

# Research Integrity and Research Misconduct

Perspectives from the U.S. Office of Research Integrity

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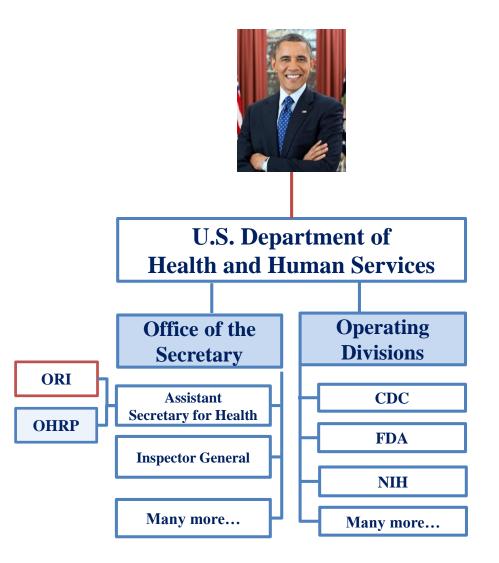


**Howard University** 

**Office of Regulatory Research Compliance** 

November 6, 2015





Promote integrity in research funded by the Public Health Service

Provide regulatory oversight for investigations of research misconduct

~ 5,000 institutions receive PHS funding







## Federal Research Funding in the U.S.

~ \$134 billion Federal Funds allocated for Research and Development in 2014

~ \$31 billion allocated for the **Department of Health and Human Services (DHHS)** 

Sources: http://fas.org/sgp/crs/misc/R43580.pdf

http://www.nih.gov/about/almanac/appropriations/index.htm

Last accessed: 5/12/2015

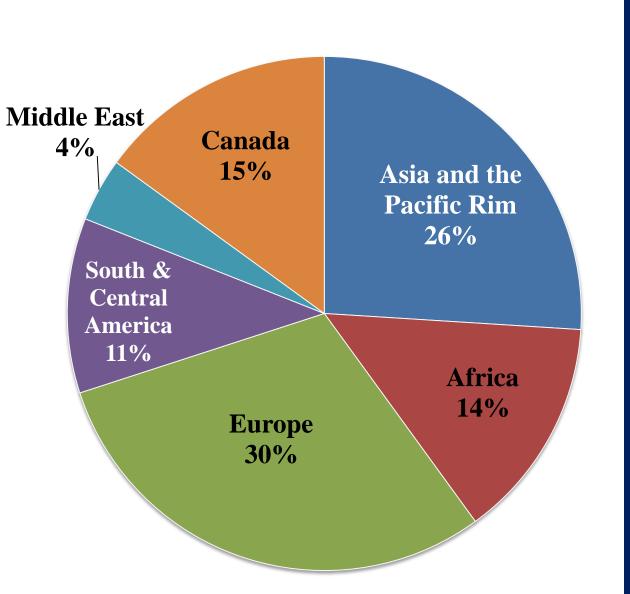


## **Requirements for ORI Assurances**

All institutions applying for or receiving research funds from U.S. Public Health Service must have an assurance with ORI:

- 1. Policies and procedures for handling allegations of research misconduct;
- 2. Foster an environment that promotes the responsible conduct of research; and
- 3. Submit an annual report to ORI.





