

Thinking Outside the Box: Overcoming Challenges of IRB Review for Ethnographic Research



IRB OVERVIEW

The purpose of the IRB is to ensure...

- The rights and welfare of participants are adequately protected, and
- Research activities are compliant with Federal and State regulations and local policies.



What is research?

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

45 CFR 46.102(d)

How does knowledge become “generalizable”?

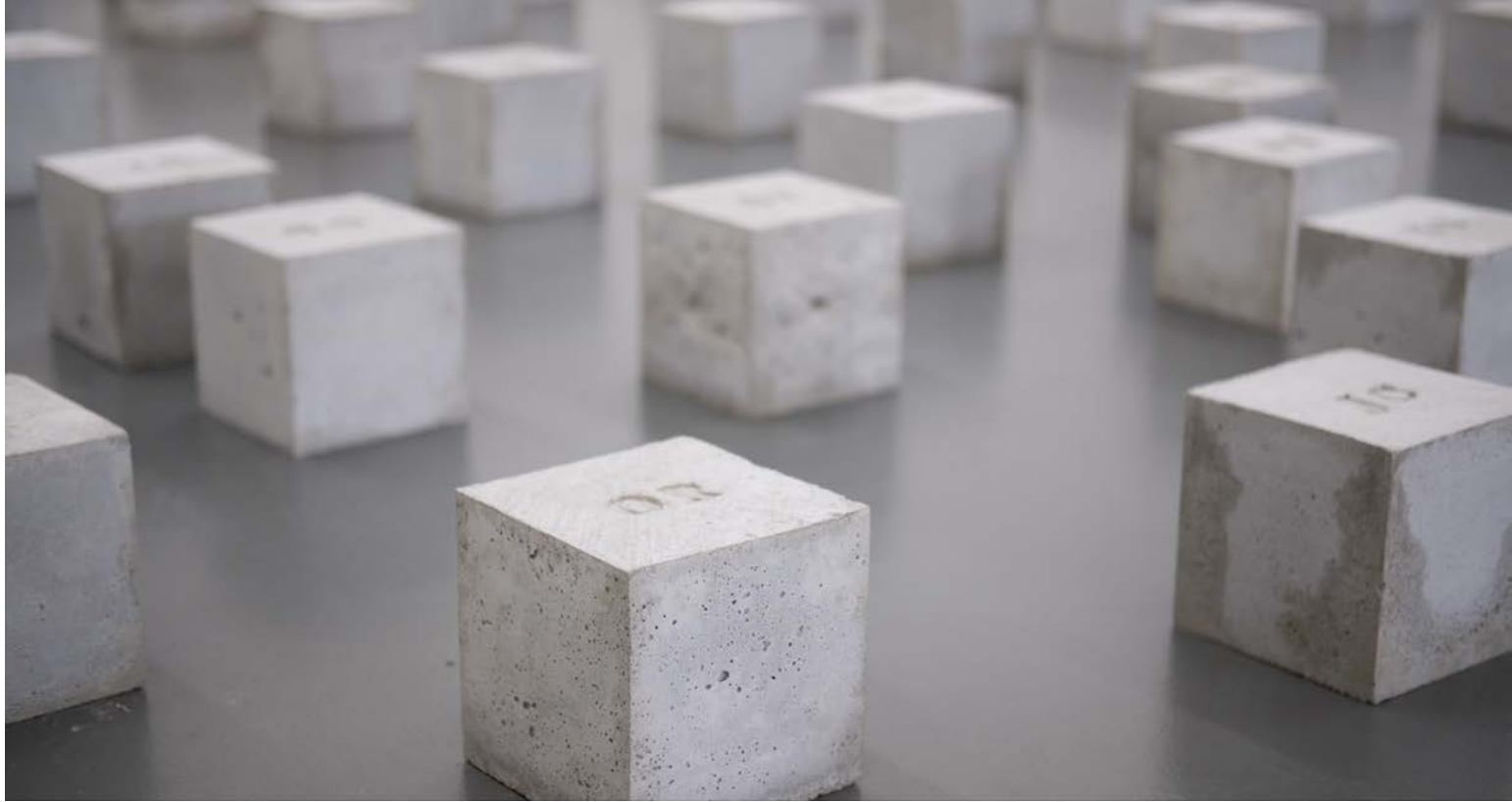
- ✓ Knowledge that contributes to a theoretical framework of an established body of knowledge.
- ✓ Results that are expected applied to a population beyond the site of data collection or population studied.
- ✓ Results that are intended to be applied to other settings.

