OFFICE OF THE VICE CHANCELLOR FOR RESEARCH

Office for the Protection of Research Subjects (OPRS)
Institutional Review Board
FWA# 00000083

201 AOB (MC 672)
1737 West Polk Street
Chicago, IL 60612-7227
Phone: 312 996-1711
Fax: 312 413-2929
http://research.uic.edu/human-subjects-irbs/

Complaints or Concerns Received from Subjects or Others

Version:1.3; Date: 10/31/2016
Approved by: Human Protections Administrator, Director of OPRS, and Executive IRB Chair
AAHRPP REF #: 174
AAHRPP Elements: I.4.A., I.5.C.

POLICY:

I. The UIC OPRS handles complaints or concerns received from subjects or all other individuals related to research involving human subjects in a timely and vigilant manner. This policy and procedure outlines the steps in the receipt, investigation and resolution of any complaints.

II. Individuals lodging complaints may include: subjects (past, present, or potential), family members, investigators, research staff or any person with a concern about a human subject research proposal.

III. Federal regulations require as a basic element of informed consent "an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject." (45 CFR 46.116(a)(7); 21 CFR 50.25(a)(7); and when applicable for CHAIRb reviewed research, 38 CFR 16.116(a)(7)).

IV. In accordance with these regulations, the informed consent templates contain a local and toll-free telephone number and e-mail address for contacting UIC OPRS with any concerns, complaints or questions.
   A. If additional templates are utilized, such as with CHAIRb, at a minimum, the contact information for UIC OPRS is included.

V. The "For Research Participants" section of the OPRS website provides a local telephone number for general questions and a toll-free telephone number and e-mail address for subjects or others to use for complaints or concerns. The telephone numbers and e-mail addresses for the OPRS staff, OPRS Director, and VCR are listed in the "Staff Directory" of the website.

VI. Complaints representing minor issues that do not involve potential risks to subjects or others are investigated and resolved at an administrative level by the Assistant Director of the relevant IRB. The OPRS Director and IRB Chair are consulted as necessary.

VII. Complaints that are determined by the Assistant Director in consultation with the OPRS Director and IRB Chair to represent potential risks to subjects or others are referred to either the IRB Chair or convened IRB for review and determination of further action based on the seriousness of the issue and level and immediacy of the risks.

VIII. The Assistant Director, OPRS Director, and IRB Chair (or designee) may consult with Eutive IRB Chair, University legal counsel,, or the Institutional Official for assistance in handling any complaint or concern.

PROCEDURES

I. Receipt of Complaint.
   A. When complaints or concerns are received via telephone, in person or e-mail by OPRS staff, the information is recorded on the UIC OPRS form *Subject Complaint Record – Telephone / Email Report* and forwarded to the Assistant Director of the relevant IRB.
   B. Anonymous contacts.
      1. The recipient of an anonymous complaint should inform the individual that the matter will be investigated to the extent possible given the information provided and degree of anonymity requested.
      2. The recipient should ask the caller for any available evidence that the caller is willing to give that will facilitate an investigation into the matter.
      3. The caller should not be required to provide a name or contact information.
   C. The OPRS staff member and Assistant Director handle the complaint in a confidential manner, and determine from the complainant the desired degree they wish their identity to be protected, and honor the request to the extent permitted.
   D. If the identity and contact information of the complainant is known, the OPRS staff member or Assistant Director inform the complainant that they will be provided with the findings of any inquiry and corrective action provided that the IRB is not prohibited from sharing such information based upon legal, privacy or confidentiality considerations.

II. Review of Complaint.
   A. The Assistant Director performs an initial review of the complaint including examination of the complaint form and IRB protocol file (i.e., protocol, consent documents) and, if warranted, conducts discussions with the investigator, other research team members and complainant. Discussions with the investigator and research staff are conducted in regard to the degree of confidentiality requested by the complainant.
   B. The Assistant Director determines whether the complaint represents:
      1. Non-compliance or allegation of non-compliance. If so, the complaint is reviewed according to the UIC HSPP policy, *Handling Complaints*

and Allegations of Potential Non-Compliance with Human Subject Protection Regulations.

2. An unanticipated problem involving risks to subjects or others. If so, the complaint is reviewed according to the UIC HSPP policy, *Unanticipated Problem and Other Events Requiring Prompt Reporting*.

C. If the Assistant Director, in consultation with the Associate Director/Director and IRB Chair, determines that the allegation has no basis in fact or the complaint is a minor administrative issue that is able to be resolved by the Assistant Director and does not represent non-compliance (e.g., isolated subject payment complaint), no further action is taken.

D. Complaints and allegations that are found to represent minor administrative issues (e.g., subject payment issues) and resolved by the Assistant Director are entered into a subject or other complaint log for that board. A compilation of these complaints is provided to the IRB annually to make them aware of issues and/or recurring concerns that may require new or revised policies and procedures.

E. If the Assistant Director determines that the nature of the complaint is more than an administrative issue, the Assistant Director compiles any collected information, including any response from the investigator, for the IRB Chair (or designee) to review and determine the subsequent course of action (i.e., level and process of review).

REFERENCES:

21 CFR 50.25(a)(7)
45 CFR 46.116(a)(7)

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 06/18/09	1.0, 10/15/08	Added Assistant Director of Quality Assurance/ Quality Improvement title.
1.2, 04/29/12	1.1, 06/18/09	Corrected titles within the policy.
1.3, 10/31/16	1.2, 04/29/12	Removal of IRB #4; Inclusion of links.