

IRB CONSULTATION

by the HCSRN IRB Workgroup

The HCSRN IRB Workgroup has developed standard operating procedures and streamlined processes for facilitating ceded IRB review among HCSRN sites. The IRB workgroup now offers consulting to individual research teams on preparing multi-site IRB submissions, use of the Network's ceding process, and more.

Purpose:

To facilitate use of the HCSRN IRB ceding SOP, streamline IRB review involving multiple institutions, and support project teams in order to reduce overall review time and ensure a positive and successful review process for all sites participating in a study.

There is no charge for this service. Requests for consultation will be scheduled on a first-come first-served basis for HCSRN members and collaborators.

Method:

The IRB Workgroup will provide these services as follows:

1. **Disseminate** the availability of the consulting services through the HCSRN listserv, website, Governing Board and Asset Stewardship Committee.
2. **Pre-screen** each request to ensure applicability and obtain the consultation question from the requestor(s). This information will be shared via the IRB Workgroup listserv prior to each call.
3. **Schedule** consultation on a first come, first serve basis during the monthly IRB Workgroup call, and spend no more than 30 minutes on consultation per call. [beginning October 2015]
4. **Address** requests on the call by referring to the specific consultation question(s) and asking for suggestions from IRB Workgroup members attending the call.
5. **Write up** the suggestions and disseminate to IRB listserv members and post to IRB Workgroup space in the Central Workbench portal site.
6. **Evaluate** consultations by following up with each requester.

Examples of Questions:

- I have a study involving sensitive patient data. What kind of concerns might IRBs have so I can address them up front and proactively?
- My multi-site study involves multiple phases and sub-studies. Not every site participates in every sub-activity. How can I structure the IRB proposal(s) to be clear and easy for IRB members to understand and review?
- What are the pros/cons of using an external IRB? Reviewing site by site? Using the ceding process?
- Only some sites are willing to cede (or part of the HCSRN). Should I still use the ceding process?

FOR MORE INFORMATION OR TO REQUEST A CONSULT:

Contact the IRB Workgroup Co-chair, Paula Tebeau (paula_tebeau@harvardpilgrim.org).