



THE NATIONAL INSTITUTES OF HEALTH and Transparency *(of animal research)*

5th International Conference of the Basel
Declaration Society

14th February 2018

Margaret Snyder, Ph.D.

Office of Extramural Research (OER), NIH



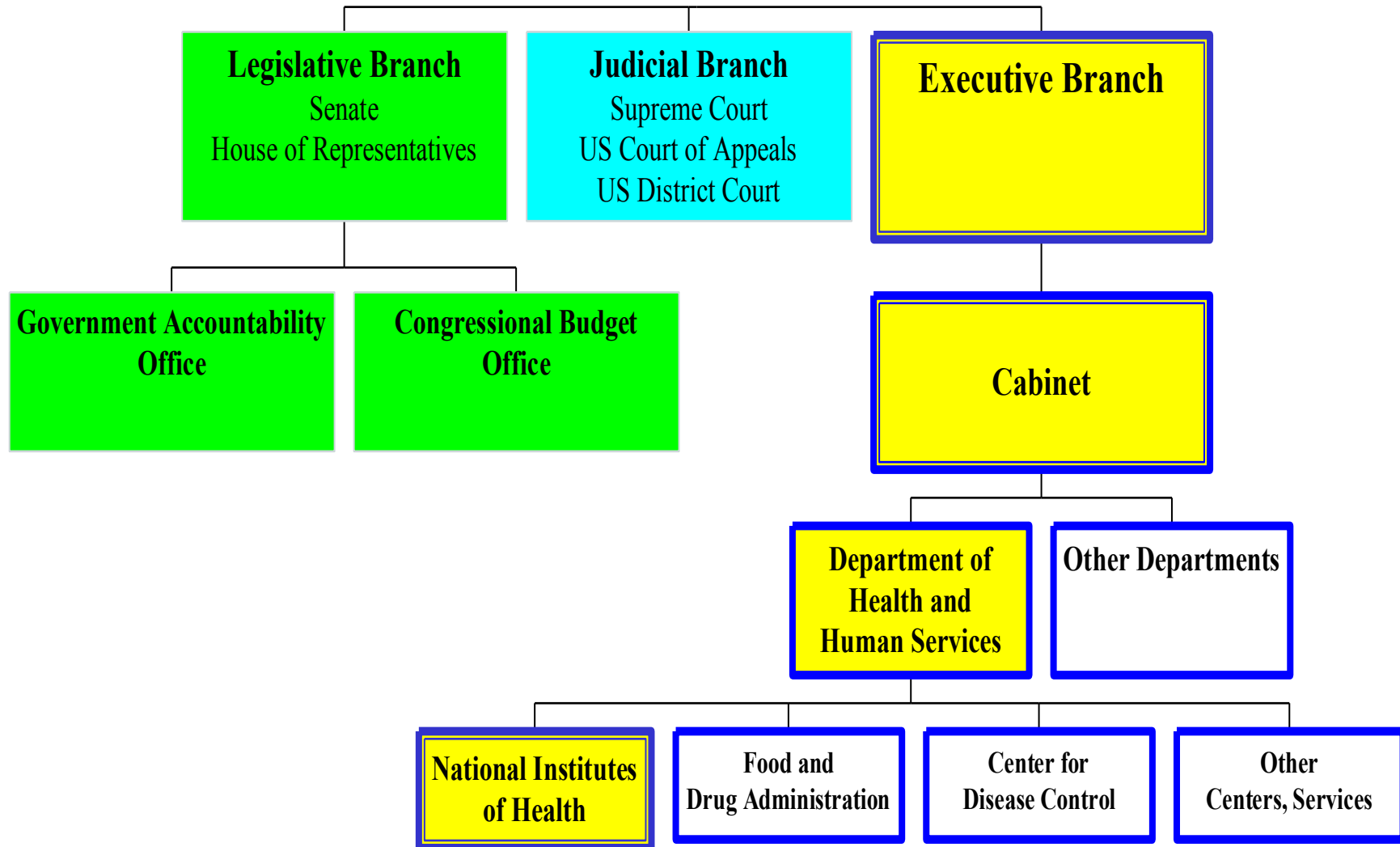
NIH National Institutes of Health
Office of Extramural Research

Today's Goals –to provide information and answer questions:

- About NIH and the research we support;
- About the information and resources we (proactively) share regarding the use of animals in research;
- About Freedom of Information Act (FOIA);
- About documents related to animal research requested under FOIA



Government of the United States



NIH: Steward of Biomedical & Behavioral Research for the Nation

*NIH's mission is to seek **fundamental knowledge** about the nature and behavior of living systems...*

*...and the **application of that knowledge** to enhance health, lengthen life, and reduce illness and disability.*



NIH Extramural Research

The Need:

An office that represents all 27 ICs with a cohesive voice, providing the corporate framework for NIH research administration, ensuring scientific integrity, public accountability, and effective stewardship of the NIH research grant portfolio.

