences.
- **2.-** Many federal agencies require applicants to list the estimated Program Income (and source) expected to be generated by the project on their grant application forms. Program Income is income earned by a grant recipient from activities which are supported by the direct costs of an award. It includes, but is not limited to:
- Fees earned for services performed under the grant, such as those resulting from laboratory drug testing.
- Rental or usage fees, such as those earned from fees charged for the use of computer equipment purchased with grant funds.
- Third-party patient reimbursement for hospital or other medical services, such as insurance payments for patients where reimbursement occurs because of the grant supported activity.
- Funds generated by the sale of commodities, such as tissue cultures, cell lines, or research animals.
- Fees received to attend conference or workshop funded by a sponsored project. Unless otherwise specified in the awarding agency regulations or the terms of the award, program income does not include:
- The receipt of principal on loans, rebates, credits, discounts, or interest earned on these.
- Interest earned on advances of federal funds.
- Income earned from license fees and royalties for copyrighted material, patents, patent applications, trademarks and inventions produced under an award.
- Income earned after the end of the project period.

INSTRUCCIONES PARA LA CUMPLIMENTACIÓN DEL DOCUMENTO BUDGET JUSTIFICATION:

- El documento Budget justification no tiene límite máximo.
- Contenido que debe incluir el documento:

Provide the **additional information** requested in each budget category identified and any other information the applicant wishes to submit **to support the budget request**. The following budget categories must be justified, where applicable: equipment, travel, participant/trainee support and other direct cost categories.

DATOS A RELLENAR PARA LA CUMPLIMENTACIÓN DE LA COVER LETTER:

Para rellenar la Cover Letter se necesita esta información:

- a) <u>List of individuals who should not review your application and why</u>: En este apartado aconsejamos poner NONE.
- b) <u>Disciplines involved, if multidisciplinary</u>.



c) <u>Subaward budget</u>: Si hay multiples IPs, y se van a solicitar presupuestos por separado, el presupuesto del segundo IP debe aparecer como un Subaward Budget. Hay que especificar si este presupuesto va a ser para los años completos del proyecto, ó sólo para un rango de tiempo concreto dentro del proyecto. EXPLANATION OF ANY SUBAWARD BUDGET COMPONENTS THAT ARE NOT ACTIVE FOR ALL PERIODS OF THE PROPOSED GRANT.

INSTRUCCIONES PARA LA CUMPLIMENTACIÓN DEL DOCUMENTO SPECIFIC AIMS:

Convocatoria PA-11-260:

- El documento Specific Aims tiene un límite de páginas de 1.
- Mandamos el documento en Word a rellenar con el formato exacto para enviarlo. NO CAMBIAR FORMATO DE WORD. El anexo se llama Carmena_Specif_aims.doc.
- No incluir referencias bibliográficas.
- Contenido que debe incluir el documento:

State concisely the **goals** of the proposed research and summarize the **expected outcome(s)**, including the **impact** that the results of the proposed research will exert on the research field(s) involved.

List succinctly the **specific objectives** of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

INSTRUCCIONES PARA LA CUMPLIMENTACIÓN DEL DOCUMENTO PROTECTION OF HUMAN SUBJECTS:

• Antes de empezar a trabajar en este Entregable debe responder a la siguiente pregunta:

Are human subjects involved?

- 1) NO: No hay que rellenar el presente documento, a menos que en el proyecto propuesto se vayan a utilizar muestras humanas de algún tipo y/o datos privados de personas pero que no implica el reclutamiento de sujetos humanos (OHRP Guidance on Research involving coded Private information or biological specimens http://www.hhs.gov/ohrp/policy/cdebiol.html), en este caso, se debe exponer en este documento una justificación del porqué el investigador entiende que NO se incluyen sujetos humanos. (Scenario A)
- 2) SI: ¿Qué tipo de investigación con humanos es su proyecto?



a) Clinical Research: NIH defines human clinical research as research with human subjects that is: (1) Patient-Oriented Research. Research Conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical studies, or (d) development of new technologies. (2) Epidemiologic and Behavioral Studies. (3) Outcomes Research and Health Services Research.

b) Clinical trial: The NIH defines a clinical trial as a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).

Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Behavioral human subjects research involving an intervention to modify behavior (diet, physical activity, cognitive therapy, etc.) fits this definition of a clinical trial. Human subjects research to develop or evaluate clinical laboratory tests (e.g. imaging or molecular diagnostic tests) might be considered to be a clinical trial if the test will be used for medical decision making for the subject or the test itself imposes more than minimal risk for subjects.

Biomedical clinical trials of experimental drug, treatment, device or behavioral intervention may proceed through four phases:

Phase I clinical trials test a new biomedical intervention in a small group of people (e.g., 20-80) for the first time to evaluate safety (e.g., to determine a safe dosage range and to identify side effects). **Phase II** clinical trials study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety.

Phase III studies investigate the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.

Phase IV studies are conducted after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

c) NIH-Defined Phase III Clinical Trial: For the purpose of the Guidelines an NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or controlled intervention or comparing two or more existing treatments.

Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.



• Una vez se ha detectado el tipo de investigación en humanos, hay que seleccionar entre los siguientes escenarios donde encaje el proyecto exactamente. Una vez seleccionado el escenario, hay que elegir el anexo correspondiente a cada Escenario en el cual se especifica el tipo de documentos a elaborar y las instrucciones.

Scenario B. Non-Exempt Human Subjects Research. Consultar secciones posteriores.

If research involving human subjects is anticipated to take place under the award.

Scenario C. Exempt Human Subjects Research. Consultar secciones posteriores.

Exemptions. The six categories of research exempt from the DHHS human subject regulations are:

Exemption 1: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exemption 2: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Exemption 3: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Exemption 4: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. The human subjects regulations decision charts (http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html) of the Office for Human Research Protection (OHRP) will determine whether the research falls under the human subjects regulations and if so, whether it meets the criteria for Exemption 4. The NIH Office of Extramural Research Web site also contains information that is helpful for determining whether human research subjects meets the criteria for Exemption http://grants.nih.gov/grants/policy/hs/index.htm. Research that meets the criteria for Exemption 4 is not considered "clinical research" as defined by NIH. Therefore the NIH policies for inclusion of women, minorities and children in clinical research, and targeted/planned enrollment tables, do not apply to research projects covered by Exemption 4.

Exemption 5: Research and demonstration projects that are conducted by or subject to the approval of Department or Agency heads and that are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs (ii) procedures for obtaining benefits or services under those programs (iii) possible changes in or alternatives to those programs or procedures or (iv) possible changes in methods or levels of payment for benefits or services under those programs. Note: It is uncommon for investigators applying for an NIH grant to qualify for this exemption.



Please seek guidance from the relevant NIH IC or from the OER Human Subject Protection staff if you think your project is eligible for Exemption 5.

Exemption 6: Taste and food quality evaluation and consumer acceptance studies (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmentalcontaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Scenario D. Delayed-Onset Human Subjects Research. Consultar secciones posteriores.

En raras ocasiones, las solicitudes se presentan con el conocimiento de que los sujetos humanos estarán involucrados durante el periodo de la ayuda, pero los planes son tan indefinidos que no es posible describir la participación de sujetos humanos en el proyecto. Los tipos de actividades que carecen de planes definidos son a menudo adjudicaciones institucionales en que la selección de proyectos específicos es responsabilidad de la institución, becas de formación de investigadores, y proyectos en los que la participación de seres humanos dependa de la finalización de alguna instrumentación, los estudios en animales, o la purificación de compuestos.

