

## SOP-R-009: TC IRB Standard Operation Procedures (SOP) on Complaints from Research Subjects or Others

### Policy

The TC IRB is committed to addressing all complaints or concerns regarding the safety, welfare, and rights of research participants in a timely, confidential, and respectful manner. The investigator and research team are responsible for the welfare of enrolled participants and must respond to complaints directly when possible. All unresolved complaints must be formally reported to the IRB through Mentor IRB using the Incident Report form.

### Scope

This SOP applies to all research studies conducted under the oversight of the TC IRB, including those conducted in collaboration with external IRBs. It covers procedures for addressing complaints or concerns raised by research subjects, staff, or other individuals associated with the research process.

### Responsibilities

- **Investigators:** Responsible for responding to and resolving complaints whenever possible. Promptly report unresolved complaints to the IRB and document all complaints at the time of continuing review.
- **IRB Staff:** Initial recipients of complaints, responsible for documenting, acknowledging receipt, and forwarding complaints to the IRB Chair or designated reviewer.
- **IRB Chair or Designee:** Oversees investigation and resolution steps for unresolved or escalated complaints, involving external resources as necessary and reporting to the convened IRB or expedited reviewer.
- **Research Compliance Director:** Available to assist investigators in addressing complaints and ensure that reporting guidelines are followed.

### Procedure

When the investigator is the direct recipient of complaints or concerns, they will do the following:

1. Attempt to resolve directly with the complainant.
2. If unresolved, complete and submit an Incident Report form in Mentor IRB.
3. Summarize resolved and unresolved complaints in the Continuing Review submission.

When the IRB office is the direct recipient of complaints or concerns, the staff will do the following:

1. Document the complaint or allegation. When appropriate, the staff may request that the subject submit the complaint in writing.
2. Reassure the subject that the IRB will take all necessary measures to inquire into the circumstances and to address the issue.
3. Provide written confirmation of receipt of the complaint to the subject if the subject is willing to provide contact information.

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4. Convey the information to the IRB of record in a timely manner.
5. When appropriate, contact the investigator for additional information or to assist with resolution.
6. When appropriate, contact other resources (e.g., General Counsel, IT) to assist with information-gathering or resolution.
7. For research under the oversight of the TC IRB, the IRB Chair or designee will consider the complaint or concern and take any reasonable steps necessary to investigate and/or resolve the issue, if appropriate, prior to review and consideration by the IRB.
  - a. A report will be provided to the IRB at the next available meeting if the research is subject to convened IRB review or provided to the designated expedited reviewer if the research is eligible for expedited review.
  - b. When reviewing complaints, the IRB will consider whether the complaint was the result of, or related to, an Unanticipated Problems Involving Risks to Subjects or Others (UPIRSO) or noncompliance, and, if so, will follow the relevant procedures.
  - c. The IRB Chair or designated expedited reviewer may refer any complaint for review by the convened IRB. The IRB minutes, or reviewer comments for expedited reviews, will reflect the action(s) taken and, if necessary, notification to the appropriate officials and/or agencies.
8. The IRB Office will maintain written copies of complaints and concerns and will document the investigation and resolution.
9. The complainant will be notified promptly following resolution of the complaint or concern, when appropriate, if contact information has been provided.
10. If the IRB receives a complaint, or identifies information while investigating a complaint, that is indicative of possible misconduct in research, TC's Institutional Official (IO) will be notified immediately.

## Documentation and Record-Keeping

All reports, correspondence, and relevant documentation are retained in accordance with TC's policies for research record retention. Records include copies of the initial report, any follow-up communications, and final resolutions, if applicable.