Global distribution

of the ~ 400

non-U.S. institutions

with assurances

from ORI



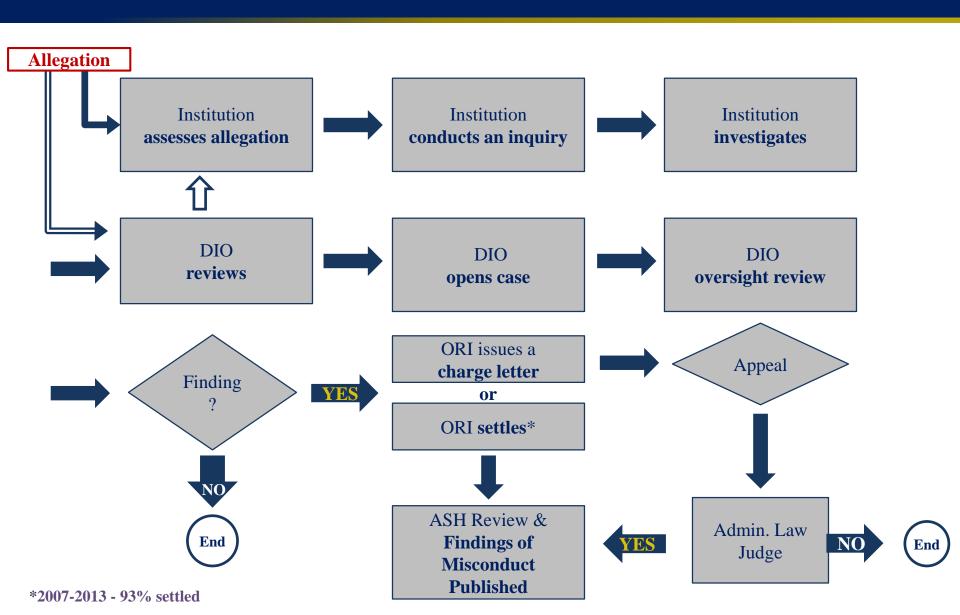
## U.S. Public Health Service Definition of Research Misconduct:

"...fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results...."

Research misconduct does not include honest error or differences of opinion.

(U.S. Federal Regulation 42 CFR Parts 50 and 93)







## Requirements for findings of research misconduct

A finding of research misconduct requires that:

- a) There be a **significant departure from accepted practices** of the relevant research community; and
- b) The misconduct be committed **intentionally**, **knowingly**, **or recklessly**; and
- c) The allegation be proven by a preponderance of the evidence.





## May New

#### New Research Misconduct Finding: Venkata J. Reddy

ORI found that Dr. Venkata J. Reddy intentionally and knowingly engaged in research misconduct by falsifying and/or fabricating data that was provided to his mentor to include in grant application.



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#### New Research Misconduct Finding: Teresita Briones

ORI found that Dr. Teresita Briones intentionally, knowingly, and recklessly engaged in research misconduct by falsifying and/or fabricating data that were included in five publications and three grant applications.



#### New Research Misconduct Finding: Ryousuke Fujita

ORI found that Dr. Ryousuke Fujita engaged in research misconduct by falsifying and fabricating data that included in figures in the following two publications and one unpublished manuscript.



#### Job Announcement: ORI Director ₪

Join the U.S. Health and Human Services team as the Director for the Office of Research Integrity. Applications are being accepted until May 15, 2015.

#### Case Summary: Reddy, Venkata J.

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.



SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Venkata J. Reddy, University of Minnesota: Based upon the evidence and findings of an investigation report by the University of Minnesota (UMN), an investigation conducted by another Federal agency, and additional information obtained by the Office of Research Integrity (ORI) during its oversight review of the UMN investigation, ORI found that Mr. Venkata J. Reddy, former Graduate Student, Department of Chemistry, UMN, engaged in research misconduct in research that was included in grant application R01 GM095559-01A1, submitted

to the National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH).

ORI found by a preponderance of the evidence that the Respondent intentionally and knowingly engaged in research misconduct by falsifying and/or fabricating data that was provided to his mentor to include in grant application R01 GM095559-01A1 submitted to NIGMS, NIH, to obtain U.S. Public Health Service (PHS) funds. Specifically, ORI found that the Respondent falsified data included in Figures 4, 9, 11, 15, and 25 in R01 GM095559-01A1 for enantiomeric excess ("ee") to falsely show a high degree of selectivity for one enantiomer over another by a cut-and-paste method and manipulation of the instrument to give the desired result. Respondent also falsified the underlying nuclear magnetic resonance spectroscopy (NMR) data for Compound 22 reported in Figure 15 in R01 GM095559-01A1 by a cut-and-paste method to manipulate the NMR spectra and give the desired result.

