

NIH Research

- **Extramural** – Research funded *by* the NIH *to* outside entities
 - More than 80% of the NIH's funding is awarded through almost 50,000 competitive grants to more than 300,000 researchers at more than 2,500 universities, medical schools, and other research institutions domestically and internationally
- **Intramural** – Research internal *to* the NIH either in laboratories or clinical settings
 - Over 1,200 Principal Investigators and over 4,000 Post Docs
- **Clinical** – Research on human subjects done to look at new ways to prevent, detect, or treat disease



Mission: 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.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

August 20, 2018

Dear Colleagues:

For many decades, the National Institutes of Health (NIH) and institutions like yours have participated in productive partnerships that greatly advance biomedical science. Scientists at universities and academic medical centers, supported by NIH, have made seminal biomedical discoveries that have led to dramatic improvements in human health. The scientists whose work NIH is proud to help support come from all over this country and the world, bringing rich, diverse perspectives and backgrounds to the biomedical research enterprise.

The NIH-funded biomedical enterprise depends on a competitive system, which, to be successful, must be fair, transparent, and trustworthy.

Unfortunately, threats to the integrity of U.S. biomedical research exist. NIH is aware that some foreign entities have mounted systematic programs to influence NIH researchers and peer reviewers and to take advantage of the long tradition of trust, fairness, and excellence of NIH-supported research activities. This kind of inappropriate influence is not limited to biomedical research; it has been a significant issue for defense and energy research for some time. Three areas of concern have emerged:

1. Diversion of intellectual property (IP) in grant applications or produced by NIH-supported biomedical research to other entities, including other countries;
2. Sharing of confidential information on grant applications by NIH peer reviewers with others, including foreign entities, or otherwise attempting to influence funding decisions; and
3. Failure by some researchers working at NIH-funded institutions in the U.S. to disclose substantial resources from other organizations, including foreign governments, which threatens to distort decisions about the appropriate use of NIH funds.

NIH is working with other government agencies and the broader biomedical research community, including NIH-funded institutions and U.S. university professional organizations, to identify steps that can help mitigate these unacceptable breaches of trust and confidentiality that undermine the integrity of U.S. biomedical research.

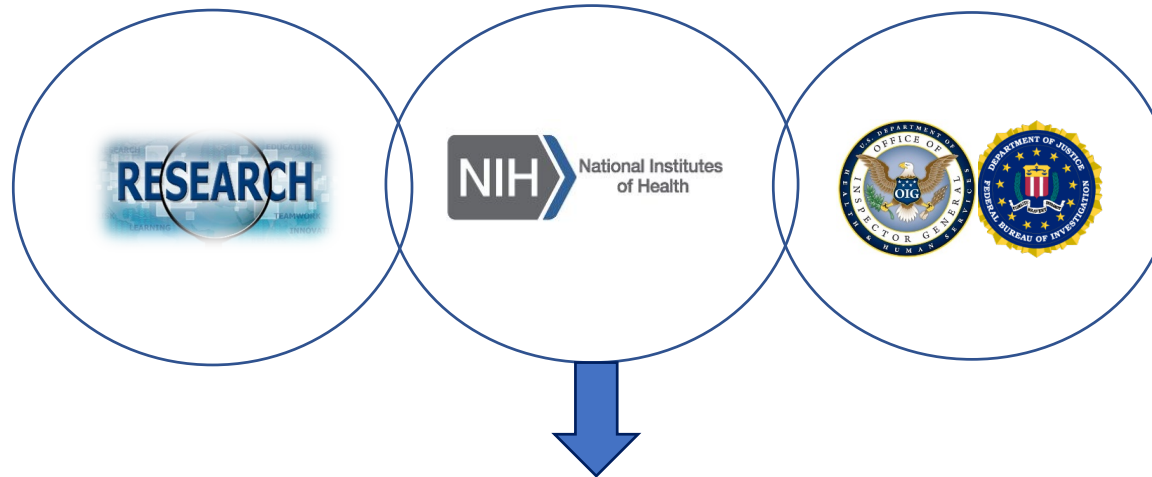
Dr. Collins' Message

Primary Concerns

- Peer Review Process
- Diversion of Intellectual Property
- Failure to disclose outside support
- NIH is focused on program integrity, strengthening collaborations, ensuring effective and fair processes with funding decisions, while preventing fraud, waste, abuse and misconduct

- ❖ Integrity issues are conduct based, not culturally driven
- ❖ NIH supports turning discovery into health – keeping our core mission intact
- ❖ NIH is a partner in program integrity and accountability and we must share a commitment to stewardship through collaboration and vigilance

Partners in Integrity - Continuum of Accountability



Office of Management Assessment

- Aggressively responding to allegations of misconduct: administering investigations, conducting audits and risk assessments
- Partner with HHS OIG and ONS, FBI, DOD, DOJ, NSF and other Federal agencies to coordinate on multi-faceted investigations of administrative and criminal allegations and address the broader threat
- Collaborates with internal NIH programs, Grant Makers and Grantee Organizations to identify conduct-based violations and develop best practice for internal controls and inquiry

