

Research Integrity

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Presentation Outline

1. Introduction
2. Approach
3. Financial Conflict of Interest Management
4. Research Misconduct Management
5. Discussion



Introduction

Research integrity is of great importance to Harvard University. This is best defined by the statement on the Office of Vice Provost Research website:

“Integrity in all scholarship is a foundational principle that underlies Harvard’s core mission to discover, transmit and apply new knowledge for the benefit of society”.



Introduction

Faculty of Arts and Sciences Statement:

“We uphold policies and procedures to foster a proper research environment, to support and monitor research activities, and to deal promptly and effectively with misconduct or allegations of misconduct in research. We offer training and guidance on the responsible conduct of research for those desiring to deepen their knowledge of ethical research and responsible conduct or fulfill the National Science Foundation (NSF) and National Institutes of Health (NIH) requirements for formal Responsible Conduct of Research (RCR) instruction”.



Introduction

The definition of research integrity is broad and includes a range of activities such as conflicts of interest, conflicts of commitments, research misconduct (fabrication, falsification, and plagiarism), ethical treatment of human and animal subjects, financial management of grants, laboratory safety, use of university resources, intellectual property, etc.



Approach

The general principle is that research integrity is the fabric of the research enterprise and it must become a “cultural norm” in which the research community is committed to doing the “right thing”.

The approach is two pronged:

- *Prevention*: provide the tools to assist the research community in understanding and meeting the requirements.
- *Response*: provide a confidential for reporting and proper response to any allegation



Prevention

Follows basic principles of

- Clearly defined policies and procedures
- Designated Officials responsible for the program
- Oversight Committees with faculty participation
- Training and awareness programs
- Monitoring and follow-up



Policies and Procedures

For any program to be successful it must have reasonable policies and procedures that clearly define the:

- Purpose of the policy
- What is required
- Who is covered
- What are roles and responsibilities
- Who is the Responsible Official
- How to comply and consequence of not complying
- Any exceptions and how to obtain
- Record keeping
- Developed at institutional level and modified to meet each school's needs
- Reviewed and updated regularly



Oversight Committees

Successful programs also require Oversight Committees with participation of *both faculty and program administrators*

Harvard University has

- Human and animal subjects
- Biological materials and toxins
- Radiation and radioactive materials
- Laboratory Safety
- Export Control
- Conflict of Interest
- Research Data and Record Retention
- School Level Committee on Professional Conduct (CPC) or equivalent
- Ad-Hoc Committees as needed to review specific issues



Training and Awareness Programs

Policies and procedures are only effective if there is a broad understanding of what they are!

To ensure awareness of the requirements there are specific training requirements for researchers that include:

- A formal responsible conduct of research
- For human subjects
- Use of animals in research
- Use of hazardous materials (biological, chemical, radioactive materials, etc.)
- Conflict of interest
- Other research management

Note: Effective training requires “relevancy”, with the understanding that “one size does not fit all”!



Monitoring Program

All policies and procedures define some level of ongoing monitoring program designed to evaluate the effectiveness of the programs and identification of changes that may be required to improved the programs. The monitoring programs include:

- Periodic inspections and program reviews
- Follow-ups for corrective action
- Program modifications, in necessary



Conflicts of Interest Policy

University Policy:

- Is based on Four (4) Governing Principles and sixteen (16) Operating Principles
- Establishes a University-wide system for identifying, evaluating, and managing financial conflicts of interest
- Schools can modify to be stricter, all changes have to be approved by the University-wide Committee on Financial Conflicts of Interest.
- Policy augmented to follow the federal policy for NIH funded research
- All faculty and “Family member” (means spouse and dependent children)
- Key personnel (e.g. involved in the design, conduct and analysis of data) on federal awards
- Senior Officials also have to disclose annually
- Policy requires disclosure at the start and annually



Conflicts of Interest Policy

University Policy:

- Defines significant interest, special role of students,
- All disclosures are reviewed and if necessary a management plan is put in place
- Management includes elimination, reduction, or developing a management plan.
- The Office of the Provost, in consultation with the University Committee on Financial Conflicts of Interest, and with the Office of General Counsel as appropriate, shall be responsible for overseeing the University-wide implementation of this policy and assuring ongoing compliance with its terms



Governing Principles

The Policy is based on the following Governing Principles:

1. Society grants special privileges to universities and with these privileges come special responsibilities and standards of conduct.
2. Societal trust in the University depends upon the independence, integrity, and transparency of the University's endeavors
3. The University's missions as well as the public interest are served by responsible interactions between faculty members and others; including government, business, and other organizations and individuals.
4. Independent inquiry and the publication of scholarly findings are vital to the integrity and objectivity of research



Operating Principles

The sixteen (16) operating principles address six major categories and are grouped to address the following:

1. Avoidance of financially conflicting interests
2. Compliance with laws
3. Free inquiry and intellectual exchange
4. Instruction and advising of students
5. Supervisory responsibility
6. Use of University resources



Research Misconduct

Integrity in all scholarship is a foundational principle that underlies Harvard's core mission to discover, transmit and apply new knowledge for the benefit of society.

The foundation our research enterprise is based on a few fundamental principle such as:

- **TRUST** - We believe and trust our colleagues, their presentations, published papers, the data they give us, etc.
- **ETHICS** – We act and conduct our research in an ethical manner.
- **SHARING** – We do share our results and data with colleagues to make sure they can reproduce and validate our work
- **COMMON GOOD** – As universities we are committed to good of the society and rely on their trust and support of our work



Research Misconduct

The following statement is from the Procedures for Responding to Allegations of Misconduct in Research that was *voted by the* President and Fellows of Harvard College on March 9, 2009

“In order to maintain confidence in the integrity of the Faculty's research enterprises, allegations of misconduct in research must be treated with the utmost seriousness and examined carefully and responsibly”.