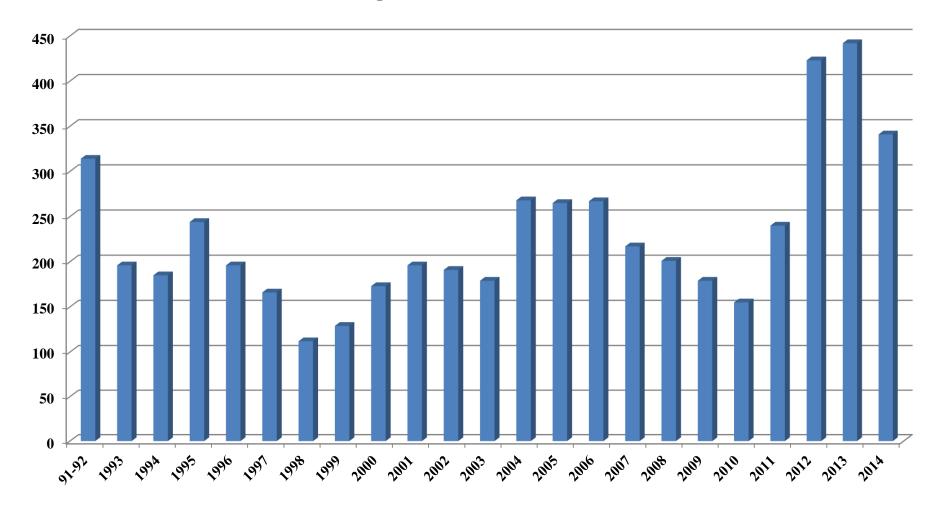
Dr. Reddy has been debarred by the Federal agency with joint jurisdiction for a period of five (5) years, ending on August 26, 2018. ORI has implemented the following administrative action to coincide with the government-wide debarment:

(1) Respondent is prohibited from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

Last Updated on Mon, 2015-05-04 11:38.

