



NATIONAL SCIENCE FOUNDATION
OFFICE OF INSPECTOR GENERAL
OFFICE OF INVESTIGATIONS

CLOSEOUT MEMORANDUM

Case Number: I-17-0095-O

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NSF OIG received an Institutional Review Board (IRB) determination letter from an institution regarding an incident of serious noncompliance with human subject regulations during the research studies of a principal investigator (PI) supported by an NSF award. The IRB determined human subjects research was conducted without proper IRB approval. The research work was reported in publications and in the annual and final reports of the NSF award, but not originally proposed in the NSF proposal. The institution implemented a corrective action plan that added an investigator with human subjects research experience to the PI's ongoing research project, added the same investigator as a co-advisor for the PI's graduate students, approved a new IRB protocol for the ongoing research project, imposed remedial training, and sought and received appropriate review of the developed device by the Food and Drug Administration (FDA). The institution contacted the journals of the four publications about the affected research work.

Our review of the matter concluded that appropriate actions were taken by the institution to address the IRB noncompliance and to ensure proper oversight of NSF-funded projects involving the use of human subjects as participants. We sent the PI a letter reminding her about IRB approval compliance requirements and her responsibilities in conducting human subjects research work, the proper reporting of research work in the NSF award annual reports, and the requirements to obtain prior NSF approval for any changes in project objectives, scope or methodology.

We note that following the serious noncompliance IRB violation at the institution, the PI has taken significant steps to address and mitigate any potential IRB issues, as evident in recently submitted NSF proposals in which a co-PI or collaborator with human subjects research expertise were added.

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