If human subjects research is anticipated within the period of the award but plans for involvement of human subjects cannot be described in the application.

Examples of delayed-onset of human subjects research include:

- Human subjects research is dependent upon the completion of animal or other studies; or
- Human subjects research protocols to be included will undergo an independent decision making process.

Scenario E. Human Subjects Research Involving a Clinical Trial. Consultar secciones posteriores.

If research involving human subjects is anticipated to take place under the award, and you intend to conduct a clinical trial during the project period.

Scenario F. Human Subjects Research Involving an NIH-Defined Phase III Clinical Trial. Consultar secciones posteriores.

If research involving human subjects is anticipated to take place under the award, and you intend to conduct an NIH-defined Phase III clinical trial during the project period

INSTRUCCIONES PARA LA CUMPLIMENTACIÓN DEL DOCUMENTO PROTECTION OF HUMAN SUBJECTS para el Escenario B:

Scenario B. Non-Exempt Human Subjects Research.

Criterios:

Human Subjects Research

Yes



Exemption Claimed No Clinical Trial No NIH-Defined Phase III Clinical Trial No

Instrucciones e información requerida:

• Aunque no hay límite de páginas se especifica que los documentos generados sean lo más concisos posibles.

• Se tienen que elaborar 4 documentos diferentes:

Protections of Human Subjects.
Inclusion of Women and Minorities.
Targeted/Planned Enrollment Table(s).
Inclusion of Children.

If the research involves collaborating sites or subprojects, provide the information identified above for each participating site.

Instrucciones generales:

Protections of Human Subjects. El documento debería contener la siguiente información:

Risks to Human Subjects

- 1.- Human Subjects Involvement, Characteristics, and Design.
- Describe the proposed involvement of human subjects in the work.
- Describe and justify the characteristics of the subject population.
- Describe and justify the sampling plan, as well as the criteria for inclusion or exclusion of any subpopulation.
- Explain the rationale for the involvement of special vulnerable populations.
- If relevant describe and justify the selection of an intervention's dose, frequency, and administration.
- List any collaborating sites where human subjects research will be performed, the role of those sites and collaborating investigators. Explain how data from the site(s) will be obtained, managed, and protected.
- 2.- Sources of Materials.
- Describe the research material obtained from living individuals (specimens records, or data).
- Indicate who will have access to individually identifiable private information about human subjects.
- Provide information about how the specimens, records, and/or data are collected, managed, and protected.
- 3.- Potential Risks.



• Describe the potential risks to subjects (physical, psychological, financial, legal, or other)

Adequacy of Protection Against Risks

- 1.- Recruitment and Informed Consent.
- Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.
- Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent.
- 2.- Protections Against Risk.
- Describe planned procedures for protecting against or minimizing potential risks (privacy of individuals or confidentiality of data).
- Research involving vulnerable populations, as described in the DHHS regulations, Subparts B-D must include additional protections. Refer to DHHS regulations, and OHRP guidance:
- Additional Protections for Pregnant Women, Human Fetuses and Neonates: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartb
- Additional Protections for Prisoners: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc
- OHRP Subpart C Guidance: http://www.hhs.gov/ohrp/policy/index.html#prisoners
- Additional Protections for Children: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd
- OHRP Subpart D Guidance: http://www.hhs.gov/ohrp/policy/index.html#children
- Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.

Potential Benefits of the Proposed Research to Human Subjects and Others

- Discuss the potential benefits of the research to research participants and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.

Importance of the Knowledge to be Gained

• Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.



• Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

Inclusion of Women and Minorities. El documento debería contener la siguiente información:

In this section of the Research Plan, address, at a minimum, the following 3 points:

- 1. A description of the subject selection criteria and rationale for selection of sex/gender and racial/ethnic group.
- 2. A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group.
- 3. A description of proposed outreach programs for recruiting sex/gender and racial/ethnic group members as subjects.

Below are <u>examples</u> of acceptable justifications for the exclusion of:

A. One gender:

- 1. One gender is excluded from the study because:
- inclusion of these individuals would be inappropriate with respect to their health;
- the research question addressed is relevant to only one gender;
- evidence from prior research strongly demonstrates no difference between genders; or
- sufficient data already exist with regard to the outcome of comparable studies in the excluded gender, and duplication is not needed in this study.
- 2. One gender is excluded or severely limited because the purpose of the research constrains the applicant's selection of study subjects by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or overriding factors dictate selection of subjects, such as matching of transplant recipients, or availability of rare surgical specimens).
- 3. Gender representation of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens, or data-sets with incomplete gender documentation are used), and this does not compromise the scientific objectives of the research.
- B. Minority groups or subgroups:
- 1. Some or all minority groups or subgroups are excluded from the study because:
- inclusion of these individuals would be inappropriate with respect to their health;
- the research question addressed is relevant to only one racial or ethnic group;
- evidence from prior research strongly demonstrates no differences between racial or ethnic groups on the outcome variables;
- a single minority group study is proposed to fill a research gap; or
- sufficient data already exists with regard to the outcome of comparable studies in the excluded racial or ethnic groups and duplication is not needed in this study.
- 2. Some minority groups or subgroups are excluded or poorly represented because the geographical location of the study has only limited numbers of these minority groups who would be eligible for the study, and the investigator has satisfactorily addressed this issue in terms of:
- the size of the study;
- the relevant characteristics of the disease, disorder or condition; or
- the feasibility of making a collaboration or consortium or other arrangements to include representation.



- 3. Some minority groups or subgroups are excluded or poorly represented because the purpose of the research constrains the applicant's selection of study subjects by race or ethnicity.
- 4. Racial or ethnic origin of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens or data sets with incomplete racial or ethnic documentation are used) and this does not compromise the scientific objectives of the research.

Targeted/Planned Enrollment Table(s). Instrucciones para rellenar la tabla:

- Provide the study title.
- If the application involves subprojects, provide Targeted Enrollment Tables for each subproject description.
- The "Total Planned Enrollment" means the number of subjects that are expected to be enrolled in the study, consistent with the definition in ClinicalTrials.gov.
- The "Total Planned Enrollment" will be reported in two ways in the table: by "Ethnic Category" and by "Racial Categories."
- "Ethnic Category": Provide the numeric distribution of the Total Planned Enrollment according to ethnicity and sex/gender in the top part of the table.
- "Racial Categories": Provide the numeric distribution of the Total Planned Enrollment, this time by racial categories and sex/gender, in the bottom part of the table. Note that Hispanic is an ethnic, not a racial, category.
- If there is more than one study/protocol, provide a separate table for each.
- List any proposed racial/ethnic subpopulations below the table.

When completing the Targeted/Planned Enrollment Tables that describe research in foreign sites, investigators should asterisk and footnote the table indicating that data include research participants in foreign sites. If the aggregated data only includes participants in foreign research sites, the investigator should provide information in one table with an asterisk and footnote.

Inclusion of Children. El documento debería contener la siguiente información:

Provide either a description of the plans to include children, or, if children will be excluded from the proposed research, present an acceptable justification for the exclusion.

If children are included, the description of the plan should include a rationale for selecting a specific age range of children. The plan also must include a description of the expertise of the investigative team for working with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

Justifications for Exclusion of Children:

All individuals under 21 are considered children; however, exclusion of any specific age group, such as individuals under 18, should be justified in this section. It is expected that children will be included in all clinical research unless one or more of the following exclusionary circumstances apply:

- 1. The research topic to be studied is not relevant to children.
- 2. Laws or regulations bar the inclusion of children in the research.



