International Research

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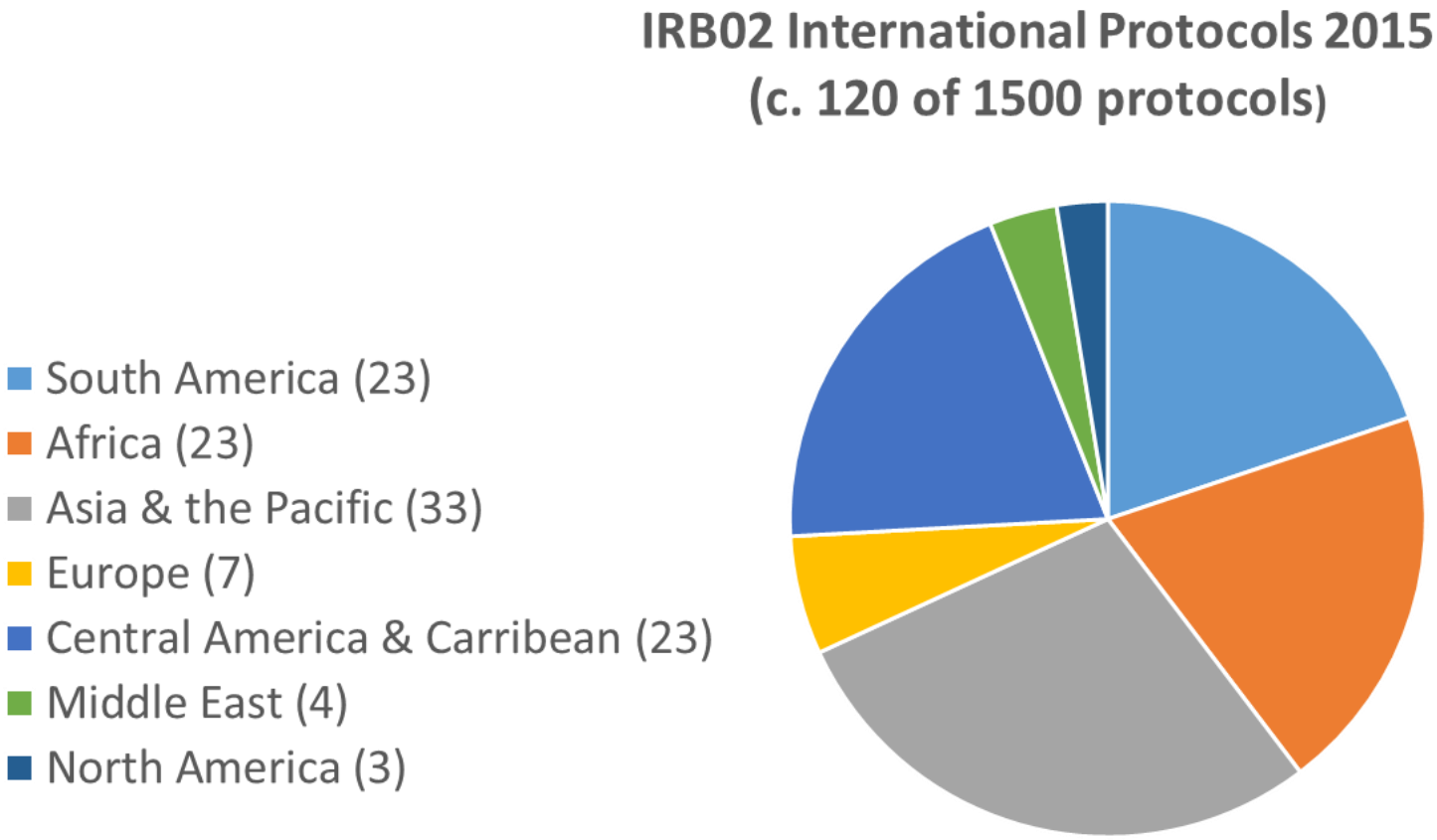
Distribution of UF Human-subjects research



Distribution of UF Human-subjects research

Researcher Responsibilities

- 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 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

