

Conducting Research Across Borders: Issues in Research Administration and Compliance

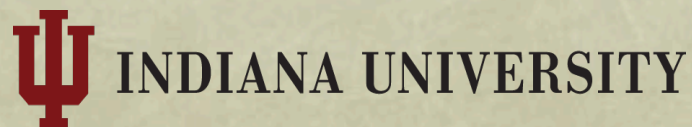
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Introduction

- ◆ Example – Journal Editor
 - ◆ An international social psychology journal
 - ◆ Prided itself on international in its title
 - ◆ Received manuscript
 - ◆ Author was a social scientist in Asia
 - ◆ Topic was culturally particularly sensitive
 - ◆ Editor said now IRB review so asked for it
 - ◆ Author said not required

Introduction

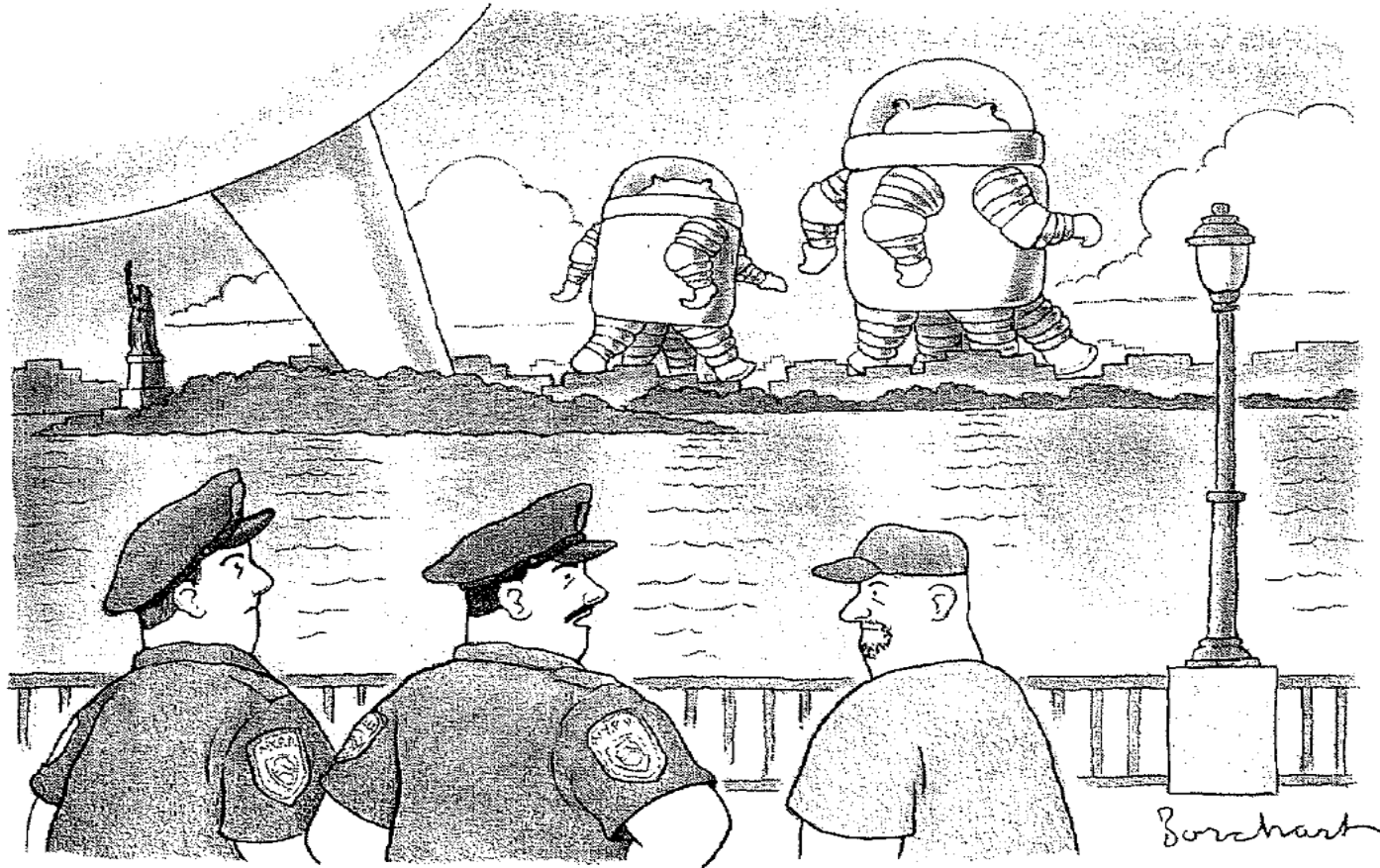
◆ The Dilemma

- ◆ Did not want to impose Western requirements
- ◆ Did not want to be totally relativistic and defer entirely to national regulations
- ◆ In other words
 - ◆ Absolute v Relativistic Approach
 - ◆ US regulations – respect for local autonomy

◆ The Solution

- ◆ Was rejected on “scientific” grounds
- ◆ We don’t quite have that out

Introduction



"Until we hear different, it's Jersey's problem."

Introduction

- ◆ Well..... It's Our Problem
- ◆ Aims:
 - ◆ Identify and discuss challenges in the oversight of international research collaborations
 - ◆ Identify best practices - policy and process - for research administration and compliance in the review of inter/trans-national human subjects research
- ◆ Include:
 - ◆ Research collaboration between US institution and non-US institution
