



NATIONAL SCIENCE FOUNDATION
OFFICE OF INSPECTOR GENERAL
OFFICE OF INVESTIGATIONS

CLOSEOUT MEMORANDUM

Case Number: A15030022

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We received an Institutional Review Board (IRB) determination letter from an institution¹ regarding an incidence of continuing serious non-compliance in the research study of a principal investigator (PI)² supported by an NSF award.³ The IRB determined the incident was serious as three enrolled subjects participated in the research study without signing the informed consent document. The IRB also determined the incident was continuing as this was the third lapse in IRB approval for the PI's research study, although this was the first instance where research was conducted during a lapse in IRB approval.

The institution took corrective actions that included remedial educational sessions and development of a training tool resource for the PI and research staff regarding appropriate human subjects research practices. The research study received IRB approval and the PI was allowed to use the data collected as the IRB determined all three subjects were found to have consented to participate in interviews for the research study without signing the consent form and there was no potential harm or risks. Our review of the matter concluded that appropriate actions were taken by the IRB to address the noncompliance and ensure the proper oversight in NSF funded projects involving the use of human subjects as participants. Accordingly, this case is closed with no further action taken.

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