Fred Hutch Cancer Center

Institutional Review Board

Policy/Procedure

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Responsible Official / Approved By:	Meghan Scott, IRO Director

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POLICY STATEMENT

The Director of the Institutional Review Office (IRO) will report each (i) unanticipated problem involving risks to research participants or others as described in *IRB Policy 2.6 Unanticipated Problems Involving Risks to Subjects or Others* (0224), (ii) serious or continuing non-compliance as described in *IRB Policy 1.9 Noncompliance* (029) or (iii) termination or suspension of the Institutional Review Board's (IRB) approval of a study as described in *IRB Policy 1.10 Suspension or Termination of IRB Approval* (037), to all government departments and agencies that are legally required to receive a report by the later of (a) thirty (30) days after the incident is reported to the IRB or (b) ten (10) business days after the completion of the IRB's review of the incident, unless otherwise described in this policy. If the incident is considered serious, the Director of the IRO will make its report under this policy as soon as possible and may, with the concurrence of the IRB Chair, file an interim report pending completion of the IRBs review. A copy of each interim and final report will be provided to the principal investigator, the IRB, the Institutional Official (IO), the Vice President and Chief Compliance Officer and the Office of the General Counsel (OGC). The IRO Director will provide certain other information concerning the activities of the IRBs and IRO to the IO, VP and Chief Compliance Officer, and the Office of the General Counsel.

DEFINITIONS

See *HRP-001 - SOP - Glossary of Terms and Acronyms* for full definitions of the following:

Designated Government Department or Agency

Reportable Incident

INDIVIDUALS AFFECTED BY THIS POLICY

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

PRINCIPALS/OVERVIEW

Federal regulations and Fred Hutch's federalwide assurance require that Fred Hutch have procedures for ensuring prompt reporting to the IRB, institutional officials and the department or agency head of the federal department or agency responsible for conducting, funding or overseeing the affected research of (i) unanticipated problems involving risks to research participants or others, (ii) serious or continuing non-compliance or (iii) termination or suspension of IRB approval of a study. This policy describes the procedures for reporting these Reportable Incidents and certain other information to the appropriate institutional and government officials.[1]

PROCEDURES

1. Reporting Requirements Relating to Reportable Incidents

a. General Requirements

Unless otherwise described in this policy, the IRO Director (or designee) will report each Reportable Incident to all Designated Government Departments and Agencies by the later of (a) thirty (30) days after the incident is reported to the IRB under the applicable IRB policy or (b) ten (10) business days after the IRB completes its review of the incident.

If, in the reasonable judgment of the IRO Director (or designee), a Reportable Incident involves a serious risk to research participants or to the integrity of the Fred Hutch Human Research Protection Program (HRPP), the IRO Director (or designee) will report the incident to all applicable Designated Government Departments and Agencies as soon as reasonably possible after the original report of the incident is received. If the IRB has not completed its review of a Reportable Incident that the IRO Director (or designee) considers serious by the time the IRO Director (or designee) is ready to report, the IRO Director (or designee), with the concurrence of the IRB Chair, may file an interim report with all applicable Designated Government Departments and Agencies indicating when the final report is anticipated. If an interim report is made the final report will be sent to all applicable Designated Government Departments and Agencies no later than ten (10) business days after the IRB completes its review.

Unless otherwise described in this policy, the IRO Director (or designee) will send a copy of any interim or final report to the principal investigator, the IRB, the IO, the VP and Chief Compliance Officer, Office of the General Counsel, and other institutional officials as appropriate concurrently with sending the report to all applicable Designated Government Departments and Agencies. The IRO Director (or designee) will distribute subsequent communications from the Designated Government Departments and Agencies to the principal investigator, the IRB, IO, VP and Chief Compliance Officer, and the Office of the General Counsel as appropriate.

If the Designated Government Department or Agency is the funding agency, the event will also be reported to the designated individual or office at the institution where the principal investigator of the research has a primary appointment. This designated individual or office will be responsible for timely notifying the funding agency. Unless the event involves study suspension, all events will be timely reported upon resolution of the event. Designated individuals or offices include:

[1] HHS: 45 CFR 46.108(a)(4), 45 CFR 46.113; FDA: 21 CFR 56.108(b)(1)-(3), 21 CFR 56.113

- Federally funded research where the principal investigator has a primary appointment at Fred Hutch or where Fred Hutch is the prime awardee of the sponsored funding: report will be sent to the Director of the Office of Sponsored Research who will inform the appropriate funding agency.
- Federally funded research where the principal investigator has a primary appointment at the University of Washington (UW) or where UW is the prime awardee of a sponsored funding award: report will be sent to the Director at the UW Human Subjects Division.
- Federally funded research where the principal investigator has a primary appointment at Seattle Children's or where Seattle Children's is the prime awardee of a sponsored funding award: report will be sent to the Director of the Office of Institutional Assurances.
- Federally funded research where the principal investigator has a primary appointment at an outside institution: report will be sent to the signatory official on the Authorization Agreement or other appropriate HRPP contact at the outside institution.

