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Logging In

1. Access the Electronic Research Administration (eRA) site by entering https://era.temple.edu/ into your browser.

2. Click “Login”

3. Log into eRA using your Accessnet Username and TUsecure password.
Adding a Delegate

There are two ways that an individual other than a PI can submit items to the IRB: 1) as a Delegate of the PI, 2) as a Study Coordinator, Student Investigator, or Other Research Personnel. Delegation is distinct because it grants the Delegate access to all of the PI's items within a selected eRA Module. Delegation should be reserved for trusted research personnel. Individuals who only need to access a portion of the PI's protocols should be added to the individual protocols as a member of the research team. For more information on this, please see the section on "Student Investigator and Study Coordinator Roles". PIs are required to acknowledge all submissions before they reach the IRB — whether submitted by the PI, a Delegate, a Study Coordinator, or a Student Investigator.

Here are the steps to view your existing Delegates or add another Delegate:

1. After logging in, select the My Profile tab and then click Edit.
2. The General screen will present. Select Delegates.
3. The Delegates screen will appear. Click Add.
4. There will be two headers that appear: 1) Individuals who may access [NAME]'s items, 2) User accounts [NAME] can access

The first one will show everyone who can view your items:

<table>
<thead>
<tr>
<th>Name</th>
<th>Department</th>
<th>Messages</th>
<th>Work Queue</th>
<th>Calendar</th>
</tr>
</thead>
<tbody>
<tr>
<td>MING-HUI CHOU</td>
<td>RESEARCH; EXECUTIVE LEADERSHIP (24100)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The second one will show everyone who has granted you access to see their items:

<table>
<thead>
<tr>
<th>Name</th>
<th>Department</th>
<th>Messages</th>
<th>Work Queue</th>
<th>Calendar</th>
</tr>
</thead>
<tbody>
<tr>
<td>ERA USER</td>
<td>MAIN FACILITIES MANAGEMENT (600)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: You will not be able to make changes under “User accounts [NAME] can see”. If you need to view another person’s items, that person will need to go into their eRA account to add you as a Delegate.
5. To add somebody as your delegate, Click Add.

6. Begin typing the name of the person you want to make a Delegate. Select the desired name and then hit Select.

7. Initially, you will see that “No modules have been associated to this user.” To add Modules, select the plus sign.

8. Highlight the Module you would like the person to be able to see and then hit Select. For IRB submissions, you will select “Human Subjects”.

9. From here, you will be able to customize the level of access that the Delegate will have. By default, the Delegate will have View access under “Record Access”. In order to give the Delegate access to Edit (which is required to make submissions), you will need to select the radio button next to Edit. In this screen, you can make other customizations such as which communications the Delegate will be copied on.
10. Once you have made all necessary customizations, be sure to Save your changes.
Viewing Items as a Delegate

Here are the steps to view another person's items as their Delegate:
If you are listed as research personnel (student, study coordinator, etc.), you can view the protocol by using the Search function. For more information on this, see the section entitled “Searching for an Existing Protocol”. However, if you are listed as a Delegate and are not also listed as research personnel on a specific study, you will not be able to use the “Search” feature to pull up that study. Instead you will need to follow these steps:

1. Click on the Delegates icon to Show Delegates.

2. Click on the name of the person you are a Delegate for and this will show you a list of their studies. You can then enter the study to make submission, view documents, etc.

Note If you see a square that says “View Mode”, check to make sure that you have been given “Edit” access to that person's items in eRA.
My Human Subjects

Logging in will take you to your individual home page within eRA, which defaults to "My Open Action Items". This page will show you any submissions that require your electronic acknowledgement, if applicable to your position at Temple.

By selecting “My Human Subjects” tab located on the left side of the page, you will be able to search for your protocols and view the status, communications, or general information on your protocol(s). Note: If you do not have a “My Human Subjects” tab, please contact era@temple.edu for assistance.

Show/List – shows you all of the protocols that you have access to as a PI or a PI's delegate.