- 3. The knowledge being sought in the research is already available for children.
- 4. A separate, age-specific study in children is warranted and preferable. Examples include:
 - a. The condition is relatively rare in children, as compared to adults.
 - b. The number of children is limited.
- c. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children.
- 5. Insufficient data are available in adults to judge potential risk in children.
- 6. Study designs are aimed at collecting additional data on pre-enrolled adult study.
- 7. Other special cases can be justified by the investigator.

INSTRUCCIONES PARA LA CUMPLIMENTACIÓN DEL DOCUMENTO PROTECTION OF HUMAN SUBJECTS para el Escenario C:

Scenario C. Exempt Human Subjects Research.

Criterios:

Human Subjects Research Yes

Exemption Claimed Yes (1, 2, 3, 4, 5 or 6)

Clinical Trial Yes/No NIH-Defined Phase III Clinical Trial No

Instrucciones e información requerida:

- Aunque no hay límite de páginas se especifica que los documentos generados sean lo más concisos posibles.
- Se tienen que elaborar 4 documentos diferentes:

Protections of Human Subjects.
Inclusion of Women and Minorities.
Targeted/Planned Enrollment Table(s).
Inclusion of Children.

If the research involves collaborating sites or subprojects, provide the information identified above for each participating site.

Instrucciones generales:

Protections of Human Subjects. El documento debería contener la siguiente información:

Primero hay que añadir en este documento la siguiente frase: "This human Subjects research falls under Exemption(s)....." identificando claramente qué número de exención y justificar el porqué de esa exención.



Si el proyecto recae en la Exención 4, NO se necesita elaborar los Documentos Inclusion of women and minorities, Targeted/Planned Enrollment Table(s) y Inclusion of children.

Risks to Human Subjects

- 1.- Human Subjects Involvement, Characteristics, and Design.
- Describe the proposed involvement of human subjects in the work.
- Describe and justify the characteristics of the subject population.
- Describe and justify the sampling plan, as well as the criteria for inclusion or exclusion of any subpopulation.
- Explain the rationale for the involvement of special vulnerable populations.
- If relevant describe and justify the selection of an intervention's dose, frequency, and administration.
- List any collaborating sites where human subjects research will be performed, the role of those sites and collaborating investigators. Explain how data from the site(s) will be obtained, managed, and protected.
- 2.- Sources of Materials.
- Describe the research material obtained from living individuals (specimens records, or data).
- Indicate who will have access to individually identifiable private information about human subjects.
- Provide information about how the specimens, records, and/or data are collected, managed, and protected.
- 3.- Potential Risks.
- Describe the potential risks to subjects (physical, psychological, financial, legal, or other)

Adequacy of Protection Against Risks

- 1.- Recruitment and Informed Consent.
- Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.
- Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent.
- 2.- Protections Against Risk.
- Describe planned procedures for protecting against or minimizing potential risks (privacy of individuals or confidentiality of data).
- Research involving vulnerable populations, as described in the DHHS regulations, Subparts B-D must include additional protections. Refer to DHHS regulations, and OHRP guidance:



- Additional Protections for Pregnant Women, Human Fetuses and Neonates: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartb
- Additional Protections for Prisoners: http://www.hhs.gov/ohrp/humansubjects/quidance/45cfr46.html#subpartc
- OHRP Subpart C Guidance: http://www.hhs.gov/ohrp/policy/index.html#prisoners
- Additional Protections for Children: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd
- OHRP Subpart D Guidance: http://www.hhs.gov/ohrp/policy/index.html#children
- Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.

Potential Benefits of the Proposed Research to Human Subjects and Others

- Discuss the potential benefits of the research to research participants and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.

Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

Inclusion of Women and Minorities. El documento debería contener la siguiente información:

In this section of the Research Plan, address, at a minimum, the following 3 points:

- 1. A description of the subject selection criteria and rationale for selection of sex/gender and racial/ethnic group.
- 2. A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group.
- 3. A description of proposed outreach programs for recruiting sex/gender and racial/ethnic group members as subjects.

Below are examples of acceptable justifications for the exclusion of:

- A. One gender:
- 1. One gender is excluded from the study because:
- inclusion of these individuals would be inappropriate with respect to their health;
- the research question addressed is relevant to only one gender;
- evidence from prior research strongly demonstrates no difference between genders; or



- sufficient data already exist with regard to the outcome of comparable studies in the excluded gender, and duplication is not needed in this study.
- 2. One gender is excluded or severely limited because the purpose of the research constrains the applicant's selection of study subjects by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or overriding factors dictate selection of subjects, such as matching of transplant recipients, or availability of rare surgical specimens).
- 3. Gender representation of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens, or data-sets with incomplete gender documentation are used), and this does not compromise the scientific objectives of the research.
- B. Minority groups or subgroups:
- 1. Some or all minority groups or subgroups are excluded from the study because:
- inclusion of these individuals would be inappropriate with respect to their health;
- the research question addressed is relevant to only one racial or ethnic group;
- evidence from prior research strongly demonstrates no differences between racial or ethnic groups on the outcome variables;
- a single minority group study is proposed to fill a research gap; or
- sufficient data already exists with regard to the outcome of comparable studies in the excluded racial or ethnic groups and duplication is not needed in this study.
- 2. Some minority groups or subgroups are excluded or poorly represented because the geographical location of the study has only limited numbers of these minority groups who would be eligible for the study, and the investigator has satisfactorily addressed this issue in terms of:
- the size of the study;
- the relevant characteristics of the disease, disorder or condition; or
- the feasibility of making a collaboration or consortium or other arrangements to include representation.
- 3. Some minority groups or subgroups are excluded or poorly represented because the purpose of the research constrains the applicant's selection of study subjects by race or ethnicity.
- 4. Racial or ethnic origin of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens or data sets with incomplete racial or ethnic documentation are used) and this does not compromise the scientific objectives of the research.

Targeted/Planned Enrollment Table(s). Instrucciones para rellenar la tabla:

- Provide the study title.
- If the application involves subprojects, provide Targeted Enrollment Tables for each subproject description.
- The "Total Planned Enrollment" means the number of subjects that are expected to be enrolled in the study, consistent with the definition in ClinicalTrials.gov.
- The "Total Planned Enrollment" will be reported in two ways in the table: by "Ethnic Category" and by "Racial Categories."
- "Ethnic Category": Provide the numeric distribution of the Total Planned Enrollment according to ethnicity and sex/gender in the top part of the table.
- "Racial Categories": Provide the numeric distribution of the Total Planned Enrollment, this time by racial categories and sex/gender, in the bottom part of the table. Note that Hispanic is an ethnic, not a racial, category.
- If there is more than one study/protocol, provide a separate table for each.



- List any proposed racial/ethnic subpopulations below the table.

When completing the Targeted/Planned Enrollment Tables that describe research in foreign sites, investigators should asterisk and footnote the table indicating that data include research participants in foreign sites. If the aggregated data only includes participants in foreign research sites, the investigator should provide information in one table with an asterisk and footnote.

Inclusion of Children. El documento debería contener la siguiente información:

Provide either a description of the plans to include children, or, if children will be excluded from the proposed research, present an acceptable justification for the exclusion.