Peer Review Process

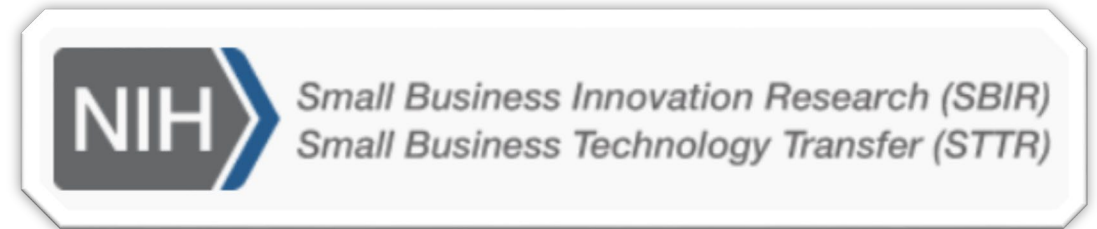


- **Confidentiality Breach (18 U.S. Code § 1001)**
 - Panel member shares information about grants, status, progress, panel information, or associated comments in violation of signed confidentiality agreement
 - Violation can occur before, during or after panel
- **Improper Communication**
 - Discussion initiated by a grantee, or other party on behalf of a grantee in an attempt to gain information or influence reviews
 - Grantee applicants identify the panel members and influence directly or indirectly
 - Any sharing or communicating status, ranking order, score, membership or comments/discussion points of panel members
- **Sharing grant applications or information**
 - Sharing unfunded grant applications with others or retaining or forwarding copies can be either a 18 U.S. Code § 1001 violation or improper communication

Peer Review Process

- Conflicts of Interest (COI)- Must report “relevant” conflicts
 - Relevant conflict can be anything that directly or indirectly causes a reasonable person to perceive a potential lack of objectivity or loss of impartiality
 - NIH makes ultimate determination of materiality and relevance*
 - Lack of objectivity, (favors certain scientific fields/areas of study, friends with or former colleague of applicant, etc.)
- Other improper actions associated with COI
 - Maneuvering to get on to specific panels
 - Creating a conflict of interest to manipulate panel membership
 - Affinity groups – groups with loyalty to one-another, backing and ensuring favorable reviews or sharing confidential information on their affinity group member’s grants either as an expected behavior or under fear of retaliation
 - Use of professional leverage to improperly influence (“get with the program or else”)
 - Subtle suggestion or explicit direction





SBIR/STTR Requirements

- Duplicate or overlapping proposals may not be submitted to multiple agencies without full disclosure to all agencies.
- The PI's primary employment must be with the company during the grant period and he or she may not be employed full time elsewhere.
- For Phase I, a minimum of two thirds of the research effort must be performed by the grantee company; for Phase II, a minimum of one-half of the research effort must be performed by the grantee company. Work performed by a university research lab is NOT work completed by the grantee company.
- University employees participating on an SBIR award are to disclose their involvement to the university as well as their use of university facilities.
- R&D must be performed in the United States.

SBIR/STTR Program Misconduct

During Application Process:

- Submitting a plagiarized proposal, (also found within Peer Review misconduct)
- Providing false information regarding the company, the PI or work to be performed
- Seeking funding for work that has already been completed, (a.k.a., research recycling)
- Providing falsified letters of reference, credentials, etc.

During Award:

- Misrepresentation of expended funds: how funds were used, work done, results achieved, and program requirement compliance
- Using funds for personal use or for any use other than the proposed activities: reporting false expenses, timesheets, overpaying vendors or concealing/altering/omitting required reporting
- Claiming results for awards that were funded by different or multiple sources

Misconduct Examples by Awardee:

- Claimed the research work was conducted at the University site while no such research was conducted.
- Did not have proper lab/equipment for the research work and claimed use of University lab/equipment; while the University claimed the awardee did not use its lab/equipment.
- Claimed inaccurate percentage of time dedicated to project, (example: reports 75% of time in lab but records show 50% of time was on travel or working at other entity).
- Duplication of funds: Awardee received multiple SBIR awards from the same or different agencies to conduct the same research. This includes submitting identical deliverables for work that is supposed to be separate.

