

GOING INTERNATIONAL- CONDUCTING RESEARCH OUTSIDE OF THE U.S.

GWU Office of
Human
Research



OVERVIEW

- Regulations and Guidance on International Research
- Local Research Guidance
- Informed Consent, Language Issues, Literacy Issues
- IRB Considerations



REGULATIONS AND GUIDANCE

- Research conducted outside the U.S. should be treated as if they are conducted within borders;
- FDA Regulations in international research only apply to FDA regulated products (drugs and devices for market in U.S.);
- International Conference on Harmonization Good Clinical practices (ICH E6, 2.3), “The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society”.



DISCUSSION QUESTION

A US researcher plans to conduct education research in two schools in Managua, Nicaragua. He wants to compare the success of two first grade (learning-to-read) books, one which is already in use in one school, and the other in use in the second school. He will obtain student reading records at the end of the school year collected for school assessment purposes. The researcher applies for an exemption at his home US IRB.

What should the IRB consider and decide?



LOCAL RESEARCH GUIDANCE

- **Laws**
- **Regulations**
- **Customs**
- **Socio-economics factors**
- **Political factors**
- **Cultural factors**
- **Language and literacy of parents for consent**
- **The local research guidance may influence every aspect of the research design!**



LOCAL RESEARCH GUIDANCE- RISK

- Even though a research method may have little or no risk in the U.S., it may be risky in other countries;
- Be careful in designing research instruments- surveys, interview questions, recruitment methods, etc.;
- Maintaining confidentiality may be more difficult;
- Become knowledgeable in the local climate issues relevant to research;
- Consult with community leaders and stake holders who may be able to assist in achieving research goals by sharing local customs, norms.



INFORMED CONSENT



INFORMED CONSENT

- Cultural appropriateness of consent should be taken into consideration;
- Different structures of authority may be in place for consent. For example, in Israel, the Spokesperson's Unit of the Ministry of Defense must process all requests to interview Israeli soldiers.
- Structures of Authority:
 - Should be honored
 - May not be wholly autonomous
 - May present ethical challenges
 - May conflict with US regulations



INFORMED CONSENT

- Despite cultural differences in obtaining consent, all elements of consent should be present:
 - Statement that study involves research
 - Purpose of research
 - Duration of participation
 - Procedures and if any are experimental
 - Risks
 - Benefits
 - Alternative procedures (as applicable)
 - Confidentiality of records
 - Contact information
 - Statement that participation is voluntary



INFORMED CONSENT- LANGUAGE ISSUES

- Use language that is most familiar to participant. If language is only spoken and not written, alert the IRB during initial review;
- The researcher may need to hire interpreters if no members of research team are fluent in local language;
- There may not be words to use in place of English such as “voluntary”;
- For IRB approval, best to wait to have documents translated until after pre-review process in case changes are requested.



INFORMED CONSENT- OBTAINING SIGNATURES

- Participant may be illiterate;
- May be culturally inappropriate for participant to sign;
- May have legal ramifications if documented signature;
- Participant may feel lack of trust if not asked to sign;
- Researcher may have different consents for different groups (standard signature vs. waiver of documentation).



DISCUSSION QUESTION

A research study in a rural town in Cambodia involves educating people about STDs. The researcher is using an approved consent document in the native dialect. A potential participant says he is happy to participate, but will not sign any documents.

What does the researcher do?



INFORMED CONSENT- ALTERNATE MEANS

- Audio or video tape consent agreement;
- Use witness;
- Document, Document, Document!!!



CHILDREN

- Age of majority?
- What is acceptable assent process?
- Do minor married children still need parental permission?
- What if child is more educated than adult? How do you word assent? Does child explain consent and study to parent?
- What if there are no parents/ guardians?



DISCUSSION QUESTION

A U.S. researcher proposes a study in Sudan interviewing homeless youth ages 13-19.

What are the important issues that the researcher and IRB should know?



WHAT DOES THE IRB NEED?

What we need
to approve
your study...



INFORMATION FOR THE IRB

******PLAN BEFORE YOU GO!!!!******

If you think you might possibly, probably, or even remotely want to do research internationally, get approval **BEFORE** you make travel arrangements!!



INFORMATION FOR THE IRB

- Where the research will be conducted (location/site, etc);
- Current conditions. Is the country safe for travel? Are you putting participants at risk? Are you putting yourself at risk?;
- Is local approval required? Some S/B studies may not need local approval;
- Minimize risk with special attention to additional risks participants may encounter;
- How will researcher communicate with IRB while in the field?;
- In what language will consent be obtained? In what language will recruitment materials, study tools, etc be presented?



SUMMARY

- Special attention should be paid to risks which may not occur in the U.S.;
- Adhere to local regulations. Some local reviews can take up to twelve weeks to complete;
- Consult regulations and authorities prior to conducting research;
- Cultural appropriateness of consent. Language barriers, use of interpreters;
- Considerations for children- assent issues, age of consent, etc.

- Resources:

<http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html>

<http://www.ich.org/home.html>



QUESTIONS??

The George Washington University
Office of Human Research
202-994-2715
ohrirb@gwu.edu