If children are included, the description of the plan should include a rationale for selecting a specific age range of children. The plan also must include a description of the expertise of the investigative team for working with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

Justifications for Exclusion of Children:

All individuals under 21 are considered children; however, exclusion of any specific age group, such as individuals under 18, should be justified in this section. It is expected that children will be included in all clinical research unless one or more of the following exclusionary circumstances apply:

- 1. The research topic to be studied is not relevant to children.
- 2. Laws or regulations bar the inclusion of children in the research.
- 3. The knowledge being sought in the research is already available for children.
- 4. A separate, age-specific study in children is warranted and preferable. Examples include:
 - a. The condition is relatively rare in children, as compared to adults.
 - b. The number of children is limited.
- c. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children.
- 5. Insufficient data are available in adults to judge potential risk in children.
- 6. Study designs are aimed at collecting additional data on pre-enrolled adult study.
- 7. Other special cases can be justified by the investigator.

INSTRUCCIONES PARA LA CUMPLIMENTACIÓN DEL DOCUMENTO PROTECTION OF HUMAN SUBJECTS para el Escenario D:

Scenario D. Delayed-Onset human subjects Research.

Criterios:

Human Subjects Research Yes
Exemption Claimed Yes/No
Clinical Trial Yes/No

Page 61 of 82



NIH-Defined Phase III Clinical Trial

Yes/No

Instrucciones e información requerida:

- Aunque no hay límite de páginas se especifica que los documentos generados sean lo más concisos posibles.
- Se tienen que elaborar 4 documentos diferentes:

Protections of Human Subjects.
Inclusion of Women and Minorities.
Targeted/Planned Enrollment Table(s).
Inclusion of Children.

If the research involves collaborating sites or subprojects, provide the information identified above for each participating site.

Instrucciones generales:

Protections of Human Subjects. El documento debería contener la siguiente información:

Primero hay que añadir en este documento una explicación detallada del porqué no es posible desarrollar planes definitivos de inclusión de sujetos humanos en ese momento, y en qué momento del proyecto puede ya ser posible. Esta explicación también tiene que estar directamente relacionada con el documento Specific Aims.

Risks to Human Subjects

- 1.- Human Subjects Involvement, Characteristics, and Design.
- Describe the proposed involvement of human subjects in the work.
- Describe and justify the characteristics of the subject population.
- Describe and justify the sampling plan, as well as the criteria for inclusion or exclusion of any subpopulation.
- Explain the rationale for the involvement of special vulnerable populations.
- If relevant describe and justify the selection of an intervention's dose, frequency, and administration.
- List any collaborating sites where human subjects research will be performed, the role of those sites and collaborating investigators. Explain how data from the site(s) will be obtained, managed, and protected.
- 2.- Sources of Materials.
- Describe the research material obtained from living individuals (specimens records, or data).
- Indicate who will have access to individually identifiable private information about human subjects.



- Provide information about how the specimens, records, and/or data are collected, managed, and protected.
- 3.- Potential Risks.
- Describe the potential risks to subjects (physical, psychological, financial, legal, or other)

Adequacy of Protection Against Risks

- 1.- Recruitment and Informed Consent.
- Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.
- Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent.
- 2.- Protections Against Risk.
- Describe planned procedures for protecting against or minimizing potential risks (privacy of individuals or confidentiality of data).
- Research involving vulnerable populations, as described in the DHHS regulations, Subparts B-D must include additional protections. Refer to DHHS regulations, and OHRP guidance:
- Additional Protections for Pregnant Women, Human Fetuses and Neonates: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartb
- Additional Protections for Prisoners: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc
- OHRP Subpart C Guidance: http://www.hhs.gov/ohrp/policy/index.html#prisoners
- Additional Protections for Children: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd
- OHRP Subpart D Guidance: http://www.hhs.gov/ohrp/policy/index.html#children
- Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.

Potential Benefits of the Proposed Research to Human Subjects and Others

- Discuss the potential benefits of the research to research participants and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.

Importance of the Knowledge to be Gained



- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

Inclusion of Women and Minorities. El documento debería contener la siguiente información:

In this section of the Research Plan, address, at a minimum, the following 3 points:

- 1. A description of the subject selection criteria and rationale for selection of sex/gender and racial/ethnic group.
- 2. A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group.
- 3. A description of proposed outreach programs for recruiting sex/gender and racial/ethnic group members as subjects.

Below are examples of acceptable justifications for the exclusion of:

A. One gender:

- 1. One gender is excluded from the study because:
- inclusion of these individuals would be inappropriate with respect to their health;
- the research question addressed is relevant to only one gender;
- evidence from prior research strongly demonstrates no difference between genders; or
- sufficient data already exist with regard to the outcome of comparable studies in the excluded gender, and duplication is not needed in this study.
- 2. One gender is excluded or severely limited because the purpose of the research constrains the applicant's selection of study subjects by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or overriding factors dictate selection of subjects, such as matching of transplant recipients, or availability of rare surgical specimens).
- 3. Gender representation of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens, or data-sets with incomplete gender documentation are used), and this does not compromise the scientific objectives of the research.
- B. Minority groups or subgroups:
- 1. Some or all minority groups or subgroups are excluded from the study because:
- inclusion of these individuals would be inappropriate with respect to their health;
- the research question addressed is relevant to only one racial or ethnic group;
- evidence from prior research strongly demonstrates no differences between racial or ethnic groups on the outcome variables;
- a single minority group study is proposed to fill a research gap; or
- sufficient data already exists with regard to the outcome of comparable studies in the excluded racial or ethnic groups and duplication is not needed in this study.
- 2. Some minority groups or subgroups are excluded or poorly represented because the geographical location of the study has only limited numbers of these minority groups who would be eligible for the study, and the investigator has satisfactorily addressed this issue in terms of:

 the size of the study;



- the relevant characteristics of the disease, disorder or condition; or
- the feasibility of making a collaboration or consortium or other arrangements to include representation.
- 3. Some minority groups or subgroups are excluded or poorly represented because the purpose of the research constrains the applicant's selection of study subjects by race or ethnicity.
- 4. Racial or ethnic origin of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens or data sets with incomplete racial or ethnic documentation are used) and this does not compromise the scientific objectives of the research.

Targeted/Planned Enrollment Table(s). Instrucciones para rellenar la tabla:

- Provide the study title.
- If the application involves subprojects, provide Targeted Enrollment Tables for each subproject description.
- The "Total Planned Enrollment" means the number of subjects that are expected to be enrolled in the study, consistent with the definition in ClinicalTrials.gov.
- The "Total Planned Enrollment" will be reported in two ways in the table: by "Ethnic Category" and by "Racial Categories."
- "Ethnic Category": Provide the numeric distribution of the Total Planned Enrollment according to ethnicity and sex/gender in the top part of the table.
- "Racial Categories": Provide the numeric distribution of the Total Planned Enrollment, this time by racial categories and sex/gender, in the bottom part of the table. Note that Hispanic is an ethnic, not a racial, category.
- If there is more than one study/protocol, provide a separate table for each.
- List any proposed racial/ethnic subpopulations below the table.

When completing the Targeted/Planned Enrollment Tables that describe research in foreign sites, investigators should asterisk and footnote the table indicating that data include research participants in foreign sites. If the aggregated data only includes participants in foreign research sites, the investigator should provide information in one table with an asterisk and footnote.

Inclusion of Children. El documento debería contener la siguiente información:

Provide either a description of the plans to include children, or, if children will be excluded from the proposed research, present an acceptable justification for the exclusion.

