TEMPLE UNIVERSITY®

Is IRB review needed? Then what?

David Comalli

IRB Director

November 13, 2025

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

TEMPLE UNIVERSITY®

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.

TEMPLE UNIVERSITY®

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.

TEMPLE UNIVERSITY®

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 organization vs several
    - A key facet is determining if the purpose and design reflect improving a given company, as opposed to extending beyond that company
  - Interviews – Warren Buffet
    - Interested in his story, or in how billionaires think and act?

TEMPLE UNIVERSITY®

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

TEMPLE UNIVERSITY®

HSR: Deeper definition dive

- “Information about whom” –
  - Questions about a person

    vs
  - Questions about the company they work for / run

    vs
  - Questions about their opinions about the company they work for / run

HSR: Deeper definition dive

- Intervention –
  - Physical procedures, manipulation of individual or their environment for research purposes.
  - Think “Experiment”
- Interaction -
  - Communication or interpersonal contact with individuals.
  - Includes posting of anonymous surveys

TEMPLE UNIVERSITY®

Common misconceptions

- Human subjects research must always involve direct intervention or interaction with individuals.

FALSE

  - Analyses of private, identifiable data.

- An anonymous survey of adults does not require IRB review

FALSE

  - Surveying people (even online surveys) is considered an interaction, so even if anonymous it involves “human subjects.”

Online observations/data scraping

- Key determiner is if the information/data/posts are private or public.
  - If you have to “friend” someone to see the content – Private
  - If you need to be a member of or approved to be in the “group” or subreddit – Private
  - Twitter posts – Public
  - Twitter DMs – Private

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

TEMPLE UNIVERSITY®

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
  - GDPR, website terms and conditions
  - DUAs, NDAs, other PiTAs, etc.

TEMPLE UNIVERSITY®

So, your protocol is Human Subjects Research…

TEMPLE UNIVERSITY®

IRB Review categories

- Exempt: A designated reviewer determines that the research is exempt from certain rules and regulations.

- Expedited: A designated reviewer approves the research initially, annually (in some cases), and any Amendments.

- Full Board: A fully convened IRB committee reviews the research initially, annually (at minimum), and any Amendments.

TEMPLE UNIVERSITY®

Exempt categories (must be minimal risk)

- Exempt 1 - Research on educational practices
- Exempt 2 - Surveys, interviews, educational tests, or observation of public
  - No minors for the first two
- Exempt 3 - Benign (and short) behavioral intervention, collecting data solely via verbal or written responses or audiovisual recording
  - No minors
- Exempt 4 - Secondary data analysis of initially identifiable information
- Exempt 5 (Federal demonstration project), 6 (Taste and food testing), 7 (Collecting identifiable data for future research with Broad Consent), and 8 (Using data collected under 7) are either not relevant or not happening at Temple

TEMPLE UNIVERSITY®

Expedited categories (must be minimal risk)

- Expedited 1 - Research on drugs or devices that don't need specific FDA approvals (INDs or IDEs)
- Expedited 2 - Collection of blood from healthy adults (<550 ml/8 wk; up to 2x/wk) or other adults and children (<50ml or 3 ml/kg/8 wk; up to 2x/wk)
- Expedited 3 - Noninvasive collection of biological specimens
- Expedited 4 - Noninvasive collection of data (MRI, EEG, US, hr, bp, etc.)
- Expedited 5 - Secondary analysis of identifiable data that isn't under HIPAA
- Expedited 6 - Data collected from video/audio recordings
- Expedited 7 - Surveys, interviews; research on cognition, perception, language, and other individual/group characteristics and behaviors

Full committee review

- Not a gathering of hooded figures.
- Group of at least 5 who review and vote on approval, requesting changes, or (rarely) disapproval.
  - Minimal risk or greater than minimal risk?
- Similar review criteria to Expedited review.
  - Additional requirements based on risk

TEMPLE UNIVERSITY®

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.

TEMPLE UNIVERSITY®

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.)

TEMPLE UNIVERSITY®

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.)

TEMPLE UNIVERSITY®

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.

TEMPLE UNIVERSITY®

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).

Temple University

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)

TEMPLE UNIVERSITY®

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

TEMPLE UNIVERSITY®

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

TEMPLE UNIVERSITY®

TEMPLE UNIVERSITY®

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

TEMPLE UNIVERSITY®

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.

Temple University

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).

Temple University

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.

Temple University

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.

Temple University

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.”

Temple University

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

Temple University

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

TEMPLE UNIVERSITY®

Relying on other IRBs

(Reliance Agreements / Institutional Authorization Agreements)

Temple University

How to submit in ERA when relying on another IRB

- Create a new study as you normally would (with all study docs).
  - Include a clearly labeled memo stating who will be the IRB of Record.

- Every IRB is unique in what other documents they require.
  - N/A for WIRB and Advarra

- Include any documents associated with the IAA (e.g., local context forms, LOIs, LOAs, ancillary committee checklists, etc.).
  - N/A for WIRB and Advarra

- **We will do a local context review. Once the submission passes local context requirements, we will provide a letter indicating that the study can be submitted to the other IRB.**

Temple University

All studies that we are ceding IRB review

- Before submitting to the IRB of record, submit to the Temple IRB for a local context review.

- Local context reviews examine:
  - PI and physician credentials
  - All research personnel CITI training
  - fCOIs?
  - Ancillary Committees (IBC & MRC)
  - Temple HIPAA Authorization
  - Consent

Temple University

Local context review (cont'd)

- Consent form:
  - PI and study team contact information
  - Injury statement is consistent with the contract – Consult w/ Lisa Landsberg
  - Reference to the separate HIPAA Authorization is included*
  - Temple IRB, Temple University, and Temple University Hospital System and its affiliates are listed as entities that have access to the study records
  - Compensation conforms w/ TU policies (e.g., ClinCard, cash exemptions, gift cards)
  - Are LAR signature blocks appropriate given what Temple is doing?
  - Is the Temple protocol number included?

- HIPAA Authorization
  - Using the new (harmonized with FCCC) HIPAA Authorization?
  - Are the study-specific sections (in blue) filled out correctly

Temple University

When relying on IRBs that **aren't** WIRB (WCG) and Advarra

- We will need to sign a reliance agreement (or LOA pointing to the SMART IRB Reliance Agreement).
  - Contact us and their IRB before submitting to start the signature process.

- Beware additional forms:
  - e.g., local context forms, LOIs, LOAs, ancillary committee checklists, etc.

- Send us via email or RNI submission:
  - When Temple is approved to start the research
  - When Temple is closed as a site.

Temple University

What needs to still be submitted to our IRB after the study is approved?

- Approval letter (unless approved by WIRB or Advarra)
- Reportable events
  - Serious or continuing noncompliance
  - Termination or suspension
  - Unanticipated problems involving risks to subjects or others
- Personnel changes
- Closure letter (unless WIRB or Advarra are the IRB of Record)

Temple University

IRB@temple.edu

http://research.temple.edu/irb

215-707-3390

TEMPLE UNIVERSITY®