In the event there is no Designated Government Department or Agency overseeing the research, the event will be reported directly to the IO with a copy to the principal investigator, the IRB, the VP and Chief Compliance Officer, the Office of the General Counsel, and other institutional officials as appropriate.

b. For multi-site studies for which Fred Hutch serves as the single IRB (sIRB), the following will be applied, unless an alternate reporting arrangement is agreed upon.

Fred Hutch will send a draft of the Reportable Incident to the involved Relying Institution(s). Relying Institutions are provided up to five (5) business days to review and comment before Fred Hutch sends the report to the external recipients. When a Relying institution is involved, the reporting timeline specified in section 1.a may be extended to allow for consideration of the Relying Institution's comments. However, Fred Hutch is under no obligation to adopt comments of a Relying Institution.

2. Form of Reports Relating to Reportable Incidents

Reports to all Designated Government Departments and Agencies under this policy will contain at least the information described in this section. Interim reports will contain the information described to the extent it is available at the time of the report and will state when the final report will be filed.

a. Unanticipated Problems. Reports of unanticipated problems involving risk to research participants or others should contain at least the following information:
   - Name of the Institution conducting the research.
   - Title of the research project and grant proposal.
   - Name of the Principal Investigator on the protocol.
   - Number of the research project assigned by the IRB and the number of any applicable Federal award(s) (grant, contract, cooperative agreement).
   - A detailed description of the problem.
   - Actions the institution is taking or plans to take to resolve the problem.

b. Noncompliance. Reports of serious or continuing noncompliance should contain at least the following information:
   - Name of the Institution conducting the research;
   - Title of the research project and grant proposal;
   - Name of the Principal Investigator on the protocol;
   - Number of the research project assigned by the IRB and the number of any applicable Federal award(s) (grant, contract, cooperative agreement);
   - A detailed description of the noncompliance;
   - Actions the institution is taking or plans to take to address the noncompliance.

c. Study Suspension or Termination. Reports of the suspension or termination of IRB approval of a study should contain at least the following information:
   - Name of the Institution conducting the research;

- Title of the research project and grant proposal;
- Name of the Principal Investigator on the protocol;
- Number of the research project assigned by the IRB and the number of any applicable Federal award(s) (grant, contract, cooperative agreement);
- A detailed description of the reason for the termination or suspension;
- Actions the institution is taking or plans to take to address the suspension or termination.

3. Other Reporting Requirements to Institutional Officials

In addition to the reports related to Reportable Incidents required under Section 1 of this policy, the IRO Director (or designee) will provide the IO and VP and Chief Compliance Officer with the following information:

- The approved IRB agenda outline and minutes for each IRB meeting; and
- An annual activity report on the operations of the IRBs and IRO including an assessment of the adequacy of resources available to effectively carry out their responsibilities under the HRPP. The reports are filed in IR 6284.

4. Reporting Requirements to the Association for the Accreditation of Human Research Protections Programs, Inc. (AAHRPP)

Full accreditation was awarded March 14, 2008. During the intervening years between accreditation site visits, the Fred Hutch IRO must submit reports to AAHRPP as applicable. The purpose of prompt reporting to AAHRPP is to ensure that AAHRPP is fully informed of compliance-related activities at Fred Hutch between regular accreditation site visits. The reports are stored in the J-drive (IRO > AAHRPP).

a. Annual reports:

The Annual report is due on or before the anniversary date of accreditation. The purpose of the annual report is to inform AAHRPP of the current status of the Human Research Protection Program.

b. Major Events:

Major Events must be reported to AAHRPP as soon as possible but generally within 48 hours of the organization, or any researcher, becoming aware of the event. Major Events include:

1) Any negative actions taken by a government oversight office, including but not limited to, OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA restrictions placed on IRBs or Investigators, and corresponding compliance actions taken by non-US authorities;

2) Any lawsuits relating to human research protection;

3) Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the Fred Hutch Human Research Protection Program.

4) Catastrophic event that results in an interruption of discontinuance in a component of or the entire Human Research Protection Program.

The IRO Staff will follow the steps outlined in *HRP-372 - WORKSHEET - Letters to External Organizations* when reporting Major Events to AAHRPP.

c. Re-certification:

The application to AAHRPP for re-certification must be submitted at least twelve months before a scheduled Council meeting.

SUPPORTING DOCUMENTS

IRB Policy 1.9 Noncompliance (029)

IRB Policy 1.10 Suspension or Termination of IRB Approval (037)

IRB Policy 2.6 Unanticipated Problems Involving Risks to Subjects or Others (0224)

HRP-001 - SOP - Glossary of Terms and Acronyms

HRP-372 - WORKSHEET - Letters to External Organizations

REFERENCES

45 CFR 46.108

45 CFR 46.113

21 CFR 56.108

21 CFR 56.113

DoD Directive 3216.02 Section 3.6.b(6)(d)

Reporting Incidents to OHRP: Guidance on When and How to File Incident Reports

Guidance on Reviewing and Reporting Unanticipated Problems Involving Risk to Subjects or Others and Adverse Events

OHRP Compliance Activities: Common Findings and Guidance # 22, #71 (a)-(c) and (m)-(o)

FDA Information Sheets: Continuing Review After Study Approval

Association for the Accreditation of Human Research Protections Programs, Inc. (AAHRPP): Maintaining Accreditation