If children are included, the description of the plan should include a rationale for selecting a specific age range of children. The plan also must include a description of the expertise of the investigative team for working with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

Justifications for Exclusion of Children:

All individuals under 21 are considered children; however, exclusion of any specific age group, such as individuals under 18, should be justified in this section. It is expected that children will be included in all clinical research unless one or more of the following exclusionary circumstances apply:



- 1. The research topic to be studied is not relevant to children.
- 2. Laws or regulations bar the inclusion of children in the research.
- 3. The knowledge being sought in the research is already available for children.
- 4. A separate, age-specific study in children is warranted and preferable. Examples include:
 - a. The condition is relatively rare in children, as compared to adults.
 - b. The number of children is limited.
- c. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children.
- 5. Insufficient data are available in adults to judge potential risk in children.
- 6. Study designs are aimed at collecting additional data on pre-enrolled adult study.
- 7. Other special cases can be justified by the investigator.

INSTRUCCIONES PARA LA CUMPLIMENTACIÓN DEL DOCUMENTO PROTECTION OF HUMAN SUBJECTS para el Escenario E:

Scenario E. Human Subjects Research Involving a Clinical Trial.

Criterios:

Human Subjects Research Yes
Exemption Claimed Yes/No
Clinical Trial Yes
NIH-Defined Phase III Clinical Trial No

Instrucciones e información requerida:

- Aunque no hay límite de páginas se especifica que los documentos generados sean lo más concisos posibles.
- Se tienen que elaborar 4 documentos diferentes:

Protections of Human Subjects. Inclusion of Women and Minorities. Targeted/Planned Enrollment Table(s). Inclusion of Children.

If the research involves collaborating sites or subprojects, provide the information identified above for each participating site.

Instrucciones generales:

Protections of Human Subjects. El documento debería contener la siguiente información (se incluyen dos apartados más, Data and safety monitoring plan, and Clinical trials-gov requirements):



Risks to Human Subjects

- 1.- Human Subjects Involvement, Characteristics, and Design.
- Describe the proposed involvement of human subjects in the work.
- Describe and justify the characteristics of the subject population.
- Describe and justify the sampling plan, as well as the criteria for inclusion or exclusion of any subpopulation.
- Explain the rationale for the involvement of special vulnerable populations.
- If relevant describe and justify the selection of an intervention's dose, frequency, and administration.
- List any collaborating sites where human subjects research will be performed, the role of those sites and collaborating investigators. Explain how data from the site(s) will be obtained, managed, and protected.
- 2.- Sources of Materials.
- Describe the research material obtained from living individuals (specimens records, or data).
- Indicate who will have access to individually identifiable private information about human subjects.
- Provide information about how the specimens, records, and/or data are collected, managed, and protected.
- 3.- Potential Risks.
- Describe the potential risks to subjects (physical, psychological, financial, legal, or other)

Adequacy of Protection Against Risks

- 1.- Recruitment and Informed Consent.
- Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.
- Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent.
- 2.- Protections Against Risk.
- Describe planned procedures for protecting against or minimizing potential risks (privacy of individuals or confidentiality of data).
- Research involving vulnerable populations, as described in the DHHS regulations, Subparts B-D must include additional protections. Refer to DHHS regulations, and OHRP guidance:
- Additional Protections for Pregnant Women, Human Fetuses and Neonates: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartb



• Additional Protections for Prisoners:

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc

- OHRP Subpart C Guidance: http://www.hhs.gov/ohrp/policy/index.html#prisoners
- Additional Protections for Children: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd
- OHRP Subpart D Guidance: http://www.hhs.gov/ohrp/policy/index.html#children
- Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.

Potential Benefits of the Proposed Research to Human Subjects and Others

- Discuss the potential benefits of the research to research participants and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.

Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

<u>Data and Safety Monitoring Plan</u> (For each proposed clinical trial, NIH requires a data and safety monitoring plan that describes oversight and monitoring to ensure the safety of participants and the validity and integrity of the data. The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial)

- Provide a general description of a monitoring plan that you plan to establish as the overall framework for data and safety monitoring. Describe the entity that will be responsible for monitoring and the process by which Adverse Events (AEs) will be reported to the Institutional Review Board (IRB), the funding I/C, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA) in accordance with Investigational New Drug (IND) or Investigational Device Exemption (IDE) regulations. Contact the FDA (http://www.fda.gov/) and also see the following Web sites for more information related to IND and IDE requirements: http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr312_01.html (IND) http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr812_01.html (IDE)
- The frequency of monitoring will depend on potential risks, complexity, and the nature of the trial; therefore, a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:
- a. PD/PI (required)
- b. Institutional Review Board (IRB) (required)
- c. Independent individual/safety officer
- d. Designated medical monitor



e. Internal Committee or Board with explicit guidelines

- f. Data and Safety Monitoring Board (DSMB). NIH specifically requires the establishment of Data and Safety Monitoring Boards (DSMBs) for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally for Phase III clinical trials. Although Phase I and Phase II clinical trials may also need DSMBs, smaller clinical trials may not require this oversight format, and alternative monitoring plans may be appropriate.
- A detailed Data and Safety Monitoring Plan must be submitted to the applicant's IRB and subsequently to the funding IC for approval prior to the accrual of human subjects. For additional guidance on creating this Plan, see http://grants.nih.gov/grants/guide/noticefiles/NOT-OD-00-038.html.

<u>ClinicalTrials.gov Requirements (se require el registro de cualquier Clinical trial)</u>

Registration is accomplished at the ClinicalTrials.gov Protocol Registration System Information Web site (http://prsinfo.clinicaltrials.gov/). A unique identifier called an NCT number, or ClinicalTrials.gov registry number, will be generated during the registration process.

The NIH implementation of FDAAA requires:

- the registration of applicable clinical trials in ClinicalTrials.gov no later than 21 days after the first subject is enrolled,
- the reporting of summary results information (including adverse events) no later than 1 year after the completion date for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA, and
- if an "applicable clinical trial" is funded in whole or in part by an NIH grant or cooperative agreement, grant and progress report forms shall include a certification that the responsible party has made all required submissions to ClinicalTrials.gov.

For competing (new and renewal) applications that include applicable clinical trials which require registration and, in certain cases, require results reporting under FDAAA, provide the NCT number/s, Brief Title/s (protocol title intended for the lay public – see Definitions), and the identity (name, organization) of the responsible party and their contact information (e-mail address is required for internal administrative use only) in the human subjects section of the Research Plan under a section heading entitled ClinicalTrials.gov. If a new applicable clinical trial is proposed, or if the grant will support an applicable clinical trial that is ongoing but not yet required to register under FDAAA (e.g. less than 21 days have passed since enrollment of the first patient), the human subjects section of the Research Plan must include a clear statement, under the heading ClinicalTrials.gov, that the project includes an applicable clinical trial which will require registration in ClinicalTrials.gov.

The entity responsible for registering the trial is the "responsible party". The statute defines the responsible party as:

(1) the sponsor of the clinical trial (as defined in 21 CFR 50.3)
(http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.3), or
(2) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee (provided that "the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish



the results of the trial, and has the ability to meet all of the requirements" for submitting information under the law)

(http://frwebgate.access.gpo.gov/cgi-

bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf). See PL 110-85, Section 801(a), (adding new 42 U.S.C. 282(j)(1)(A)(ix)).

