

HIMORN IRB Workshop

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HMORN IRB Workshop

■ Agenda

- Overview of some alternative models
- Recap of CCSN progress in streamlining IRB review
- Discuss resources & tools needed to help overcome barriers
- Discuss where we'd like to be in 5 years

Alternative IRB Models

Alternative IRB Models

- I. Local IRB review - single site study
 - Local IRB reviews research at its own site
- II. Local IRB review - multi-site study
 - Each local IRB participating in a multi-site study does its own review

Alternative IRB Models

- III. Institution relies on another institution's IRB review – single site study
 - For a given study, one institution turns to the IRB of another (e.g., the latter has more appropriate expertise)
- IV. Independent IRB review – single or multi-site studies
 - A single independent (commercial) IRB conducts review on behalf of one or more sites - all sites accept the independent review - no local review (e.g., Western, Chesapeake, Quorum)

Alternative IRB Models

- V. Facilitated central IRB review – multi-site studies
 - Local IRB or representative accepts central IRB review, modifies it, or conducts full review (e.g., NCI Central IRB [CIRB])
- VI. IRB reciprocity – multi-site studies
 - Different sites form a consortium and utilize the IRB of one of the sites for review of a collaborative protocol (e.g., the Multicenter Academic Clinical Research Organization [MACRO], a consortium of 4 academic medical centers)

IRB Models

- VII. Local IRBs share common materials and exchange information to facilitate work on multi-site studies (e.g., IRBNet)
- VIII. A national and regional IRB review the same protocol concurrently (e.g., Indian Health Service)

IRB Models

- IX. Sites form a consortium and a new entity is created for review purposes (e.g., Biomedical Research Alliance of New York [BRANY])
- X. Multiple IRBs review protocol – single site studies
 - Multiple IRBs review research at a single foreign site (e.g., U.S. IRB, foreign IRB, and sponsor's IRB such as NIH)

**CCSN Progress on
Streamlining Multi-site
IRB Review**

Streamlining Multi-site Review in the HMORN

- Streamlining the current review process

CCSN Web-based IRB Navigation Tool

- site-by-site guide to IRB processes & timelines
- IRB forms & templates (where available)

- Consider future models for Multi-site IRB Review in the HMORN

Web-based IRB Navigation Tool

The screenshot displays the CCSN website interface. At the top left, the logo 'CCSN The Coordinated Clinical Studies Network of the HMORN' is visible, with a '[Log off]' link. A navigation menu includes 'Home', 'Projects', 'Documents', 'Calendar', 'Directory', 'Groups', and 'My Info'. On the top right, there is a search box for 'Specific Content' with fields for 'Keyword(s):', 'Type:', and a 'Go' button. Below the navigation, the page is divided into several sections:

- Network stats at-a-glance:** Includes a 'Click to collapse list' link and a list of member organizations: Group Health Cooperative, Harvard Pilgrim Health Care, Health Partners Research Foundation, Henry Ford Health System, KP Colorado, KP Georgia, KP Northern California, KP Northwest/Hawaii, KP Southern California, Lovelace Clinic Foundation, and Meyers Primary Care Institute.
- CCSN Projects:** Includes a 'Click to collapse list' link and a list of project areas: Analytic cores, Budget, Closeout, Coordinating trials, Governance, IT, Recruitment & Survey Research, Research Review, and System liaisons. A yellow arrow points to the 'Coordinating trials' link, which is circled in yellow.
- Our mission...:** States the mission of the CCSN to foster a sustainable, shared research infrastructure to enhance collaborative multi-site clinical research.
- CCSN Project overview:** A section header.
- Multisite Studies Guide:** Includes links to guides for optimizing recruitment and data collection in multi-site studies.
- Data Resources:** Includes links to the NIH Roadmap/Reengineering the Clinical Research Enterprise, the Roadmap Clinical Research Network web portal, NIH Roadmap, and NIH funding opportunities.
- The HMO Research Network and its Consortium Projects:** Lists various research networks and consortia such as HMO Research Network, Centers for Education and Research on Therapeutics, Cancer Research Network, Integrated Delivery System Research Network (IDSRN), and CanCORS.
- Data Standards Development:** Includes links to the Clinical Data Interchange Standards Consortium and the NCI Center for Bioinformatics.
- What is new!:** A section for announcements, currently showing 'Announcement Archive'.
- What is still to come?:** Another section for announcements, also showing 'Announcement Archive'.

