



NSF OIG CORNER

Human Subjects Research Compliance

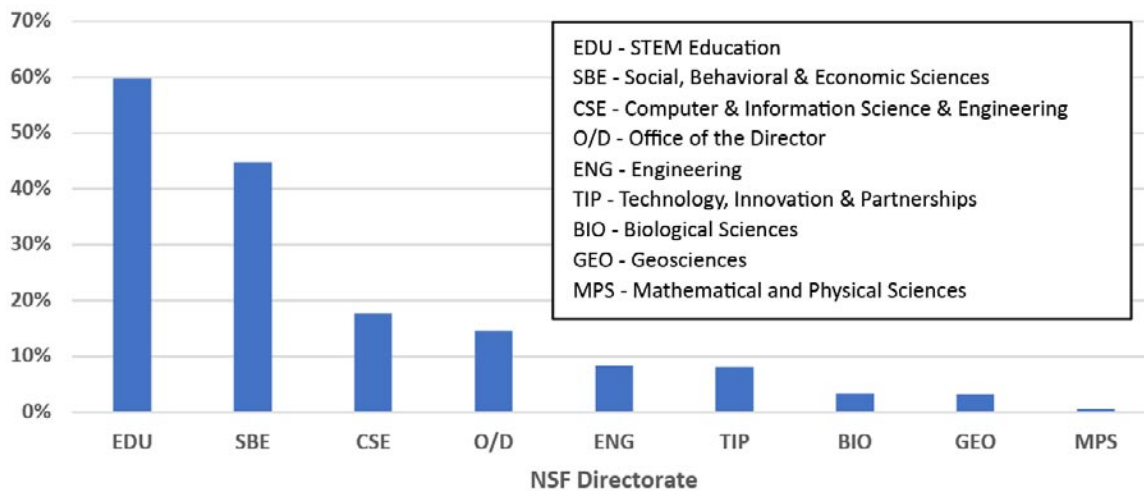
By Laurel L. Hester and Jeff Mantz
 Science analyst Erin McKenna provided data assistance.

The National Science Foundation requires Institutional Review Board (IRB) exemption, pending, or approval documents for human subjects research. Since NSF has a statutory mission to fund basic science, it primarily supports education-related human subjects research and projects in the social and behavioral sciences. In this article, we'll discuss the prevalence of NSF awards involving human subjects research and oversight related to human subjects research.

Prevalence of NSF Research Awards Involving Human Subjects Research

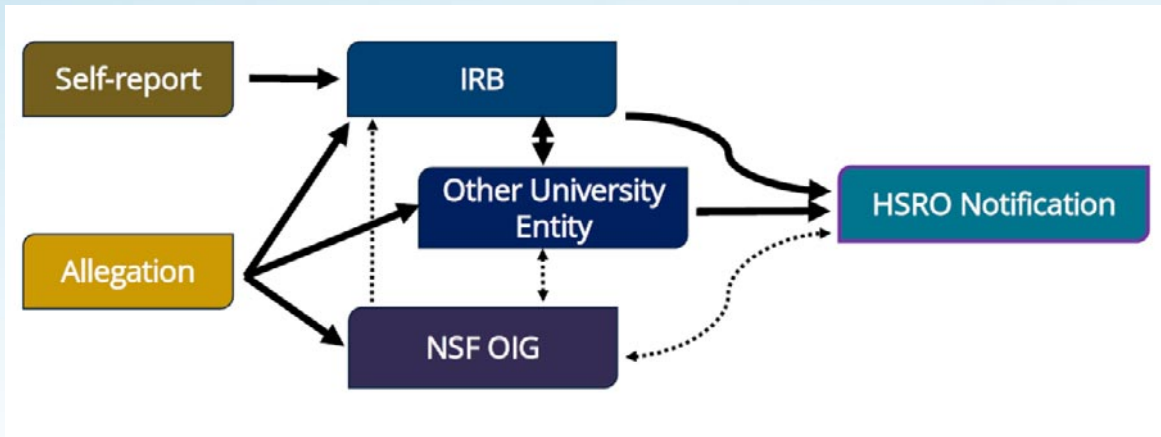
According to our analysis of NSF's fiscal year 2022 research awards, 14.1% of awards included plans for human subjects research, with specific percentages varying widely across NSF directorates as shown in the table below. (Graduate research fellowship and equipment awards were excluded, leaving n = 10,970 awards in our analysis). Overall, compared to proposals without human subjects research, the funding rate for proposals involving human subjects research was lower in every directorate (averaging 8% lower across all directorates for fiscal year 2022 proposals included in our analysis).

Percent Research Awards Involving Human Subjects Research by Directorate



Oversight Responsibility for Monitoring Human Subjects Research

Awardee institutions have primary oversight responsibility for monitoring human subjects research but are required to notify NSF's Human Subjects Research Officer (HSRO) in cases of serious or continuing noncompliance related to NSF-funded research. Typically, any non-compliance with human subjects research regulations would be reported directly to the cognizant IRB. The IRB would then investigate the matter, take corrective action as necessary, and inform NSF's HSRO if the IRB confirmed unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance (see 45 CFR 690). The IRB must also inform the HSRO any time it suspends or terminates its approval for NSF-funded research. Via its hotline, NSF OIG can also receive allegations of human subjects research noncompliance. The figure below depicts communication flow in response to allegations.



NSF OIG Investigations of Human Subject Research Violations

Based on our analysis of ten years of data (2013–2023) from NSF OIG’s [case closeout memoranda](#), 21 cases involved human subject regulation violations. Of these, 19% involved award or subcontract cancellation and/or the return of funds to NSF. In most cases, the university notified NSF of the noncompliance. In one case, an independent IRB firm informed the NSF Program Officer; in another case, concerns were raised during an NSF reverse site visit; and in three cases, OIG received an allegation directly from a complainant. Three cases included research misconduct findings, and one led to a civil false claims settlement with a PI who allegedly falsified NSF IRB letters for four proposals. NSF OIG almost always concurred with the University’s actions; independently, it sent Questionable Research Practices letters to researchers in 48% of cases.


Final Thoughts

NSF does not fund public health research, where the potential risks to research participants tend to be more severe. As a result, most of NSF-funded human subjects research is minimal risk or exempt, and the awardee institution’s IRB members and experts are best positioned to directly evaluate and oversee the research. In our experience, universities have taken appropriate actions to protect the public interest and ensure appropriate regulatory oversight in most serious or continuing non-compliance cases.

We encourage all institutions to reach out to NSF’s HSRO with any questions. ■

To report research misconduct or other forms of fraud, waste, abuse, or whistleblower reprisal, please contact us by:

- **Web:** <https://oig.nsf.gov/contact/hotline>
- **Anonymous Hotline:** 1-800-428-2189
- **Email:** oig@nsf.gov
- **Mail:** 2415 Eisenhower Avenue, Alexandria, VA 22314
ATTN: OIG HOTLINE.



Have a question or an idea for NSF OIG’s Corner?
Please contact us at OIGPublicAffairs@nsf.gov



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