Country	Key Organizations	Legislation	Regulations	Guidelines
	4. Myanmar Academy of Medical Sciences Ethics Awareness Program			
Drugs and Devices	Ministry of Health, Food and Drug Administration	National Drug Law (1992)		
China, People's Republic of				
General	1. National Health and Family Planning Commission of the People's Republic of China (NHFPC) (Mandarin): http://www.moh.gov.cn/zhuzhan/ 2. Ministry of Science and Technology: http://www.most.cn/eng/	Law on Practicing Doctors (June 26, 1998), Articles 26 and 37 (Mandarin): http://www.gov.cn/banshi/2005-08/01/content_18970.htm		NHFPC: Interim Measures for Guidelines on Ethical Review of Biomedical Research Involving Human Subjects (2007) (Mandarin): http://www.moh.gov.cn/qjjys/s3581/200804/b9f1bfee4ab344ec892e68097296e2a8.shtml
Drugs and Devices	*Drugs*			
	China Food and Drug Administration: http://eng.sfda.gov.cn/WS03/CL0755/	Drug Administration Law of the People's Republic of China (2001) (English):	1. Regulations for Implementation of the Drug Administration Law of the	1. Guideline for HIV Vaccine Research Technology (2003) (Mandarin): http://www.sfda.gov.cn/WS01/CL0237/15705.

- Database for Registered IORGs, IRBs, and FWAs
  - http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc

IRB Number	Institutional Review Board	City	IRB Type	Status
IRB00007432	Chaoyang District Center for Disease Control and Prevention IRB #1	Beijing	OHRP Only	Deactivated
IRB00007733	Guangzhou Medical Association IRB #3	Guangzhou	OHRP Only	Deactivated
IRB00003620	(CICAMS)Cancer Institute, Chinese Academy Med Sci IRB #1	Beijing	OHRP/FDA	Active
IRB00009150	302 Military Hospital of China IRB #1	Beijing	OHRP/FDA	Active
IRB00008798	302 Millitary Hospital of China IRB #1	Beijing	FDA Only	Active
IRB00004550	Affiliated Hosp Nanjing U TCM IRB #1	Nanjing	OHRP Only	Deactivated
IRB00004659	AIDS Rsch Ctr of Chinese Academy of Med Sciences IRB #1	Beijing	OHRP Only	Deactivated

Some IRB02 Studies and local oversight

South Korea	Apple blotch disease in Gunwi-Gun, Korea	Univ	Chonbuck Natl Univ
Cambodia	Observation of staff planning resaerch program	Hospital	Angkor Hospital for Children, Naro Kong Exec
Costa Rica	Living with Big Cats workshop	Gov	Costa Rican Ministry of Environment
Cambodia	Assessment competencies of nurses	Hospital	Sonja Kill Mem Hospital, Kampot
Colombia	Sustainable business at SAB Miller	Univ	Prof. Qusada, practicum manager, Univ of the
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Swaziland	Perceptions of scavengers (vultures)	Univ	Univ of Swaziland
Guatemala, Mexic	Migration and exploitation in Mexico & Guatemala	NGO (G) Univ (M)	Human Rights NGOs (Refugio de la Ninez etc)
Russia	Desirability of US travel for Russian tourists	Univ	Dean, Univ of Nizhni Novgorod
Ethiopia	Gender equality and relations	Univ	Institute of Ethiopian Studies
Bolivia	Social integration of native women	Govt, NGO, Univ	Ministry of Culture; several Women's welfare
Costa Rica	Oyster farming community	Univ	Univ of Costa Rica (Dr. Paniagua)
Chile	Forest plantation and small farmers	Gov & NGOs	Matl Inst of Agri Research; Center of Ed and T
Ethiopia	Childbirth and reproductive rights	Univ	Institute of Ethiopian Studies
Brazil & Chile	How TV shows shape "memory" of repressive years	Univ & NGO	Brazil: School of Public Admin / Vargas Found
Brazil	Gender relations and public welfare program	Univ	Univ Fed de Pernambuco etc
Haiti	Educational use of mobile phones	Univ	Univ of Quisqueya)
Argentina	Cashmere commerce and conservation	NGO	Wildlife Conserv Society (Dr. Walker)

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