The Place:

The Office of Extramural Research (OER)



*All figures are estimates.
Office of Extramural Research

Scientific Integrity

OER's

Human Research
Protections

Animal Welfare
Assurance and
Compliance

Research
Misconduct

Intellectual Property

Financial Conflict of
Interest

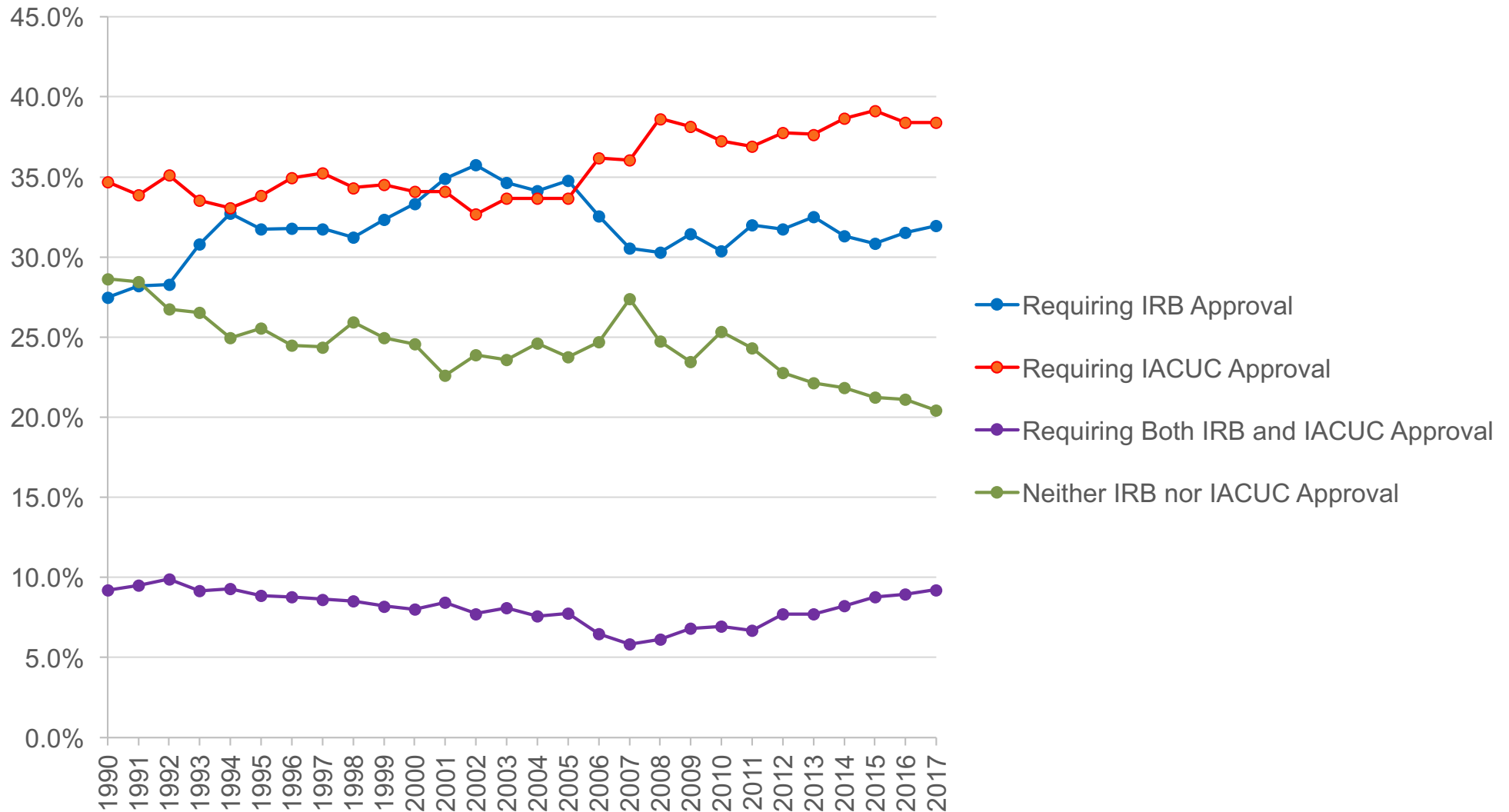


Grants Policy and Procedure
Development, Implementation, and Oversight

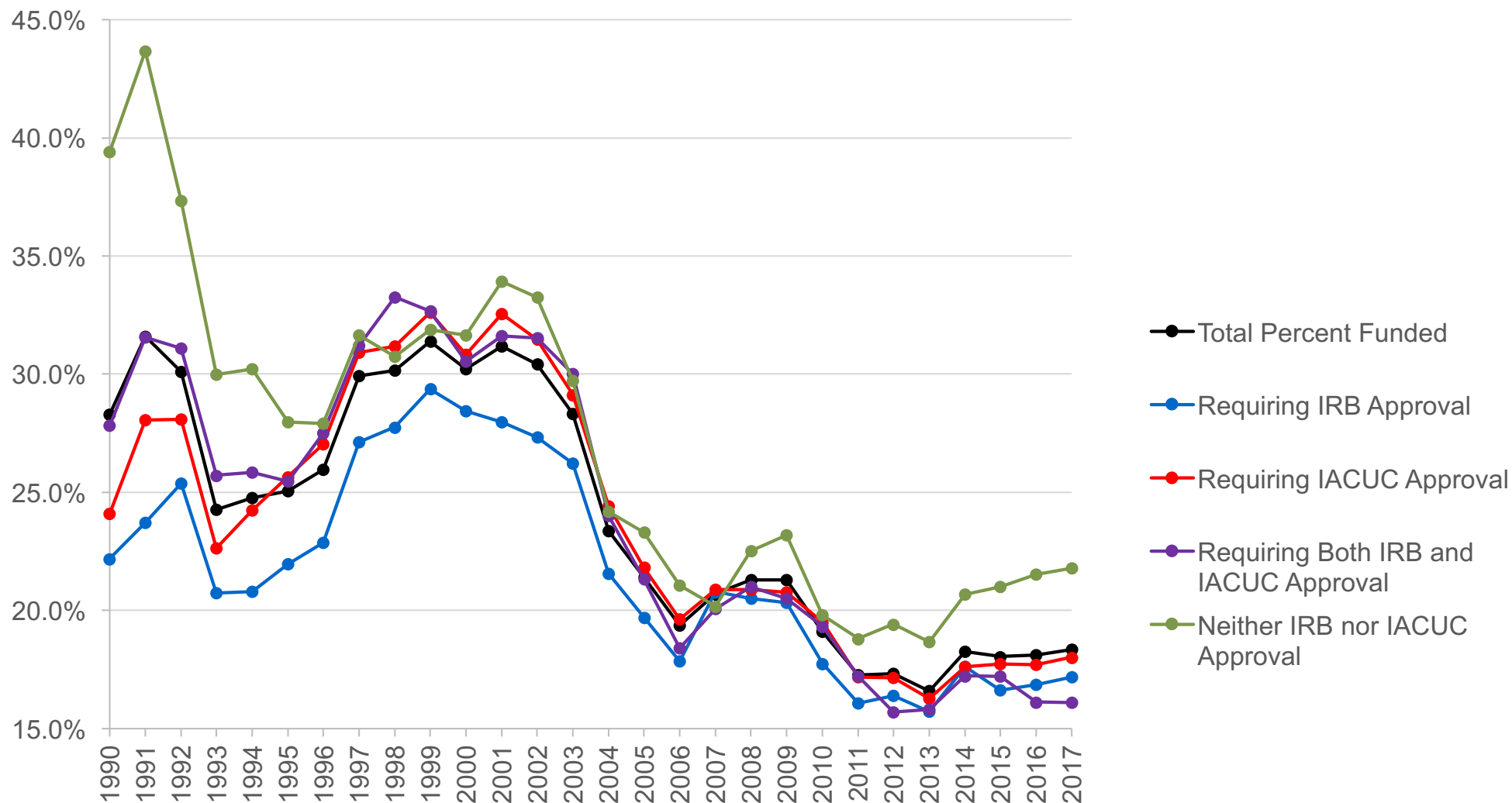



National Institutes of Health
Office of Extramural Research

Percent NIH Competitive Research Application By Fiscal Year



Percent NIH Competitive Application Funded By Fiscal Year



**National Institutes of Health**
Turning Discovery Into Health

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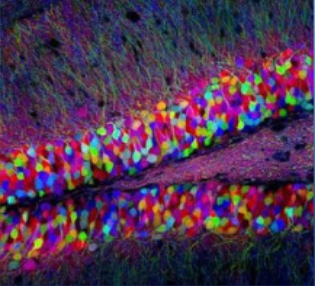
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BRAIN Initiative


A bold new quest to revolutionize our understanding of the human brain.


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1 2 3 4 5



IN THE NEWS

**BRAIN Feedback**
Discuss revolutionizing our understanding of the human brain.
Posted on Aug 22, 2013


**Malaria Vaccine**
A candidate vaccine protects against infection in adults.
Posted on Aug 22, 2013

**Online Course for Clinicians**
Helping identify alcohol-related problems in youth.
Posted on Aug 15, 2013