**Note:** For instructions on how to view items as a delegate, please see the section entitled “Viewing Items as a Delegate”

Search For – enables you to search for a specific protocol by Protocol Number, PI Name, Co-Investigator, Title, etc.

**Note:** Study Coordinators and Student Investigators can only access protocols by searching. They will not appear in Show/List.
Searching for an Existing Protocol

1. To search for a specific existing protocol, enter the Record Number.

2. Select “Open/Locate” or press Enter on your keyboard.

3. The protocol will appear on the bottom of the search page.

The following areas are present in the Results bar:

- Folder Icon – when this is clicked, it will open the protocol
- Protocol Number and Start Date
- Title of the Protocol
- Sponsor/PI/Department
- Quick Status Icon – If you hover your mouse over the Quick Status Icon, a quick status of the protocol will become visible

4. To enter the protocol, click on the Folder Icon.
My Profile

1. The My Profile tab is located on the left hand side of the screen.
   - **Edit** – allows the user to manage different aspects of their Profile including education, research interests, and publications.
   - **Settings** – allow the user to select preferences for how their portal will appear.

My Messages

1. The My Messages tab is located on the right hand side of the screen. It functions like a regular email account. Any messages sent to your Temple email account via the eRA system will also be stored and can be managed here.
Creating an Initial Application for a New Protocol

1. In the **My Human Subjects** tab, select **Create New**.

2. A pop up window will present asking you how you wish to create the protocol. By default, **New Human Protocol in Human Subjects Development** will be checked. Click on **Continue**.

3. Enter a **Title** for your new protocol, and click on **Continue**.

---

**My Human Subjects**

- Show/List
- Search For
  - Create New
  - Program Tools
  - Help - Dev
  - Help - Mgmt

**Create**

- New Human Protocol in My Human Subjects Development
- New Human Protocol in My Human Subjects Management

**Protocol Creation**

- Title
  - Test Protocol Creation

---

**Cancel**  **Spell Check**  **Continue**
4. Select your PI. Your own name will populate by default. If you are not the PI, you may (remove your name) and type in box next to Member by PI’s last name, then first name. Once the drop down box populates with the correct PI name, click Continue.

**Note:** Students, residents and non-faculty may not serve as the PI. If you are unsure whether you meet the criteria to serve as the PI, please contact irb@temple.edu

5. The protocol shell has now been created. Several key areas are highlighted below.

- Protocol Title
- PI
- Temporary Protocol Number
- Submission Type
- Add Institution Forms/Supporting Documents
Adding and Filling Out the Application eForm

1. From the Components for Initial Submission page, click Add Institution Forms/Supporting Documents.

2. Select the Initial Application form type which you will be submitting and select Add.

You must choose one of the two standard application forms – either the Application for Classroom Projects or the Application for Human Research. You must choose and complete the application in an eForm. Do not upload a Word version of the application form. Your submission will not be accepted by the IRB unless it includes an application eForm.

Note: The Application for Classroom Projects should be used if the professor requires the students to conduct human subjects research as part of an assigned project. The Application for Classroom Projects should not be used for a student’s Diamond Scholar research project, master’s thesis, doctoral dissertation, Capstone Project, or other similar intensive project. If you have any questions about which eForm should be used, please contact the IRB at irb@temple.edu.

This will bring you into the Application for Human Research eForm (see next page).
General Notes and Completing Section I:

- Complete all required fields (denoted with a red asterisk).
- Periodically Save to ensure that your work is not lost.
- The form does not have to be completed in one sitting. Hit Save to save and return later.
- Edit histories will be recorded for each individual user. They are visible under Form Hist.
- Section I: The Study Title, PI, and PI’s Department populate automatically. Enter the PI’s Physical Address and Phone number.
Completing Section II:
- Complete basic information on the research.
- Answer all questions required as indicated with a red asterisk.
- Answers to certain questions will prompt additional questions:
  - If you answer YES to External Sites, Appendix A will be added to the end of the application form.
  - If you answer YES to Drugs, Appendix B will be added to the end of the application form.
  - If you answer YES to Devices, Appendix C will be added to the end of the form.