Diversion of Intellectual Property (IP)



- **Sharing of pre-award grant information (funded or unfunded)**
 - Passing information from review panels or advisory boards outside the review or advisory process

- **Sharing of research information during grant execution**
 - Sharing confidential research or pre-outcome information in furtherance of other research
 - Can lead to conflicts over authorship and ownership of future grants or intellectual property
 - Identical or highly similar applications submitted for funding to both the NIH and a foreign/other entity

- **Patent preemption**
 - Filing a patent on outcomes of research in another country, superseding IP rights of grantee or fair opportunity on release for commercial use
 - Use of patent process to usurp research outcomes for individual or other party gain
 - Infringes on commercial fair opportunity or creates loss of proprietary information rights for institution

- **Loss of discovery**
 - IP claimed by foreign governments even though US government funding support aided in the discovery

- **Non-traditional Collection of Information**
 - Collect seemingly innocuous information from various providers (persons/systems) within a program area
 - Not as easy to detect because each piece alone appears to be less important

Failure to Disclose Outside Support



- **Required to report on all other funding or outside support**
 - Designed to avoid dual funding on same or substantially similar research
 - Unreported outside support by grantee or panel member can also be a conflict of interest

- **Individual funding to influence grant research performance**
 - Receiving support or committing to actions unrelated to the specific research but which is designed to influence the progress, provide information, or to otherwise manipulate the grant making process, research progress or outcomes

- **May impact funding decisions and distribution**
 - Materiality of source, amount, conflict, or similarity is determined by NIH

- **Can create conflicts and vulnerability for intellectual property rights research outcomes**

Patterns of Conduct – Consistently Failing to Disclose Financial Support

There are *multiple* check points throughout the grant process requiring disclosure of outside funding

42 CFR Part 50 Subpart F

- Recipients/Investigators are required to disclose *ALL other funding support* and collaborations. There are multiple opportunities for the grant recipient to disclose this to the NIH, either prior, during or after the grant is awarded:
 - Complete annual NIH progress reports disclosing financial support, including foreign
 - “Other Information” box on grant application – used to disclose foreign support, collaborations or sharing of resources which initiates a clearance process with the State Department
 - “Just-in-Time” auto-generated by eRA Commons to submit all support not yet disclosed
- Financial Conflicts of Interest (FCOIs) occur when the recipient determines an investigator's financial interest is related to his/her NIH-funded research and could directly and significantly affect the design, conduct, or reporting of the research.

Recipient organizations are *required* to develop a policy, enforce it, and make it publicly available on a website. They must review investigator disclosures, manage those that are determined to be FCOIs, and report to the NIH.

NIH Office of Extramural Research Actions



Communications with Grantees

- ❖ 70+ Institutions received a letter from Dr. Lauer with >140 individuals (PIs) identified with indicators of activity posing a threat to research integrity
- ❖ Types of potential threats identified (*some individuals had more than one – percentages are approximate*)
 - 81% Undisclosed foreign grants
 - 60% Undisclosed Talent Program affiliation
 - 10% Undisclosed foreign company
 - 6% Peer Review violation
 - 3% Undisclosed foreign patents

OER Actions

- 25+ cases referred to OIG
- 10 referred for debarment or suspension
- Directed termination or suspension of awards and grants
- Imposed civil monetary penalties

Institution Level Actions

- 25+ resigned or terminated
- Grant reassignment
- Demotion, tenure, and/or salary adjustments

Institution/University actions are independent of and not influenced or directed by NIH

How to Protect Your University or Institution

AAU and APLU campus representative survey of examples of effective policies, practices, tool and resources.

- AWARENESS BUILDING AND COMMUNICATIONS
- COORDINATION
- TRAINING OF FACULTY AND STUDENTS
- REVIEW OF FOREIGN GIFTS, GRANTS, CONTRACTS, AND COLLABORATIONS
- REVIEW OF FACULTY FOREIGN FINANCIAL INTERESTS AND AFFILIATIONS
- PROTECTION OF DATA AND CYBERSECURITY
- PROTECTION OF INTELLECTUAL PROPERTY AND USE OF TECHNOLOGY CONTROL PLANS
- REGULAR INTERACTIONS WITH FEDERAL SECURITY AND INTELLIGENCE AGENCIES
- FOREIGN TRAVEL SAFEGUARDS AND PROTECTIONS
- INTERNATIONAL VISITORS TO CAMPUS
- EXPORT CONTROL COMPLIANCE



Integrity – Responsibility – Accountability

- NIH's core mission is to help science succeed. We work to ensure internal controls exist to prevent, identify and correct fraud, waste, abuse and misconduct in order to maintain program integrity and accountability.
- The objective is to keep properly awarded grants in place. We do this by balancing the mission to administer research funds while ensuring stewardship.
- When should you contact NIH? Sooner is better, but no later than when a planned event has a material impact on the grant or grant agreement terms (i.e. notify NIH when the PI is no longer doing the work considered by the peer review panel at the time of application).
- Reference Notice Number: [NOT-OD-19-114](#) for more specifics and clarification of current policy.

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NIH Office of the Director Contacts:

Mike D. Shannon

Director, Office of Management Assessment (OMA)

Michael.Shannon@nih.gov

Deborah Kearse

Director, OMA Division of Program Integrity

Deborah.Kearse@nih.gov

Ashley Sanders

Program Investigations Lead, OMA Division of Program Integrity

Ashley.Sanders@nih.gov