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NIH is the nation's medical research agency—supporting scientific studies that turn discovery into health.

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Learn how NH-supported research has had a major positive impact on nearly all of our lives

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Video highlights of NH leadership, scientists, patients and caregivers.

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Find resources and interactive activities for teaching and learning about science

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- [Stem Cell Information](#)
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NIH RESEARCH MATTERS

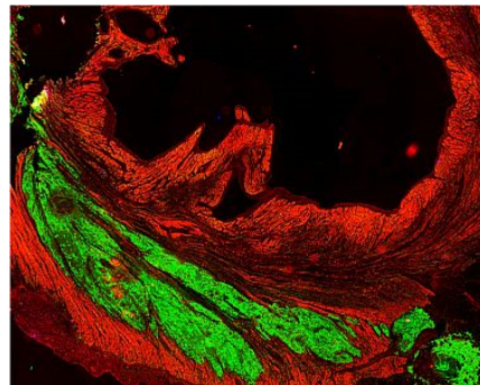
May 12, 2014

Stem Cell Therapy Rebuilds Heart Muscle in Primates



Scientists used human embryonic stem cells to regenerate damaged primate hearts. The strategy might one day be used to repair human hearts, but challenges still need to be overcome.

Damage to the heart—such as that caused by a heart attack— isn't easy to mend. The heart's muscle cells, called cardiomyocytes, don't readily replenish themselves. After a typical heart attack, an estimated billion cardiomyocytes die. This jeopardizes heart function and can lead to chronic heart failure and possibly death.



