International Human Subjects Research

What do I need to know?

Outline

- Background
- Definitions
- What do I need to know?
- Who do I contact for help?

History: Guatemala STD Experiments (1940s)

- Originally began with prisoners in the U.S. but was moved to Guatemala when researchers were unable to consistently produce gonorrhea infections there.
- 1,500 vulnerable individuals (children, orphans, child and adult prostitutes, Guatemalan Indians, leprosy patients, mental patients, prisoners, and soldiers) were intentionally infected with STDs
- Did not consent or receive treatment after exposed

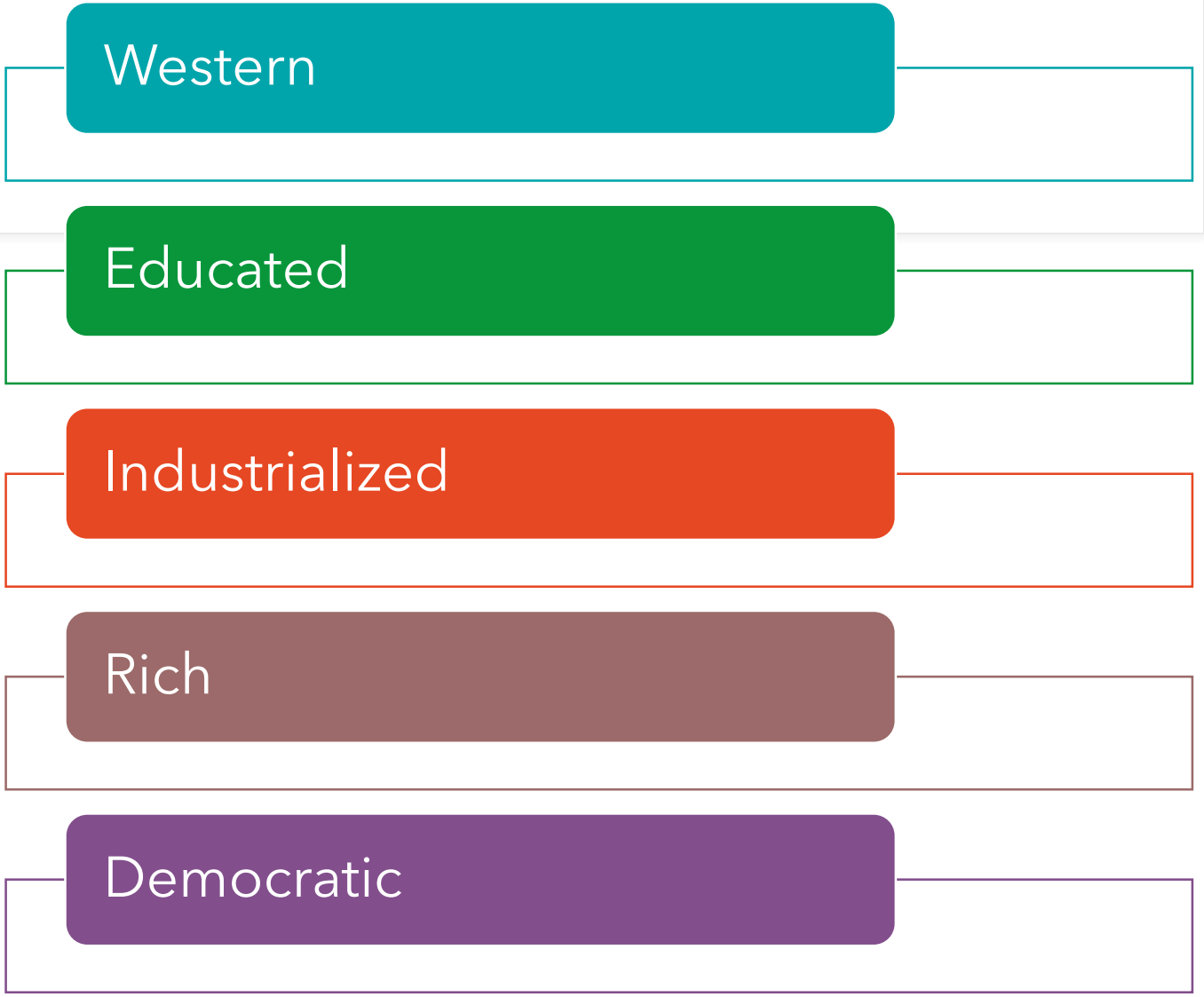
History: Havasupai Indians (1990s)

- Arizona State University researchers collected DNA samples from tribe members to help assess whether there was a genetic component of the high rate of diabetes in the tribe
- Blood samples were also used to study mental illness and theories of the tribe's geographical origins that contradict their traditional stories
- Tribe banished Arizona State University employees from their reservation and the university paid $7,000 to the tribe, returned the blood samples, and provided additional assistance to the tribe

More Recent and Ongoing

- Unregulated drug trials in India, Africa, Peru, China, and the Dominican Republic
- Participants do not understand what they are consenting to
- Potential for coercion and financial conflicts of interest
- Not sharing results or offering beneficial treatments to control group at end of trial

Most research is W.E.I.R.D.



