New Investigator IRB Information Packet – The Basics

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IRB Resources

- IRB office phone number and email
  - 215-707-7792; 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 TUPortal > My Offices > Research > IRB Submission Tutorials: https://tuportal6.temple.edu/group/research/home#DynaContentContainer_ysia_6

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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/investigaor-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.

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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.

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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 TUPortal > My Offices > Research > IRB Submission Tutorials: https://tuportal6.temple.edu/group/research/home#DynaContentContainer_ysia_6

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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.

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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

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CITI Requirements

- 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.

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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

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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.

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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/ovpr-updates/staff-directory#OTDC)
- 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/ovpr-updates/staff-directory#OTDC)
- 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/ovpr-updates/staff-directory#Grants%20Administration

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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/ovpr-updates/staff-directory#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.

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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.

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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.