

Creating in Independent Community IRB: When is it right for you?

**Conference Call Series on Institutional Review Boards
and Ethical Issues in Research**

Co-sponsored by

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Hy'shqe siam

- *Thank you respected mentors & teachers*
 - Francine Romero
 - Sam Deloria
 - Wylie Burke
 - Laura Arbour
 - Roger Gollub
 - Ann Macaulay
 - Alex McComber
 - Jerry Mohatt
 - Terry Powell
 - + many others
- *Thank you respected wife*
 - Carolyn M. Robbins

Why do communities form their own IRB?

– from the prior presentations

- *Growing trend*
- *To ensure that community "has a voice"*
- *Required by funder*
- *To protect special features of the community*
- *No or little representation on university IRB[s]*
- *To ensure truly informed consent by community members in the community*

Two frequent motivators for communities to start their own IRB

- *A bad experience with research, in this community or a related community*
 - to prevent a similar bad experience from happening
- *The community's assertion of control*

Practical challenges to form & maintain an IRB - 1

- *Staffing*
- *Other Support resources*
- *Develop Policies and Procedures ("P&Ps")*
- *Time to develop the IRB*
 - one year!
 - including learning about the process
- *Person-intensive, work-intensive, & time-intensive!*

Possible aids to help with challenges - 1a

- *Borrow P&Ps from other IRBs*
 - still need to spend much time going over the borrowed P&Ps -- to understand them, revise them to your circumstances, etc.
 - but much less time than writing them from nothing

Possible aids to help with challenges - 1b

- *Attend conferences*
 - regional and national
 - PRIM&R -- Public Responsibility in Medicine and Research -- <http://www.primr.org>
 - Annual Human Research Protection Program Conference
 - December 1-4, 2007 - Boston, MA
 - special scholarships for new or developing IRBs in institutions serving medically underserved population
 - contact for scholarship program: Maeve Luthin - MLuthin@primr.org
 - webpage for scholarship program will be up in ~1 month

Possible aids to help with challenges - 1c

- *Do "on the job" learning*
 - (our best learning often is when we are doing what we need to learn)
 - for example, have as an active member of your IRB a knowledgeable & experienced IRBer from a nearby IRB
 - must believe in the need for and worth of your IRB!
 - must be willing to discuss the human research protection issues, and the IRB regulations, involved in each protocol as the IRB reviews it

Practical challenges to form & maintain an IRB - 2

- *"[Some] researchers [may] question the need to obtain community IRB approval when they've already received university/hospital IRB approval"*

Solutions to challenge - 2a

- *Get OHRP's "stamp of approval" [my term]*
 - Office for Human Research Protections
 - <http://www.hhs.gov/ohrp/>
 - first - Register your IRB
 - second - Apply for a Federal-Wide Assurance
- *Use OHRP's FWA status for your IRB*
 - FWA IRBs can pressure federal funders to make researchers comply with the IRB

Solutions to challenge - 2b

- *Researcher and community organization agreement about terms of doing the research in the community*
 - consider a mutual contract, signed
 - meet the requirement for a legal contract
 - community may need a lawyer to include the required elements

Additional Help:

See my handout to Tribes & TCUs on the webpage for today's Conference

- *Reasons to form an IRB*
- *National and regional resources*
- *How to fill out Registration for IRB and FWA application, step-by-step*