For the complete statutory definitions of "responsible party" and "applicable clinical trial", refer to Elaboration of Definitions of Responsible Party and Applicable Clinical Trial.

The signature on the application of the Authorized Organization Representative assures compliance with FDAAA.

Additional information can be found on the ClinicalTrials.gov Web site (http://grants.nih.gov/ClinicalTrials_fdaaa).

Inclusion of Women and Minorities. El documento debería contener la siguiente información:

In this section of the Research Plan, address, at a minimum, the following 3 points:

- 1. A description of the subject selection criteria and rationale for selection of sex/gender and racial/ethnic group.
- 2. A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group.
- 3. A description of proposed outreach programs for recruiting sex/gender and racial/ethnic group members as subjects.

Below are examples of acceptable justifications for the exclusion of:

A. One gender:

- 1. One gender is excluded from the study because:
- inclusion of these individuals would be inappropriate with respect to their health;
- the research question addressed is relevant to only one gender;
- evidence from prior research strongly demonstrates no difference between genders; or
- sufficient data already exist with regard to the outcome of comparable studies in the excluded gender, and duplication is not needed in this study.
- 2. One gender is excluded or severely limited because the purpose of the research constrains the applicant's selection of study subjects by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or overriding factors dictate selection of subjects, such as matching of transplant recipients, or availability of rare surgical specimens).
- 3. Gender representation of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens, or data-sets with incomplete gender documentation are used), and this does not compromise the scientific objectives of the research.
- B. Minority groups or subgroups:
- 1. Some or all minority groups or subgroups are excluded from the study because:
- inclusion of these individuals would be inappropriate with respect to their health;
- the research question addressed is relevant to only one racial or ethnic group;



- evidence from prior research strongly demonstrates no differences between racial or ethnic groups on the outcome variables;
- a single minority group study is proposed to fill a research gap; or
- sufficient data already exists with regard to the outcome of comparable studies in the excluded racial or ethnic groups and duplication is not needed in this study.
- 2. Some minority groups or subgroups are excluded or poorly represented because the geographical location of the study has only limited numbers of these minority groups who would be eligible for the study, and the investigator has satisfactorily addressed this issue in terms of:
- the size of the study;
- the relevant characteristics of the disease, disorder or condition; or
- the feasibility of making a collaboration or consortium or other arrangements to include representation.
- 3. Some minority groups or subgroups are excluded or poorly represented because the purpose of the research constrains the applicant's selection of study subjects by race or ethnicity.
- 4. Racial or ethnic origin of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens or data sets with incomplete racial or ethnic documentation are used) and this does not compromise the scientific objectives of the research.

Targeted/Planned Enrollment Table(s). Instrucciones para rellenar la tabla:

- Provide the study title.
- If the application involves subprojects, provide Targeted Enrollment Tables for each subproject description.
- The "Total Planned Enrollment" means the number of subjects that are expected to be enrolled in the study, consistent with the definition in ClinicalTrials.gov.
- The "Total Planned Enrollment" will be reported in two ways in the table: by "Ethnic Category" and by "Racial Categories."
- "Ethnic Category": Provide the numeric distribution of the Total Planned Enrollment according to ethnicity and sex/gender in the top part of the table.
- "Racial Categories": Provide the numeric distribution of the Total Planned Enrollment, this time by racial categories and sex/gender, in the bottom part of the table. Note that Hispanic is an ethnic, not a racial, category.
- If there is more than one study/protocol, provide a separate table for each.
- List any proposed racial/ethnic subpopulations below the table.

When completing the Targeted/Planned Enrollment Tables that describe research in foreign sites, investigators should asterisk and footnote the table indicating that data include research participants in foreign sites. If the aggregated data only includes participants in foreign research sites, the investigator should provide information in one table with an asterisk and footnote.

Inclusion of Children. El documento debería contener la siguiente información:

Provide either a description of the plans to include children, or, if children will be excluded from the proposed research, present an acceptable justification for the exclusion.

If children are included, the description of the plan should include a rationale for selecting a specific age range of children. The plan also must include a description of the expertise of the investigative team for working with children at the ages included, of the appropriateness of the



available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

Justifications for Exclusion of Children:

All individuals under 21 are considered children; however, exclusion of any specific age group, such as individuals under 18, should be justified in this section. It is expected that children will be included in all clinical research unless one or more of the following exclusionary circumstances apply:

- 1. The research topic to be studied is not relevant to children.
- 2. Laws or regulations bar the inclusion of children in the research.
- 3. The knowledge being sought in the research is already available for children.
- 4. A separate, age-specific study in children is warranted and preferable. Examples include:
 - a. The condition is relatively rare in children, as compared to adults.
 - b. The number of children is limited.
- c. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children.
- 5. Insufficient data are available in adults to judge potential risk in children.
- 6. Study designs are aimed at collecting additional data on pre-enrolled adult study.
- 7. Other special cases can be justified by the investigator.

INSTRUCCIONES PARA LA CUMPLIMENTACIÓN DEL DOCUMENTO PROTECTION OF HUMAN SUBJECTS para el Escenario F.

Scenario F. Human Subjects Research Involving an NIH-Defined Phase III Clinical Trial.

Criterios:

Human Subjects Research Yes
Exemption Claimed No
Clinical Trial Yes
NIH-Defined Phase III Clinical Trial Yes

Instrucciones e información requerida:

- Aunque no hay límite de páginas se especifica que los documentos generados sean lo más concisos posibles.
- Se tienen que elaborar 4 documentos diferentes:

Protections of Human Subjects.
Inclusion of Women and Minorities.
Targeted/Planned Enrollment Table(s).
Inclusion of Children.



If the research involves collaborating sites or subprojects, provide the information identified above for each participating site.

Instrucciones generales:

Protections of Human Subjects. El documento debería contener la siguiente información (se incluyen dos apartados más, Data and safety monitoring plan, and Clinical trials-gov requirements):

Primero hay que añadir en este documento la siguiente frase: "This human Subjects research involves an NIH-defined Phase III clinical trial"

Risks to Human Subjects

- 1.- Human Subjects Involvement, Characteristics, and Design.
- Describe the proposed involvement of human subjects in the work.
- Describe and justify the characteristics of the subject population.
- Describe and justify the sampling plan, as well as the criteria for inclusion or exclusion of any subpopulation.
- Explain the rationale for the involvement of special vulnerable populations.
- If relevant describe and justify the selection of an intervention's dose, frequency, and administration.
- List any collaborating sites where human subjects research will be performed, the role of those sites and collaborating investigators. Explain how data from the site(s) will be obtained, managed, and protected.
- 2.- Sources of Materials.
- Describe the research material obtained from living individuals (specimens records, or data).
- Indicate who will have access to individually identifiable private information about human subjects.
- Provide information about how the specimens, records, and/or data are collected, managed, and protected.
- 3.- Potential Risks.
- Describe the potential risks to subjects (physical, psychological, financial, legal, or other)

Adequacy of Protection Against Risks

- 1.- Recruitment and Informed Consent.
- Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.



- Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent.
- 2.- Protections Against Risk.
- Describe planned procedures for protecting against or minimizing potential risks (privacy of individuals or confidentiality of data).
- Research involving vulnerable populations, as described in the DHHS regulations, Subparts B-D must include additional protections. Refer to DHHS regulations, and OHRP guidance:
- Additional Protections for Pregnant Women, Human Fetuses and Neonates: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartb
- Additional Protections for Prisoners: http://www.hhs.gov/ohrp/humansubjects/quidance/45cfr46.html#subpartc
- OHRP Subpart C Guidance: http://www.hhs.gov/ohrp/policy/index.html#prisoners
- Additional Protections for Children: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd
- OHRP Subpart D Guidance: http://www.hhs.gov/ohrp/policy/index.html#children
- Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects.

