

## NATIONAL SCIENCE FOUNDATION OFFICE OF INSPECTOR GENERAL OFFICE OF INVESTIGATIONS

## CLOSEOUT MEMORANDUM

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NSF OIG received an Institutional Review Board (IRB) determination letter from an institution (Institution 1) regarding an incident of serious non-compliance relating to the research studies of a principal investigator (PI) supported by an NSF award (Award 1). The IRB determined the PI conducted human subject research without IRB approval and the subjects who participated in the research studies did so without informed consent. Institution 1's investigation determined the non-compliance did not constitute a reportable privacy breach. Institution 1 prohibited the use of the data collected from the human subject participants; prohibited the transfer of the data to another institution; and identified the published conference proceeding that contained the affected data and ensured it was withdrawn by the PI. The PI was suspended from research activities and remedial courses in research ethics and data management were directed. Institution 1 also directed enhanced training in research compliance for faculty and research staff, specifically in the areas of human subject research, data storage, and privacy. The PI did not complete the remedial training, as she resigned from Institution 1. After NSF declined Institution 1's request to designate a new PI for the Award 1, Institution 1 terminated Award 1, which resulted in nearly \$630,000 of funds returned to NSF.

Our review of the matter concluded that appropriate actions were taken by Institution 1 to address the IRB non-compliance and to ensure proper oversight of NSF-funded projects involving the use of human subjects as participants. We sent the PI, who has since moved to another institution, a letter reminding her about IRB approval compliance requirements and her responsibilities when conducting human subject research work and collecting data in NSF-funded projects. We note that following the serious non-compliance IRB violation at Institution 1, the PI has taken significant steps to address and mitigate any potential IRB issues, as evident in the research plans of a submitted NSF proposal while at her new institution.

Accordingly, this case is *closed* with no further action taken.