Who is a human subject?

A living individual about whom an investigator (whether professional or student) conducting research:

- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

45 CFR 46.102(e)(1)



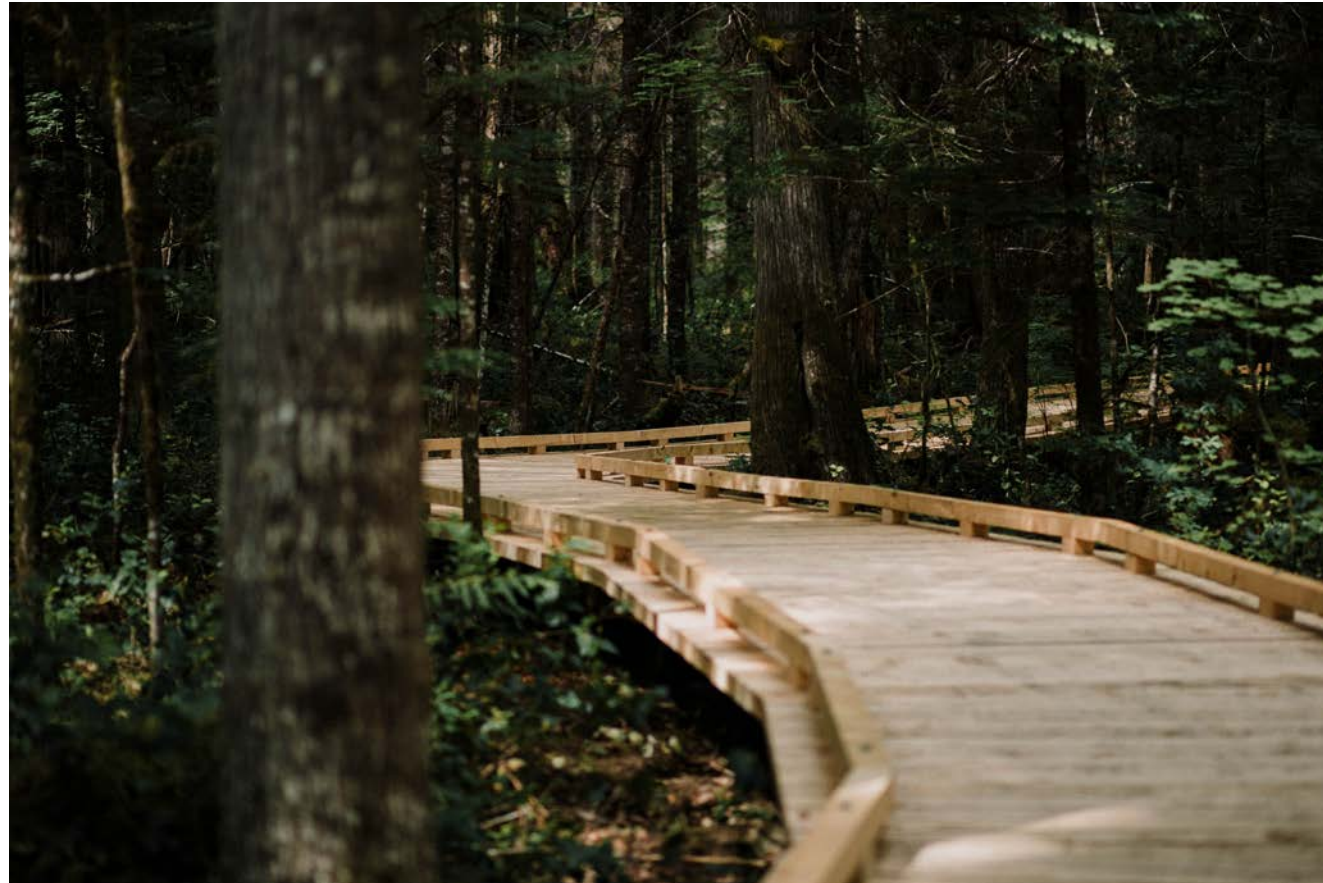
What if your research does not fit in the box?

