


Title:	Funding Source Document (FSD) Review
Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director
	 7/28/09
	Signature/date
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Policy:	2.18

POLICY STATEMENT

The Fred Hutchinson Cancer Research Center (FHCRC) Institutional Review Office (IRO) is responsible to review the funding source document (FSD) with the research activity it supports. This funding source review assures at a minimum, that there are adequate resources to conduct the research activity and to confirm that the activity described in the funding proposal matches the activity proposed in the application form. The IRO is also responsible to issue when appropriate, any assurance, certification, or declaration forms indicating that the protection of research participants regulations have been met.

DEFINITIONS

Attachment A: The internal routing and approval form submitted along with a proposal for an activity to be performed at FHCRC under a grant, contract or other sponsored agreement.

Funding Source Document (FSD): The grant, contract or other sponsored agreement that supports the research study.

Just-in-Time (JIT): This status applies to any new or competing funding proposal in which the principal investigator (PI) provides assurance that if the funding proposal is approved and there is no IRB file, the PI will submit the appropriate IRB application for review and approval before initiating research with human subjects.

REFERENCES

OHRP Guidance: IRB Review of Applications for HHS Support

PRINCIPLES/OVERVIEW

The FHCRC IRO developed policies and procedures to ensure that Principal Investigators and study staff provide information in the Attachment A that is both accurate and current. It is also the responsibility of the IRO to review all FSDs related to a research study to safeguard the safety and welfare of its research participants.

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. Attachment A Procedures

2. The IRO provides periodic training and decision support tools to investigators and their teams regarding Attachment A and associated requirements for completing their grant applications. Funding source document (FSD) review

- a. The NIH requires that the grant application, and the human subjects research activity to be supported by it, be reviewed by the IRB. FHCRC extends the NIH requirement to review grant proposals to all types and sources of funding, including industry contracts and private foundation funding. Review of the FSD is a necessary and integral part of IRB review.

All parts of the FSD that might directly or indirectly affect the conduct of human research must be reviewed—including but not limited to sections on specific aims, methods, human subjects, budget, personnel, and facilities. If a new application is submitted without a referenced grant proposal, the application is determined to be incomplete and review will not take place until the FSD has been submitted.

- b. When adding a new funding source or deleting a funding source to/from an existing IR file, the PI submits a *Protocol Modification Form* with the FSD attached. A *Funding Source Supplement Form* is used when submitting a new funding source. See *IRB 2.5 Policy Modifications to Ongoing Activities*.

If adding or deleting a funding source is in addition to other modifications, a separate *Protocol Modification Form* is not required. However, the *Protocol Modification Form* must clearly mention the FSD addition or deletion.

- **Face Page:** If the new funding source is a NIH application, the IRB requests that the Face Page be submitted because it includes the following required information:
 - i. Name of the Principal Investigator listed on the FSD
 - ii. Title of the Proposal
 - iii. Name of the Funding Agency
 - iv. Support Dates
 - **Grant applications:** Full copy of most recent competing application (new, competing renewal, supplement, etc.). "Full" is everything but appendices. "Full" means the face page, personnel, budget, facilities pages as well as scientific and human subjects sections. "Specific aims" section is not sufficient, nor is a progress report from a non-competing continuation. Individual salaries may be blacked out, but the overall budget information must be provided. For program project grants, submit the relevant project(s), from the most recent competing application.
- c. If the new funding source involves an industry sponsored agreement, a Research Trials Office (RTO) *Industry Sponsorship Form* and Final Contract memo must be completed and submitted along with the *Application for Review* or *Protocol Modification Form* (to an existing IR File) to the IRB. When the final contract is signed, a copy of the contract

must be submitted to the IRB for review with a copy of the most currently proposed consent document(s).

The final contract and the most currently proposed consent document(s) are reviewed by Office of the General Counsel.

- d. When a competitive renewal proposal has been awarded, the PI submits a copy of the proposal for IRB review along with the face page and *Protocol Modification Form*.
- e. If the *Continuation Review Report* lacks a requested FSD, it is incomplete and will not be reviewed until the FSD is supplied. This can cause a lapse in IRB approval.
- f. Contracts involve three parts:
 - i. study protocol
 - ii. investigator brochure (if one exists)
 - iii. the contract/research agreement (which is usually the only source of information about budget and about statements re: indemnification for adverse events).

For clinical trials, the study protocol and investigator brochure are already part of the IRB application, so only contract/research agreement needs to be submitted. (However, if new contract support is added, all elements of the new FSD do need to be submitted for review, unless already received as part of a modification request).

All other sponsored research must submit all three parts of the FSD, as appropriate.

- g. Exceptions:
 - Copies of the Core grant are not required because it undergoes a comprehensive separate review.
 - Cooperative Oncology Group studies (i.e. NSABP, GOG) do not require individual FSD's since the FSD is reviewed with the "master" coordinating center.
 - Cooperative review files do not need FSD review, since the IRB of record reviews the FSD.
- h. The IRO is also responsible for the FSD review for the Institutional Animal Care and Use Committee (IACUC) activities.

3. Certification of Approval

If a funding proposal is awarded, the PI may request an IRB certification and the IRO staff follows the instructions in the *Screener: Certification of Approval*.

4. IRO Approval for Limited Activity

- a. PIs submit the *IRO Approval for Limited Activity Form* requesting release of funds prior to IRB or IACUC review. The activities may not involve the use of human subjects or live vertebrate. Only activities that are clearly severable and independent from activities that involve human or animal subjects may be conducted under this award until the project has received approvals, and approvals have been submitted and accepted by the agency as appropriate.
- b. The IRO staff follows the instructions in the *Screener: IRO Approval for Limited Activity*.

SUPPORTING DOCUMENTS

IRB 2.1 Policy New Application

IRB 2.5 Policy Modification to Ongoing Activities

IRB 2.20 Policy Training

Application For Review
Continuation Review Report
Funding Source Supplement
Just In Time Letter
Screener: Certification of Approval
Human Subjects Use Certification Letter
IRB Assurance Identification IRB Certification Declaration of Exemption Form
OSR Attachment A
RTO Industry Sponsorship Form
RTO Final Contract Memo
IRO Approval for Limited Activity
Screener: IRO Approval of Limited Activity