

NATIONAL SCIENCE FOUNDATION OFFICE OF INSPECTOR GENERAL OFFICE OF INVESTIGATIONS

CLOSEOUT MEMORANDUM

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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 award² after the IRB suspended the human subjects research studies. The IRB directed an on-site audit which found several IRB protocol deviations. The PI implemented several corrective measures which included the modification of recruitment procedures, enrollment log documentation, permission forms and the destruction of collected information that was deemed unapproved. Although the PI was advised that all modifications to an IRB protocol should be submitted and approved through an amendment, the PI instead submitted a new IRB protocol which was subsequently reviewed and approved. The IRB lifted the suspension of the PI's research activities and imposed a requirement that the PI and research staff attend IRB educational sessions. Furthermore, the institution's Office of Research Support scheduled quarterly audits of the PI's compliance with the IRB protocol. NSF rescinded the suspension of the PI's NSF award. Our conclusion is that the human subjects concerns were appropriately remediated. Accordingly, this case is *closed* with no further action taken.