Challenges of Ethnographic Research

- It is experiential
- It is interactive
- It is not easily bounded by time and place
- It is often exploratory
- It morphs easily and often (new questions emerge during research)
- The boundaries between normal activities and communication and data collection are blurred

Arwood, T., and McGough, H., 2007 PRIM&R SBER Conference

Create a path; Make a plan



Define

- **Research Goals**
- **Research Procedures**
- **Research Setting**
- **Recruitment and Consent**
- **Risks and Benefits**
- **Data Protection**



RESEARCH GOALS

Research Goals: Define Objectives

- **What topic is being studied?**
- **What do you hope to learn?**
- **Provide context but avoid jargon and theory**
- **If your goals evolve over time, submit a modification**



Examples

- This research project aims to explore the ways in which religious beliefs affect the medical-decision making of Ghanaians in Accra. (Duke [Undergrad Research Grant Writing Support](#)
Example proposal: Cultural Anthropology)
- Determine the impact of tribal environment on an individual's personality
(Dissertation Help Desk Qualitative Research Samples)
- To identify the change in personality if an individual is shifted from his comfort environment (Dissertation Help Desk Qualitative Research Samples)

Research Goals: Generalizable Knowledge

- Clearly state how you intend to apply the knowledge gained.
- Clearly state if your intention is to collect information to make generalizations about a group



RESEARCH PROCEDURES

Research Procedures: Describe your process



- **Observation**
- **Interview**
- **Survey**
- **Focus group**

Examples

- *I will conduct interviews with [type of participants]. The interviews are designed to last 30-45 minutes and will be audio recorded with the participants' permission. They will take place [location(s)].*
- *I will observe and take notes on naturally occurring interactions and conversations among [place/people/situation].*
- *I will conduct participant observation: I will observe and take notes on naturally occurring interactions and conversations among [place/people/situation] and I will also participate [in such-and-such by doing such-and-such].*

Interviews and Focus Groups: Outline your topics



- **List of questions**
- **Interview Guide**
- **Describe themes**
- **If topic changes, submit a modification**

RESEARCH SETTING

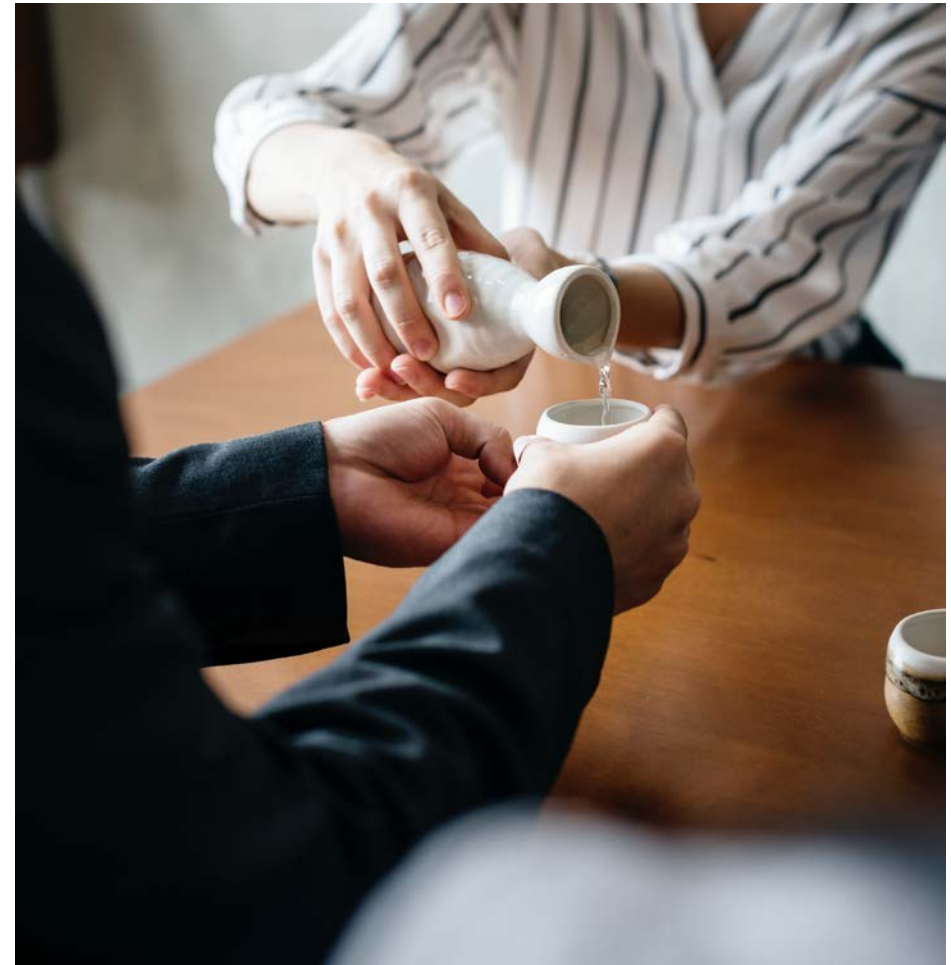
Research Setting: Where will you conduct research procedures?

