



**Temple  
University**

# IRB Submissions: Various Research Types and Clinical Research vs QI

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October 16, 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 and chart reviews 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
  - HIPAA, FDA, consent, FERPA, etc.
- Temple's Policies
  - CITI training, approval routes, etc.

# Example: Chart review & excess samples

- Ethical –
  - A proportion of our patient population would not want their charts accessed without consent.
  - A higher proportion would not want their tissue used without consent.
- Risks/benefits –
  - Possible risk of loss of confidentiality.
    - While lesser than risks associated with care, it is a very real risk.
  - Possible benefits to science and healthcare.

# Chart reviews as an example (cont'd)

- Regulatory (HIPAA) –
  - Criteria for a waiver of HIPAA (impracticable, minimum necessary, earliest destruction of identifiers)
  - Non-intuitive identifiers
  - DUAs & MTAs (signed by the institution, not investigator)
  - Reportable breaches
- Temple Policies –
  - TUHS AI Committee
  - Transferring data/specimens from TUHS to TU

# 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.

# Case Studies

- Generally, are considered not human subjects research
  - If there are more than 3 patients in a case series, Temple IRB will likely want to review it
- No IRB review does not mean ethics should not be followed
  - When possible, get consent
  - HIPAA regulations still apply
    - Do not publish any of the 18 HIPAA identifiers
  - Maintain patient confidentiality

# QI vs Research

- A majority of QI does not meet the definition of HSR, but some does
- The IRB considers the design of a study, and some QI is designed to be generalizable
- A key facet is determining if the purpose and design reflect improving a given clinic / hospital system, as opposed to extending beyond that clinic / hospital system
  - Difficult to argue that analyses of patient outcomes is not designed to be generalizable

# Examples of HSR and Not HSR

- Case study/series of 1-3 patients – NHR
- Case series of 4+ patients – HSR
- Anonymous survey of physicians about their methods, knowledge, and opinions – HSR
- Identifiable survey of physicians about their hospital's practices – NHR
- Meta-analysis of published works to determine frequency of X – NHR
- QA/QI that is specific to Temple's operations – NHR
- QA/QI that involves other institutions – likely HSR
- Comparing two SOC treatments via chart review – HSR
- Analysis of de-identified data and tissue – Could be HSR or NHR

# 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)

- Retrospective – Data that exists as of today. Not a synonym for observational study.
- HIPAA Waiver – When HIPAA Authorization for research is not required. Not synonymous with HIPAA Authorization.
- 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).

# NHSR Determination tips...

- If unsure email a 2-3 paragraph summary to [irb@temple.edu](mailto:irb@temple.edu) with the subject “Research Determination.”
  - Brief summary of the project including: the objective, methods, and site(s). If using surveys or interviews, include a draft.
- Journals and colleagues may ask for IRB approval
  - Having an email in hand saves you from ulcers

So, your protocol is Human Subjects Research. What's next?



Submit to the IRB via ERA

# 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) and HIPAA Authorization
  - Questionnaires and/or Interview guides
  - Recruitment materials (flyers, phone scripts, email scripts)
  - Data collection tools
  - Other study-specific documents (drug brochures, intervention materials, etc.)

# 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 post-approval changes, submit an Amendment.

# 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 currently approved consent when enrolling subjects.

# Website: Protocol and Consent Templates

# Chart reviews and the IRB

- **Use our new Chart Review Template!**
- The IRB must review and approve a chart review, before you begin accessing study records.
- The primary function of the IRB for chart reviews is HIPAA compliance.
- Accessing records (even your own patients') for research without IRB approval, is a HIPAA violation.

# Data Collection: Know what you can collect

- IRB approved protocol should be followed when collecting data. If a data collection sheet has been submitted and approved, this is the only data you can collect unless you submit an Amendment.
- The protocol sets the constraints on what data can be obtained:
  - Inclusion / Exclusion criteria (best when using ICD- 9/10 codes).
  - Date range of data to be collected.
  - Variables that can be collected.
    - This can be presented via a separate data collection sheet
  - When identifiers will be destroyed

# HIPAA's 18 identifiers

- Name
- Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)
- All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)
- Telephone numbers
- Fax number
- Email address
- Social Security Number
- Medical record number
- Health plan beneficiary number
- Account number
- Certificate or license number
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web URL
- Internet Protocol (IP) Address
- Finger or voice print
- Photographic image - Photographic images are not limited to images of the face.
- Any other characteristic that could uniquely identify the individual