Search NIH Research Matters

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[Post-Surgery Steroids in Infants With a Rare Liver Disease](#)

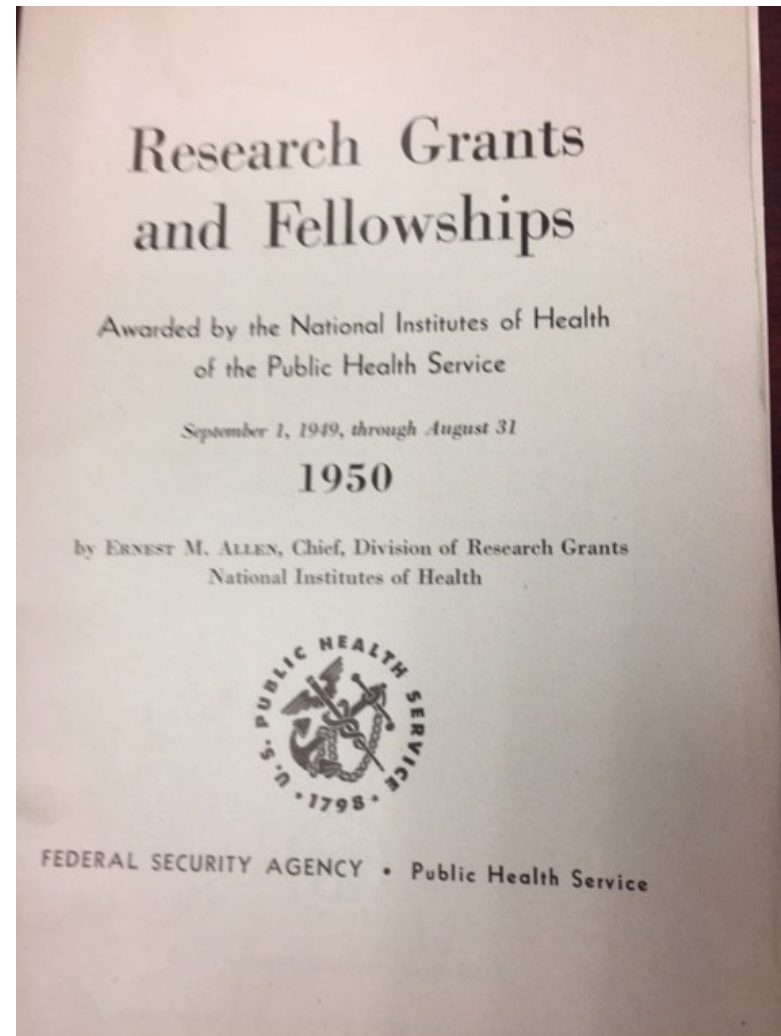
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 How to Apply

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(RePORT)**



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Navigate the NIH grants process from finding a funding opportunity to monitoring your award.

- Grants Process Overview 
- Get Started 
- How to Apply 
- Application Referral and Review 
- Pre-Award and Post-Award Processes 
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Policy and Compliance









Learn about the policy and compliance obligations of your grant award and find helpful resources on select policy topics.

- NIH Grants Policy Statement 
- Notices of Policy Changes 
- Compliance and Oversight 
- Select Policy Topics 



Information for...

Find key resources just for you.

- Researchers 
- Research Administrators 
- Reviewers 
- Small Businesses 
- Foreign Applicants 
- Media and the Public 
- NIH Staff  

Grant Number Decoded:

1R01GM987654-01-A1



The screenshot shows the NIH Research Portfolio Online Reporting Tools (RePORT) website. At the top, there is a search bar and navigation links for HOME, ABOUT RePORT, FAQs, GLOSSARY, and CONTACT US. Below this is a horizontal menu with categories: QUICK LINKS, RESEARCH, ORGANIZATIONS, WORKFORCE, FUNDING, REPORTS, and LINKS & DATA. The main content area features a large map of the United States with location pins. To the right of the map, the text "Awards by Location" is circled in red. Below the map is a row of icons for various tools: RePORTER, AWARDS BY LOCATION (with a "CLICK TO VIEW" button), NIH DATA BOOK, FUNDING FACTS, CATEGORICAL SPENDING, REPORT CATALOG, SPECIAL REPORTS, and ABOUT REPORT. Below the map area, there is a section titled "Research Portfolio Online Reporting Tools (RePORT) Awards by Location (RePORT)". This section includes a paragraph describing the tool's purpose and a "News Updates" box with two entries: "Fiscal Year 2012 report on NIH Collaborations with Other HHS Agencies now available" and "Release of RePORTER ver. 5.8.0: Enhancements made to the RePORTER tool". To the right of the main content is an "ADVANCED SEARCH" form with dropdown menus for "Institute/Center" (options: ALL, NCI, NEI, NHLBI, NHGRI, NIA) and "Fiscal Year" (options: ACTIVE, 2013, 2012, 2011, 2010, 2009), input fields for "Principal Investigator" and "Organization", and a "Project Number" field with a grid for digits and letters. "SUBMIT" and "CLEAR" buttons are at the bottom of the search form.





