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Is IRB review needed? Then what?

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What is the IRB?

An **Institutional Review Board (IRB)**, is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving human subjects.

- #1 Priority: Protect subjects from physical, psychological, or status/financial harm
 - Even surveys can carry risks
- #2 Priority: Protect Temple's research program
 - Federal penalties, less funding, damage to Temple's image

What does the IRB do, specifically?

- We review Human Subjects Research for:
 - Ethical concerns and risk/benefit ratio
 - Regulatory compliance
 - FERPA, HIPAA, DOD, ED, NSF, HHS, etc.
 - Temple's Policies
 - CITI training, approval routes, who can be the PI, etc.

Human subjects research (HSR)

- A systematic investigation—designed to develop/contribute to **generalizable knowledge**—involving living individuals about whom an investigator conducting research obtains:
 - 1. **Identifiable private information** or
 - 2. Data through **intervention or interaction** with the individual.
- If a project is Human Subjects Research, it must be reviewed/approved by the IRB before it starts.

HSR: Deeper definition dive

- Generalizable knowledge –
 - Truths, facts, information that expands scientific understanding or the knowledge base of a field of study; knowledge that is universally or widely accepted.
 - QI/QA – single institution vs several
 - A key facet is determining if the purpose and design reflect improving a given school or classroom, as opposed to extending beyond that school or university
 - Interviews – Taylor Swift
 - Interested in her story, or in how billionaires think and act?

HSR: Deeper definition dive

- Identifiable information –
 - Individuals' identities can be readily ascertained or associated with the information.
 - Can be direct identifiers (e.g., name, email, TUID, phone #, address etc.)
or
 - Indirect identifiers (e.g., combination of demographic information)
 - E.g., Age + gender + university + department = some folks will be identifiable

HSR determinations are not always easy

- Designed to be Generalizable? Is the secondary data identifiable?
- If you have a question, email us (IRB@temple.edu)
 - Email > phone
- Journals and colleagues may ask for IRB approval
 - Having an email in hand saves you from ulcers

Determination tips...

- If unsure email a 2-3 paragraph summary to irb@temple.edu with the subject “Human Subjects Research Determination.”
 - Quick synopsis/abstract of what the research entails
 - Research objective
 - Research methodology
 - Sample questions/survey/materials for review

No IRB approval needed; party time? Not necessarily

- No IRB does not mean ethics or regulations can go by the wayside
 - When possible/sensible, get consent
 - Secure your data
 - FERPA

So, your protocol is Human Subjects Research...



Submit to the IRB

Submitting to the IRB: Expectations

- Most studies require at least one round of Modifications Required to Secure Approval.
 - Inexperienced submitters should plan for two rounds.
- Turnaround times fluctuate between 2-4 weeks from receipt.
 - Mods Required reviews should occur in less than 10 business days (usually within a week).
- Plan for at least two months from submission to approval.

What does IRB review mean?

- Minimal risk reviews are done by staff; greater than min risk by the Committee.
- We review:
 - Study protocol
 - Consent(s)
 - Recruitment materials (flyers, phone scripts, email scripts)
 - Questionnaires and/or Interview guides
 - Data collection tools
 - Other study-specific documents (site approvals, intervention materials, etc.)

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Study protocol

- The protocol tells the IRB what you're doing and why.
 - Think of it as a methods section that is really interested in confidentiality and consent
- It is critical that the protocol reflects what you will actually do, and that the protocol is followed.
- If you need to make changes, submit an Amendment.

Amendments are always needed for:

- Change in PI (even if we are not the IRB of Record)
 - Note: The PI must be current, full-time faculty at Temple University
 - If the PI leaves Temple (including retires), then the PI must be changed.
- Adding new research personnel.
 - Use the Personnel Amendment submission-type.
- Change in external funding (gaining or losing).

What does the IRB focus on? – Protocol

- Inclusion / Exclusion criteria – More rigorous review if minors or adults lacking capacity to consent are eligible
- Risks – namely loss of confidentiality and “triggering”
 - Describe how these risks are mitigated
 - Undue influence – Generally, teachers should not be consenting / interviewing their students
- Consistency –
 - Methods the same in the protocol and consent?
 - Does the protocol make sense given the methods?
 - Longitudinal research (including member checks) generally require identifiable data. Don't say it's de-identified.
- Confidentiality/Security (e.g., Transcription services)

Consent

- The consent tells the subjects what it means to participate in the study.
- Not as involved in methods, but clearly telling them what is involved and how their data will be stored / shared.
- Even if not getting signed consent, the consent should be provided to the subject, they should understand it and have opportunities to ask questions before participating.
- Use the consent that the IRB approves.

