



HSRB POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Complaint Resolution Process

Policy/Procedure ID: 02-12-009 **Effective:** December 4, 2002

A. Background

A *complaint* is defined as a concern about a research project involving human participants that is brought to the HSRB's attention. If the complaint is deemed to be serious in nature, the HSRB may suspend or terminate approval of the research (45 CFR 46 113). Any suspension or termination of approval shall include a statement of reasons for the HSRB's actions and shall be reported to the Principal Investigator (PI), Advisor (if applicable), appropriate institutional officials (e.g., the Institutional Official, Dean), the Office for Human Research Protections (OHRP) and the head of the Department or Agency funding the research (if federally funded).

B. Procedure

Upon notification of the Office of Research Compliance (ORC) regarding a complaint:

1. The HSRB Administrator will consult with the HSRB Chair to determine if immediate temporary suspension of participant enrollment is required for the project in question as well as for other projects involving the same PI. The initial decision will be based on preliminary information and the seriousness of the situation. Consultation and/or collection of additional information in conjunction with the complaint will determine the length of time of the suspension. If applicable, the grant proposal/award notice will be reviewed to determine if notification of the granting agency is required.
2. The HSRB Administrator and Chair will determine whether the involvement of the full Board in the resolution of the issue is required.
3. PI and Advisor (if applicable) may be requested to meet with the Administrator, Chair, and Board, if appropriate, to discuss the complaint and determine a resolution.
4. ORC gathers more information regarding complaint.
5. Based on information accumulated, actions to be taken, if any, are determined (if necessary, in a meeting). Actions may include project modification, consent revision, re-consent of subjects, project suspension or termination, etc.
6. The necessary actions are communicated to all relevant parties (e.g., PI, Advisor (if applicable), Board) by the ORC. If the result is a determination that the situation reflects serious or continuing non-compliance, or requires suspension or termination of HSRB approval, then the necessary institutional, regulatory, and funding agency officials are also notified.