

Title:	Communications
Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director
	<i>Signature/date</i>
Effective Date:	August 1, 2007
Policy:	2.21

POLICY STATEMENT

It is the policy of the Fred Hutchinson Cancer Research Center (FHCRC) that the Institutional Review Board (IRB) reviews the methods and materials principal investigators (PIs) plan to use to communicate with their research participants in order to safeguard their safety and welfare, as well as to protect their confidentiality and privacy.

It is the policy of Fred Hutchinson Cancer Research Center (FHCRC) that all study recruitment materials that will be used to recruit potential research participants must first receive IRB review and approval prior to use of the material. IRB review is required to ensure that the information contained in the materials is not misleading or imbalanced, coercive, or promises a certainty of cure beyond what is outlined in the consent and the protocol to potential research participants especially when the study may involve vulnerable (e.g. children, pregnant women) research participants.

DEFINITIONS

None.

REFERENCES

21CFR312.7(a)
 21CFR812.7(d)
 OHRP Guidance on Institutional Review Board Review of Clinical Trial Websites
 45 CFR 46.109(b)
 FDA Information Sheets: Investigational Studies – Updated 9/1998. Recruiting found at <http://www.fda.gov/oc/ohrt/irbs/toc4.html#recruiting>)
 FHCRC Writing Style Sheet

PRINCIPLES/OVERVIEW

The FHCRC IRB follows policies and procedures to review and approve materials used to communicate with research participants and others for various purposes, including recruitment. This policy also describes the methods used by the Institutional Review Office (IRO) to communicate information to investigators.

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

1. Handling media relations

Any media inquiries should be directed to the FHCRC Communications Officer at 667-2896.

Study specific information cannot be provided by the IRO staff. All records are treated as confidential and it is the responsibility of the Communications Officer to make the appropriate authorizations for release of study information.

2. Referencing FHCRC in publication or other research related correspondence

Per the [FHCRC Writing Style Sheet](#), when including Fred Hutchinson Cancer Research Center, use the complete name in first reference. Do not precede with “the.” In subsequent references, use “the Hutchinson Center” or “the Center.” Do not use “FHCRC” or “the Hutch.” Exception: In *Center News* and other pieces for an internal audience, the full name is generally not needed in first reference. If needed, “Center” or “Hutchinson Center” may be used in first reference in these publications.

3. IRO eNewsletter

- a. The IRO eNewsletter provides “real time” information and updates relevant to human subjects research protection program to FHCRC Investigators and the research community. See *Sample eNewsletter*.
- b. Developing the eNewsletter
 - When IRO staff has new and updated information (e.g. updated federal regulations), they will email the draft article to the IRO Administrative Assistant (AA) I.
 - The IRO AA will format the article(s) into a new eNewsletter template and email back to the author(s) of the article(s) for their final review.
 - The author(s) will review the article(s) and provide additional edits to the IRO AA, if necessary.
 - The IRO AA will forward the draft eNewsletter to the IRO Assistant Director for review.
 - After the IRO Assistant Director’s review, the draft eNewsletter will be forwarded to the IRO Director for final review.
 - The IRO Assistant Director is the contact person for non IRO staff who are requesting information to be included in the eNewsletter.
- c. Disseminating the eNewsletter
 - The IRO AA maintains email distribution lists, which includes research and administrative staff at FHCRC, CHRMC, UW and other institutions involved in human subjects research.
 - New staff names are given to the IRO AA to add to the email distribution list.
 - The eNewsletter is also distributed to individuals at the Seattle Cancer Care Alliance (SCCA), Radiation Safety Review Committees, pharmacy and other outside review entities as applicable.

- When the IRO Director finalizes the eNewsletter, the IRO AA will email the eNewsletter using the email distribution lists.
 - The IRO web editor adds the eNewsletter to the IRO webpage.
- d. Timing of eNewsletter
- The eNewsletter is published once a year, or more frequently if required.

4. Subpoenas or Legal Requests

The IRO records may be subpoenaed. The following guidelines have been developed with FHCRC general counsel to assist IRO staff to respond appropriately to such requests.

- a. Anyone attempting to serve a subpoena or any legal documents directly on IRO staff should be directed to serve the subpoena on the General Counsel of FHCRC, Doug Shaeffer. If for any reason a subpoena or other legal document should be served on IRO staff, the subpoena should be delivered promptly (the same day) to the General Counsel's office.
- b. After a subpoena is received by FHCRC General Counsel's office, that office will advise the IRO staff if records are required from the IRO based on the subpoena or legal documents. Typically, IRO records such as meeting minutes and related IRO documents must be produced.
- c. When reproducing IRO documents, identify any documents for legal counsel that you believe may be confidential. Often IRO records contain confidential or proprietary information that can often be protected by a court order.
- d. If there are agreements with private sponsors such as drug companies, legal counsel will review applicable contracts to determine what notice must be given to the sponsor. As a courtesy, the IRO Director or IRO Assistant Director notifies the PI of a study being produced.
- e. The FHCRC general counsel is Doug Shaeffer, 667-6493. If Mr. Shaeffer is not available and you need immediate assistance, contact Associate General Counsel, Gerianne Sands at 667-1224. If neither can be reached, contact Myra Tanita, Executive Vice President and Chief Operating Officer at 667-5987.

5. Doctor to Doctor Letters

Letters that are sent by FHCRC PIs to physicians affiliated with outside clinics or institutions providing basic information about FHCRC investigators' research studies to outside physicians do not require IRB approval. For further guidance on recruitment please see *IRB Policy 2.0 Recruitment Methods, Advertising Materials, and Participation Payment*

SUPPORTING DOCUMENTS

Sample eNewsletter

IRO Policy 2.0 Recruitment Methods, Advertising Materials, and Participation Payment