How to submit to the Temple IRB, external IRBs, and navigate ERA

Updated 1/12/22
Slides Summary / Table of Contents

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Tips and Tricks for avoiding common pitfalls and navigating the submission process
Beware the “Exempt” trap!

• Not Human Subjects Research =! Exempt

• HHS pulled cruel jokes with certain IRB terms like “Exempt”

• Exempt has a specific meaning in the IRB world
  • All “Exempt” studies are human subjects research

• The IRB must review Exempt research prior to starting
Know who can be the PI!

• Only fulltime faculty members can be the PI, unless a special PI Exception form is signed by your dean and the Vice President for Research (Michele Masucci).

• If you are not fulltime faculty and don’t have that form, make sure you are not listed as the PI.
  • Even if the study is your idea, and you’re doing the vast majority of work.

• If you assign the wrong PI, reach out to the IRB.
  • Only the IRB staff can change the PI for a created study.
Funding matters

• Federally-funded studies:
  • May require Single IRB.
  • Require additional language in the consent.
  • Consult with the IRB prior to submitting the protocol (and grant if multi-site).

• Industry-initiated studies:
  • Must be reviewed by WIRB or Advarra, but will be submitted to the Temple IRB prior to external IRB review.
Submitting to the IRB: Basics

• CITI training
  • First time: research.temple.edu > Research 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

• IRB template documents
  • research.temple.edu > Research Compliance > Institutional Review Board (IRB) > Investigator Quick Links
    • https://research.temple.edu/research-compliance/institutional-review-board-irb/investigator-quick-links

• ERA (the website that submissions to and communications from the IRB occur)
  • era.temple.edu
  • User guide at research.temple.edu > ERA > Training Tutorials & Documentation
    • https://atlas.ocis.temple.edu/research/researchadmin/era/era_user_guide.asp
CITI training

• Be sure to affiliate with Temple University, **not** Temple Hospital
  • Easiest way is signing in via the IRB Training and Resources webpage
    (https://research.temple.edu/research-compliance/institutional-review-board-irb/irb-trainings-and-resources)

• Two required courses:
  • Biomedical Research or Social/Behavioral Research – takes ~1-4 hours
  • Practice Runs Training – 1 module, takes ~5 minutes
  • GCP (Good Clinical Practice) – Required if conducting a clinical trial that is NIH- or FDA regulated. – takes ~1-3 hours

• Does not need to be completed prior to submitting to the IRB but…
• Needs to be completed by everyone on the study before the IRB will approve the study
General IRB tips

• When planning, give at least 2 months for a submission to be approved.
  • The first review can take up to a month and there may be Mods Required.
  • Check in with a coordinator if you haven’t heard from us after a month.
• Read HRP-070, -071, -802, and -803.
  • [https://research.temple.edu/research-compliance/institutional-review-board-irb/irb-forms-standard-operating-procedures](https://research.temple.edu/research-compliance/institutional-review-board-irb/irb-forms-standard-operating-procedures)
• An hour of checking your work can save weeks in time-to-approval.
• The IRB stamps all non-Exempt consents forms and consent scripts.
• Use ERA as your repository for clean protocols, consents, and recruitment materials
  • That way you are always using / modifying the approved documents.
• If you have questions, reach out to a coordinator.
  • [https://research.temple.edu/research-compliance/meet-our-staff#IRB](https://research.temple.edu/research-compliance/meet-our-staff#IRB)
INSTITUTIONAL REVIEW BOARD

The mission of Temple University’s Human Research Protection Program (HRPP) is to protect the rights, dignity, and welfare of human subjects who participate in the research programs of the Temple System. Specifically, the HRPP has authority over all human subjects research conducted using any property or facility of Temple and under the direction of any employee, student, or agent of Temple. This authority extends to Temple University Hospital System employees, who must submit human subjects research to HRPP.

- Human subjects research is reviewed via three methods: a convened IRB; expedited review; or exempt review. Note that the determination for exemption is made by HRPP, not the investigator, and therefore must always be submitted formally.
- The HRPP supports Temple’s dedication to excellence in research by promoting the ethical principles of respect for persons, beneficence, and justice as discussed in The Belmont Report. Investigators have ethical and Institutional responsibilities in conducting human research.

IN THIS SECTION
- Work Environment
- Export Control
- Conflict of Interest
- Institutional Animal Care & Use Committee (IACUC)
- Responsible Conduct of Research (RCR)
- Institutional Review Board (IRB)
- IRB Guidance on Human Subjects Protections Considerations Related to COVID-19
- Investigator Quick Links
- IRB Forms & Standard Operating Procedures
- FAQs | Institutional Review Board
- IRB Trainings and Resources
Protocol and consent templates

• Download the Word docs from the website.

• Don’t leave in the instructional language.