What does the IRB focus on? – Consent

- Study title & ideally protocol number
- PI name and researcher contact info
- Description of what will happen and for how long
 - Including potential member checks or follow-up interviews
- Any risks
- Reference to and contact information for the IRB
- If recording will take place
- If there are any 3rd party transcription services
- Does NOT require signature
 - Unless including minors or adults lacking capacity to consent

What does the IRB focus on? – Recruitment material

- We will ask for and review: Emails, social media posts, flyers, phone scripts
- Privacy of potential participants –
 - How is the contact info obtained
 - Who makes first contact?
- General requirements
 - Does it refer to the project as research?
 - Ensure that compensation is **not bolded** or **bigger text**



Potpourri



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Warnings: Bots

- Beware bots and bad actors!
- Offering compensation & online data collection? Bots are likely
- Recommend proactively putting in prevention/mitigation measures
 - Have attention checks
 - Have time minimums and maximums for completion
 - Limit one compensation per participant (may include IP address collection)
 - Captcha
- Be sure to include this in your protocol and reference it in the consent

Troublesome terminology

- Anonymous – The data was never (including at the point of collection) identifiable, and it's impossible to re-identify.
- De-identified – It is not reasonably possible for the Investigator to re-identify the subject.
- Coded – The Investigator retains a key that can re-identify subject ID.
- Confidential – Identifiable information will not be shared beyond described in the consent.

Troublesome terminology (cont'd)

- **Exempt** – Requires IRB review and approval, prior to implementation.
- Expedited – Subject to all approval requirements in 45 CFR 46.111. Not synonymous with faster (unfortunately).

Best practices: Online surveys

- Include the consent form at the start of the survey along with an option to consent or not consent with not consenting ending the survey.
- Only refer to the survey as anonymous only if it will truly be anonymous (i.e., no identifiable information will be collected in the survey and none will be automatically linked by the survey platform).
- Many survey platforms will automatically collect identifiable information (e.g., IP address, email address, etc.) unless explicitly disabled.

Best practices: Interviews

- Tailor the confidentiality measures to the sensitivity of the data being collected.
- Remember: video-recording faces is identifiable!
- Transcription via videoconference application (e.g., Zoom) is likely to include the name of the researcher and participant unless modified.
- Use pseudonyms when appropriate.

Best practices: Focus Groups

- Similar to interviews, but with increased potential confidentiality risks due to the group nature.
- Include a statement in the consent and introduction script to this effect.
 - For example: “We can't promise that everyone in the focus group will keep things private, but we are asking you and all other participants not to share anything said in the group with anyone outside the session.”

Best practices: Recordings and transcriptions

- If recording will take place (video or audio) the consent should clearly state this.
- If recordings will be transcribed by any 3rd party transcription services/software (including Zoom auto-transcription), the service/software should be named in the protocol and consent form.
- Cloud-based, AI transcription services are typically not secure or confidential.
 - Future iterations of the AI will be trained on the data provided.
- It is recommended to use transcription software that can run without the internet or involves real humans and real NDAs.
 - Example offline transcription options (aTrain and noScribe):
 - [Temple library page on transcriptions](#)

Consent and video-recording in your classroom

- Efforts to reduce or eliminate the possibility of undue influence (even if it is just the perception of undue influence) are paramount when researching your students.
 - Have someone who is not affiliated with the research consent subjects.
 - When possible, set up mechanisms so that you will not know who participated until after grades are in.
- Not participating in research should mean that you are not impacted by the research.
 - Asking non-participants to move seats can be problematic.

Submitting to the IRB: Basics

- IRB template documents
 - research.temple.edu > Compliance > Institutional Review Board (IRB) > Investigator Quick Links
 - <https://research.temple.edu/research-compliance/institutional-review-board-irb/investigator-quick-links>
- CITI training
 - First time: research.temple.edu > Compliance > Institutional Review Board (IRB) > IRB Trainings and Resources
 - <https://research.temple.edu/research-compliance/institutional-review-board-irb/irb-trainings-and-resources>
 - Subsequent visits: citiprogram.org
- ERA submission “How to” videos
 - research.temple.edu > Compliance > Institutional Review Board (IRB) > IRB Submission Video Tutorials
 - <https://temple.hosted.panopto.com/Panopto/Pages/Sessions/List.aspx?folderID=40de74d4-3cd0-4172-a08a-b1b000dce45b%3F>



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