1. PURPOSE

1.1. This procedure establishes the process to manage questions, concerns, and complaints related to the protection of research subjects. This procedure applies to questions, concerns, and complaints received from research subjects, KP members, third parties on behalf of subjects, research staff, research compliance staff, or others involved in research. The individual who brings up the question, concern, or complaint is referred to as the complainant in this SOP.

1.2. This procedure begins when the [Subject Protection Specialist] is made aware of a question, concern, or complaint.

1.3. This procedure ends when the [Subject Protection Specialist] has successfully resolved the question, concern, or complaint.

2. POLICY

2.1. All questions, concerns, and complaints are referred to the [Subject Protection Specialist].

2.2. Initial reviews of new subject inquiries/complaints are to be completed within one business day of receipt.

2.3. Complainants are to be contacted within two business days of receipt of their inquiry/complaint.

2.4. Appropriate IRB members, managers, staff, and other stakeholders will be engaged as needed.

2.5. The HRPP maintains accurate and complete written documentation of concerns and complaints, including all significant aspects of any investigation and its resolution.

2.6. Interventions designed to respond to participant concerns or complaints, as appropriate, will assure that reasonable and necessary steps are taken to protect the:

   2.6.1. Privacy rights of the complainant and others, as appropriate;
   
   2.6.2. Complainant, individual(s) complained against, and others, as appropriate, from retaliation; and
   
   2.6.3. Reputations of the investigators, research staff and others, as appropriate, unless and until wrongdoing has been established by due process.

2.7. Reasonable and necessary steps will be taken to minimize harm to research subjects and protect them from undue risk.

3. RESPONSIBILITY

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

4. PROCEDURE

4.1. If the issue is a question, respond as appropriate and consider the issue resolved. If the question should be followed up and/or documented as a concern/complaint, continue following this SOP.

4.2. If the issue is a concern/complaint, verify that the concern/complaint is not a duplicate from the same individual.

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. If necessary, 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 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 study staff on their behalf.
4.4.4. Ask the complainant if his or her name can be used when the study staff is contacted.
4.4.5. Ask whether the complainant wishes to be advised when contact has been made with the study staff and others, as applicable, and the anticipated next steps.

4.5. Advise the [IRB Executive Chair] and PI of the concern or complaint.
4.6. Gather relevant information and review the documentation or processes.
4.7. Assess the situation and identify any possible past reported complaints associated to the same research staff and or study to determine if there is a pattern of reported subject complaints.
4.8. Determine that the concern or complaint is unsubstantiated, substantiated, or inconclusive.\(^1\)
4.9. If the concern or complaint involves another institution via an IRB reliance agreement, notify the other IRB or institution of the issue and follow any applicable agreements.
4.10. Determine, in consultation with the [IRB Executive Chair], whether any additional actions are required. These actions may include, but are not limited to:

4.10.1. Notifying KP officials, sponsors, and/or federal agencies (e.g., unanticipated problem involving risks to subjects or others, serious or continuing noncompliance);
4.10.2. Conducting a monitoring visit;
4.10.3. Requesting additional information from the PI or others;
4.10.4. Requiring the PI to provide all participants with new information regarding the study;
4.10.5. Requiring a modification to the protocol and/or informed consent document;
4.10.6. Requiring the PI and others involved in the research to participate in additional training; and/or
4.10.7. Suspending or terminating the study to protect the participants.
4.10.8. Authorizing an assessment of the study by an independent third party to provide:

4.10.8.1. Verification that no material changes have occurred in the study since the previous IRB review;
4.10.8.2. Verification that the study is being conducted in compliance with the IRB-approved protocol;
4.10.8.3. Verification from study data or other sources that the facts of the complaint are correct; or
4.10.8.4. Other information as requested by the IRB.

4.11. If necessary, in consultation with the [IRB Executive Chair], appoint an IRB subcommittee to consider and/or resolve the concern or complaint.
4.12. Notify the complainant, the individual(s) complained against, and others as appropriate, of any findings, actions, and resolutions.
4.13. Work with the involved individuals to resolve the concern or complaint.

\(^1\) Substantiated – There is sufficient evidence to prove the allegation did occur (No question of doubt exists)
Unsubstantiated – There is evidence to prove the allegation did not occur (No question of doubt exists)
Inconclusive – The evidence does not substantively prove or disprove the allegation (Question of doubt exists)
4.13.1. If the concern or 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)”.

4.13.2. If the concern or complaint cannot be resolved for any other reason, refer it to the IRB for resolution in accordance with “SOP: New Information (HRP-112).”

4.13.3. If requested by the complainant, advise the complainant when contact has been made with the study team and others involved, and of the anticipated next steps.

4.13.4. If a sponsor or another institution or IRB is working to resolve the concern or complaint, communicate regularly to stay informed of steps they are taking to resolve the issue.


4.14.1. Consider the privacy issues involved and the wishes of the complainant, and sponsor.

4.14.2. When appropriate, draft separate responses to the investigator, sponsor, and other institution(s) following resolution of the concern or complaint.

5. REFERENCES

5.1. None