Potential Benefits of the Proposed Research to Human Subjects and Others

- Discuss the potential benefits of the research to research participants and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.

Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

<u>Data and Safety Monitoring Plan</u> (For each proposed clinical trial, NIH requires a data and safety monitoring plan that describes oversight and monitoring to ensure the safety of participants and the validity and integrity of the data. The level of monitoring should be commensurate with the risks and the size and complexity of the clinical trial)

• Provide a general description of a monitoring plan that you plan to establish as the overall framework for data and safety monitoring. Describe the entity that will be responsible for monitoring and the process by which Adverse Events (AEs) will be reported to the Institutional



Review Board (IRB), the funding I/C, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA) in accordance with Investigational New Drug (IND) or Investigational Device Exemption (IDE) regulations. Contact the FDA (http://www.fda.gov/) and also see the following Web sites for more information related to IND and IDE requirements: http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr312_01.html (IND) http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr812_01.html (IDE)

- The frequency of monitoring will depend on potential risks, complexity, and the nature of the trial; therefore, a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:
- a. PD/PI (required)
- b. Institutional Review Board (IRB) (required)
- c. Independent individual/safety officer
- d. Designated medical monitor
- e. Internal Committee or Board with explicit guidelines
- f. Data and Safety Monitoring Board (DSMB). NIH specifically requires the establishment of Data and Safety Monitoring Boards (DSMBs) for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally for Phase III clinical trials. Although Phase I and Phase II clinical trials may also need DSMBs, smaller clinical trials may not require this oversight format, and alternative monitoring plans may be appropriate.
- A detailed Data and Safety Monitoring Plan must be submitted to the applicant's IRB and subsequently to the funding IC for approval prior to the accrual of human subjects. For additional guidance on creating this Plan, see http://grants.nih.gov/grants/guide/noticefiles/NOT-OD-00-038.html.

ClinicalTrials.gov Requirements (se require el registro de cualquier Clinical trial)

Registration is accomplished at the ClinicalTrials.gov Protocol Registration System Information Web site (http://prsinfo.clinicaltrials.gov/). A unique identifier called an NCT number, or ClinicalTrials.gov registry number, will be generated during the registration process.

The NIH implementation of FDAAA requires:

- the registration of applicable clinical trials in ClinicalTrials.gov no later than 21 days after the first subject is enrolled,
- the reporting of summary results information (including adverse events) no later than 1 year after the completion date for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA, and
- if an "applicable clinical trial" is funded in whole or in part by an NIH grant or cooperative agreement, grant and progress report forms shall include a certification that the responsible party has made all required submissions to ClinicalTrials.gov.

For competing (new and renewal) applications that include applicable clinical trials which require registration and, in certain cases, require results reporting under FDAAA, provide the NCT number/s, Brief Title/s (protocol title intended for the lay public – see Definitions), and the identity (name, organization) of the responsible party and their contact information (e-mail address is required for internal administrative use only) in the human subjects section of the Research Plan under a section heading entitled ClinicalTrials.gov. If a new applicable clinical trial



is proposed, or if the grant will support an applicable clinical trial that is ongoing but not yet required to register under FDAAA (e.g. less than 21 days have passed since enrollment of the first patient), the human subjects section of the Research Plan must include a clear statement, under the heading ClinicalTrials.gov, that the project includes an applicable clinical trial which will require registration in ClinicalTrials.gov.

The entity responsible for registering the trial is the "responsible party". The statute defines the responsible party as:

(1) the sponsor of the clinical trial (as defined in 21 CFR 50.3)

(http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.3), or

(2) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee (provided that "the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements" for submitting information under the law)

(http://frwebgate.access.gpo.gov/cgi-

bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf). See PL 110-85, Section 801(a), (adding new 42 U.S.C. 282(j)(1)(A)(ix)).

For the complete statutory definitions of "responsible party" and "applicable clinical trial", refer to Elaboration of Definitions of Responsible Party and Applicable Clinical Trial.

The signature on the application of the Authorized Organization Representative assures compliance with FDAAA.

Additional information can be found on the ClinicalTrials.gov Web site (http://grants.nih.gov/ClinicalTrials_fdaaa).

Inclusion of Women and Minorities. El documento debería contener la siguiente información (se tiene que ampliar según instrucciones debajo cuando es un NIH-defined phase III clinical trial):

In this section of the Research Plan, address, at a minimum, the following 3 points:

- 1. A description of the subject selection criteria and rationale for selection of sex/gender and racial/ethnic group.
- 2. A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group.
- 3. A description of proposed outreach programs for recruiting sex/gender and racial/ethnic group members as subjects.

Below are examples of acceptable justifications for the exclusion of:

- A. One gender:
- 1. One gender is excluded from the study because:
- inclusion of these individuals would be inappropriate with respect to their health;
- the research question addressed is relevant to only one gender;
- evidence from prior research strongly demonstrates no difference between genders; or



- sufficient data already exist with regard to the outcome of comparable studies in the excluded gender, and duplication is not needed in this study.
- 2. One gender is excluded or severely limited because the purpose of the research constrains the applicant's selection of study subjects by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or overriding factors dictate selection of subjects, such as matching of transplant recipients, or availability of rare surgical specimens).
- 3. Gender representation of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens, or data-sets with incomplete gender documentation are used), and this does not compromise the scientific objectives of the research.
- B. Minority groups or subgroups:
- 1. Some or all minority groups or subgroups are excluded from the study because:
- inclusion of these individuals would be inappropriate with respect to their health;
- the research question addressed is relevant to only one racial or ethnic group;
- evidence from prior research strongly demonstrates no differences between racial or ethnic groups on the outcome variables;
- a single minority group study is proposed to fill a research gap; or
- sufficient data already exists with regard to the outcome of comparable studies in the excluded racial or ethnic groups and duplication is not needed in this study.
- 2. Some minority groups or subgroups are excluded or poorly represented because the geographical location of the study has only limited numbers of these minority groups who would be eligible for the study, and the investigator has satisfactorily addressed this issue in terms of:
- the size of the study;
- the relevant characteristics of the disease, disorder or condition; or
- the feasibility of making a collaboration or consortium or other arrangements to include representation.
- 3. Some minority groups or subgroups are excluded or poorly represented because the purpose of the research constrains the applicant's selection of study subjects by race or ethnicity.
- 4. Racial or ethnic origin of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens or data sets with incomplete racial or ethnic documentation are used) and this does not compromise the scientific objectives of the research.
- ▶ If the proposed research includes an NIH-Defined Phase III Clinical Trial, the section on Inclusion of Women and Minorities also must address whether clinically important sex/gender and/or race/ethnicity differences are expected from the intervention effect. The discussion may include supporting evidence and/or data derived from animal studies, clinical observations, metabolic studies, genetic studies, pharmacology studies, and observational, natural history, epidemiology and other relevant studies. The discussion of expected sex/gender and/or race/ethnicity differences in intervention effect must include selection and discussion of one of the following analysis plans:
- Plans to conduct valid analyses to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, or
- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups. (Representation of sex/gender and racial/ethnic groups is not required as subject selection criteria, but inclusion is encouraged.), or



• Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect among subgroups.