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# Obtaining data

- When possible, use [TUHS Service Now](#)
- Service Now + needing no identifiable data = no IRB submission or approval necessary
- New REDCap IRB Self-Determination
  - [redcap.templehealth.org/redcap/surveys/?s=WCWYTTTLTRN4KTLP](https://redcap.templehealth.org/redcap/surveys/?s=WCWYTTTLTRN4KTLP)

# Data collection best practices

- Data collection procedures are outlined in the study protocol.
- Your initial query will generate a list of potentially eligible patients

MRN	Study ID#
9824658	001
4585689	002
3895687	003

# Data collection best practices

- You can then create a separate spreadsheet of the actual data
- Best practice will always separate identifiable data from study data.

MRN	Study ID#
9824658	001
4585689	002
3895687	003

Study ID#	Age	Sex	BMI	Asthma
001	48	M	28	N
002	65	M	32	N
003	33	F	27.5	Y

- The IRB still considers this identifiable data, because a key exists.

# Data collection best practices

- Ideally, once all data is collected, the identifying key will be erased/destroyed to remove any identifying link.

Study ID#	Age	Sex	BMI	Asthma
001	48	M	28	N
002	65	M	32	N
003	33	F	27.5	Y

# Data collection best practices

- Maintaining a master linking spreadsheet may be necessary, depending on your study.

MRN	Study ID#
9824658	001
4585689	002
3895687	003

Study ID#	Age	Sex	BMI	Asthma
001	48	M	28	N
002	65	M	32	N
003	33	F	27.5	Y

- **Provide a justification (in the protocol) for maintaining the key beyond data collection.**

# Data protection

- Only approved personnel should have access to the data set.
- All personnel should be appropriately trained on using relevant data collection and storage protocols.
- HIPAA-required confidentiality measures:
  - All study files should be password protected
  - Files should be stored in an encrypted machine (TUHS computers already provide this if connected to the network)
  - Strongly encourage using **REDCap**
  - Any paper documents must be kept behind a locked cabinet in a locked office
  - Secure shredding must be used when destroying paper data
  - When possible, data should never be stored with identifiable information

# Sharing data

- If you intend to share data that includes any of the 18 HIPAA identifiers, this must be described in the protocol.
- Sharing identifiable data outside of Temple will require a Data Use Agreement (DUA).
  - Mark.Kats@temple.edu or Dan.Starr@tuhs.temple.edu
- Data can only be shared using a “Limited Data set” which can include
  - dates such as admission, discharge, service, DOB, DOD;
  - city, state, five digit or more zip code; and
  - ages in years, months or days or hours.
- All other identifiers must be excluded from a limited data set.

# Potpourri

- Amendments are always needed for:
  - Change in PI (even if we are not the IRB of Record)
  - Adding new sites/hospitals. Even within TUHS (e.g., WFH)
    - Unfortunately, Chestnut Hill is not covered by our IRB
  - Change in external funding (gaining or losing)

# Potpourri (cont'd)

- HIPAA Authorization: Have participants sign **both** signature blocks

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***By signing this section 11, you acknowledge that your medical records regarding HIV status, mental health, genetic information and substance abuse may be used or disclosed as a part of the research.***

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
Or Legal Representative Signature: \_\_\_\_\_ Date: \_\_\_\_\_



\*\*\*\*\*

*Signatures:*

I agree that my protected health information may be used for the research purposes described in this form.

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
or Legal Representative: \_\_\_\_\_ Date: \_\_\_\_\_



\_\_\_\_\_  
Printed Name of Patient (if signed by LAR)

\_\_\_\_\_  
Printed Name of Legal Representative (if any):

\_\_\_\_\_  
Relationship of LAR to Participant

(Indicate why the LAR is authorized to act as a surrogate health care decision-maker under the Commonwealth of Pennsylvania)

\*\*\*\*\*



# Potpourri (cont'd)

- Subscribe to the Temple University IRB listserv to receive regular updates on human subjects research policies, procedures, news, and information - including changes and upgrades to the Human Subjects Module in ERA. To join this listserv send an email to [listserv@listserv.temple.edu](mailto:listserv@listserv.temple.edu).
- In the body of the email enter, "subscribe IRB-UPDATES yourfirstname yourlastname" (no quotes)