Categorical Spending

View annual support level for various research, condition, and disease categories based on grants, contracts, and other funding mechanisms used across the National Institutes of Health (NIH).



RePORTER | AWARDS BY LOCATION | NIH DATA BOOK | FUNDING TRENDS | **CATEGORICAL SPENDING** (CLICK TO VIEW)


Annual funding for various research, condition, and disease categories

How much did NIH spend on a particular disease or research area?



Research
In addition to
accountability
and analyses
supported re

Reports (RePORT)
the highest level of public
access to reports, data,
and the results of NIH

RePORTER Query


**NIH RePORTER**
Version: 7.24.0

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QUERY | **BROWSE NIH** | **MATCHMAKER** | **SEARCH PUBLICATIONS** ^{BETA}


[SUBMIT QUERY](#) | [CLEAR QUERY](#)


Fiscal Year (FY):  [SELECT](#)
Current FY is 2018


RESEARCHER AND ORGANIZATION


Principal Investigator (PI) / Project Leader:  ,
(Last Name, First Name) Use '%' for wildcard in PI names
[Enter several PI/Project Leader names OR PI Profile IDs](#)


Organization:  [LOOKUP](#)
Please enter at least 3 characters to use Lookup.
 Contains Begins with Exact


Department Type:  [SELECT](#)


Organization Type:  [SELECT](#)

City: 
Use '%' for wildcard


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Country:  [SELECT](#)

Congressional District:  [SELECT](#)

DUNS Number: 

TEXT SEARCH

Text Search (Logic): 
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Limit Project search to Project Title Project Terms Project Abstracts

Limit Publication search to Start Year End Year

Characters left: 2493



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 Page of 76 [Next](#) [Last](#)

T: Application Type; Act: Activity Code; Project: Admin IC, Serial No.; Year: Support Year/Supplement/Amendment

<input type="checkbox"/>	T	Act	Project	Year	Sub #	Project Title	Contact PI/ Project Leader	Organization	FY	Admin IC	Funding IC	FY Total Cost by IC	Similar Projects
<input type="checkbox"/>	2	R01	DK089201	06A1		CONSERVED FETAL EPIGENOMIC AND METAGENOMIC SIGNATURES IN A PRIMATE MODEL OF MATERNAL OBESITY	AAGAARD, KJERSTI MARIE	BAYLOR COLLEGE OF MEDICINE	2017	NIDDK	NIDDK	\$664,282	<input type="button" value="📄"/>
<input type="checkbox"/>	1	R56	AI130330	01A1		MECHANISMS OF ISLET TRANSPLANT IMMUNE TOLERANCE	ABDULREDA, MIDHAT H	UNIVERSITY OF MIAMI SCHOOL OF MEDICINE	2017	NIAID	NIAID	\$383,750	<input type="button" value="📄"/>
<input type="checkbox"/>	1	P40	OD024628	01	5621	RESOURCE CORE	ABEE, CHRISTIAN R	UNIVERSITY OF TX MD ANDERSON CAN CTR	2017	OD		\$874,020	<input type="button" value="📄"/>
<input type="checkbox"/>	1	P40	OD024628	01		SPECIFIC PATHOGEN FREE BABOON RESEARCH RESOURCE (SPFBRR)	ABEE, CHRISTIAN R	UNIVERSITY OF TX MD ANDERSON CAN CTR	2017	OD	OD	\$946,402	<input type="button" value="📄"/>
<input type="checkbox"/>	7	DP5	OD023084	02		ANTIBODY THERAPEUTICS FOR HUMAN VIRAL HEMORRHAGIC FEVERS AND PREVENTION OF LATE NEUROLOGICAL SYNDROMES	ABRAHAM, JONATHAN	HARVARD MEDICAL SCHOOL	2017	OD	NIDCR	\$1	<input type="button" value="📄"/>



Publications

Publications: [Publications missing?](#) [Principal Investigators click here](#)
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Page 1 of 3 [Next](#) [Last](#) [▶▶](#)

= PubMed
 = PubMed Central
 = Google Scholar
 [EXPORT](#)