Targeted/Planned Enrollment Table(s). Instrucciones para rellenar la tabla:

- Provide the study title.
- If the application involves subprojects, provide Targeted Enrollment Tables for each subproject description.
- The "Total Planned Enrollment" means the number of subjects that are expected to be enrolled in the study, consistent with the definition in ClinicalTrials.gov.
- The "Total Planned Enrollment" will be reported in two ways in the table: by "Ethnic Category" and by "Racial Categories."
- "Ethnic Category": Provide the numeric distribution of the Total Planned Enrollment according to ethnicity and sex/gender in the top part of the table.
- "Racial Categories": Provide the numeric distribution of the Total Planned Enrollment, this time by racial categories and sex/gender, in the bottom part of the table. Note that Hispanic is an ethnic, not a racial, category.
- If there is more than one study/protocol, provide a separate table for each.
- List any proposed racial/ethnic subpopulations below the table.

When completing the Targeted/Planned Enrollment Tables that describe research in foreign sites, investigators should asterisk and footnote the table indicating that data include research participants in foreign sites. If the aggregated data only includes participants in foreign research sites, the investigator should provide information in one table with an asterisk and footnote.

Inclusion of Children. El documento debería contener la siguiente información:

Provide either a description of the plans to include children, or, if children will be excluded from the proposed research, present an acceptable justification for the exclusion.

If children are included, the description of the plan should include a rationale for selecting a specific age range of children. The plan also must include a description of the expertise of the investigative team for working with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

Justifications for Exclusion of Children:

All individuals under 21 are considered children; however, exclusion of any specific age group, such as individuals under 18, should be justified in this section. It is expected that children will be included in all clinical research unless one or more of the following exclusionary circumstances apply:

- 1. The research topic to be studied is not relevant to children.
- 2. Laws or regulations bar the inclusion of children in the research.
- 3. The knowledge being sought in the research is already available for children.
- 4. A separate, age-specific study in children is warranted and preferable. Examples include:



- a. The condition is relatively rare in children, as compared to adults.
- b. The number of children is limited.
- c. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children.
- 5. Insufficient data are available in adults to judge potential risk in children.
- 6. Study designs are aimed at collecting additional data on pre-enrolled adult study.
- 7. Other special cases can be justified by the investigator.

INSTRUCCIONES PARA LA CUMPLIMENTACIÓN DEL DOCUMENTO VERTEBRATE ANIMALS:

• Antes de empezar a trabajar en este Entregable debe responder a la siguiente pregunta:

Are vertebrate animals used?

- 1) <u>NO</u>: No hay que rellenar el presente documento, a menos que la inclusión de animales vertebrados en el proyecto sea indeterminada, en este caso se tendrá que aportar en este documento una explicación y en qué momento del proyecto se anticipa el uso de animales.
- **2)** <u>SI</u>: Si se van a utilizar animales vertebrados en el proyecto, hay que generar el documento *Vertebrate animals* para incluirlo en la solicitud. Este documento debe ser lo más <u>conciso</u> posible y debe incluir los siguientes puntos:
- a) Provide a detailed description of the proposed use of the animals in the work. Identify the species, strains, ages, sex, and numbers of animals to be use.
- b) Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
- c) Provide information on the veterinary care of the animals involved.
- d) Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
- e) Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association(AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations.

INSTRUCCIONES PARA LA CUMPLIMENTACIÓN DEL LEADERSHIP PLAN:

En el caso de que el proyecto haya <u>IPs múltiples</u>, hay que elaborar un plan de liderazgo, en el cual se debe especificar el gobierno y la estructura en el transcurso del proyecto, plan de comunicación, toma de decisiones,.... Etc.



INSTRUCCIONES:

For applications designating multiple PD/PIs, all such individuals must be assigned the PD/PI role on the Senior/Key Profile form, even those at organizations other than the applicant organization. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs and other collaborators.

If budget allocation is planned, the distribution of resources to specific components of the project or the individual PD/PIs should be delineated in the Leadership Plan.

INSTRUCCIONES PARA LA CUMPLIMENTACIÓN DEL CONSORTIUM/CONTRACTUAL ARRANGEMENTS:

En el caso de que el proyecto tenga <u>IPs múltiples en diferentes instituciones</u> y se vayan a pedir <u>presupuestos por separado</u>, las instrucciones para la elaboración del contrato de colaboración entre ambos IPs son las siguientes:

INSTRUCCIONES:

Explain the <u>programmatic</u>, <u>fiscal</u>, <u>and administrative arrangements</u> to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee.

LETTERS OF SUPPORT PARA LA PROPUESTA NIH:

INSTRUCCIONES:

SE NECESITAN <u>LETTERS OF SUPPORT DE TODOS LOS INVESTIGADORES</u> QUE VAN A TRABAJAR EN EL PROYECTO DE MANERA SUSTANCIOSA, INCLUIDOS LOS IPS, POSTDOCTORAL, OSCS Y CONSULTANTS (estos últimos deben incluir los costes de los servicios que ofrecen).

Attach all appropriate <u>letters of support</u>, including any letters necessary to demonstrate the support of <u>consortium participants</u> and collaborators such as senior/key personnel and <u>Other Significant Contributors</u> included in the grant application. Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project. For <u>consultants</u>, letters should include rate/charge for consulting services.

INSTRUCCIONES PARA LA CUMPLIMENTACIÓN DEL RESOURCE SHARING PLAN:



- Los NIH aconsejan a los investigadores que reciban financiación de los mismos, un plan de difusión de resultados científicos lo más amplia posible y que se compartan y se pongan a disposición estos hallazgos a la Comunidad Científica. Por tanto, el investigador debe realizar un plan de difusión lo más "amplio" posible, siempre y cuando sus intereses los proteja previamente y así debe quedar reflejado en este documento.
- Contenido que debe incluir el documento:
- <u>1. Data Sharing Plan</u>: Investigators are expected to include <u>a brief 1-paragraph description</u> of how final research data will be shared, or explain why data-sharing is not possible.

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

2.- <u>Sharing Model Organisms</u>: All applications where the development of model organisms is anticipated are expected to include <u>a description of a specific plan for sharing and distributing unique model organisms</u> or state why such sharing is restricted or not possible.

Model organisms include but are not restricted to mammalian models, such as the mouse and rat; and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

3.- Genome Wide Association Studies (GWAS): Applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or an appropriate explanation why submission to the repository is not possible. GWAS is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight) or the presence or absence of a disease or condition.

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html

INSTRUCCIONES PARA LA CUMPLIMENTACIÓN DEL DOCUMENTO HUMAN EMBRYONIC STEM CELLS:

• Antes de empezar a trabajar en este documento debe responder a la siguiente pregunta:

Does the proposed Project involve human embryonic stem cells?

- 1) NO: No hay que rellenar el presente documento.
- 2) SI: hay que especificar el número de registro de la/s línea/s celular/es que se van a utilizar:
- ► List the <u>4-digit NIH Registration Number</u> of the specific cell line(s) from the NIH Human Embryonic Stem Cell Registry.

http://stemcells.nih.gov/research/registry/



▶ If a specific line cannot be referenced at the time of application submission, check this bo		If (a specii	fic line	cannot be	referen	ced at th	e time o	f application	submission.	. check this bo	OX.
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 $\ \square$ Specific stem cell line cannot be referenced at this time. One from the registry will be used.