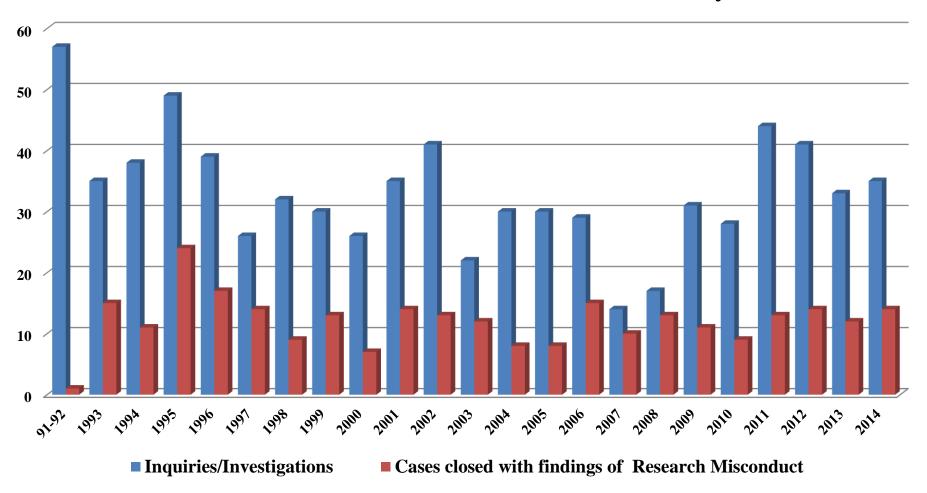


#### Number of Queries/Allegations submitted to ORI (U.S. and Non-U.S.)



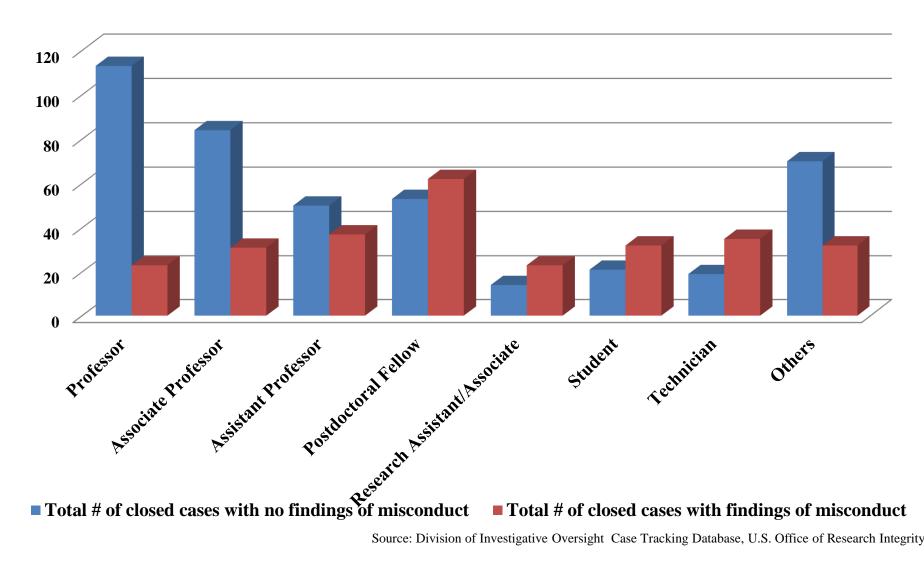


#### **Number of Research Misconduct Cases handled by ORI**





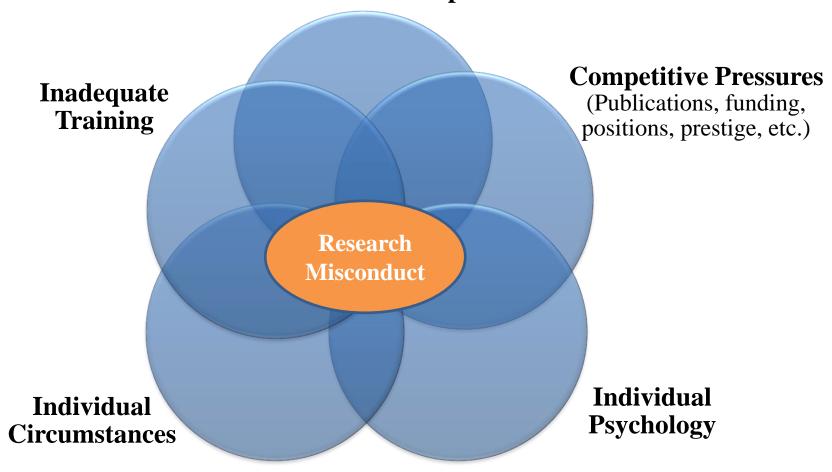
## Closed ORI Cases by Rank (1993-2014)





## "Causes" of Research Misconduct

### **Poor Mentorship**





"My data was never once reviewed by any of the co-authors..."

Graduate Student Respondent



		From 1.K.
4/14/03		
Common	s'	
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Scared	to 98 to him! referring	to Dr. This
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Research Assistant Respondent
Response to Draft Institutional Inquiry Report



"...I made a big mistake by manipulating data on a poster ... I thought this kind of modifications didn't change the conclusions.

... Being a green hand from a different culture background ... I had been ignorant about some rules of scientific ethics..."

