



**Temple
University**

Investigator IRB Information Packet – The Basics

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IRB Resources

- IRB office phone number and email
 - 215-707-3390; IRB@temple.edu
- For direct contact information: research.temple.edu/ovpr-updates/staff-directory#IRB
 - We respond to emails and calls within 1-2 business days.
- For videos on how to navigate ERA for various submissions go to [IRB Training and Resources](#) > Access IRB Submission Tutorials via AccessNet

<https://temple.hosted.panopto.com/Panopto/Pages/Sessions/List.aspx?folderID=40de74d4-3cd0-4172-a08a-b1b000dce45b>

Protocol and Consent Templates

- All protocol and consent templates and our HIPAA Authorization are located on the Investigator Quick Links page (<https://research.temple.edu/research-compliance/institutional-review-board-irb/investigator-quick-links>)
- There are specific consent templates for common research methods.
- Protocol – Detailed document that tells the IRB how you will conduct the study
- Consent – Document that tells the potential subject what will happen if they participate in the study.

Protocol and Consent Template Tips

- Don't leave in the instructional language.
- The IRB focuses on the abstract, title, investigator, and study procedures
 - Particularly: timing, inclusion/exclusion, what data will be accessed / collected, privacy & confidentiality, recruitment, study methods, and consent methods.
- Be consistent across all study documents.
 - Participant duration, N, if identifiers are linked to data via a key, etc.
- Don't describe durations with dates, use months / weeks / years.
 - Bad: Recruitment to be completed by December 2019.
 - Good: Recruitment to be completed 3 months after IRB approval.

ERA (submitting to the IRB)

- All submissions, reviews, and approved documents occur in ERA (era.temple.edu).
 - IRB submissions all occur in the “My Human Subjects” tab, not the “My Proposals and Awards” tab.
- If you are not the PI of a project, you can find it via “Quick Find” (if you have been added as personnel).
 - “Locate My Records” only shows you studies that you are the PI for.
- For videos on how to navigate ERA for various submissions go to [IRB Training and Resources](#) > Access IRB Submission Tutorials via AccessNet

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Personnel

- All personnel conducting human subjects research must be approved by the IRB before working on a project.
 - This includes the PI, anyone consenting subjects, anyone interacting with the subjects, anyone conducting the intervention, and anyone handling identifiable data
- Only full-time faculty can be the PI.
 - Exceptions are possible but require signatures from the Dean and VPR.
(https://research.temple.edu/sites/research/files/images/OVPR_Request_for_Principal_Investigator_Status_10062023.pdf)
- Students, fellows, and adjunct faculty often do not have ERA access by default, they should go to era.temple.edu and follow the steps for First Time Users.

Personnel (continued)

- The PI is responsible for ensuring all research personnel have appropriate training and credentials to fulfill their expected research roles
- All research personnel must complete CITI Training
- If adding personnel from outside of Temple:
 - They must sign the Research Personnel Signature (located on the [Investigator Quick Links page](#)) and provide proof of their human subjects training

CITI Requirements ([IRB Training and Resources](#))

- All Temple-affiliated research personnel must have CITI Training through either Temple University or Fox Chase.
- CITI requirements are the same for the PI and any other research personnel:
 - Biomedical Research Course or Social Behavioral Research Course
 - Practice Runs Training Course
- Good Clinical Practice (GCP) and ICH is required if conducting an NIH-funded or FDA-regulated clinical trial.
- Responsible Conduct of Research (RCR) is required for NSF-funded research.

Turnaround Times & meeting dates

- Initial submissions and Amendments are generally reviewed within 3 weeks of IRB receipt.
- Continuing Reviews are reviewed within 30-20 days of the expiration date.
- Responses to Modifications Required to Secure Approval are reviewed within 5-10 business days after receipt.
- Personnel Amendments (where no study documents—including the protocol—are altered) are reviewed within 3 business days.
- We have two IRB Committees: A1 and A2
 - A1 meets every 2nd Wednesday of the month
 - A2 meets every 4th Wednesday of the month

Turnaround Times & meeting dates (cont)

- There are two issues that can substantially delay hearing from the IRB:
 - **Not actually submitting.** Unless the status of the submission changes from “Under Development” to “Electronic Submission Pending,” it has not been submitted, and the IRB will not know it exists.
 - **Slow approval route.** The IRB does not receive a submission until everyone in the approval route (minimum of the PI) has Acknowledged a submission.
- If you do not hear from the IRB within about 3 weeks of receipt, contact us, because something likely went wrong.

Non-IRB Requirements and Resources

- If transferring or receiving biological specimens:
 - Material Transfer Agreement (MTAs) – Contact **Contract Specialists** within the Office of Technology Commercialization & Business Development (<https://research.temple.edu/about-us/staff-directory#commercialization--ip>)
- If transferring or receiving identifiable data or a Limited Data Set (e.g., PHI that includes zip code or dates):
 - Data Use Agreement (DUA) - Contact **Contract Specialists** within the Office of Technology Commercialization & Business Development (<https://research.temple.edu/about-us/staff-directory#commercialization--ip>)
- All funded (industry, non-profit, government, etc.) research must have an associated Proposal in ERA.
 - For help navigating the grant process: <https://research.temple.edu/about-us/staff-directory#pre-award-management>

Non-IRB Requirements and Resources

- IBC (Institutional Biosafety Committee) – ibc@temple.edu
 - Needed if collecting or storing biological specimens in a non-clinical laboratory
<https://research.temple.edu/about-us/staff-directory#institutional-biosafety>
- MRC (Medical Radiation safety Committee) – mrc@temple.edu and ehrs@temple.edu
 - Needed if subjecting participants to any amount of radiation for research purposes.
 - <https://campusoperations.temple.edu/ehrs/radiation-safety>
- COI (Conflict of Interest):
 - All Schools and Colleges (except Lewis Katz School of Medicine):
(215) 707-7819; coitemple@temple.edu
 - Lewis Katz School of Medicine only: (215) 707-1986; coisom@temple.edu
- Export Control (i.e., working with foreign collaborators):
 - <https://research.temple.edu/research-compliance/export-control>; exportcontrol@temple.edu.

Consent

- The consent should be written in lay language that is understandable to the participants that will enroll into the research.
- Unless the study is approved as Exempt, the IRB stamps consent forms.
 - The IRB Approved and Stamped Consent(s) should be the ones provided to subjects.
- If you have a consent, the expectation is that it is provided to subjects to read, even if signed consent is not required.
- For most minimal risk research, the IRB encourages requesting a waiver of documentation of consent.

Consent (cont'd)

- If signed consent is necessary, be sure to have the person obtaining consent sign and date the consent.
- When including minors or individuals who lack capacity to consent:
 - Ensure that a parent or legally authorized representative is consented.
 - Be sure that the protocol describes how consent and assent will be obtained and documented.
 - Include in the protocol how capacity to consent will be determined.
 - Ensure there are additional protections to ensure the participants are not coerced into participating.

Approved Docs

- For non-Exempt studies (i.e., studies approved via Expedited or Full Board review), the approved protocol, consent(s), assent(s), and the Temple HIPAA Authorization (as applicable) to the Approved Docs tab.
- Use the Approved Docs tab to easily access approved documents.
- All Amendments involving changes to the above documents should download the clean protocols/consents and make tracked changes to those documents.
- The [submission tutorials](#) includes a video of how to access and download.