<table>
<thead>
<tr>
<th>Estimated number of local subjects:</th>
<th>Age Range:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes ☐ No ☑ The study will enroll Minors</td>
<td>Minors</td>
</tr>
<tr>
<td>Yes ☐ No ☑ The study will enroll Prisoners</td>
<td>Prisoners</td>
</tr>
<tr>
<td>Yes ☐ No ☑ The study will enroll Cognitively Impaired Adults</td>
<td>Cognitively Impaired</td>
</tr>
<tr>
<td>Yes ☐ No ☑ The study will enroll Pregnant Woman</td>
<td>Pregnant woman</td>
</tr>
<tr>
<td>Yes ☐ No ☑ The study will enroll Employees</td>
<td>Employees</td>
</tr>
<tr>
<td>Yes ☐ No ☑ The study will enroll Students</td>
<td>Students</td>
</tr>
</tbody>
</table>

Please complete Appendix A: External Site Approvals below

Yes ☐ No ☑ Use of drugs other than the use of approved drugs in the course of medical practice

Please complete Appendix B: Drugs below

Yes ☐ No ☑ Evaluation of the safety or effectiveness of a device

Please complete Appendix C: Devices below

Yes ☐ No ☑ Concurrent submission to the Temple Institutional Biosafety Committee (IBC)
Yes ☐ No ☑ Concurrent submission to the Temple Medical Radiation Committee (MRC)
Yes ☐ No ☑ Humanitarian Use Device (HUD). (If you are evaluating the safety or effectiveness of a HUD, complete this application. If not, complete PORI: Application for Humanitarian Use Device)
Yes ☐ No ☑ The study will use a tissue repository
Yes ☐ No ☑ The study will involve genetic testing
Yes ☐ No ☑ The study will use stem cells
Yes ☐ No ☑ Faculty research
Yes ☐ No ☑ Fellow's research
Yes ☐ No ☑ Resident's research
Yes ☐ No ☑ Dissertation research
Yes ☐ No ☑ Master's research
Yes ☐ No ☑ Undergraduate research or independent study
Listing the Funding Source:
• Click the Edit icon to choose from a list of approved Temple Sponsors

Funding Source

Industry Sponsor (if there is no industry sponsor, enter “No External Funding” from the Preferred Pick List)

* Sponsor NO EXTERNAL SPONSOR

Funding Information (company name if different from above):

Phone and Email:

Address (Street, City, State/Province, Postal Code, Country):

• If your sponsor is not on the list, contact the IRB.
• If you are not externally funded, choose No External Sponsor from the list.
• Choose your sponsor from the list by clicking Select.

Adding Research Personnel:
• Every member of the research team involved in the conduct, design, or reporting of the research must be listed in the Personnel section of the Application form.
• The PI will be added to the form by default.
• To add all others, click the yellow plus sign, search and select individuals.
  • Note: if an individual is not on the list, see the eRA FAQs website for instructions on how to proceed.
• Once you select an individual, they are added to the application form.
• If their CITI account is current and affiliated with Temple University, their CITI status will display.
  • Note: all research personnel are required to have current CITI training. See the Human Subjects Research Training page of the IRB’s website for more information.
• Answer the three questions about their involvement with the research.
List of Applicable Documents:

- Check off supplemental documents that you will or will not be including with your application.
- Ensure that if you check Yes, you include those documents. For more information, refer to the section entitled “Adding Supplemental Documents”.

- **Note:** Investigator Protocols are required for all research excluding studies that will be submitted to WIRB. If you need clarification on whether your study will be sent to WIRB, please contact the IRB office.

Please list and provide one each of the following documents (if applicable to your study):

- This Application for Human Research, including as applicable:
  - Yes [ ]  No [ ] Appendix A: External Site Approvals
  - Yes [ ]  No [ ] Appendix B: Drugs
  - Yes [ ]  No [ ] Appendix C: Devices

- Investigator Protocol (the study will be operationalized at Temple University. See the FAQ page for more information). An Investigator Protocol is not required for WIRB studies.