• The IRB focuses on the abstract, title, investigator, and study design
  • Particularly: timing, inclusion/exclusion, what data will be accessed / collected, privacy & confidentiality, recruitment, study methods, and consent methods

• Make sure the IRB knows what you’re doing, why you’re doing it, and can grant a waiver of HIPAA authorization (consult HRP-428 for the requirements) if doing a retrospective chart review.
Protocol and supplemental document tips

• Don’t leave in the instructional language
• Provide Word docs and tracked changes in Word (if a response)
• 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 completed by December 2019.
  • Good: Recruitment completed 3 months after IRB approval.
• Double-check you’re using the approved document as the base for any Modifications.
• The IRB focuses on the abstract, title, investigator, and study design (particularly timing, inclusion/exclusion, what will be accessed, and privacy & confidentiality).
Chart review protocol template

• Don’t leave in the instructional language

• When possible, use the methodology provided in the table (section 8d)
  • Be sure you can actually follow it if you plan to use it

• The IRB focuses on the abstract, title, investigator, and study design (particularly timing, inclusion/exclusion, what will be accessed, and privacy & confidentiality)

• Make sure the IRB knows what you’re doing, why you’re doing it, and can grant a waiver of HIPAA authorization (consult HRP-428 for the requirements)

• To the website! (https://research.temple.edu/research-compliance/institutional-review-board-irb/investigator-quick-links)
Consent tips

• If recording (video or audio), it must be in the consent.
• If using a contractor to transcribe, it must be in the consent.
• Minimal risk research usually does not require signed consent.
• Be clear about the potential for follow-up contacts (including member checks).
• Unless your study has an intervention, the Survey Interview and Focus Group Consent Template is the best bet.
• If using the Minimal Risk Consent Template:
  • Only include the consent summary if the study is federally funded and the consent body is longer than 4 pages.
• To the website! (https://research.temple.edu/research-compliance/institutional-review-board-irb/investigator-quick-links)
Remote research considerations - Consent

- Is a waiver of documentation of consent appropriate?
  - No for HIPAA-regulated research or greater than minimal risk research

- Ensure your protocol has a plan for how you know the person signing is the participant (e.g., video-conference or phone call while consenting)

- Use REDCap to acquire signatures when possible

- FDA-regulated research cannot have remote consent at this time
Remote research considerations - Risks

• Are there people in the background of the participant’s video or phone call that should not be privy to the discussion or activity?
  • How about on your end?

• Is transmitted data securely?
  • HIPAA-compliant video calls
  • Survey responses encrypted?

• Are extra precautions necessary because an activity is occurring at someone’s home?
  • Exercise interventions
  • At-home sample collection
ERA

• ERA is the portal through which Investigators and the IRB communicate (submissions and responses) officially.

• The IRB / ERA User Guide is helpful and has screen shots, but you will waste time and effort if you don’t use the table of contents.
  • [https://atlas.ocis.temple.edu/research/researchadmin/era/era_user_guide.asp](https://atlas.ocis.temple.edu/research/researchadmin/era/era_user_guide.asp)

• era.temple.edu > sign in > My Human Subjects

• Before going to the website, some tips.
ERA tips

• Make sure that you’re in My Human Subjects, not My Proposals.
• Only full-time faculty can be the PI.
  • The 3rd prompt will ask for the PI, but will automatically have your name in it. Change to the correct PI.
• Immediately add the Application for Human Research (see ERA User Guide pages 13-15).
• Immediately add yourself to the Application for Human Research (eForm).
  • If you don’t you won’t be able to access the record in the future.
• When all documents (minimum eForm and protocol) are uploaded, click submit, I agree, and continue.
  • Ensure it says “Electronic Submission Pending” on the Submissions page.
  • Emails are generally sent to your / your PI’s @temple.edu address.
• The Department Head needs to be in the approval route for initial subs.
  • If your PI is the DH, then add the Dean.
• Upload docs via “Add” button, Not the Attachments tab.
External IRB Process: sIRB, WIRB, Advarra
Know the IRB of Record

• IRB of Record - provides approval for Initial & subsequent submissions.

• Temple will not always be the IRB of Record

• The federal government* mandated single IRB (sIRB) review for multisite, government-funded research
  • *Excluding the DOJ and FDA**
    • **Unless funded by a federal agency that is not the DOJ

• Industry-initiated studies must go to either WIRB or Advarra

• Another IRB can be the IRB of Record*, even if not required
  • *Depending on IAA constraints discussed later
Steps involved in relying on another IRB

• Determine who the IRB of Record will be, preferably in the grant stage.

• Collaborators at the institution whose IRB will review the study should talk with their IRB about their process.

• Contact the Temple IRB and discuss methods for facilitating the process.

• Start the IAA process.