 - ◆ Research carried out by US researchers in non-US nations

Regulatory Context: RA

- ◆ PHS Grants Manual Policy
 - ◆ 40 references to “foreign” in PHS GMP
 - ◆ Most pretty innocuous
 - ◆ Certification that apply or do not apply
 - ◆ Other misc stuff
 - ◆ <https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>
 - ◆ 16: GRANTS TO FOREIGN ORGANIZATIONS, INTERNATIONAL ORGANIZATIONS, AND DOMESTIC GRANTS WITH FOREIGN COMPONENTS
 - ◆ Not Much Right?

Regulatory Context: RA

- ◆ PHS Grants Manual Policy
 - ◆ So where does that leave us?
 - ◆ Basically same rules
- ◆ The Challenge
 - ◆ How do you implement?
 - ◆ How do you enforce?

Regulatory Context: RC

- ◆ Focus on HSR as Largest Volume
- ◆ Common Rule: 45CFR46
 - ◆ 46.101(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.
 - ◆ 46.101(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy.... In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy.

Regulatory Context: RC

- ◆ Institutional requirements, if any
 - ◆ IU: Students conducting research outside of US
- ◆ Accreditation: Standard I-3:
 - ◆ The Organization's transnational research activities are consistent with the ethical principles set forth in its Human Research Protection Program and meet equivalent levels of participant protection as research conducted in the Organization's principal location while complying with local laws and taking into account cultural context.

Are you Ready?

