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
Community-Campus Partnerships for Health & Tuskegee University National Center for Bioethics in Research and Health Care

May 24, 2007

William L. Freeman, MD, MPH, CIP
Director of Tribal Community Health Programs
Human Protections Administrator
Northwest Indian College  http://www.nwic.edu
Lummi Nation  http://www.lummi-nsn.gov
2522 Kwina Road, Bellingham, WA  98226-9217
360-758-2175  (360-392-4284)  fax 360-647-7084
wfreeman@nwic.edu
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
  - 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