- Requirement
- Consent
- Data collection



Research Setting: Things to address

- **Privacy**
- **Cultural norms**
- **Local law**

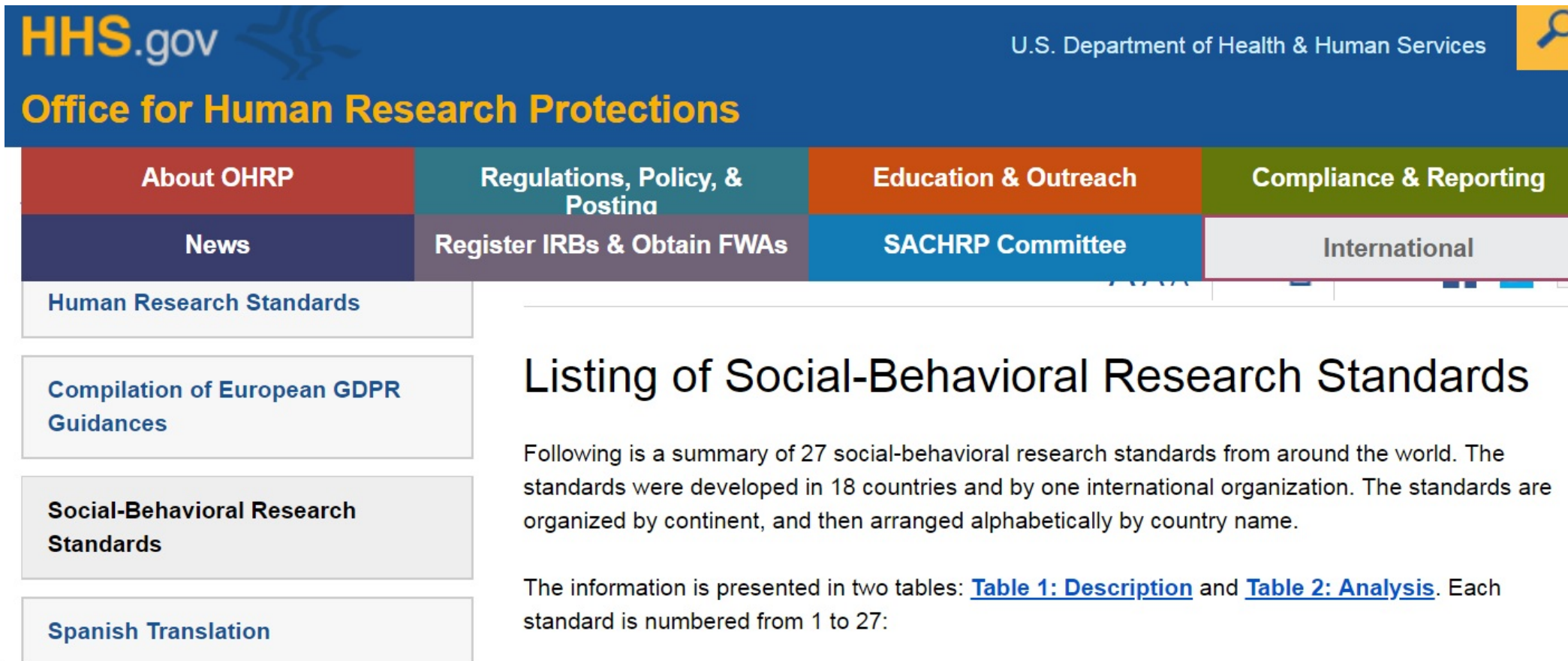


International Approval

The UC Davis IRB will require approval from local ethics board or authority prior to beginning research.



Resource for International Research



The screenshot shows the HHS.gov website for the Office for Human Research Protections. The header includes the HHS.gov logo, the text "U.S. Department of Health & Human Services", and a search icon. Below the header is a navigation bar with four main tabs: "About OHRP", "Regulations, Policy, & Postings", "Education & Outreach", and "Compliance & Reporting". Underneath these are secondary tabs: "News", "Register IRBs & Obtain FWAs", "SACHRP Committee", and "International". A sidebar on the left contains four menu items: "Human Research Standards", "Compilation of European GDPR Guidances", "Social-Behavioral Research Standards", and "Spanish Translation". The main content area displays the title "Listing of Social-Behavioral Research Standards" and a paragraph of introductory text.

HHS.gov U.S. Department of Health & Human Services

Office for Human Research Protections

Navigation tabs: About OHRP, Regulations, Policy, & Postings, Education & Outreach, Compliance & Reporting

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Sidebar menu: Human Research Standards, Compilation of European GDPR Guidances, Social-Behavioral Research Standards, Spanish Translation

Listing of Social-Behavioral Research Standards

Following is a summary of 27 social-behavioral research standards from around the world. The standards were developed in 18 countries and by one international organization. The standards are organized by continent, and then arranged alphabetically by country name.

The information is presented in two tables: [Table 1: Description](#) and [Table 2: Analysis](#). Each standard is numbered from 1 to 27:

RECRUITMENT AND CONSENT

Subject Selection: Who will you collect data about?

- Describe the target population(s): list defining characteristics
- Will you intentionally enroll vulnerable populations: Children, pregnant women, prisoners, cognitively impaired, other disadvantaged groups



Subject Selection

- **How will you identify potential subjects?**
- **Report the maximum number you believe you might enroll.**
- **If the target population or number of subjects changes, submit a modification**



Example

- Since I have previous contact with this community through [INSERT DETAILS]. My initial participants will be individuals with whom I have already established relationships in a non-research setting.
- I plan to recruit further participants through informal snowball sampling, a standard qualitative method, as participants introduce me to their families and friends and others in their social networks.
- I will collect data from 200-300 individuals

(<https://reo.mcmaster.ca/download/boilerplate-wording-for-ethnography>)

Recruitment



- How will you introduce yourself as a researcher?
- How will you inform subjects of research procedures?
- If there are language barriers, describe how you will overcome them.

