International Research

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Distribution of UF Human-subjects research

IRB02 International Protocols 2015
(c. 120 of 1500 protocols)

- South America (23)
- Africa (23)
- Asia & the Pacific (33)
- Europe (7)
- Central America & Carribean (23)
- Middle East (4)
- North America (3)
Distribution of UF Human-subjects research
Researchers must comply with not only the usual US, state, and UF requirements *(which remain the same)*, but also any additional regulations & requirements of the host country.

**Host requirements apply anytime your research involves their country,** including:

– If you travel to host country *(even virtually)* to conduct research
– You *collaborate* with others in the host country
– You *receive any data* or tissue from the host country
– *[does not apply to U.S. citizens travelling abroad]*
Challenges

• Identifying host regulations/requirements.
  – Translating if not in English

• Identifying any local IRB, research ethics committee and/or other oversight bodies whose review and approval may be needed
  – (e.g., Ministries of Health or Education, community leaders, etc.)

• Understanding cultural / regulatory differences (e.g. consenting)

• Translating documents for use with study subjects (e.g. informed consent forms)
  – Qualifications of translator
  – Certification that translation is not only appropriate, but all material has been translated (no missing issues, sentences, or paragraphs)
Issues

- Cultural issues/sensitivities
- Export Control
- Embargoed countries
- Information Security
- Privacy requirements
- Collect/use tissue

- Risks
  - To subjects
  - To researcher: conflict, disease outbreak, etc
  - To institution
What to Include and Where to Put it

• International Addendum (& Protocol Narrative; other Forms)
  – Indicate relevant laws, regs or guidelines, and how you will address them
  – Describe your qualifications and experience for research of this sort in that country or context, language facility if appropriate, etc.
  – Explicitly assess the risks that may be specific to that country or culture, including those that might arise if identifiable information about the participants were disclosed outside of the research
  – Identify any consultants (here or in the host country) who will help with the legal, cultural, ethical and/or regulatory challenges of the research
    • Best if not a collaborator or co-investigator
OHRP Resources

• International Compilation of Human Research Standards
  – http://www.hhs.gov/ohrp/international/index.html

<table>
<thead>
<tr>
<th>Country</th>
<th>Key Organizations</th>
<th>Legislation</th>
<th>Regulations</th>
<th>Guidelines</th>
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</thead>
<tbody>
<tr>
<td>Drugs and Devices</td>
<td>Ministry of Health, Food and Drug Administration</td>
<td>National Drug Law (1992)</td>
<td></td>
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</tbody>
</table>

• Database for Registered IORGs, IRBs, and FWAs
<table>
<thead>
<tr>
<th>Country</th>
<th>Study Details</th>
<th>Institution</th>
<th>Note</th>
</tr>
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<tbody>
<tr>
<td>South Korea</td>
<td>Apple blotch disease in Gunwi-Gun, Korea</td>
<td>Univ Chonbuck Natl Univ</td>
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<tr>
<td>Cambodia</td>
<td>Observation of staff planning resaerch program</td>
<td>Hospital</td>
<td>Angkor Hospital for Children, Naro Kong Exec Dir</td>
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<td>Costa Rica</td>
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<tr>
<td>Guatemala, Mexico, Guatemala</td>
<td>Migration and exploitation in Mexico &amp; Guatemala</td>
<td>NGO (G) Univ (M)</td>
<td>Human Rights NGOs (Refugio de la Ninez etc)</td>
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<tr>
<td>Russia</td>
<td>Desirability of US travel for Russian tourists</td>
<td>Univ</td>
<td>Dean, Univ of Nizhni Novgorod</td>
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<tr>
<td>Ethiopia</td>
<td>Gender equality and relations</td>
<td>Univ</td>
<td>Institute of Ethiopian Studies</td>
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<tr>
<td>Bolivia</td>
<td>Social integration of native women</td>
<td>Govt, NGO, Univ</td>
<td>Ministry of Culture; several Women's welfare organizations</td>
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<tr>
<td>Costa Rica</td>
<td>Oyster farming community</td>
<td>Univ</td>
<td>Univ of Costa Rica (Dr. Paniagua)</td>
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<tr>
<td>Chile</td>
<td>Forest plantation and small farmers</td>
<td>Gov &amp; NGOs</td>
<td>Matl Inst of Agri Research; Center of Ed and Tech</td>
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<td>Childbirth and reproductive rights</td>
<td>Univ</td>
<td>Institute of Ethiopian Studies</td>
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<td>Brazil &amp; Chile</td>
<td>How TV shows shape &quot;memory&quot; of repressive years</td>
<td>Univ &amp; NGO</td>
<td>Brazil: School of Public Admin / Vargas Found</td>
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<td>Gender relations and public welfare program</td>
<td>Univ</td>
<td>Univ Fed de Pernambuco etc</td>
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<td>Haiti</td>
<td>Educational use of mobile phones</td>
<td>Univ</td>
<td>Univ of Quisqueya</td>
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<tr>
<td>Argentina</td>
<td>Cashmere commerce and conservation</td>
<td>NGO</td>
<td>Wildlife Conserv Society (Dr. Walker)</td>
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More work & time

• Typically must be addressed on a case by case basis
  – Study details always impact ability to approve
  – Identifying host country requirements is challenging
    • Can change, so must always be confirmed / reassessed.

• Start earlier, follow up
  – Certain federally-funded studies with local collaborators may require
    the creation of a local IRB and FWA!

• Contact IRB offices and others (e.g., Privacy, Information Security) as needed during “presubmission” period