(<https://www.kpchr.org/ccsn>)

Web-based IRB Navigation Tool

Research Review
[-] Click to collapse list

Introduction
Review Requirements & Timelines by Site
Group Health Cooperative
Harvard Pilgrim Health Care
Health Partners Research Foundation
Henry Ford Health System
KP Colorado
KP Georgia
KP Hawaii
KP Northern California
KP Northwest
KP Southern California
Lovelace Clinic Foundation
Meyers Primary Care Institute

Repository of Application Forms, Templates & Guidelines
External Links to IRB Resources

CCSN Projects
[-] Click to collapse list

Analytic cores
Budget
Closeout
Coordinating trials
Governance
IT
Recruitment & Survey Research
Research Review
System Issues
Network stats at-a-glance
[-] Click to collapse list

Review Requirements and Timelines by Site

Review requirements and timelines for each site:

Group Health Cooperative	Kaiser Permanente Hawaii
Harvard Pilgrim Health Care	Kaiser Permanente Northern California
Health Partners Research Foundation	Kaiser Permanente Northwest
Henry Ford Health System	Kaiser Permanente Southern California
Kaiser Permanente Colorado	Lovelace Clinic Foundation
Kaiser Permanente Georgia	Meyers Primary Care Institute

Review requirements and timelines for each site are presented in a series of tables on the following topics (select the site from the drop down list of topic you want to review):

- The **Overview** table provides a description of the IRB, meeting details and schedules, and contact information for the Administrator and other key staff members.
- **Application, Submission, and Timeline Details** includes information on how to apply for IRB approval at each site. Whenever possible, links to relevant application forms have been provided.
- **Approval and Review Details** describes the range of IRB decisions at each site. This table also provides details on expedited review and coding review authority.
- The **Additional Reviews** table lists other compulsory review processes or committees.
- The **Institutional Guidelines** table provides information on various requirements at each site, such as investigator training and informed consent guidelines. Whenever possible, links to guiding documents and public websites have been provided.
- **State Guidelines** describes relevant state laws and regulations that affect research activities.

Web-based IRB Navigation Tool

- Analytic cores
- Budget
- Closeout
- Coordinating trials
- Governance
- IT
- Recruitment & Survey Research
- Research Review
- System liaisons
- Network stats at-a-glance
- Click to collapse list

- Group Health Cooperative
- Harvard Pilgrim Health Care
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- Henry Ford Health System
- KP Colorado
- KP Georgia
- KP Northern California
- KP Northwest/Hawaii
- KP Southern California
- Lovelace Clinic Foundation
- Meyers Primary Care Institute

Overview

IRB Details	<ul style="list-style-type: none"> 17 members, 1-4 new full Board reviews per month Not accredited (but thinking about it)
Administrator and primary contact	<ul style="list-style-type: none"> Bobette Godding 651-254-3391 bobette.k.godding@HealthPartners.com <p>8100 34th Ave S PO Box 1524, MS 21111R Minneapolis, MN 55440</p>
Meeting schedule and details	<ul style="list-style-type: none"> Once per month on the third Thursday. PIs do not attend meetings.
Review responsibilities	<ul style="list-style-type: none"> Human subjects protection, HIPAA compliance (as it relates to research review)

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Application, Submission, and Timeline Details

Application	<ul style="list-style-type: none"> 4 types of application forms: Clinical Research, Health Services Research, Exempt Research 1&2, and Exempt Research 4 One application form fulfills additional review requirements (see Table 4: Additional Reviews). Instructions and checklists are included in the application forms, which are available on a public website. www.hprf.org
Submission	<ul style="list-style-type: none"> Submit 1 original & 15 copies Paper submissions only.
Timeline	<ul style="list-style-type: none"> Applications are due 1 month before the IRB meeting, on the 3rd Friday of the preceding month. 2006 submission deadlines Report to PI usually sent within three days of the meeting. 4.5 weeks from submission until PI is notified of decision.

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Approval and Review Types

Range of Decisions	<ul style="list-style-type: none"> Approval, Approval with stipulations, Deferral, Disapproval
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Web-based IRB Navigation Tool

Approval and Review Types	
Range of Decisions	<ul style="list-style-type: none"> Approval, Approval with minor modifications, Contingent Approval (if modifications are more extensive), Deferral, Disapproval
Expedited review	<ul style="list-style-type: none"> Yes, per Regulations 45CFR46.110 and Kaiser SOPs New applications are only expedited if they are studies of existing data or anonymous survey (i.e. – no contact with any subjects). Clinical trials are always reviewed by the convened board; administrative changes may be reviewed by Expedited procedures as applicable. Modifications may be expedited if the initial review was expedited. The average timeline for expedited review is approximately 2 weeks.
Ceding IRB Review Authority	<ul style="list-style-type: none"> Yes, on a case by case within Kaiser, using the Interregional Application
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Additional Reviews	
Other review committees	<ul style="list-style-type: none"> Research Committee (RC) – Review of scientific merit and organizational/delivery system impact. RC reviews a study even if it is exempt from IRB review. Projects that are not approved by the RC cannot be conducted at KPGA. RC meets once per month on the fourth Friday.
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Institutional Guidelines	
General guidelines or requirements	<p>Georgia Regional Guidelines</p> <ul style="list-style-type: none"> General guidelines and requirements are provided in Investigator & Research Staff Guidelines for Submitting a Research Proposal KPGA investigator required for all studies; IRB application must come from the local investigator Outside projects must be compatible and in line with regional goals as determined by the RC. Educational requirements for investigators, including the exam piece of the NIH Human Subjects training and HIPAA privacy training specific to research. All consent forms are finalized by an on-staff paralegal prior to review by the IRB. <p>Click here for Kaiser Permanente program-wide forms, guidelines and policies.</p>
Written guidelines, checklists, and	

