

Title:	IRB Requirements for Reporting to Institutional and External Officials
Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director <i>Karen Hansen May 6, 2009</i> Signature/date
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Policy:	2.8

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*, (ii) serious or continuing non-compliance as described in *IRB Policy 1.9, Noncompliance* or (iii) termination or suspension of the IRBs approval of a study as described in *IRB Policy 1.10, Suspension and Termination of IRB Approval*, 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) seven (7) business days after the completion of the IRBs review of the incident. 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 President & Director and the Office of the General Counsel. The IRO Director will provide certain other information concerning the activities of the IRBs and IRO to the President & Director and Deputy Director.

DEFINITIONS

Designated Government Department or Agency. The federal department or agency to which Reportable Incidents must be reported under this policy and applicable federal regulations. If there is more than one Designated Government Department or Agency the reports will be made to all Designated Government Departments or Agencies.

- For research conducted, funded or overseen by the Department of Health and Human Services, the Office for Human Research Protections (OHRP) is a Designated Government Department or Agency.
- For research regulated by the Food and Drug Administration (FDA), the FDA is a Designated Government Department or Agency.
- For research conducted, funded or overseen by another federal department or agency that is a signatory to the Common rule, that department or agency is a Designated Government Department or Agency.

Reportable Incident. An incident that (i) is determined by the convened IRB to represent an unanticipated problem involving risks to research participants or others as described in *IRB Policy 2.6, Unanticipated Problems Involving Risks to Subjects or Others*, (ii) is determined by the convened IRB to represent serious or continuing non-compliance as described in *IRB Policy*

1.9, *Noncompliance* or (iii) termination or suspension of the IRBs approval of a study as described in *IRB Policy 1.10, Suspension or Termination of IRB Approval*.

REFERENCES

45 CFR §46.103(b)(5)

45 CFR §46.113

21 CFR §56.108(b)(3)

21 CFR §56.113

Guidance on Reporting Incidences to OHRP

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

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.

PRINCIPALS/OVERVIEW

Federal regulations and FHCRCs federalwide assurance require that FHCRC 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.

PROCEDURES

1. Reporting Requirements Relating to Reportable Incidents

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) seven (7) days after the IRB completes its review of the incident.

If, in the reasonable judgment of the IRO Director, a Reportable Incident involves a serious risk to research participants or to the integrity of the FHCRC human subjects protection program (HRPP), the IRO Director (or designee) will report the incident to all 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 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 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 Designated Government Departments and Agencies not later than seven (7) days after the IRB completes its review.

The IRO Director (or designee) will send a copy of any interim or final report to the principal investigator, the IRB, the President & Director (or designee) and the Office of the General Counsel concurrently with sending the report to all Designated Government Departments and Agencies.

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 relating to Reportable Incidents required under Section 1 of this policy, the IRO Director or his or her designee will provide the President & Director and the Deputy Director 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 is awarded for three years from the date of accreditation (March 14, 2008) and during the intervening years between triennial site visits, the FHCRC IRO must submit three types of reports (when applicable). The purpose of prompt reporting to AAHRPP is to ensure that AAHRPP is fully informed of compliance-related activities at FHCRC between regular triennial site visits. The reports are filed in IR 6924.

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 major changes or problems related to its Human Research Protection Program. The FHCRC must submit a standard form that includes the following information. See *Sample Annual Report form*.

- A summary or table of major problems or deficiencies identified in the last 12 months and how they were resolved;
- A brief description of all programmatic changes that positively or negatively influenced the FHCRC Human Research Protection program.
- The results of any federal review of the FHCRC Human Research Protection program.

b. Inquiries from a government oversight office:

Any inquiries from a government oversight office (e.g., Office of Human Research Protections or the Food and Drug Administration) when the inquiry could result in a for-cause investigation must be reported to AAHRPP.

Inquiries of this nature must be reported to AAHRPP preferably within 72 hours. The IRO Staff will follow the steps outlined in the *IRB Staff Screener: Letters to External Organizations*.

c. Any sanctions taken by a government oversight office:

Any sanction taken by a government oversight office must be reported to AAHRPP within 24 hours. The IRO Staff will follow the steps outlined in the *IRB Staff Screener: Letters to External Organizations*.

Re-certification

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

SUPPORTING DOCUMENTS

IRB Policy 2.6 Unanticipated Problems Involving Risks to Subjects or Others
IRB Policy 1.9 Noncompliance IRB Policy 1.10 Suspension or Termination of IRB Approval
Screener: Expedited Reporting and Adverse Event (AE) Reporting Forms
Screener: Expedited Reporting and 3rd Party Safety Reporting Forms Screener: Expedited Reporting Form for Unanticipated Problems and Noncompliance
Screener: Expedited Reporting Form for Unanticipated Problems or Noncompliance
Screener: Allegation of Human Subjects Research Noncompliance Reporting Form
Template Letter to Applicable Federal Agencies Reporting
Screener: Letter to External Organizations
Annual Activity Report
Sample AAHRPP Annual Report form