Research in International Settings:

Considerations for PIs and the IRB

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Conflicts of Interest

I have no conflicts, financial or otherwise, to declare.
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Overview

• What is International Research?
• Regulatory Considerations
• Ethical Considerations
• Local Context
• Challenges for researchers
• Resources for investigators and IRB/REC members
What Is International Research?

• It is not a multi-site trial where some of the sites happen to be in other countries.
• It is not a project that may happen to include individual from a foreign country or culture.
What Is International Research?

• It is research where the University of Kentucky IRB will be responsible for reviewing activities that involve UK investigators traveling to a foreign country, interacting remotely with subjects in a foreign country, or in some cases working domestically with citizens from a foreign country or culture.
Do U.S. regulations still apply?

• Short answer: Yes

• Federawide Assurance (FWA)-Statement of principles and assurance to the U.S. government that an institution will follow required regulations

• In return, we get to use federal grants to support research activities
Do U.S. regulations still apply?

• Statement from DHHS 2006 notice on the applicability of the regulations to research activities covered by a FWA:
  • “HHS clarifies that the requirements of HHS regulations must be satisfied for all HHS-conducted or -supported research covered by an FWA, regardless of whether the research is conducted domestically or internationally.”
Ethical principles in the international context

• The Belmont Report (1979)
  • Respect for persons → Informed Consent
  • Beneficence → Risk/Benefit Analysis
  • Justice → Equitable selection of research subjects

• Belmont is our guiding ethical document, but not the case everywhere
  • For example, the Declaration of Helsinki (first adopted 1964)
Ethical principles in the international context

Remember, the ethical principles which guide us will not be viewed the same way everywhere

- Is it appropriate to apply our principles to other cultures?
- How do we apply them without offending the native culture?

There are no absolutely correct answers to these questions

- IRBs and investigators must work to find balance
- They must also work to avoid allowing cultural or personal biases from influence decisions
Ethical principles in the international context

• Belmont’s importance:
  • Respect for persons: belief in the autonomy of the individual is not a value everywhere
    • Investigators and IRBs must recognize the community aspect of many societies
  • Beneficence: how is the evaluation of risk and benefit different when the population may be half way around the world?
  • Justice: perhaps more important than ever when talking about international research
    • What are you as a researcher leaving behind after the study is over?
Local Context

• At UK, international research typically requires the input of a consultant with expertise or fluent knowledge of the culture and/or languages involved in the research
  • Advises the IRB regarding any concerns for the specific protocol
  • Verifies translated documents accurately convey protocol information
  • If you know anyone, PLEASE let me know
Local Context

• Local review sometimes required
  • Local IRB/REC may be required by collaborating institution, or funding agency (ex., NIH)
    • May be fine for cultural context, but may not always be sufficient for granting agency
Local Context

• Recruitment of subjects
  • Is the method of recruitment appropriate for the culture? For the topic?
    • Surveys and focus groups: cautionary tales
  • Local buy-in
    • The classic tale of the village elder
• Informed Consent: remember, it’s a process, not a form
  • Who is the population?
    • Educated?
    • Rural vs. urban?
    • Documentation?
  • Think outside the box
Local Context

• Translations
  • Don’t use online translation programs... Trust me, just don’t do it.
Challenges

• Logistics
  • How will you store and protect data or specimens in the field?
  • How will you transport it back to home base?
  • Are there import/export issues to be addressed? Agency permits?
    • What kind of equipment might you need?
    • How will you get it there? Get it back out?
  • Safe Harbor compliance may be necessary if working in the European Union
Challenges

• Language barriers: If you can’t read or speak the language, it doesn't matter if you have a translated consent form
  • In-country research assistants may be needed

• And of course... Money
  • Logistical issues need to be addressed before funding is sought, not after
  • May need to build into grant budget
We are always here to help, but...

Remember that it is your research

- International Compilation of Human Research Standards [HTML] - Visit this web site for a listing of over 1,000 laws, regulations, and guidelines on human subjects protections in over 100 countries and from several international organizations.
ClinReg - Clinical research regulations from around the globe. Hosted by the NIH National Institute of Allergy and Infectious Diseases [HTML]
Additional challenges

• Don’t be influenced by stereotypes of a setting or past information that may no longer be true.

• Obtain current, objective, and accurate information about a setting, its norms, and customs.

*Slide credit to Dean Gallant and George Gasparis
Perceptions can be misleading

Taipei, Taiwan

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Tokyo, Japan

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Kuala Lumpur, Malaysia

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Singapore (Marina Bay Sands Hotel)

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Urban Mongolia

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Yet, this is also... Taipei, Taiwan

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And Tokyo...

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Perceptions can be misleading

And Kuala Lumpur...

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Rural Mongolia

*Slide credit to Dean Gallant and George Gasparis*
And let’s not forget...

United States

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Resources


• CIA World Factbook: https://www.cia.gov/library/publications/the-world-factbook/

• International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use: http://www.ich.org/
Resources

• World Health Organization’s Casebook on Ethical Issues in International Health Research:  

• Council for International Organizations of Medical Sciences:  
  http://www.cioms.ch/

• European Union Safe Harbor information:  
  http://export.gov/safeharbor/eu/index.asp
References


Questions

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