

<b>Title:</b>	Cooperative Review Agreements
<b>Responsible Office:</b>	Institutional Review Office (IRO)
<b>Responsible Official:</b>	Karen Hansen, IRO Director
	<i>Signature/date</i>
<b>Effective Date:</b>	August 1, 2007
<b>Policy:</b>	2.3

---

## **POLICY STATEMENT**

FHCRC will comply with the requirements set forth in 45 CFR 46, Section 114 regarding cooperative research projects. These institutions may accept, for the purpose of meeting the IRB review requirements, the review of an IRB established under another assurance of compliance with DHHS. Such acceptance will be in writing, approved and signed by this institutions' directors, approved and signed by correlative officials of each of the other cooperating institutions.

---

## **DEFINITIONS**

None

---

## **REFERENCES**

45 CFR 46.114

---

## **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. Institutions**

FHCRC has six signed Cooperative Review Agreements with organizations within the state of Washington. The following institutions are involved in these agreements and copies are appended to this policy:

- Children's Hospital and Medical Center (CHMC)
- Group Health Cooperative (GHC)
- Swedish Medical Center (SMC)
- University of Washington (UW)
- Benaroya Research Institute at Virginia Mason (BRI at VM) (formerly Virginia Mason Research Center (VMRC) / Virginia Mason Medical Center (VMMC)
- Washington State Department of Health (WSDH)

## 2. Referencing cooperative review reliance at the time of institutional sign-off for funding activities undertaken with cooperative institutions

### a. Grant Sign Off:

If a funding proposal's human subject activity has been reviewed by an organization's IRB with whom FHCRC has a cooperative review agreement, the FHCRC Principal Investigator (PI) provides the IRO a copy of the most current approval documents filed with the cooperative site's Institutional Review Board within 30 days of the cooperative site's approval.

### b. FHCRC IRB Review Process:

The FHCRC PI will:

- Provide the FHCRC IRB a copy of the *Protocol Disposition Form for Application For Review or Continuation Review Report (CRR)*
- Provide all formally APPROVED documents (IRB approval form, protocol, consent, questionnaires, etc.) after the cooperative IRBs review process have been complete. (All signatures and dates of approval must be included.)

The IRO Staff will:

- Follow all steps noted on the following screeners:
  - *Screener: New Cooperative Application Form*
  - *Screener: CRR Cooperative Form*
- Aid the FHCRC PI by the distribution of a *Cooperative Review CRR Renewal Notice* reminding them of any upcoming cooperative study expiration(s). It is the responsibility of the FHCRC PI to contact the cooperative site's Institutional Review Board Office to familiarize themselves with the cooperative site's review procedures.
- Forward the documents to the FHCRC IRB Chair at the time of New Application or CRR. Note: Funding Source Document (FSD) review is not required for Cooperative applications because the IRB of record will have reviewed the FSD.
- Confirm that the approval information will be included in the Expedited Agenda that will be provided to the Full FHCRC IRB Committee at the next available Committee meeting.

If a certification form of any type is requested from funding agencies, the FHCRC Institutional Review file must be current and valid.

---

## SUPPORTING DOCUMENTS

CRR Cooperative Renewal Notice  
Screener: New Cooperative Application Form  
Screener: CRR Cooperative Form  
Protocol Disposition Form

---

## ATTACHMENTS

Cooperative Review Agreements within State of Washington:

- Children's Hospital and Regional Medical Center (CHMC)
- Group Health Cooperative (GHC)
- Swedish Medical Center (SMC)
- University of Washington (UW)
- Benaroya Research Institute at Virginia Mason (BRI at VM)
- Washington State Department of Health (WSDH)