Procedure

Subject: Procedure for Complaints Regarding Human Subjects Research

Procedure:
The purpose of this procedure is to outline the actions of the Human Research Protection Program (HRPP) in managing a complaint received regarding human subjects research.

I. Investigator Responsibilities.
   A. It is the responsibility of the Investigator to notify the HRPP of any participant or other individual’s complaints regarding the research. The complaint may be reported at continuing review if it involves no risk to the participants or others or does not change the risk/benefit ratio (e.g., a participant complains that he/she does not like the Investigator’s clinic hours and subsequently withdraws from the research).
   B. It is the responsibility of the Investigator to report complaints that involve potential risks to participants or others or result in a potential change in the risk/benefit ratio as an unanticipated problem (e.g., the school where the research is conducted complains that the research assistant has not maintained her research notes in a confidential manner which may have potentially breached confidentiality) as soon as possible, but no later than 7 calendar days after the Investigator first learns of the complaint (See HRPP Policy III.L). C. Investigators are to cooperate with the HRPP by making documents accessible, responding to written requests within the designated time frame, and being available for questions by the HRPP or IRB.

II. IRB Committee Responsibilities.
   A. Initial Complaint.
      1. The assigned IRB Chair or his/her designee will be notified by the HRPP staff member conducting the investigation or directed audit of planned activities.
      2. The IRB Chair or his/her designee may request revisions or additions to the planned investigation or directed audit activities.
   B. Committee Review.
      1. At the completion of the investigation or directed audit, the findings (if warranted) will be taken to full Committee for review.
      2. A determination will be made by the Committee of any further actions that are to be taken.

III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.
   A. Initial complaint.
      1. When an HRPP staff member receives a verbal complaint, he/she will collect as much information as possible while completing the “HRPP Complaint Information Form”.
      2. All written complaints or completed complaint forms are to be forwarded to the HRPP Director and the Research Subject Advocate for investigation into the nature of the complaint.
A. Review and Follow-up.
1. When a complaint is substantiated, the HRPP Director will forward the complaint to the appropriate RCA for further investigation or a directed audit.
2. When the complaint involves sensitive issues, the complaint may be forwarded to the HRPP Optimization Committee for discussion and recommendations prior to initiating any activity.
3. The results of the investigation will be reported to the HRPP Director. If the complaint is study-related, the appropriate IRB Committee will also be notified of the results. If warranted, the results of the investigation will be forwarded to the IRB full Committee for further determinations and/or recommendations.
4. The RCA will forward Committee determinations and/or recommendations regarding the investigation to the HRPP Director.
5. If warranted, the HRPP Director will notify the HRPP Medical Director of the investigation or directed audit outcomes (See HRPP Policy II.B).
6. The RCA will update the HRPP database accordingly.
7. Records of the complaint and subsequent investigation will be kept in a separate file in the HRPP Office.

B. The HRPP suggestion box will be frequently checked and responses given if suggestions are not anonymous.

References
HRPP II.E - Compliants Regarding Human Subjects Research