FRED HUTCH
Institutional Review Board

Policy/Procedure

Title:	Research Participant Inquiries
Policy:	2.10
Version	3.05
Effective Date:	January 21, 2019
Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director for Karen Hansen 1/17/2019 *Signature/date*

Version History	Effective Date
3.04	07-03-2017
3.03	06-25-2014
3.02	05-15-2009
3.01	01-14-2008

POLICY STATEMENT

It is the policy of the Institutional Review Office (IRO) and the Institutional Review Board (IRB) that the research participants will be provided with ways in which to ask questions and express concerns and complaints about the research study. The complaints or questions will be addressed and responded to in a timely manner.

DEFINITIONS

None

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to IRO staff, IRB members, employees of Fred Hutchinson Cancer Research Center (Fred Hutch) and investigators from other institutions who submit research studies to the Fred Hutch IRB for review and approval.

PROCEDURES

Notification to Research Participants:

- Fred Hutch requires that the name and contact information of a principal investigator (PI), research staff person, and the IRO Director will be provided to research participants so there is a way for them to express concerns and ask questions about the research study.

- All written consents for research studies must include contact information for research participants if they have concerns about their rights as a research participant. The *Model Consent for Research Template*, available on the IRB website instructs PIs to include the appropriate contact information in the consent.[1]

The IRB will:

- Review and confirm that the appropriate safeguards and information are in place to allow research participants to ask questions and voice concerns or complaints.
- Use the *IRB Member Checklist* (071) for Full and Expedited review to ensure the appropriate contact information sections and language are included in the consent.

The IRO Director (or designee) will:

- Evaluate the inquiry to determine if the research participant inquiry involves noncompliance or an allegation of noncompliance. If it is determined there may be an issue of noncompliance the IRO director (or designee) will follow *IRB Policy 1.9 Noncompliance* (029).
- Evaluate the inquiry to determine if the research participant inquiry involves an unanticipated problem involving risks to subjects or others. If it is determined that there is an unanticipated problem involving risks to subjects or others the IRO Director (or designee) will follow *IRB Policy 2.6 Unanticipated Problems Involving Risks to Subjects or Others* (0224).

The IRO Director (or designee), PI, and research study staff are required to respond promptly and adequately to all requests for information or complaints received from research participants, prospective research participants and their family members or designated representative. The IRO Director (or designee), PI or research study staff will:

- Allow the caller to tell exactly what their concern(s) is relating to their rights as a research participant
- Ask specific questions to try and determine which research study they are involved in
- Reassure research participants that the study is voluntary if they have not yet signed the consent and are in the decision-making process
- Encourage them to discuss the issues with their physician if appropriate
- Assure them the issues will be looked into and that their concerns were heard and will be dealt with
- Stay objective and listen
- Let the research participant know you will get back with them about the resolve if they want to hear back
- Ask the research participant if they want to continue on the study and if they say no assure them that their contact information will be removed
- Obtain contact information and ask for permission to share that information with anyone you may determine might be better at addressing their concerns
- Not leave research participant contact information on voice mail or put the information in an email

[1] 45 CFR 46.116(b)(7); FDA: 21 CFR 50.25(a)(7)

If the PI or research study staff receives the complaint they will report the complaint to the IRB as soon as possible or in summary format on the *Continuing Review Report* (045) depending on the severity of the complaint.

If the IRB Staff receives a research participant complaint they will forward the complaint on to the IRO Director (or designee) who will:

- Contact the PI of the study to report the research participants concern and request feedback and possible follow-up
- Brief the IRB Chairs, IRB Committee and the Institutional Official as needed depending on the severity of the research participants complaint or concern
- Provide feedback to the research participant when appropriate
- Complete the *Research Participant Inquiry Form* (0110)

At the time of IRB New Application approval, the IRB Analysts will attach the Principal Investigator Responsibilities Memorandum (091) which will remind PIs of the reporting requirements to the IRB of research participant concerns and complaints.

SUPPORTING DOCUMENTS

IRB Policy 1.9 Noncompliance (029)
IRB Policy 2.6 Unanticipated Problems Involving Risks to Subjects or Others (0224)
Continuing Review Report (045)
IRB Member Checklist (071)
Principal Investigator Responsibilities Memorandum (091)
Research Participant Inquiry Form (0110)

REFERENCES

45 CFR 46.116
21 CFR 50.25
OHRP Compliance Activities: Common Findings and Guidance #5