- Yes [ ]  No [ ] Complete sponsor protocol including DHHS-approved protocol (this is distinct from the Investigator Protocol. See the FAQ page for more information).

- Yes [ ]  No [ ] Data collection instruments (questionnaires, etc.; do not submit case report forms)
  - All written material to be provided to or meant to be seen or heard by subjects, including:
    - Yes [ ]  No [ ] Evaluation instruments and surveys
    - Yes [ ]  No [ ] Advertisements (printed, audio, and video)
    - Yes [ ]  No [ ] Recruitment materials and scripts
    - Yes [ ]  No [ ] HIPAA authorization form (if applicable)
    - Yes [ ]  No [ ] Consent documents
    - Yes [ ]  No [ ] If consent will not be documented in writing, a script of information to be provided orally to subjects
    - Yes [ ]  No [ ] Grant application
    - Yes [ ]  No [ ] Manual of Operations, if available
    - Yes [ ]  No [ ] DHHS-approved sample consent document
    - Yes [ ]  No [ ] Current investigator brochure for each investigational drug
    - Yes [ ]  No [ ] Current package insert for each marketed drug
    - Yes [ ]  No [ ] Current product information for each investigational device
    - Yes [ ]  No [ ] Foreign language version of any written material to be provided to or meant to be seen or heard by subjects
    - Yes [ ]  No [ ] Copy of the investigator’s current curriculum vitae or other documentation evidencing qualifications
    - Yes [ ]  No [ ] If the research is conducted or funded by the Department of Energy, a completed “Checklist for IRBs to Use in Verifying that DOE Research Protocols are in Compliance with DOE Requirements”
Completing Appendix A: External Sites:

- If you answered YES to the question regarding the involvement of External Sites in Section II of the Application, Appendix A will be added to the bottom of this form.
- Fill out the required information for each site.
- **Note:** if you have more than three external sites, attach a Word document as a supplemental document to your application that includes the other sites.

### Appendix A: External Sites

Complete for each external site at which you will conduct or oversee the research.

<table>
<thead>
<tr>
<th>Site Name</th>
<th>Contact Name</th>
<th>Contact Phone or Email</th>
<th>Will the site’s IRB review the research?</th>
<th>Will the site rely on this institution’s IRB?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site A</td>
<td>Mary Coordinator</td>
<td><a href="mailto:mary@sitea.com">mary@sitea.com</a></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Site B</td>
<td>John Coordinator</td>
<td><a href="mailto:john@siteb.com">john@siteb.com</a></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Site C</td>
<td>Jane Coordinator</td>
<td><a href="mailto:jane@sitesc.com">jane@sitesc.com</a></td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>


Completing Appendix B: Drugs:

- If you answered YES to the question regarding the involvement of Drugs in Section II of the Application, Appendix B will be added to the bottom of this form.
- To select a Drug, click the yellow plus sign.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Marketed - Manufacturer Name</th>
<th>Investigational Name</th>
<th>Drug Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMOXICILLIN</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- A new screen will open. Here you can search a list of drugs that Temple has in our database.
- Search by All, Generic, Investigational, or Marketed drug name.
- Select to add the drug to your application.
- **Note:** If you do not see the drug you would like to add on this list, please email irb@temple.edu the following information:
  1. The drug’s generic name
  2. The drug’s investigational name
  3. Is the drug FDA approved (yes or no)?
  4. If the drug is FDA approved, the date of FDA approval.

- You are returned to the application form, where the drug will be listed and you can fill out the additional information as applicable.
Completing Appendix C: Devices:

- If you answered YES to the question regarding the involvement of Devices in Section II of the Application, Appendix C will be added to the bottom of this form.
- To select a Device, click the yellow plus sign.

