Subject: Complaints Regarding Human Subjects Research

Definitions:
Whistle-blower: An individual who reports sensitive information to the HRPP regarding potential non-compliance issues or research activities that have potentially placed participants or others at increased risk in relationship to the conduct of the research.

Policy:
It is the policy of the HRPP to investigate all complaints received regarding human subjects research conducted under its jurisdiction.

I. The HRPP Director or the Research Subject Advocate must investigate all complaints received regarding human subjects in research under the HRPP’s jurisdiction. The level of investigation will depend on the seriousness of the situation and the potential risk to participants. Complaints may come from any source including IRB Committee members, Investigators, participants and their families, Institutional personnel, other Institutional Committees, VUMC Patient Affairs, Research Subject Advocate, the media, anonymous sources, or the public.

II. Complaints may come from any category of research reviewed and may include anyone involved or not directly involved in the research process/study.

III. Investigations should result in finding a suitable resolution and response to the complainant in a timely manner.

IV. All complaints will be handled in a confidential manner. This includes any individual involved in notifying the HRPP of an alleged violation of Investigator compliance (e.g., whistle-blower).

V. Complaints that are substantiated will be further investigated through a directed audit conducted by a Regulatory Compliance Analyst, and actions will be taken as deemed appropriate by the IRB. The IRB Committee may involve the Research Subject Advocate or VUMC Patient Affairs if applicable.

VI. Complaints of a sensitive nature may be brought to the HRPP Optimization Committee for discussion and recommendation.

VII. The HRPP houses a suggestion box on the website to voice any suggestions, concerns or complaints. If any concerns are emergent in nature or are such that a participant may potentially be placed at risk, the suggestion box states to please call the HRPP directly at (615) 322-2918 or (866) 224-8273. The suggestion box is located at: www.vanderbilt.edu/irb

References:
IRB Management and Function; Amdur, R. and Bankert, E.; 2002
HRPP II.E.1 - Procedure for Complaints Regarding Human Subjects Research