Title (Link to full-text in PubMed Central)	Journal (Link to PubMed abstract)	Authors	Similar Publications	Cited By
Mapping White Matter Microstructure in the One Month Human Brain.	Scientific reports. 2017 Aug 29; 7 (1) :9759	Dean 3rd, D C; Planalp, E M; Wooten, W; Adluru, N; Kecskemeti, S R; Frye, C; Schmidt, C K; Schmidt, N L; Styner, M A; Goldsmith, H H; Davidson, R J; Alexander, A L		
Imaging Genetics and Genomics in Psychiatry: A Critical Review of Progress and Potential.	Biological psychiatry. 2017 Aug 01; 82 (3) :165-175	Bogdan, Ryan; Salmeron, Betty Jo; Carey, Caitlin E; Agrawal, Arpana; Calhoun, Vince D; Garavan, Hugh; Hariri, Ahmad R; Heinz, Andreas; Hill, Matthew N; Holmes, Andrew; Kalin, Ned H; Goldman, David		
Infant stranger fear trajectories predict anxious behaviors and diurnal cortisol rhythm during childhood.	Development and psychopathology. 2017 Aug; 29 (3) :1119-1130	Van Hulle, Carol A; Moore, Mollie N; Lemery-Chalfant, Kathryn; Goldsmith, H Hill; Brooker, Rebecca J		
Short- and long-term stability of alpha asymmetry in infants: Baseline and affective measures.	Psychophysiology. 2017 Aug; 54 (8) :1100-1109	Brooker, Rebecca J; Canen, Mara J; Davidson, Richard J; Hill Goldsmith, H		
Integrative Structural Brain Network Analysis in Diffusion Tensor Imaging.	Brain connectivity. 2017 Aug; 7 (6) :331-346	Chung, Moo K; Hanson, Jamie L; Adluru, Nagesh; Alexander, Andrew L; Davidson, Richard J; Pollak, Seth D		
Early adversity and learning: implications for typical and atypical behavioral development.	Journal of child psychology and psychiatry, and allied disciplines. 2017 Jul; 58 (7) :770-778	Hanson, Jamie L; van den Bos, Wouter; Roeber, Barbara J; Rudolph, Karen D; Davidson, Richard J; Pollak, Seth D		
Inhibition of Lateral Prefrontal Cortex Produces Emotionally Biased First Impressions: A Transcranial Magnetic Stimulation and Electroencephalography Study.	Psychological science. 2017 Jul; 28 (7) :942-953	Lapate, Regina C; Samaha, Jason; Rokers, Bas; Hamzah, Hamdi; Postle, Bradley R; Davidson, Richard J		
Genetic associations with reflexive visual attention in infancy and childhood.	Developmental science. 2017 May; 20 (3)	Lundwall, Rebecca A; Dannemiller, James L; Goldsmith, H Hill		
Heightened extended amygdala metabolism following threat characterizes the early phenotypic risk to develop anxiety-related psychopathology.	Molecular psychiatry. 2017 May; 22 (5) :724-732	Shackman, A J; Fox, A S; Oler, J A; Shelton, S E; Oakes, T R; Davidson, R J; Kalin, N H		
The Shared Etiology of Attentional Control and Anxiety.	Journal of research on adolescence : the official journal	Gagne, Jeffrey R; O'Sullivan, Deirdre L; Schmidt, Nicole		



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1 2 3 4 ... 74 75 76

Page of 76 [Next](#) [Last](#)

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<input type="checkbox"/>	1	R56	AI130330	01A1		MECHANISMS OF ISLET TRANSPLANT IMMUNE TOLERANCE	ABDULREDA, MIDHAT H	UNIVERSITY OF MIAMI SCHOOL OF MEDICINE	2017	NIAID	NIAID	\$383,750	<input type="button" value="📄"/>
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<input type="checkbox"/>	7	DP5	OD023084	02		ANTIBODY THERAPEUTICS FOR HUMAN VIRAL HEMORRHAGIC FEVERS AND PREVENTION OF LATE NEUROLOGICAL SYNDROMES	ABRAHAM, JONATHAN	HARVARD MEDICAL SCHOOL	2017	OD	NIDCR	\$1	<input type="button" value="📄"/>



Abstract and Relevance

QUICK LINKS RESEARCH ORGANIZATIONS WORKFORCE FUNDING REPORTS LINKS & DATA

Home > RePORTER > Project Information MyRePORTER Login | Register | RePORTER Manual System Health: ■ GREEN

Project Information Back to Query Form Back to Search Results Print Version

5P50MH100031-05 PREVIOUS Project 23 of 1905 NEXT

DESCRIPTION DETAILS RESULTS SIMILAR PROJECTS NEARBY PROJECTS BETA LINKS NEWS AND MORE

Parent Project Number: [5P50MH100031-05](#) **Sub-Project ID:** 6273 **Contact PI / Project Leader:** [ALEXANDER, ANDREW L](#)
Title: IMAGING CORE **Awardee Organization:** UNIVERSITY OF WISCONSIN-MADISON

Abstract Text:

The Imaging Core will provide support for the acquisition, analysis and interpretation of magnetic resonance imaging data that is being collected in the Center Projects. More specifically, the core will be responsible for developing and maintaining pulse sequences and protocols that will be used in the Projects, and will also be responsible for ensuring high and consistent image quality. Imaging protocols for human infants and adolescents, and very young nonhuman primates will be employed for structural, microstructural (diffusion tensor imaging), functional (both resting/sleeping and task-based) mapping of the brain. The core will also be responsible for developing and maintaining image analysis pipelines used in the projects. These include methods for analyzing structural morphometry (including amygdala and prefrontal volumes), diffusion tensor imaging measures of amygdala, limbic and prefrontal white matter pathways, task-based functional MRI measures and resting-state functional connectivity measures. Selective strategies for analysis in very young monkeys and human infants will be developed to facilitate measurements in the young brain with immature myelination. Finally, the core will help to evaluate and implement new image acquisition techniques and image analysis strategies that the Center investigators deem to provide novel useful and/or more accurate measurements.

Public Health Relevance Statement:

RELEVANCE (See instructions): This Center will relate measurements of brain macrostructure, microstructure and function to measures of anxious temperament in both prospective (infant/toddler) and retrospective (adolescent) designs for both human and nonhuman primates. Accurate measures of brain structure and function are essential for improving the understanding the role of neurobiology on the development of anxiety and related disorders.