A new screen will open. Here you can search a list of devices that Temple has in our database.
- Search by device name or short name.
- Select to add the device to your application.
- Note: - If you do not see the device you would like to add on this list, please email irb@temple.edu the following information:
  1. All names of the Devices
  2. The Device name.
  3. The short name of the Device.
  4. Is it a Significant Risk Device (yes or no)

You are returned to the application form, where the drug will be listed and you can fill out the additional information as applicable.

Completing the eForm

Once you believe that the Application eForm is complete, check the Complete box in the upper right hand corner. The form will save and close. This may take a few moments.
Adding Supplemental Documents

After checking Complete on the application eForm, you will be returned to the Components for Initial Submission page. Here you will be able to complete your submission by uploading all supplemental documents.

1. Click Add Institutional Forms/Supporting Documents to add supplemental components. You can do this before or after completing the Initial Application eForm. You can find templates for supplemental documents such as Investigator Protocols, HIPAA Authorizations, Consent Forms, etc. on the Forms and Templates section of the IRB’s website.
2. To Upload a New Document, do the following:
   - Give the document a Name
   - Click Browse to access your computer and retrieve a saved document to upload.
   - Under Category, choose the appropriate classification for the document.
   - When finished, click on Upload. You will then be prompted to click Close to complete the upload of your documents.
   - **Note:** You do not need to fill out the Folder, Document ID, Document Version Number, or Document Version Date fields when adding new documents. Make sure that you are choosing “Add a New Document” rather than a “Version of Existing Document”.

3. If you have filled out the application eForm and successfully uploaded all supporting documents, your application should now be ready to submit. The status of each Form/Document should read “Completed”. Once you are ready, you can hit the Submit icon to move on to the next step.

   **Note:** you are not finished submitting yet!
Viewing and Editing the Submission Route and Submitting

Once you have hit the Submit icon, a new window will open displaying the submission route. Every individual listed in the Research Personnel section of the Application e-form is automatically added to the submission route. They must acknowledge the submission in eRA before it can reach the IRB for review. Department Head acknowledgement is also required for all new applications to the IRB. If your Department Head or any other personnel who are required to acknowledge the submission are not automatically added to the route, you may either add them to the route, or contact the IRB office to have them added.

1. To add a new person to the top of the submission route, click “Add New Person to Review Path”.

2. A new window will open. Search for the individual by clicking the first letter of their last name, and then begin to type their name into the Search for a Particular Entry box. When their name appears, ensure that the “Acknowledgement Required” button is selected under “Routing Step Insert”, and then click Select.
3. The individual will be added to the top of the route.

4. Alternatively, to add an individual in a particular location on the submission route, click the box to the right of the individual after whom you want the new individual to acknowledge. For example, if I want Ming to give her acknowledgement after Maureen acknowledges, I can add Ming to the route by clicking on the box to the right of Maureen's name (see red arrow below). I will choose Ming, select Acknowledgement Required, and then click select. Ming has now been added to the route after Maureen (see green arrow below).

5. When the submission route is complete, click Submit (blue arrow above).

**Note:** You will know the submission has been made when the page changes color and the word “Submitting...” appears across the screen. You will also know because the Submit (Thumbs Up) button will be replaced with a scroll:
Viewing Progress of a Submission

1. The page will return to the Components page of your Initial Submission. You know that this has been submitted because the Scroll icon has replaced the Submit icon. You can view the routing progress from the Components page, or by clicking on the Scroll icon.

![Initial Submission Table]

2. You can check back in on the submission to monitor its progress through the submission route. When an individual on the route acknowledges, their decision will be listed, and by hovering your mouse over the decision, you will see the date and time of the decision.

*No comments have been recorded yet*

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![Active Routing Progress Table]

*Please be advised that the IRB does not receive submissions until every individual on the route acknowledges the submission.* PIs are required to acknowledge all submissions, even if the PI makes the submission directly.
Creating a New Submission in an IRB-Approved Protocol
Adding Continuing Reviews, Closing Protocols, Modifications, or Reportable New Information

1. Find and open your existing protocol by searching in the fields provided on the home screen in My Human Subjects (see instructions for Searching for an Existing Protocol). PIs (only) can also see all of their existing protocols by clicking on Show/List in the My Human Subjects tab.