It’s not just the IRB involved….

- Legal Counsel
- Sponsored Projects
- Office of Information Technology
- Biosafety
- Export Control
- Office of Global Engagement
- Conflict of Interest
- External sites

What is international research?

Human Subjects Research (HSR)

Research

A *systematic investigation* including research development, testing, and evaluation designed to develop or contribute to *generalizable knowledge*

Human Subject

A living individual about whom an investigator conducting research

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, analyzes the information or biospecimens, or
- Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens

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HSR Determination Worksheet

- HSR Worksheet
- HSR Worksheet Video Tutorial
- Public Use Data sets
- Contact us with questions or for a formal letter of determination

What is international research?

- US Study teams conducting research in other nations in collaboration with researchers/ institutions in the host country
- US study teams conducting research in other nations without local collaborator(s)
- US study teams conduct research from within the US but recruit participants from other countries (e.g., WhatsApp, Qualtrics, MTurk)
- US study teams receive biospecimens or data from collaborators in other countries
- US study teams participate in a multi-site, transnational research study but do not conduct or are not responsible for research that occurs in foreign countries

Transnational Research within the US

- 573 sovereign tribal nations in the United States
- Tribal governments exercise jurisdiction over their land and communities

Regulatory Framework

- The researcher must provide the same or equivalent protections to human subjects in research conducted in other countries
  - Subject autonomy and dignity should be respected
  - Protections should encompass the ethical principles of respect for persons, beneficence, and justice

The Researcher Must…

- be familiar with and comply with local laws, regulations, political, and socio-economic factors, and cultural context in all locations where the research is conducted
- have sufficient knowledge of the local context, which may impact all aspects of the research design, and in particular, the protection of the rights and welfare of subjects

Variations in Local Laws and Regulations

- Age of consent
- Who can serve as a Legally Authorized Representative (LAR)
- Reporting requirements (violence, abuse, STD, etc.)
- Local institutions/ organizations policies and procedures
- Required elements of consent

What do I need to do to get IRB Approval?

- Contact the HRPP before filling out the application

- Determine if local ethics review is required
  - OHRP International Standards for Human Subjects Research
  - If yes, contact the local ethics board ASAP

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What to do if local ethics review is required?

- Consult with:
  - Local human research protection expert (ethics board)
  - Country's health ministry, consulate, embassy or government officials
- Establish collaborative relationships with local universities or institutions

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What do I need for IRB Review?

	Foreign IRB or Ethics Approval	Memo of Cultural Appropriateness (CA)	CA Memo must say no ethics review required	Site Permission	Translated Documents
Exempt	If required by foreign regulations	YES	Required, if foreign IRB not required	YES	YES
Expedited	If required by foreign regulations	YES	Required, if foreign IRB not required	YES	YES
Full Board	Contact your college liaison			YES	YES

Memo of Cultural Appropriateness

- If local ethics review not required, must submit a memo of cultural appropriateness
- Letter writer must be independent from research team and familiar with the culture of the community where the research will take place

- Reference the title of the study as displayed in the iMedRIS application
- Describe the expertise of the individual preparing the letter to address cultural and social norms
- Confirm the individual writing the letter understands the intent of the research activities to be performed
- Confirm the planned study does not conflict with local and cultural norms
- Include signature, date, and contact information for the signee

Additional Application Questions

- Do you have a local contact or organization you are working with?
- Description of research team's knowledge of or experience in the host country
- Scientific/ethical justification for conducting the research in an international setting
- Current events or socio-political environment in the country that may impact research conduct or alter the risks or benefits to subjects
- Societal and cultural beliefs in the country that may impact research conduct or alter the risks or benefits to subjects

Additional Questions..

- If women and children are part of the subject population, their role in society, including their autonomy and legal capacity to make decisions
- A description of how the plan for recruitment and subject selection will avoid undue influence or favoritism with the subject population
- Will the study be conducted in another language? What is the literacy rate of your participants?

Additional Questions…

- What is the compensation equivalency?
- Are you collecting Personal Health Information (PHI)?
  - Once a researcher sends identified health information collect international across a U.S. Network or UTK server it becomes PHI
- Describe the data security for all stages of research
  - Collection while in country
  - Storage while travelling
  - Sharing between local contacts
  - Storage when back at UTK

Do you have an external researcher?

- Contact the HRPP about getting an individual investigator agreement (IIA) for the external researcher
- Have the external researcher complete CITI training
- Will you have locals conduct the recruitment/ collection?
  - Develop an ethics training for them
  - Create a confidentiality statement

Additional Considerations

- General Data Protection Regulation (GDPR)
- Export Control
- Translators

Templates and Guidance

- Memo of Cultural Appropriateness
- Tips for Research with Translators and Interpreters
- Tips for Studies with Audio and Video Recordings
- GDPR Privacy Notice Template
- Transcriber's Pledge of Confidentiality
- Research Team Member's Pledge of Confidentiality

Questions?

Thanks for joining us!

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Office hours on website