Project Terms:

Adolescent; Amygdaloid structure; Anxiety; anxiety-related disorders; anxious temperament; base; Brain; brain behavior; Brain imaging; Brain Mapping; Data; Data Analyses; Data Set; design; Development; Diffusion Magnetic Resonance Imaging; Emotions; Ensure; Functional Magnetic Resonance Imaging; Health; Human; Image; Image Analysis; imaging modality; imaging study; improved; Infant; Instruction; Laboratories; Magnetic Resonance Imaging; Measurement; Measures; Methods; Monkeys; Morphologic artifacts; morphometry; myelination; Neurobiology; neurodevelopment; neuroimaging; nonhuman **Primate**; novel; Pathway interactions; Performance; Physiologic pulse; prospective;



Grants.nih.gov Website

NIH National Institutes of Health
Office of Extramural Research

Grants & Funding
NIH's Central Resource for Grants and Funding Information

Entire Site Search this Site

eRA | Glossary & Acronyms | FAQs | Help

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

201 **GRANTS.nih.gov – the home base for info on NIH grant opportunities, policies, processes and awards**

- Find Funding
- How to Apply
- Explore NIH Funded Research (RePORT)

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National Institutes of Health
Office of Extramural Research

Transparency

The screenshot displays the NIH Office of Extramural Research website. At the top left is the NIH logo and the text 'National Institutes of Health Office of Extramural Research'. To the right is a search bar labeled 'Search this Site' and a link for 'Glossary & Acronyms'. Below this is a navigation menu with links: HOME, ABOUT GRANTS, FUNDING, FORMS & DEADLINES, GRANTS POLICY, eRA, NEWS & EVENT, and ABOUT OER. A large blue banner reads 'Grants & Funding' with a small image of a woman. On the left, an 'About Grants' sidebar lists: Grants Process Overview, Grant Application Basics, Types of Grant Programs, How to Apply, Peer Review Process, Award Management, Foreign Grants Information, Funding Strategies, and Avoid Grant Scams. The main content area features a large banner for the '2015 NIH Regional Seminar' in San Diego, CA, from October 14-16, 2015, with a 'Register Today' call to action. Below this is a 'FUNDING' section with a search bar and a link to 'Funding Opportunities & Notices'. On the right, a 'Rock Talk' section includes a photo of a woman, a Twitter follow link for @RockTalking, and the text 'Help Us Help You! Welcoming the Inaugural Director of the NIH Division of Biomedical Research Workforce Programs Understanding the Capacity of NIH's Peer Review System'. Below that is a 'Latest News' section with a link for 'Application Submission News-12/9/14'.



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National Institutes of Health
Office of Extramural Research

Real Worries!

Unreliable research

Trouble at the lab

Scientists like to think of science as self-correcting. To an alarming degree, it is not



"I SEE a train wreck looming," warned Daniel Kahneman, an eminent psychologist, in an open letter last year. The premonition concerned

RIGOR MORTIS

HOW SLOPPY SCIENCE
CREATES WORTHLESS
CURES, CRUSHES HOPE,
AND WASTES BILLIONS

RICHARD HARRIS

Problems:

- Animal models
- Cell lines
- Antibodies
- Poor study design
- Broken culture

<http://www.economist.com/news/briefing/21588057-scientists-think-science-self-correcting-alarming-degree-it-not-trouble>



NIH National Institutes of Health
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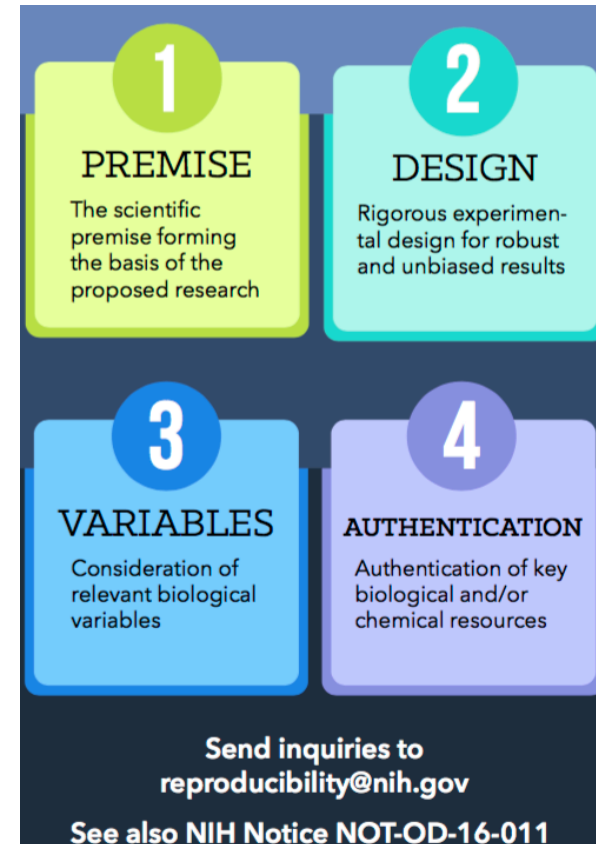
Key Components

Rigor and Reproducibility

Scientific rigor and transparency in conducting biomedical research outcomes. The information provided on this website is designed for NIH grant applications and progress reports.