2. A new window will open called Submissions. In the drop down box on the right side, choose the type of submission you are entering, and then click on Add New.

Note: while “Initial Submission” is an option here, you will not use this choice in an existing protocol.

3. A new window will open that contains the Continuing Review. The eForm for your submission is included automatically and is mandatory. The Components page will also display Existing Protocol Document Attachments – which are attachments that were submitted with other submissions in the protocol (i.e. the Child Assent was submitted with the Initial Submission). These documents are not a part of the submission in progress, but you can view them for informational purposes by clicking View.

4. To complete the eForm, click Continuing Review.
5. Every e-form is different for each type of submission. The following eForms are mandatory components of the following submission types, and will be included automatically with each submission:

- Continuing Review – Continuing Review eForm.
- Modification – Modification of Approved Human Research eForm.
- Reportable New Information – Reportable New Information eForm.

6. In the eForm, complete all mandatory fields, as indicated with a red asterisk. Some fields will populate automatically based on the PI’s eRA profile and existing information about the protocol. When you are finished filling out the form, check the Complete box in the upper right-hand corner of the eForm. The form will save, and return to the Components page of the submission. This may take several moments.

7. When complete, the status of the eForm will read Completed.

8. Click Add Institution Forms/Supporting Documents to add supplemental documents to your submission.

**Note:** If submitting a Continuing Review, please include clean copies of all consent documents that need to be stamped. This is not required if the protocol is permanently closed to enrollment.
9. To Upload a New Document, do the following:
   • Give the document a **Name**
   • Click **Browse** to access your computer and retrieve a saved document to upload.
   • Under **Category**, choose the appropriate classification for the document.
   • When finished, click on **Upload**. You will then be prompted to click **Close** to complete the upload of your documents.

   **Note:** You do not need to fill out the Folder, Document ID, Document Version Number, or Document Version Date fields when adding new documents. Make sure that you are choosing to “Add a New Document” rather than a “Version of Existing Document”.

10. Complete the same steps from Step 9 as many times as necessary to upload all of your documents. Ensure that you are uploading a new “document” rather than a “version of an existing document” every time you add a new document. Click close to complete the upload of all
11. Once you have completed the mandatory eForm and added all supporting documents, you can return to the Components screen. If all Statuses are listed as Completed, click Submit.
12. You will receive a pop up message asking you to certify that you will conduct your research in accordance with all applicable rules, laws, and regulations. Click Accepted and continue.

13. The submission route will display. PIs are required to acknowledge all submissions, even if the PI makes the submission directly. For more information on editing the submission route of a submission, reference the section titled “Viewing and Editing the Submission Route and Submitting”. The submission will not reach the IRB Office until every individual on the route acknowledges it. Click Continue to start the submission on the route.

Note: If you are submitting a Modification to add a new researcher to the protocol, you need to manually add that person to the submission route.

14. You will be returned to the Components page of the submission. The Submit icon has been replaced with the Scroll icon, which will display the Routing Progress, also displayed on the Components screen. For more information on Submission Route and Submitting.”
Reviewing Comments on Items Returned to You (PI Clarification)

Anyone on the submission route can choose to stop the route and return a submission to the PI for “PI Clarification”. The IRB Office will return a submission for PI Clarification if the submission is incomplete and cannot be reviewed. This often happens when a significant portion of the application is missing, for example – if an investigator protocol or an application form is not included.

1. The PI will receive an email notification from the IRB office. Click on Open Submission Package to review the comments left by reviewers (see illustration below).

2. Clicking on Open Submission Package will take you to the Components page for the submission. Click on the (Route History) link.
3. A new window will open. You can see the PI Clarification Step, who completed it and when. Please see reviewer comment(s) below.

4. To edit documents and resubmit, return to the Submissions page. To edit an eForm, click the Form (see yellow arrow). The form will open. Uncheck the “Complete” box to make edits. When finished, check the “Complete” box and hit save. To remove a document, click Remove (see red arrow). To add a new document, click on Add next to Document/Form (see green arrow), and follow the instructions. When finished, click Submit (see blue arrow).