Graduate Student Respondent



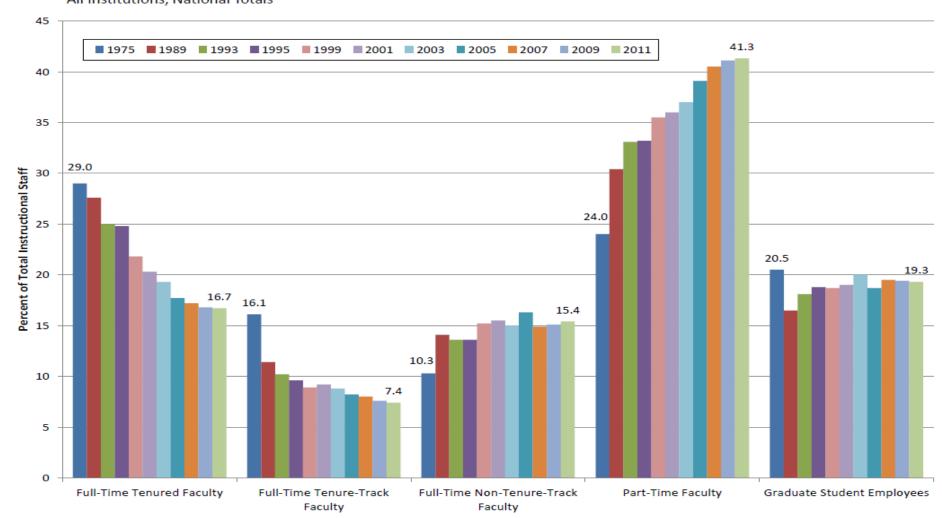
"I wanted to get out of grad school so badly that I would do anything."

Graduate Student Respondent



#### Trends in Instructional Staff Employment Status, 1975-2011

All Institutions, National Totals



Notes: Figures for 2011 are estimated. Figures from 2005 have been corrected from those published in 2012. Figures are for degree-granting institutions only, but the precise category of institutions included has changed over time. Graduate student employee figure for 1975 is from 1976. Percentages may not add to 100 due to rounding.

Source: US Department of Education, IPEDS Fall Staff Survey. Tabulation by AAUP Research Office, Washington, DC. Released April 2013.

Responsible Conduct of Research (RCR) Instructional Areas

1

2

3

4

5

Research Misconduct

Human Subjects **Animal** Welfare

Mentor/ Trainee Responsibilities Data
Acquisition,
Management,
Sharing, &
Ownership

6

8

9

10

Publication Practices & Responsible Authorship

**Peer Review** 

Conflict of Interest and Commitment

**Collaborative Science** 

?





#### The Lab



#### Interactive Movie on Research Misconduct

**PLAY FULL VERSION**  **EL LABORATORIO** 

PLAY SPANISH VERSION

繁體中文版

PLAY CHINESE VERSION

Download The Lab Guide

Desci

and addr mento practices

## Educational Resources

The Characters

You assume the role of four characters confronted with the pressures of working in a



Lessons Worth

KIM PARK, a third-year aduate student, who uestions the use of her ata by another esearcher.

BETH RIDGELY, a role as the university's



PLAY FULL VIDEO (>)

In this simulat

clinical resear

institutional re

#### Description

The Office of Research Integrity ORI) and the Office for Human

resent The Rese nteractive training protecting research characters and de

selecting decision for each "playable Case Two: Risky Authorship

The Char RCR Casebook: Authorship and Publication

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OFFICE OF RESEARCH INTEGRITY The Role of the RIO



Office of Public Health and Science
U. S. Department of Health and Human Services

ORI

Introduction to the **Responsible Conduct** of Research

Nicholas H. Steneck



#### COMMUNICATIONS and TECHNICAL ASSISTANCE



Website ~1 M visits per year

Blog

Twitter @HHS\_ORI

Newsletter

Monthly Email Blasts
Sign up on ORI website

Rapid Response
Technical Assistance



#### **CONFERENCES AND WORKSHOPS and GRANTS**



May 31 - June 3, 2015; Rio di Janeiro

**Research Misconduct in Clinical Research** 

June 18-19, 2015, Washington, DC

**Research Integrity Officer Boot Camps** 

**ORI 2017 Conference** 

**GRANTS** for Conferences and Research





#### INTERNATIONAL NETWORKS











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## THANK YOU!



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