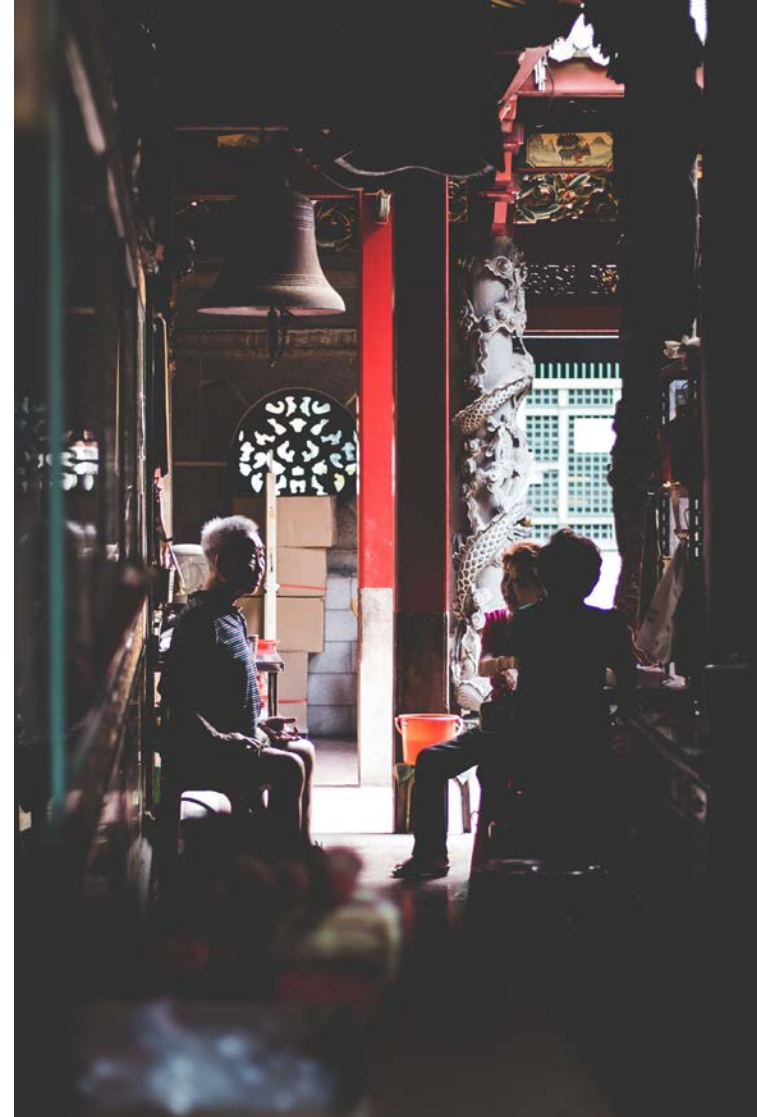
Example

I will provide all potential participants with a recruitment brochure (**Appendix E**) that introduces myself, explains the research project and methods, and provides my contact information. If, having read the brochure, individuals choose to be interviewed, I will ask them to contact me and we will arrange a convenient time and location to meet.

(<https://reo.mcmaster.ca/download/boilerplate-wording-for-ethnography>)

Consent Process Exempt Research

- This is research
- Description of procedures
- Participation is voluntary
- PI contact information



Minors in Research

- **Define the age of majority**
- **Parental permission will be required if minors are research subjects**
- **Assent will be required when the child is capable of understanding the research and providing assent**



RISKS AND BENEFITS

Common Risks

- **Psychological: Stress, discomfort, embarrassment, guilt, when thinking and talking about experiences or opinions**
- **Social: Stigma or condemnation**
- **Possible disclosure of personal information**



Additional Risk Factors

- **Local law:** Are the research procedures legal at the location?
- **Politically volatile regions:** Is there additional risk because of local politics?
- **Cultural appropriateness:** Are the interactions appropriate for this culture.





Minimize Risk

Clearly state how you will minimize risks for research subjects

Benefits: What will be gained?

Direct Benefits

- Often no direct benefit
- Opportunity to reflect and share important experiences
- Do not describe compensation as a benefit

Indirect Benefits

- Contribute to the public record
- Develop understanding of a particular social phenomenon
- Assess the challenges and needs of particular groups and institutions.

DATA PROTECTION

Data in the Field

- **Who will have access?**
- **How will you ensure confidentiality?**
- **Where will it be stored once field work is complete?**



Terms for Data

- **Identifiable**: the data will be directly labeled/recorded with the personal identifying information when acquired.
- **Coded**: Each person's data is given a code and the research personnel can link the code to personal identifying information using a key.
- **Anonymous**: data is not labeled with any personal identifying information, nor with a code that the research team can link to personal identifying information.