On This Page:

- [Goals](#)
- [Guidance: Rigor and Reproducibility in Grant Applications](#)
- [Resources](#)
- [News](#)
- [References](#)



<https://grants.nih.gov/reproducibility/index.htm>

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

Home » Policy & Compliance » Office of Laboratory Animal Welfare

Policy &

- NIH Grants Policy Statement
- Notices of Policy Changes
- Compliance & Oversight
- Select Policy Topics**
- Animal Welfare**
- Application Submission Policies
- Clinical Trial Requirements
- NIH Funding Strategies
- Human Subjects Research

Office of Laboratory Animal Welfare



ICARE Academy & Train the Trainer Institute REGISTRATION

OLAW Fast Facts

- Mission Statement
- Contact OLAW
- Departures from the Guide
- Obtaining an Assurance
- Reporting Noncompliance
- Significant Changes
- Assured Institutions (Domestic | Foreign)

Policy Updates

Simplification of the Vertebrate Animals Section of NIH Grant Applications and Contract Proposals

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Training for IACUC Trainers at the ICARE TTI: February 20-23, Atlanta, GA



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

Home » Policy & Compliance » Office of Laboratory Animal Welfare » Adverse Events at Research Facilities - December 7, 2017

Adverse Events at Research Facilities - December 7, 2017

Categorizing Adverse Events into a Matrix
OLAW Online Seminar - Adverse Events at Research Facilities

- Many adverse events have unforeseen sequelae.
- Risk management requires assessment of probability, function/system that may be disrupted, and impact.
- Identifying possible events and categorizing them can help with:
 - planning effective preventive measures,
 - prioritizing action plans, and

Policy & Compliance

- NIH Grants Policy Statement
- Notices of Policy Changes
- Compliance & Oversight

Select Policy Topics

- Animal Welfare**
- Application Submission Policies
- Clinical Trial Requirements +
- NIH Funding Strategies
- Human Subjects Research
- Intellectual Property Policy

CORRESPONDENCE

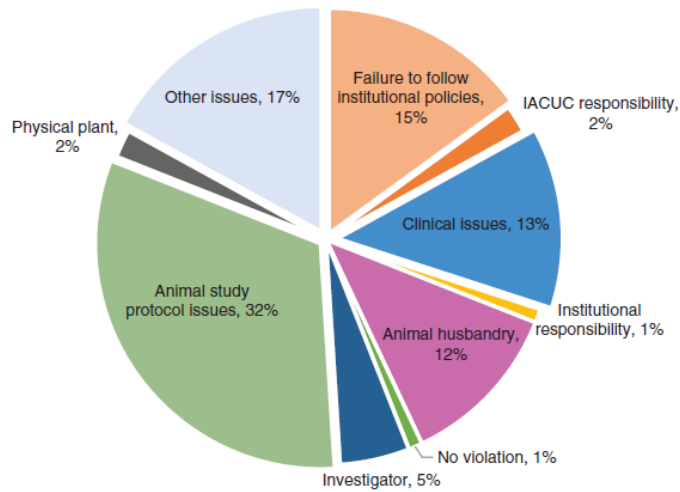


FIGURE 3 | Non-compliance cases reported to OLAW in the 2009-2016 period

TABLE 2 | Technical extensive adverse events

Adverse event	Secondary effects
Hazardous materials	
Water supply contamination	Spread of hazardous materials
Chemical spills	Health hazard
Radiation leak	Long-term effects
Large scale failures	
Mechanical	Temperature fluctuations
Electrical	Disruption of the light/dark cycle

decided to disable automatic, electronically controlled equipment during severe weather. This example highlights the importance of understanding and preparing for secondary events. Other examples of natural events and their consequences are listed in **Table 1**.

Other natural adverse events include disease outbreaks that can affect, in addition to animal welfare and health, the research quality and outcome due to the introduction of additional variables.



Freedom Of Information Act (FOIA)

- **The Purpose**
 - **Open Access to information fosters democracy and empowers an informed citizenry, i.e. Statutory right for person /organization to obtain US government information**
- **Requirements**
 - **US Government Agencies make records available to Public**
 - **Affirmatively/Proactively**
 - **Upon receipt of a written request**
- **Signed July 4, 1966**



- As noted at the signing...



“A democracy works best when the people have all the information that the security of the nation permits.”

“At the same time, the welfare of the Nation or the rights of individuals may require that some documents not be made available.”



FOIA Exemptions

- Exemption 4
 - “Trade secrets and commercial or financial information”
- Exemption 5
 - Inter-agency or intra-agency memoranda and incorporates; Certain Privileges
- Exemption 6
 - Certain information if disclosure would constitute of clearly unwarranted invasion of personal privacy” (e.g. personnel actions)
- Exemption 7
 - Protects certain information in law enforcement files



2017 NIH FOIA Data

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NCATS	5
NIAID	82
NHLBI	83
NIEHS	86
OER	146
OD	153
<u>NCI</u>	<u>156</u>
Total	1,390



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