



NATIONAL SCIENCE FOUNDATION
OFFICE OF INSPECTOR GENERAL
OFFICE OF INVESTIGATIONS

CLOSEOUT MEMORANDUM

Case Number: A11040025

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We assessed an allegation that the human subjects research activities of a principal investigator¹ (PI) resulted in human subjects violations due to serious and continuing noncompliance with the Institutional Review Board (IRB). NSF suspended the awards² after the IRB suspended the human subjects research studies. NSF also had concerns about the university's oversight of human subjects research and management of grant funds. The PI's noncompliance with the IRB included poor record keeping, unapproved protocol or consent form modifications and the over-enrollment of human subjects in research studies. Following our evaluation of the university's policies and procedures, the university instituted a revision of its IRB review processes and post-award approval monitoring process for human subjects projects. This included additional oversight and education regarding occurrences of IRB noncompliance. Although the university imposed several corrective measures upon the PI, the PI subsequently left the institution for a faculty position at a foreign university.³ Our conclusion is that the human subjects concerns were appropriately remediated by the university in conjunction with the IRB. The suspended NSF grants were terminated and the remaining obligations cancelled with \$310,454 recovered and returned to the Treasury. Accordingly, this case is closed with no further action taken.

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