## INSTITUTIONAL REVIEW BOARD (IRB) CHECKLIST FOR HUMAN SUBJECTS RESEARCH

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Prior to conducting any research involving human subjects, university-based researchers and research teams in the United States are required to submit a proposal to their Institutional Review Board (IRB). Increasingly, there are similar ethical requirements for human subjects research outside of the United States. The Code of Federal Regulations (45 CFR 46, 2020) states that the University will apply the same standards to all projects involving human subjects, regardless of funding or funding source. While requirements for developing an IRB protocol may vary by institution, this check sheet provides a description of what is typically required and what researchers might need to begin preparing an IRB proposal for submission. All IRB's are mandated to be in compliance with new 2018 federal regulations as of January 21, 2019 (45 CFR 46, 2020).

☐ **Determine if your project is "research."** The 45 CFR 46 defines research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46.102(d)).

☐ **Determine if your project involves "human subjects."** The 45 CFR 46 defines a human subject as "a living individual about whom an investigator (whether professional or student) is 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))
   - There are four parts to consider when determining if your research involves human subjects (Colorado State University, 2019):
     1. Living Individual—Is the study about a living human?
     2. About Whom—Is the study about the individual him/herself?
     3. Intervention/Interaction—Does the researcher intervene or interact with a participant in person, via the phone, via the internet, or through interviews, surveys, questionnaires, etc.? and
     4. Identifiable Private Information—Does the researcher collect names or other identifiers so that the data could be linked back to an individual?

☐ **Complete research ethics training.** Principal Investigators (PIs), Co-PIs, and anyone else who will be interacting with research participants or will have access to identifiable data needs to complete human subjects protection training. Academic researchers can fulfill this requirement through online CITI training courses. Training must be renewed every three years through the completion of online modules and refresher courses provided by CITI.

☐ **Understand regulatory classifications for IRB review.** There are four primary classifications of research activities. It is the responsibility of the university IRB-and NOT the individual researcher-to determine which category each research project falls under.
   1. *Not Human Subject Research.* This determination will be made if activities are not deemed to involve "human subjects" or meet the definition of "research" as outlined in the Code of Federal Regulations (45 CFR 46.104).

2. *Exempt* projects typically have lower risk to human subjects. Some activities may be deemed exempt, but still require IRB review. Exempt research may involve human subjects in the following categories ([45 CFR 46.101(b)](#)):
    - Research conducted in common educational settings
    - Research using anonmous research instruments such as tests, surveys, interviews, or observations
    - Research involving public officials
    - Research involving the collection of publically available or de-identified data
    - Research investigating public benefit or service programs
    - Food evaluation and consumer acceptance studies
3. *Expedited* reviews include projects that are not eligible for exempt status, but involve only minimal risk, with no intentional deception, no inclusion of sensitive populations or topics, and use appropriate informed consent procedures. The project may only need to be reviewed by a single designated IRB reviewer, rather than the full board. A full list of qualifying expedited categories can be found here: ([45 CFR 46.110](#)).
4. *Full board* review is required when research cannot be exempt or expedited, involves more than minimal risk, includes protected populations or sensitive topics, or can be considered potentially intrusive or stressful for the participants.

☐ **Understand and complete the requirements for an IRB protocol.** Although IRB forms and submission processes may vary by university, most IRB applications require the following:
- A summary of the study using clear language that is jargon free and easily understood by individuals outside of your discipline
- A description of the study population, including number of participants and inclusion/exclusion criteria
- A description of any vulnerable populations that require additional protections as described in 45 CFR 46, such as pregnant women, children, the elderly, or prisoners
- A plan for recruiting participants and, if necessary, letters or support or collaboration that will help the researcher to gain access
- An outline of the time commitment if individuals agree to be involved in the study
- A statement of potential risks and/or benefits, such as those related to psychological, employment, social, or physical/medical health (note: it is important not to overstate or understate risks)
- A description of how confidentiality will be maintained (or not) and a data management and storage plan
- A plan for gaining consent and/or assent from each participant

