

SYRACUSE UNIVERSITY HUMAN RESEARCH PROTECTION PROGRAM STANDARD OPERATING PROCEDURES			
TITLE: COMPLAINTS REGARDING HUMAN SUBJECTS RESEARCH			DOCUMENT NUMBER: 025
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Title: COMPLAINTS REGARDING HUMAN SUBJECTS RESEARCH

1.0 Purpose:

The purpose of this Standard Operating Procedure (SOP) is to outline the actions of the Syracuse University (SU) Institutional Review Board (IRB) in managing a complaint received regarding human subjects research.

2.0 Policy:

It is the policy of the SU IRB to investigate all complaints received regarding human subjects research conducted under its jurisdiction. The ORIP Director in consultation with the IRB Chair must investigate all complaints received regarding human subjects in research under the SU IRB'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 members, investigators, participants and their families, institutional personnel, other institutional committees, the media, anonymous sources, or the public. Complaints may come from any category of research reviewed and may include anyone involved or not directly involved in the research process/study. Investigations should result in finding a suitable resolution and response to the complainant in a timely manner. All complaints will be handled in a confidential manner. This includes any individual involved in notifying the SU IRB of an alleged violation of Investigator compliance (e.g., whistleblower).

Complaints that are substantiated will be further investigated by the IRB, and actions will be taken as deemed appropriate by the IRB. The IRB houses a space on the ORIP website to voice any suggestions, concerns or complaints, which is available at <http://orip.syr.edu>. If any concerns are emergent in nature or are such that a participant may potentially be placed at risk, the website states to please call the Office of Research Integrity and Protections/IRB Office directly at (315) 443-3013.

3.0 References and Reference Documents:

SOP 027, Reporting of Unanticipated Problems Involving Risk to Participants or Others
SOP 028, Investigating and Managing Potential Issues of Non-compliance

4.0 Procedure:

4.1 Investigator Responsibilities.

- 4.1.1** It is the responsibility of the Investigator to notify the IRB 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).
- 4.1.2** 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 10 working days after the Investigator first learns of the complaint. (See *SOP 027*).

4.1.3 Investigators are to cooperate with the IRB by making documents accessible, responding to written requests within the designated time frame, and being available for questions by the IRB.

4.2 IRB Responsibilities.

4.2.1 Initial Complaint.

4.2.1.1 The IRB Chair or designee will be notified by the IRB staff member conducting the investigation.

4.2.1.2 The IRB Chair or designee, or ORIP Director may request additional information from the investigator or the person filing the complaint.

4.2.1.3 The IRB Chair or designee, decides whether the reported complaint is an unanticipated problem involving risks to participants or others in accordance with *SOP 027*.

4.2.1.4 The IRB will decide whether each reported complaint involves non-compliance in accordance with *SOP 028*.

4.2.2 IRB Review.

4.2.2.1 At the completion of the investigation the findings (if warranted) will be taken to the full IRB for review.

4.2.2.2 A determination will be made by the IRB of any further actions that are to be taken.

4.3 ORIP/IRB Responsibilities.

4.3.1 Initial Complaint.

4.3.1.1 When an IRB staff member receives a complaint, the ORIP Director or designee will collect as much information as possible while completing the “IRB Unanticipated Problem Form.”

4.3.1.2 All written complaints or completed complaint forms are to be forwarded to the ORIP Director for investigation into the nature of the complaint.

4.3.2 Review and Follow-up.

4.3.2.1 When a complaint is substantiated, the ORIP Director will forward the complaint to the IRB Chair within two working days. The ORIP Director and Chair will conduct a further investigation. The IRB Chair will make a recommendation based on the results of the investigation.

4.3.2.2 When the complaint involves sensitive issues, the IRB Chair may forward the complaint to the IRB for discussion and recommendations prior to initiating any activity.

4.3.2.3 If warranted, the results of the investigation will be forwarded to the IRB full Committee for further determinations and recommendations.

4.3.2.4 The ORIP/IRB Administrator will forward Committee determinations and/or recommendations regarding the investigation to the Investigator.

4.3.2.5 The ORIP/IRB Administrator will update the IRB protocol file accordingly.

4.3.2.6 Records of the complaint and subsequent investigation will be kept in a separate file in the IRB Office.

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