Response

All allegations of misconduct in research are taken seriously.

Follow the Office of Research Integrity process:

- Initial review to determine if there is merit; if yes, then start the conduct if Inquiry.
- The Dean is fully informed of the steps to be taken, and the information on which the steps are based.
- Take appropriate steps to obtain and secure relevant records or other evidence that may bear upon the proceedings.
- Appoint members of Inquiry Committee
- Review evidence and determine if there should be an Investigation
- If yes; appoint Investigating Committee

All Committee members are required to inform the chair if they have any relationship to the accused party or parties, or to the party or parties bringing the allegation, that may affect their ability to review the information with impartiality.



Personal Thoughts

Research integrity:

- Is a contract between researchers and the society (both general society and their fellow researchers).
 - It **cannot be enforced**, it **must be practiced** by all involved.
 - Must be embraced at the highest level.
 - Must become part of the “Culture of Responsibility” where everyone assumes responsibility for acting ethically.
- The researchers must act in an open and honest environment that allows for individuals to express doubts and contrary opinions.

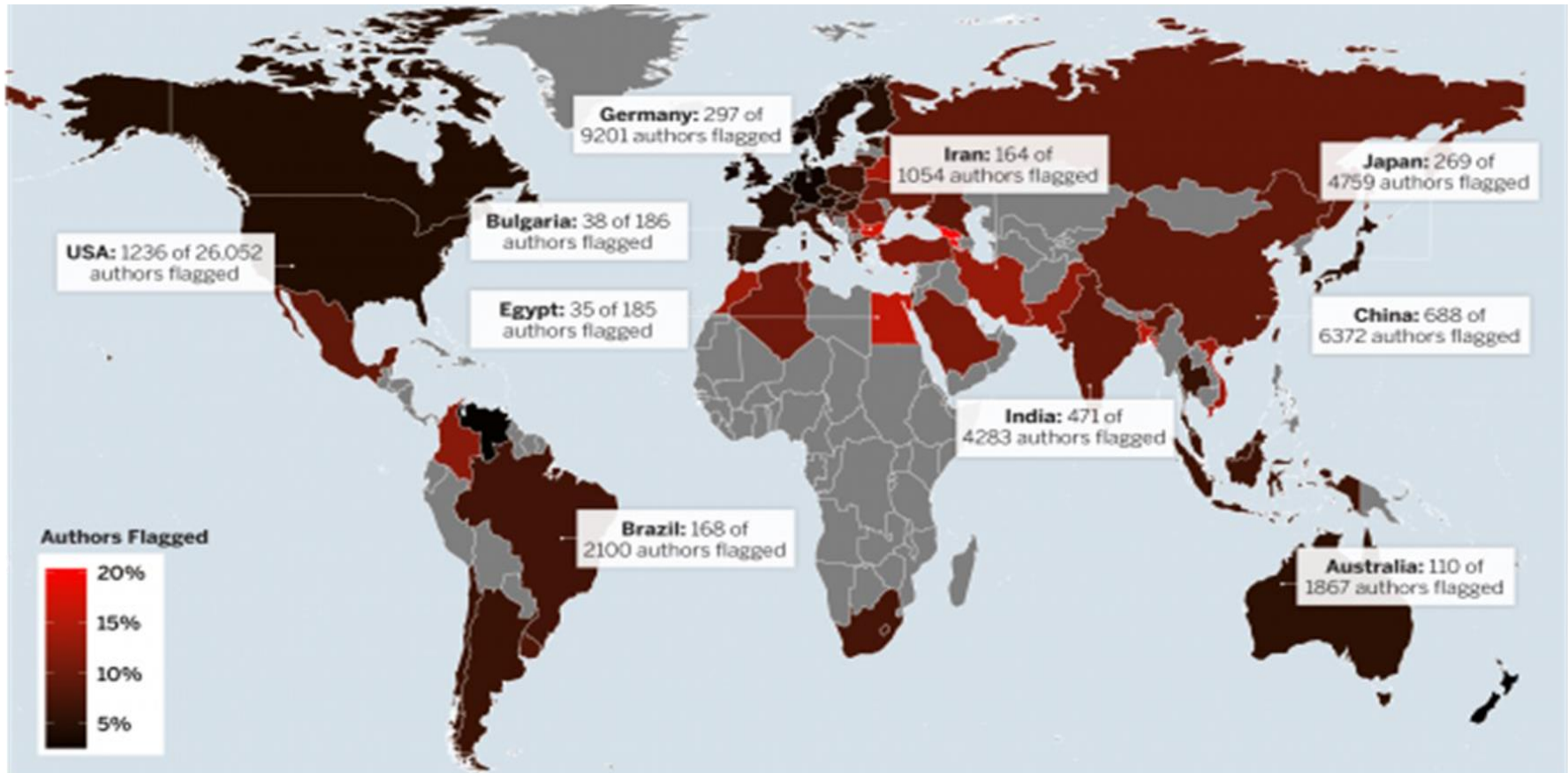


Personal Thoughts

- The Principal Investigator must review all “raw” information, data, images, etc., and question any discrepancies or unusual results.
- The **importance to publish** discoveries, **must be secondary to honesty** in reporting results.
- Researchers must recognize that “false reporting” impact not just their work but also those of others involved in the research, or those who rely on their published results.
- Research is global, collaborative, and interconnected; any problem in one part of the world has global impact!



From Science Magazine: John Bohannon Article (Dec./12/14): *Study of massive preprint archive hints at geography of plagiarism*



Thank You