• Submit in ERA so the Temple IRB can perform a local context review.
  • We will release the study to the other IRB after it passes our local requirements.
IAAs (reliance agreements)

• IAA = Institutional Authorization Agreement (i.e., a reliance agreement)

• IAAs are required in anytime Temple will not be the IRB of Record
  • Except if the study is being submitted to a WCG IRB (.e.g., WIRB) or Advarra

• IAAs are not a painless process and will likely result in slower approval to start research, so start early
IAA constraints

- The IRB of Record must be AAHRPP Accredited.
  - Ask their IRB or check [https://www.aahrpp.org/learn/find-an-accredited-organization](https://www.aahrpp.org/learn/find-an-accredited-organization)

- The SMART IRB agreement should be used unless the IRB of Record requires otherwise.
  - [https://smartirb.org/reliance/](https://smartirb.org/reliance/)

- Beware additional documents required by the IRB of Record!
  - Local context review forms
  - Letter of Intent or Indemnification
  - Letter of Acknowledgement

- The study cannot be Exempt.
How to submit in ERA when relying on another IRB

- Create a new study as you normally would, and include a clearly labeled memo stating who will be the IRB of Record and if the IAA will use SMART IRB.

- Include any documents associated with the IAA (e.g., local context forms, LOIs, LOAs, ancillary committee checklists, etc.).
  - Every IRB is unique in what other documents they require

- If submitting to WIRB, include the WIRB Initial Submission Form

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

• Can the PI be a PI?

• Do research personnel have required CITI trainings and are in the route?

• Is there a known fCOI, and is the required language in the consent?

• Ancillary committee (e.g., MRC, IBC, etc.) notification or approval, as appropriate

• Are there any differences between the main protocol and how it will happen here?
Local context review (cont’d)

• Consent form:
  • PI and study team contact information
  • Injury statement is consistent with the contract
  • 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
  • Are LAR signature blocks appropriate given what Temple is doing?
  • Are the additional signature blocks necessary given the protocol?
    • Are HIV status, substance abuse, or mental health records being accessed, even solely for exclusionary purposes?
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)
Screenshot notes

• This is not a 1 slide, 1 click format. There are some gaps and some steps that are combined within 1 screenshot.

• Pop-up windows that are in the screenshot will not exist until a button (like “Add”) on the main page is clicked.

• The pop-ups may appear in a different part of the screen or not be fully visible as they are in the screenshots.

• Use the red arrows to denote the button/clicking sequence.
Click “My Human Subjects” > Create New
Click Continue
MAKE SURE TO SELECT THE RIGHT PI
If you’re not the PI, you must change the PI before moving forward

Select PI - Google Chrome

[ Protocol Creation ]

Institution Number
25248

Title

Select PI
COMALLI, DAVID - RESEARCH: EXECUTIVE LEADERSHIP (24010)
Your name will show up automatically, delete and search for PI if it's not you. Then click the correct PI's name and then click “Continue”.
Add documents by clicking the “Add” button
Always create the Application for Human Research eForm first
Click the lower “Add” button to add the eForm.

Add Components - Google Chrome
Open the eForm
Add all research personnel, especially yourself (if you’re not the PI)
Start typing the last name of the person you’re adding and click their name.
Click “Select” button; continue adding personnel and then complete the eForm.
Add additional study documents by clicking the “Add” button.
Click “Choose File” and find the document.
“Name” should be succinct and informative; It’s what the IRB will see
Click “Upload”; See pop-up window refresh; repeat
Clicking “Close” will refresh the main page and show all uploaded documents.
Click “Submit” when all documents are uploaded; Note it’s not actually submitted yet.
After the attestation, inspect the approval route and click submit; Make sure the Dept. Head is there.
Status will change from “Under Development” to “Electronic Submission Pending” once it’s submitted.
If adding Temple (Hospital or University) personnel, add them to the approval route by clicking “Add New Person to Review Path”
Type the last name and select the person
Click “Add” and repeat until all new personnel are added.
Look at the approval route and click “Continue”
You will get an email after the person ahead of you (as indicated in the previous approval route pop-up) has acknowledged the submission.
An Initial Application For Your Review

OFFICE_OLD, IRB
to me

An Initial Application has been submitted to the Institutional Review Board. Your Approval is required for this submission.

Please click the link below to review and comment on the following application

IRB #: 26289
Principal Investigator: DAVID COMALLI
Department: RESEARCH EXECUTIVE LEADERSHIP (24010)
Title: My example protocol for the talk that I'm giving right now
Sponsor: NO EXTERNAL SPONSOR

Your approval is required for this submission.

Click here for a short version of instructions on how to review this submission.

REMEMBER TO SAVE YOUR WORK BY CLICKING ON "SAVE" IN THE UPPER RIGHT-HAND SIDE OF THE REVIEWER'S DASHBOARD!!!!!!

