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|------------------------------|-----------------------------------|
| <b>Title:</b>                | Research Participant Inquiries    |
| <b>Responsible Office:</b>   | Institutional Review Office (IRO) |
| <b>Responsible Official:</b> | Karen Hansen, IRO Director        |
|                              | <i>Karen Hansen May 6, 2009</i>   |
|                              | Signature/date                    |
| <b>Effective Date:</b>       | May 15, 2009                      |
| <b>Policy:</b>               | 2.10                              |

**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 manor.

**DEFINITIONS**

None

**REFERENCES**

45 CFR §46.116(a)(6), 45 CFR §46.116(a)(7)  
 21 CFR §50.25(a)(6), 21 CFR §50.25(a)(7)  
 45 CFR 46 Subpart A  
 OHRP Compliance Activities: Common Findings and Guidance #5

**INDIVIDUALS AFFECTED BY THIS POLICY**

The contents of this policy apply to Institutional Review Office (IRO) staff, IRB members, employees of FHCRC and investigators from other institutions who submit research studies to the FHCRC IRB for review and approval.

**PROCEDURES**

Notification to Research Participants:

- FHCRC requires that the name and contact information of a 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.

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* for Full and Expedited review to ensure the appropriate contact information sections and language are included in the consent.

The IRO Director will:

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

The IRO Director, 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, 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

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 *Continuation Review Report* 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 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 Inquiries Form*

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

## **SUPPORTING DOCUMENTS**

Research Participant Inquires Form  
Principal Investigator Responsibilities Memorandum  
Continuation Review Report  
Model Consent for Research  
IRB Member Checklist  
IRB Policy 2.6 Unanticipated Problems Involving Risks to Subjects or Others  
IRB Policy 1.9 Noncompliance