# Human Subjects Research and Institutional Review Board (IRB)

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# When does the IRB get involved?

## When it is Human Subjects Research.

**Research** is a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

A **human subject** is as a living individual about whom an investigator conducting research obtains (1) data or biospecimens through intervention or interaction with the individual; or (2) identifiable private information or identifiable biospecimens.

It is Human Subjects Research when:

There is the *systematic collection* of information *about people* designed to develop or contribute to *generalizable knowledge*.

Not all research is human research. You may be conducting a systematic investigation that involves people, but it may not be generalizable. Or it may be generalizable but it is not about people.

HRP-213-FORM-Not Human Subjects Research Request Determination

# Submitting to the IRB

1. Ensure that everyone on the study team has current human subjects projection training, such as CITI or NIH
2. Prepare the IRB protocol using the latest template. What the IRB looks for in the protocol:
   - Rationale for the study and how it contributes to knowledge
   - The research methodology is reasonable and will accomplish the purpose of the study
   - Recruitment and selection of subjects is equitable
   - Informed consent is sought from each participant and is appropriately documented
   - Risks to subjects are minimized and reasonable in relation to anticipated benefits
   - Privacy and confidentiality of participants is protected
3. Prepare the recruitment material (e.g. mTurk ad, flyers, email template)
4. Prepare the consent form(s) using the latest template(s)
5. Prepare the data collection forms (e.g. surveys, interview guides, experiment outline)
6. Upload all study documents to ESTR and have the PI click submit

# Tips on creating the protocol

The ESTR submission system is protocol driven. Everything about your study design from nuts to bolts goes in the protocol.

Remember the sole mission of the IRB is the protection of participants. Do not skimp on the details of all of your interactions with participants, including:

1. How you are identifying and inviting people to participate in your research (recruitment).
2. When, where, and how you will inform them of what you are doing and asking them to do (consent).
3. Your data collection process and instruments (i.e., interview, survey, observation, etc.) including whether you are audio or video recording.
4. Your data protection plan including data storage, who will have access and whether you are collecting and retaining identifiers.

# Are my data identifiable?

**Direct identifiers -** variables that point explicitly to particular individuals. Examples include: names, addresses, telephone numbers, Social Security numbers, etc.

**Indirect identifiers -** variables that may be used together or in conjunction with other information to identify individual respondents. Examples include: detailed geographic information, organizations to which the respondent belongs, detailed occupational titles, exact dates of events, offices or posts held by respondent.

# Incomplete Disclosure and Deception

**Incomplete disclosure** is when you withhold information about some aspect of the research, whether it is in the procedures or the purpose of the research.

**Deception** is when researchers purposely mislead participants by providing them with overt misdirection or false information about some aspect of the research, whether it is in the procedures or the purpose of the research.

To utilize incomplete disclosure or deception, you must justify the following:

1. The research presents no more than minimal risk to participants
2. The incomplete disclosure/deception will not adversely affect the rights and welfare of the participants
3. The research could not practicably be carried out without the incomplete disclosure/deception
4. Where appropriate, the participants will be provided with additional pertinent information after participation

**Debriefing** – When research includes incomplete disclosure or deception, debriefing participants is typically required.

# International research

Cultural Context

- What is the research team's experience conducting research in the setting
- What are the customs and norms of the population you wish to include
- How will the participants/society benefit from the research

Local regulations

- Does the location have research-related laws you must adhere to
- Local IRB review may be required
- Permission from local leaders

Risks to participants

- In addition to individual risks, need to consider group harms
- Just because the research is intended to do good, does not mean it will not cause harm
- Respect for cultural norms

# International Research - GDPR

**General Data Protection Regulation (GDPR)** is a regulation from the European Economic Area (EEA) that establishes protections for individuals' personal data

- If collecting identifiable information from a data subject, an additional consent process will be required (see consent form template for GDPR Addendum)
    - Consent is required under GDPR
- Anyone within the (EEA) is protected (including visitors to the EEA)
- Special categories of data require an additional Data Protection Impact Assessment (DPIA)
    - Racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, sexual orientation, data concerning a person's sex life, biometric data, and genetic data

# Collaborations

Collaborating with other researchers

- The expectation is that each collaborator will seek IRB approval from their own institution

Collaborating with a company

- The IRB needs to understand the nature of the relationship, such as:
  - Who is implementing the study
  - What is the company's role in the research
  - What is standard business practice versus what is the research

# Other institutional approval processes to consider

Harvard and HBS have policies in place to oversee and manage certain types of activities. For example:

- Using space on Harvard campus
- Students as research participants
- Analyzing secondary Harvard data (e.g. student, alumni)
- IT Data Safety Review (for data classified as level 3 or higher)
- Office of the Vice Provost for Research (OVPR) review for international, non-exempt research
- Harvard Office of the General Counsel review for research posing reputational and legal risks to HBS/Harvard

**NOTE: Some institutional approvals may impact the IRB review process**

# Resources

- ESTR Library - the Library houses the protocol and consent form templates (only use templates with “HUA” in the document name)
- ESTR Job Aids – the following webpage includes instructions for completing an array of ESTR-related tasks: https://estrsupport.fss.harvard.edu/study- submission-guide
- Required human subjects protection training: https://cuhs.harvard.edu/required-ethics-training

# Communicating with the HUA IRB

- **Alain Bonacossa** and **Kathleen Murphy** are your points of contact with the Harvard University Area (HUA) IRB and review IRB applications on behalf of Harvard's Committee on the Use of Human Subjects (CUHS).
- Email, call, or set up a meeting if you have questions
- Have a question about a study currently being reviewed? Ask your question directly in ESTR using the "Add comment" feature.

Do not hit "submit" from the left hand navigation to communicate with the IRB as that sends the project back to the IRB.