- ◆ Be Prepared

- ◆ Need to

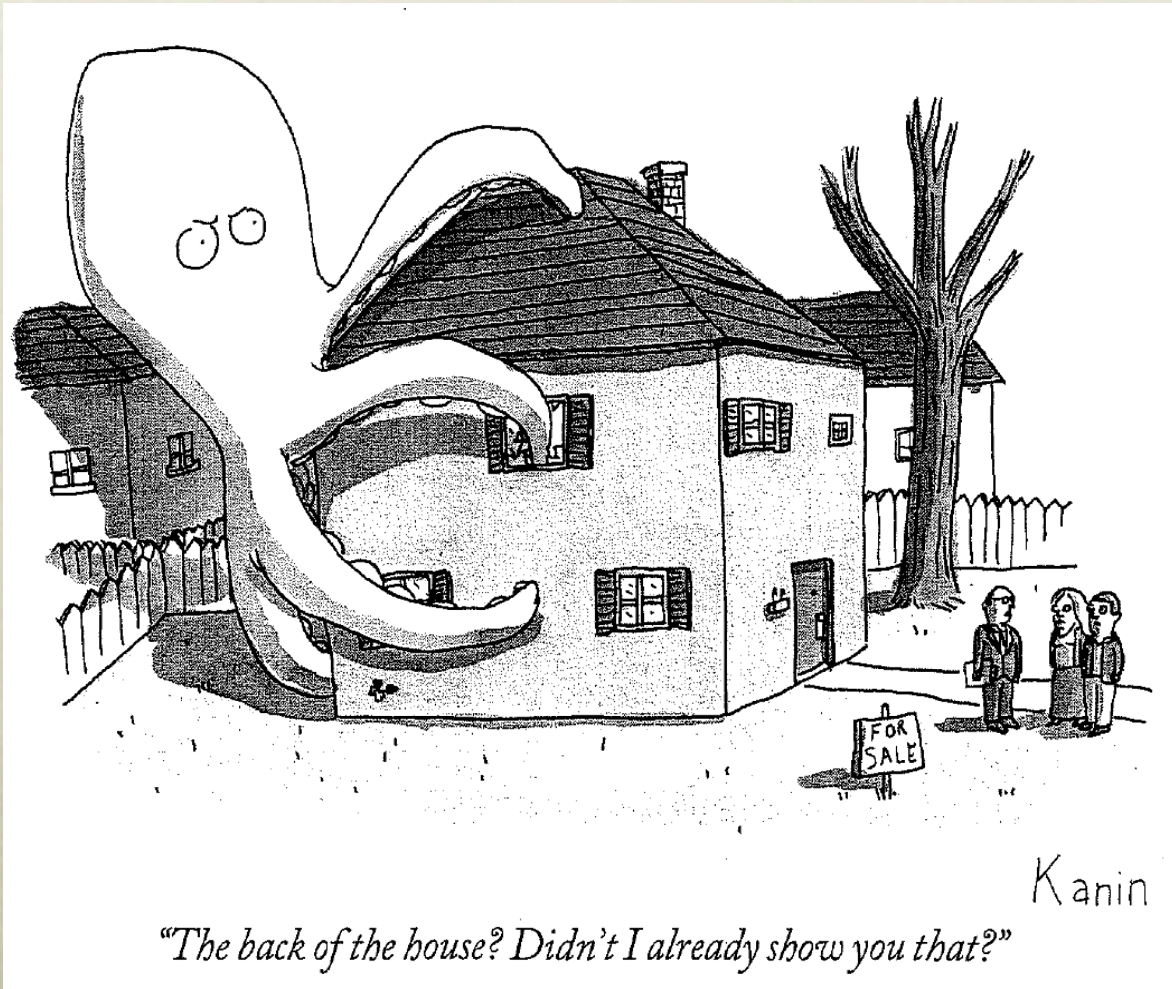
- ◆ Know what you know

- ◆ Find out what you don't know

- ◆ What you don't know can hurt you

- ◆ Ignorance is not bliss – its unapproved costs and non-compliance, at best

Are You Ready



"The back of the house? Didn't I already show you that?"

Are you Ready?

- ◆ Be Prepared

- ◆ Involve your campus/organization
- ◆ Learn from your campus/organization
 - ◆ Reach out to academic units
 - ◆ To learn about possible future research
 - ◆ To identify resources/consultants
 - ◆ Reach out to other relevant administrative offices
 - ◆ International office?

Knowledge: Local Laws and Regulations

- ◆ Research Compliance
 - ◆ Need to know: IRB and Researchers
 - ◆ Age of Majority
 - ◆ Legally Authorized Representative
 - ◆ Reporting requirements (HIV, STD, Violence)
 - ◆ HSR requirements
 - ◆ Is local IRB/EC approval required by national government
 - ◆ Institutional policies/procedures
- ◆ How do you find out?
 - ◆ Local collaborators
 - ◆ Your campus resources: GC, Finance, Faculty/Researchers
 - ◆ Researchers
 - ◆ Other resources?

Knowledge: Local Laws and Regulations

- ◆ Research Administration
 - ◆ Need to know: Grants Office and Researchers
 - ◆ Employment laws
 - ◆ Financial/currency laws/regulations
 - ◆ Wage structure
 - ◆ Tax laws
 - ◆ Institutional policies/procedures
 - ◆ Etc.
- ◆ How do you find out?

