



SOP: Subject Complaints

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1. PURPOSE

- 1.1. This procedure establishes the process to manage subject inquiries/complaints.
- 1.2. This procedure begins when the [Subject Protection Specialist] is made aware of a subject inquiry/complaint.
- 1.3. This procedure ends when the [Subject Protection Specialist] has successfully resolved subject inquiry/ complaint.

2. POLICY

- 2.1. All subject inquiries/complaints are referred to the [Subject Protection Specialist], including complaints reported by the site/sponsor via a continuing review form or a promptly reportable information form or other method.
- 2.2. A subject inquiry or complaint includes an inquiry or complaint by a third party on behalf of a subject. This individual is referred to as the complainant in this SOP.
- 2.3. Initial reviews of new subject inquiries/complaints are to be completed within four work hours of receipt.
- 2.4. Complainants are to be contacted within 24 hours of receipt of their inquiry/complaint.
- 2.5. Ask for guidance from appropriate IRB members, managers, and staff as needed.

3. RESPONSIBILITY

- 3.1. The [Subject Protection Specialist] performs these procedures.

4. PROCEDURE

- 4.1. If the call or email is concerning a complaint, follow the process outlined below, but if the contact is just a simple inquiry from a subject/subject's representative, it is acceptable to respond to the inquiry and consider the issue resolved.
- 4.2. Verify that the complaint is not a duplicate.
- 4.3. Create a new subject complaint record and record on-going progress and resolution in the record, including association of any documents received, such as e-mails or faxes.
- 4.4. Contact the complainant to discuss the reported issue.
 - 4.4.1. Inform the complainant of the role of the IRB and ask the complainant what their expectation is for the IRB to assist in resolving concern.
 - 4.4.2. As appropriate, gather information as necessary from the complainant; e.g., subject number, e-mail address, cell phone number, work number, etc.
 - 4.4.3. Ask the complainant for permission to contact the site on their behalf.
 - 4.4.4. Ask the complainant if his or her name can be used when the site is contacted.
 - 4.4.5. Ask whether the complainant wishes to be advised when contact has been made with the site and the sponsor/ contract research organization (and institution, if applicable), and the anticipated next steps.
- 4.5. Assess the situation and identify any possible past reported complaints associated to the same research staff and or site to determine if there is a pattern of reported subject complaints.
- 4.6. If permitted by the complainant, contact the site.
 - 4.6.1. Outline the nature of the call.
 - 4.6.2. Explain that the sponsor/ contract research organization will likely be appraised of the call.
- 4.7. Notify the sponsor/contract research organization of the complaint.
- 4.8. If the study has dual or split IRB oversight, notify the other IRB that a subject complaint has been received.
- 4.9. If the investigator is at an institution for which the [Organization] is providing IRB services, notify the institution's contact.



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- 4.10. If the institution, sponsor/contract research organization, or other third parties authorized by the [Chief Compliance Officer] asks for a copy of the complaint, provide a copy and redact private information unless authorized by the complainant and requested by the requestor.
- 4.11. Follow "SOP: New Information (HRP-112)".
- 4.12. Work with the involved individuals to resolve the complaint.
 - 4.12.1. If the complaint cannot be resolved due to inaction of an involved individual, consider the complaint to be <Continuing Noncompliance> and follow "SOP: New Information (HRP-112)".
- 4.13. If requested by the complainant, advise the complainant when contact has been made with the site and the sponsor/CRO (and institution, if applicable), and the anticipated next steps.
- 4.14. If appropriate, ask the sponsor/CRO (and institution, if applicable) to keep the IRB informed of steps being taken to resolve the complaint.
- 4.15. If the complaint remains unresolved, review every 15 days and record any actions taken or reasons why the complaint remains open.
 - 4.15.1. If the complaint remains unresolved for 30 days, discuss with the appropriate IRB manager how to proceed.
- 4.16. If appropriate, draft a written response.
 - 4.16.1. Consider the privacy issues involved and the wishes of the complainant, CRO and sponsor.
 - 4.16.2. When appropriate draft separate responses to the investigator, sponsor/CRO, and institution (when applicable) following resolution of the complaint.

5. REFERENCES

- 5.1. None