☐ **Prepare required forms for submission.** Although each IRB is slightly different, there are standard forms that will need to be submitted for review as part of the IRB protocol. Many university IRBs offer templates for common forms as well as specific recommendations for creating these forms prior to submission. Some common forms that will likely need to be created for your hazards or disaster project include:
- **Project Description:** This is a brief, easily understandable description of the project that can be given to participants. It should include contact information for the project lead(s). Sometimes this information may be included in the consent forms that are provided to participants.
- **Informed Consent/Assent:** Human subject participants need to provide their informed consent to participate in research. This process typically involves three key features: (1) the researcher discloses enough information about the project so that the participants can make a fully-informed decision of whether or not to participate; (2) the researcher facilitates the understanding of what has been disclosed through age- and education-level appropriate language; and (3) the researcher makes it clear that all decisions about whether or not to participate in the research are voluntary.
    - Informed consent must be legally effective and prospectively obtained. The U.S. Department of Health and Human Services (HHS) regulations at [45 CFR 46.116](#) and [45 CFR 46.117](#) describe the informed consent requirements. A U.S. Office for Human Research Protections (OHRP): General Informed Consent Requirements educational video can be viewed here: [https://www.youtube.com/watch?v=URo4x4pv68A&feature=youtu.be&list=SP5965CB14C2506914](https://www.youtube.com/watch?v=URo4x4pv68A&feature=youtu.be&list=SP5965CB14C2506914)
- **Recruitment Scripts:** If you are actively recruiting participants through phone, email, listservs, flyers/handouts, or in person, you will need to prepare a brief recruitment script for review by the IRB and for use in your study.
- **Letter of Cooperation:** If your research requires the partnership of an organization or group to recruit participants, to gain access to a research site, or to otherwise conduct your study, you will likely be required to obtain a letter of cooperation to submit to your IRB.

**•Photo/Video Release:** If you will use any photos or videos in your final publications, on websites, or in future research that includes people's faces or other identifiable information, you will need to generate a photo or video release form for submission to the IRB.

- **Data Collection Instruments:** All data collection instruments, including interview guides, survey questionnaires, focus group guides, observational protocols, or other research instruments that will be used to collect data will need to be submitted to the IRB. These data collection instruments should be written in the final language that you will use with participants, and they should be formatted appropriately for review and distribution.
  - If midway through your study your project requires that you update a data collection instrument, you will need to submit the modified instrument to the IRB for approval via an amendment.
- **Local Resources:** When conducting disaster research it is recommended that you prepare lists of free and locally available mental health and disaster recovery resources as part of your due diligence for protecting disaster-affected participants. These can be submitted to your IRB for approval and handed out to research participants when appropriate.

☐ **Waiting for approval.** Once you submit all of the required documentation to your institution's IRB, you will need to wait until they grant final approval before collecting any data. The IRB review process can take anywhere from two to six weeks, depending on the institution and type of review.

☐ **Obtaining IRB approval for projects that include multiple institutions.** If the study includes Principal Investigators from multiple institutions, it will be necessary to gain IRB approval from each institution involved in the study. In some cases, IRB Authorization Agreements (IAAs) can be created to allow one institution to act as the lead approving institution.

☐ **Launching the research study.** Once IRB approval is granted, you will receive a formal letter from the IRB. After that, data collection can commence, and all IRB-approved documents should be used in the process.

**ADDITONAL RESOURCE:**

For more information on the IRB and extreme events research, please see the CONVERGE Institutional Review Board (IRB) Procedures and Extreme Events Research Training Module at: https://converge.colorado.edu/resources/training-modules.

**REFERENCES:**

CITI Program. Research Ethics and Compliance Training. Retrieved from: https://about.citiprogram.org/en/homepage/

Colorado State University, Research Integrity and Compliance Review Office. Does My Project Involve "Human Subjects"? Retrieved from: https://www.research.colostate.edu/ricro/irb/does-my-project-involve-human-subjects/

U.S. Department of Health and Human Services, Office for Human Research Protections. Electronic Code of Federal Regulations, 45CFR46. Retrieved from: https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c-6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML

U.S. Department of Health and Human Services, Office for Human Research Protections. Initial Considerations for Single IRB Review: Points to Consider. Retrieved from:
https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-a-november-2-2016-letter/index.html

U.S. Department of Health and Human Services, Office for Human Research Protections. International. Retrieved from:
https://www.hhs.gov/ohrp/international/index.html