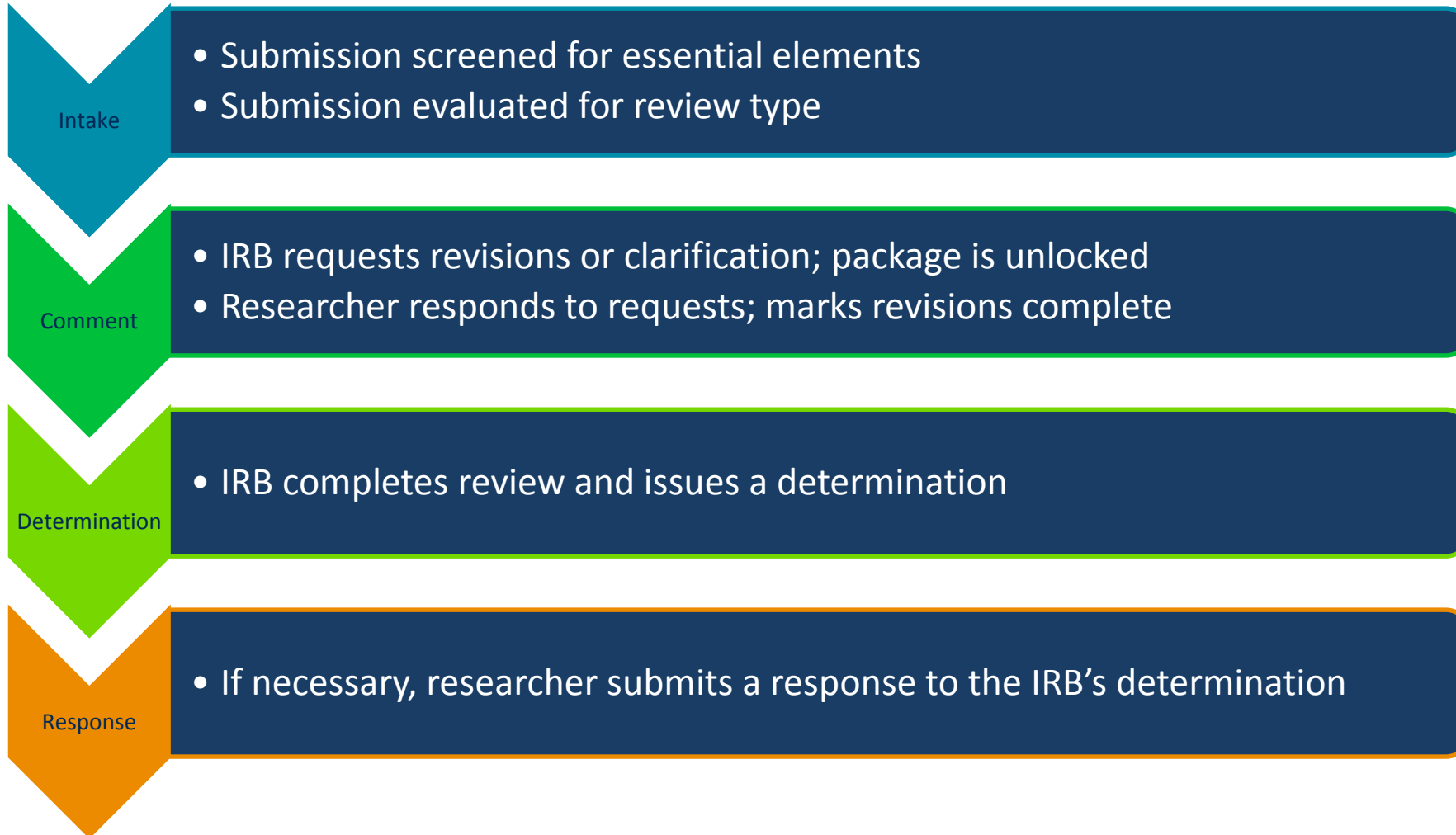
Data Protection

- Encrypted, password protected computer
- Locked storage
- Remove identifiers



IRB REVIEW PROCESS

IRB Review Process





Work with your IRB analyst

Do not hesitate to call or email with questions