

# Partnerships with International IRBs and Capacity Building

Lia M. Haley, JD

Sarah B. Putney, JD

Harvard School of Public Health

© President and Fellows of Harvard College

# Overview

- International Research Partnerships with IRBs
- Rationale for IRB capacity building
- Summary of HSPH IRB's capacity-building efforts
- Challenges
- Areas for future focus

# International research partnerships

- Public health issues
  - Global common problems
  - Regionally intensive burdens
  - Ethical action across borders
- Areas of greatest need = greatest potential success for those involved
- Mutually enriching, rewarding
- Partnership as a best-practice model

# Rationales for Capacity Building

- Partnership as a team of equals
  - Collaborations can best solve shared problems
    - For example, a participant voices a complaint...
- Disparities in resources and capacity exist
  - Sponsor country having more power = more say
  - IRB in country acting as shadow of sponsor IRB
- ...Lead to teams of unequals
- Ethics and good faith call for working toward lessening the gaps
  - Capacity building is a means to reducing dependence in the long term
  - Collegial basis, rather than oversight/punitive basis

# HSPH's C-B Efforts

- Site Visits are key
  - To meet colleagues
  - To see and better understand the research site
  - To lay the groundwork for communications and working together on issues of concern
  - Funded by IRB budget (line item for international travel/educational programs/quality assurance)
  - To tackle both theory and application together

# HSPH IRB Site Visits

- Botswana 2x since 2002
- China 2x since 2003
- Costa Rica 1x since 2004
- Kuwait 2x since 2003
- Mexico 1x planned for 2005
- Nigeria 2x since 2003
- Tanzania 2x since 2002
  - Excluding this workshop visit
- Thailand 1x planned for 2005

# HSPH Hosting Visitors

- Research Ethics Fellows 2005 spending 2 weeks with IRB on-site
- Mexican IRB visit 2005
- Russian IRB visit 2001
- Chinese consent monitor visit 2004
- Chinese IRB on-site Jan-May 2005
  - Piloting an on-site training program, self-funded visitor

# Issues for Discussion

- Policies & Procedures/Theory into Practice
  - Understanding reasons for requirements
  - Using a template offered by HSPH, covering issues included in Terms of Federal Wide Assurance and federal rules
  - Prioritizing quality improvements to fit small staffs and budgets
    - Membership, minutes
    - Continuing review

# Site Visit Activities

- Tour of research facilities
- Meetings with researchers
- Meetings with IRB Chair/Members and/or administrators
- Possibly meetings with CAB members and study participants
  - Interpreters may be needed; if affiliated with researchers, may not allow for freest discussion
- Consent monitoring

# More Site Visit Activities

- Reviews of informed consent records
- Presentation of an educational session on a topic requested by host
- Visits to non-research clinical facilities
- Touring of environs
- Informal discussions with all stakeholders

# Consent Monitoring

- Identify studies with open enrollment
- Pair up: visiting IRB member with host IRB member
- Explain in advance to study staff the approach
  - Minimize disruption of consent process
  - Minimal additional people present (only monitors, if possible)
  - Obtain each participant's consent to monitoring

# Consent Monitoring, cont.

- Approach, cont.
  - Listen quietly and observe body language
  - Do not take written notes
  - Do not talk during consent session
  - Demonstrate a respectful expression; do not react visibly to dialogue between researcher and participant
  - Thank the participant
  - Debrief immediately together to confirm or clarify impressions
  - Give constructive feedback to host IRB and researchers

# HSPH C-B Activities

- Ways we try to help
  - Template Policies & Procedures
  - Make IRB worksheets and training materials available as a starting point for developing new ones or revising existing ones
  - Listening to the practical problems and suggesting creative solutions
  - Supporting translations of key training materials into local languages, making them available for free

# Challenges

- How can low-budget, small-staff IRBs build capacity?
  - Start with the low-cost changes
    - Helpful guidelines, worksheets, minutes templates, and policies & procedures templates
  - Leverage free materials and help from colleagues
  - Ask for more support from institution, government and sponsors (and keep asking)

# Challenges, cont.

- Find funding to bring visitors from Tanzanian IRBs to spend time onsite at HSPH IRB
  - Costs of living in Boston (high)
    - Shared apartment unfurnished \$700/month+up
    - Health insurance (required)
    - Food, misc.
  - Air transportation round-trip
  - Substitute help back at home a hidden cost

# Challenges, cont.

- How to stay informed about risks and benefits offered to study participants and communities in Tanzania
- How to reassess risk and benefits of studies in view of new findings
  - E.g., ARV-drug-resistance developed by HIV-positive mothers after receiving single-dose Nevirapine at delivery

# Areas for Future Focus

Will accreditation in any form appear on the scene?

- Two non-governmental accrediting organizations are gaining ground in the US (voluntary basis)
- [www.AAHRPP.org](http://www.AAHRPP.org) and [www.PHRP.org](http://www.PHRP.org)
- If voluntary accreditation is widespread, federal government may not bother to mandate it Watch for regulatory changes in Tanzania

Will Tanzanian rules become stricter?

- For example, will there be new enforcement mechanisms for noncompliance?

# Areas for Future Focus

- How to improve communication between US and Tanzanian IRB memberships?
  - Since site visits involve only a minority of members/administrators
  - How to dissolve presumptions and educate US IRB members about the realities in Tanzania
    - E.g., do “activists” involved in support for PLWHA in Dar es Salaam have the same pro-research biases as you would find among “activists” in the US?

# Final Thoughts

- Encourage needs assessments from Tanzanian IRBs, with clear statements of priorities
- Continue to develop ties and offer capacity-building assistance as much as possible
- Take the “long view” and celebrate progress, no matter how slow
- Practice mutual respect

# Asante

- Acknowledgments: thank you to our wonderful IRB colleagues and the researchers at KCMC and MUCHS, Dr. Max Essex, Dr. Saidi Kapiga, and Dr. Wafaie Fawzi of HSPH, the NIH Fogarty grants, our workshop co-directors at Dartmouth and Duke, and institutional support we receive from HSPH.
- Lia Haley [lhaley@hsph.harvard.edu](mailto:lhaley@hsph.harvard.edu)
- Sarah Putney [sputney@hsph.harvard.edu](mailto:sputney@hsph.harvard.edu)
- [www.hsph.harvard.edu/hsc](http://www.hsph.harvard.edu/hsc)