Knowledge: Cultural Factors

- ◆ Research Compliance
 - ◆ Customs, Values, Norms, and Roles
 - ◆ For instance: Who may approach whom, how, and where
 - ◆ Language and Literacy
 - ◆ Consent
 - ◆ Individual-Community
 - ◆ Woman-Husband/Father
 - ◆ Child-Parent/Guardian
 - ◆ Oral-Written
 - ◆ Sensitivities
 - ◆ Information
 - ◆ Dress
 - ◆ Behaviors
- ◆ How do you find out?

Knowledge: Cultural Factors

- ◆ Research Administration
 - ◆ Customs, Values, Norms, and Roles
 - ◆ Hiring Practices
 - ◆ India example
 - ◆ Documentation of expenditures
 - ◆ More?
- ◆ How do you find out?

Knowledge: Other Local Context

- ◆ Research Compliance
 - ◆ Political factors that effect risk
 - ◆ Risks due to political context
 - ◆ Refuge camps
- ◆ Research Administration
 - ◆ ?
- ◆ Research Compliance/Administration
 - ◆ Local institutional policies/procedures
 - ◆ Communication with local institutions
 - ◆ IRB/ECs
 - ◆ Grants offices

Knowledge: Researcher

- ◆ Research Compliance/Administration
 - ◆ Local Qualifications:
 - ◆ Confirming that the researchers and research staff have appropriate the qualifications for conducting that research in that country
 - ◆ Knowledge, experience/expertise, degrees/certifications, etc.

Knowledge

◆ Research Plan

- ◆ Includes Processes/procedures for monitoring the research
 - ◆ Post-approval monitoring
 - ◆ Monitoring/Audit plan of expenditures
- ◆ Handling of complaints, non-compliance, and unanticipated
- ◆ Need to think of this in terms of local context

What is to Be Done

- ◆ One Thing to Have the Knowledge
 - ◆ Now it has to be put into practice
 - ◆ Are your Research Administration/Compliance Offices up to the challenge?

What is to Be Done

- ◆ Existing Organizations

- ◆ As default

- ◆ If at ALL possible, rely on existing organizations within the local area
 - ◆ Research Compliance: Existing IRBs/ECs
 - ◆ Research Administration: Local universities, NGOs, etc
 - ◆ If researcher unaware, try to find one
 - ◆ For approvals and/or certifications

What is to Be Done

- ◆ Be Willing to be Creative in Support of the Research/Researcher
 - ◆ Need to approach with a level of openness/flexibility that generally do not need to express
 - ◆ But the question:
 - ◆ How flexible can you be before integrity is sacrificed?

What is to Be Done

- ◆ Research Compliance

- ◆ Be Willing to be Creative

- ◆ Illiterate Subjects

- ◆ Developed of Pictorial Based project and informed consent material

- ◆ HIV Risk Reduction projects

- ◆ Could not just get consent from women

- ◆ Multiple levels of “permission” within a community

- ◆ Project:

- ◆ No regulations

- ◆ Create IRB that followed US standards for IRB

What is to Be Done

- ◆ Research Administration
 - ◆ Be Willing to be Creative
 - ◆ Cash economy
 - ◆ Kenya M-pesa
 - ◆ Payment in non-cash items

Wrap Up

- ◆ The best international research
 - ◆ Is scientifically sound
 - ◆ Is subject to independent, transparent and competent ethical and regulatory review(s)
 - ◆ Provides adequate resources for infrastructure for all the participants in the research process
 - ◆ Promotes culturally respectful/appropriate standards and procedures for enhancing respect and capacity for decision-making among subjects
 - ◆ In other words, not so different

Wrap Up

- ◆ At the End of the Day: Be Careful to Neither
 - ◆ Over consider the issues, exaggerate the risks/issues, over-demand and over-regulate
 - ◆ Under consider the issues, underappreciate the risks/issues, under-demand and under-regulate
- ◆ What Happens at your institution?
- ◆ Discussion and Questions