To add your review, click here Reviewer Dashboard

To review the entire submission, click here Open Submission Package

If you have questions about the approval process, please contact the IRB Office at (215) 707-3390.
You may need to sign into ERA; Click the “Review” tab
Review documents by clicking on them

**Human Subject Protocol - Modifications Required to Secure Approval**

**Number:** 20289  
**Title:** My example protocol for the talk that I'm giving right now  
**Sponsor:** NO EXTERNAL SPONSOR  
**Submitted:** 08-Nov-2019 11:15:10 AM

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</thead>
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<td>IRB Application</td>
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<td>Consent Client 11.11.19</td>
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<td>Survey</td>
<td>Attachment</td>
<td>08-Nov-2019 11:15:09 AM</td>
<td>Modify</td>
</tr>
</tbody>
</table>

**Add Comments:**

To be shared with everyone

**Select a decision:**

- Acknowledge
- PI Clarification
If you notice an error, you can stop the approval route (so the error can be fixed) by adding a Comment and clicking “PI Clarification”; Re-submit after fix(es)
If the contents are acceptable, click “Acknowledge” and agree to the subsequent attestation.
Status can be viewed on the “Submissions” page as well; “Under Development” means not submitted.

<table>
<thead>
<tr>
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<th>Management Submitted On Date</th>
<th>Internal ID</th>
<th>Determination</th>
<th>Determination Date</th>
<th>Date From</th>
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<td>N/A</td>
<td>N/A</td>
<td>Log</td>
</tr>
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</table>
If something is “Electronic Submission Pending,” Then it’s been submitted to—but not brought into—the IRB.
At any time, click “Show Route” to see who has Acknowledged and been notified.
The date under “Notified” only reflects when a person was notified.
They haven’t acknowledged without the “Acknowledge - Acknowledge” under “Decision”; Hover over Ack – Ack to see (left hand, top corner) when the person Acknowledged
“Workflow Step 2” reflects that the IRB has the submission, but has yet to review it.
Respond to “Modifications Required to Secure Approval” by clicking the “Respond…” link; Don’t create a “Modification” to respond to requested changes.
Select “Modifications Required to Secure Approval” from the dropdown (or “Deferred” if appropriate)
Remove documents that are requested to be changed; Don’t remove the eForm; Don’t use the Modify feature.
Add the new (Tracked Changes and Clean versions) documents

<table>
<thead>
<tr>
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<th>Type</th>
<th>Status</th>
<th>Actions</th>
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</thead>
<tbody>
<tr>
<td>Application for Human Research</td>
<td>IRR Application</td>
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<tr>
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<tr>
<td>Flyer</td>
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<td>Medical Record Abstraction Sheet</td>
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</tr>
<tr>
<td>Survey</td>
<td>Attachment</td>
<td>Completed</td>
<td>Modify</td>
</tr>
</tbody>
</table>

Show Existing Protocol Attachments
Click “Submit” once all updated documents are submitted; Don’t remove unchanged documents.
After the submission is approved, retrieve stamped consent forms by going to the “Approved” submission.
Click on the “Attachments” link within the submission
Find the IRB Approved and Stamped consent(s)

<table>
<thead>
<tr>
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<th>Category</th>
<th>Folder</th>
<th>Managed by</th>
<th>Submission</th>
<th>Versions</th>
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They should be sortable by “Category,” labeled as “<b>Stamped Consent</b>”.
Clicking “Category” will sort alphabetically; Clicking again sorts in the opposite direction.
All documents for the study can be viewed in the general “Attachments” tab
Sort "Category" or "Managed by" to bring Stamped Consents to top (generally)
<table>
<thead>
<tr>
<th>Name</th>
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<th>Managed by</th>
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<th>Versions</th>
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Mind “Last Updated” to ensure the correct version is being downloaded.
Create another submission by clicking the dropdown menu on the “Submissions” page.
Select the desired submission type; This example is creating a “Modification”
**My example protocol for the talk that I'm giving right now**

DAVID COMALLI - RESEARCH: EXECUTIVE LEADERSHIP (2010) (NO EXTERNAL SPONSOR)

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Click “Add”
Click and then complete the “Modification of Approved Human Research” eForm.
Click “Add” to add any additional documents; If changing approved documents, include tracked changes and clean versions.
When ready, click “Submit” and get to the approval route.
After signing in, type the Record # into the “Quick Find” search bar and hit Enter (or click the magnifying glass).
You can also search by the PI’s name, but this method is less specific.
Make sure the “Record Type” is “Human Subjects Protocol”
Then single click on the protocol number
Hover over “Edit”
It is suggested to avoid the other options, unless you are an **expert** ERA user.
Hover over “Edit”
It is suggested to avoid the other options, unless you are an expert ERA user
Move mouse over to the right then click on “Additional Submissions”
If that is not an option, click “Master Record”
If you clicked “Master Record,” click on Submissions to get to the Submissions page.