New Models for IRB Review

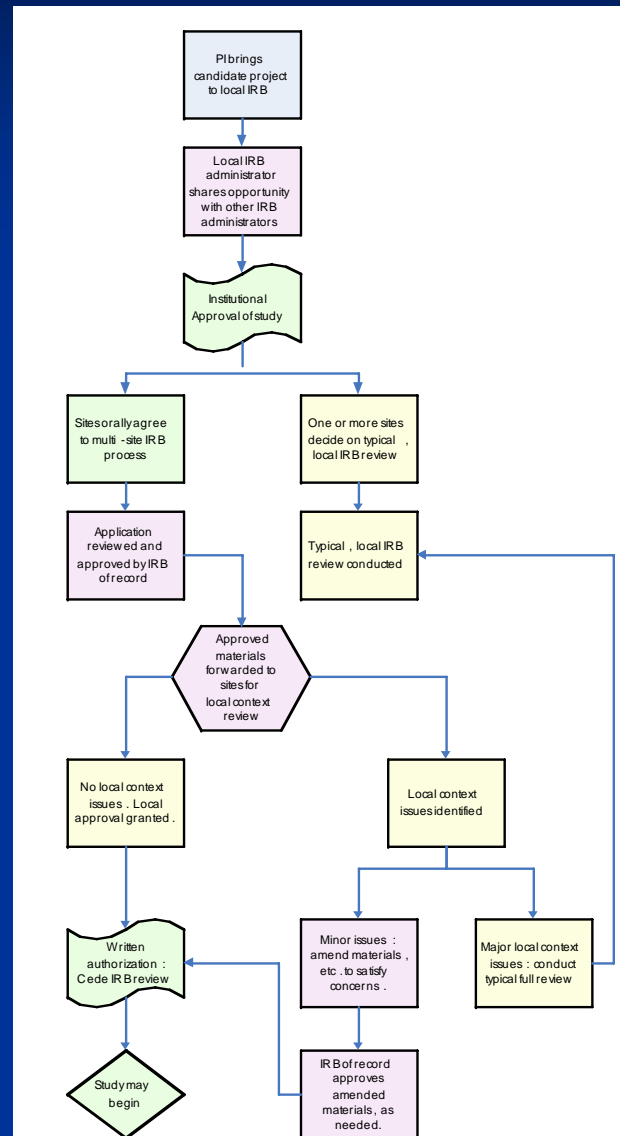
- Held workshop with HMORN IRB administrators/chairs in late 2006
- All 15 HMORN IRBs were represented
- Discussed alternative models in detail for consideration in the HMORN
- focusing on risks & benefits, and ethical, financial, technical and interpersonal aspects
- Models of particular interest were a Central IRB (like the VA), a Facilitated Central IRB (like the NCI CIRB), and the models that were predicated on ceding or reciprocity (like the MACRO and BRANY consortia).

New Models for IRB Review

- Agreed that we should pilot a consortium approach using a distributed model
- Consider only low-risk data-only studies to start
- The model employs a lead IRB (where the Principal Investigator resides) and other IRBs would either agree to cede review authority or conduct own review
- Agreed to use other IRBs forms

New Models for IRB Review

Process Diagram for
Proposed HMORN
Multi-site IRB Review



New Models for IRB Review

IRB Pilot

- Initial pilot of 3 studies
- Include only low-risk, data-only studies
- At least 3 sites with both Kaiser and non-Kaiser members
- Looking for investigators willing to work with IRB administrators as new process develops

Discussion, Part 1

- **What resources & tools do IRB administrators and investigators need to help overcome barriers to acceptance of multi-site review?**
- **Are there natural experiments taking place?**
- **Are there data we can collect on the current process to inform future directions?**

Discussion, Part 2

- If everything aligned, (culture, process, policies), what would we want the HMORN's IRB review environment to look like in 3-5 years?
- How would we accommodate other review elements (e.g., impact reviews) at the local site?
- How will this apply to studies, other than data-only studies?
- Is it conceivable that the HMORN could create a specialized health services IRB available to others?