

## **Non-Compliance Policy and Procedures**

### Background

The IRB has as its primary concern the protection of the rights and welfare of human subjects involved in research and is responsible for the review and approval of all investigations involving human subjects. No study involving human subjects may be undertaken at the University or by faculty/students of the University at other sites without prior approval of the IRB.

### Definition

Non-compliance means significant failure by an investigator to abide by University policy and relevant government regulations for protecting human subjects in research. Instances of non-compliance would include, but are not limited to beginning research before securing Institutional Review Board (IRB) approval, misuse or non-use of approved consent forms, failure to secure IRB approval before introducing changes in an on-going protocol, and continuing to gather study data from subjects after IRB approval expires.

### Policy

Non-compliance with IRB guidelines is a violation of University of South Carolina policy and federal regulations for the protection of human subjects. Incidents of non-compliance must be reported both to ensure the protection of the rights of human subjects and to uphold the University of South Carolina's Assurance to the Federal government. Non-compliance presents a serious challenge to the IRB. Regardless of investigator intent, unapproved research involving human subjects places those subjects at unacceptable risk. Any incident of non-compliance with IRB guidelines must be reported immediately to the Office of Research Compliance or the Chair of the IRB.

### Procedure

The USC IRB will promptly investigate reported instances of non-compliance, and may suspend approval of the research while the investigation is ongoing. On receipt of information indicating possible non-compliance, the Chair advises the Principal investigator that a non-compliance review has been initiated by the IRB. Depending upon the complexity and seriousness of the possible non-compliance, the Chair may conduct the investigation through discussions or correspondence with the responsible investigators or the IRB may impanel an investigative subcommittee. In the latter instance, the subcommittee reviews the evidence and makes recommendations to the full committee. The Principal investigator is invited to submit in writing his/her account and explanation of the events possibly

constituting non-compliance. At his/her request, the Principal investigator may also appear before the IRB.

If, after deliberation, the IRB determines that non-compliance has occurred, appropriate action will be taken to protect the rights and welfare of human subjects. In the case of serious or continuing non-compliance, the IRB and the University will address the question of the investigators' fitness to conduct human subject research. The IRB will also take remedial action, as necessary, regarding the welfare of the subjects and the research data gathered in non-compliance. Further, the IRB will refer instances of serious non-compliance to an appropriate University administrator who must decide whether to impose disciplinary sanctions. The distinction between remedial action taken by an IRB and disciplinary action taken by an administrator is: Remedial action is action that the IRB takes on behalf of present or future human subjects of research; Disciplinary action, in this context, is a penalty imposed by administrators on an investigator for serious non-compliance with the regulations protecting human subjects of research.

In addition, Federal Policy mandates that any serious or continuing non-compliance with IRB determinations and/or Department of Health and Human Services regulations promptly be reported to the Office of Human Research Protection (OHRP). In any event, University and Federal regulations prevent the IRB from approving the use of data not gathered in compliance with these regulations.

An investigator, who believes that the IRB has erred in its finding of non-compliance, may submit a written request asking the IRB to reconsider. The request should clearly indicate the facts and the IRB interpretation in dispute, providing supporting evidence where applicable. In all non-compliance reviews, the IRB provides notice to investigators of its determinations and remedial actions, if any. If the IRB determines that the non-compliance was sufficiently serious to warrant the consideration of disciplinary sanctions (as opposed to remedial actions intended to protect subjects or the integrity of the research environment), it will forward that recommendation to the appropriate University administrator. No one in the University may approve research that has been disapproved by the IRB (45 CFR 46.112). Investigators who believe that the IRB has acted contrary to provisions of 45 CFR 46 or contrary to terms of its Assurance to the federal government may contact the OHRP.

If the IRB fails to find that non-compliance has occurred, the issue is ended. At this time, diligent efforts should be made toward the restoration of the reputation of those under investigation, and should also include efforts to protect the positions and reputations of those who in good faith made the allegations. Notification of the results should be sent to any sponsoring agencies or organizations previously alerted to the problem.