**Note:** you are not finished submitting yet! Be sure that you go through the steps listed in “Viewing and Editing the Submission Route and Submitting”.

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Submitting a Response to Modifications Required to Secure Approval

If you have submitted an item to the IRB, and the IRB has responded with a Modifications Required to Secure Approval memorandum, you can respond to the requested modifications by logging into eRA.

1. Find and open your protocol by searching in the fields provided on the home screen in My Human Subjects (see instructions for Searching for an Existing Protocol). If you are the PI, you can also see all of your existing protocols by clicking on Show/List in the My Human Subjects tab. Refer to the Protocol Number listed in the memo you received from the IRB office.

2. When you open your protocol, you will see the Submissions screen that will show you the status of your submission(s). If Modifications are required, you will see a Respond to Modifications Requested link below. Hover over it and click on it.

![Submissions screenshot]

**Note:** You can only use this link once. If you or another person on the research team has hit the link, but not completed the response submission, the Respond link will disappear and be replaced with a "Mods Required to Secure Approval" submission with the status "Under Development" (as below). To resume this response, hover over to open the Response you wish to continue.

![Submissions screenshot]

3. In the drop down box under Select Submission, choose Mods Required to Secure Approval. Click Save and Close.
4. A new window will open displaying the Modifications Required to Secure Approval screen. This is your Modifications Required to Secure Approval, or response, submission. Here you can edit your eForms or submit any additional documents or edits requested by the IRB.

- Please note that when a Modifications Required to Secure Approval submission is initiated, the system will automatically include all of the documents that were a part of the submission to which you are responding. For example, my Initial Submission included the Application form, child assent, HIPAA Authorization, Investigator Protocol, Parental Consent, and Sponsor Protocol documents. The user must choose which documents to include, remove, or replace based on the changes that the IRB requested. **Do not just re-submit what you already submitted!**
- This page will also list Existing Protocol Documents that are a part of the protocol as a whole, but not a part of this particular submission.

5. To edit an eForm, hover over and click on the Form (see red arrow below).

<table>
<thead>
<tr>
<th>Document/Form</th>
<th>Add</th>
<th>Type</th>
<th>Status</th>
<th>Submit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application for Human Research</td>
<td></td>
<td>IRB Application</td>
<td>Completed</td>
<td>Remove</td>
</tr>
<tr>
<td>Bauer Form</td>
<td></td>
<td>Attachment</td>
<td>Completed</td>
<td>Attributes Replace Remove</td>
</tr>
<tr>
<td>Cam Form</td>
<td></td>
<td>Attachment</td>
<td>Completed</td>
<td>Attributes Replace Remove</td>
</tr>
<tr>
<td>Ethics Certificates Donnelly</td>
<td></td>
<td>Attachment</td>
<td>Completed</td>
<td>Attributes Replace Remove</td>
</tr>
<tr>
<td>Ethics Certs Gonzalez</td>
<td></td>
<td>Attachment</td>
<td>Completed</td>
<td>Attributes Replace Remove</td>
</tr>
<tr>
<td>Ethics Certs Hayden</td>
<td></td>
<td>Attachment</td>
<td>Completed</td>
<td>Attributes Replace Remove</td>
</tr>
<tr>
<td>Ethics Gonzalez Practice Runs</td>
<td></td>
<td>Attachment</td>
<td>Completed</td>
<td>Attributes Replace Remove</td>
</tr>
<tr>
<td>HIPAA</td>
<td></td>
<td>Attachment</td>
<td>Completed</td>
<td>Replace Remove</td>
</tr>
<tr>
<td>Informed Consent</td>
<td></td>
<td>Attachment</td>
<td>Completed</td>
<td>Attributes Replace Remove</td>
</tr>
<tr>
<td>Sponsor Study Protocol</td>
<td></td>
<td>Attachment</td>
<td>Completed</td>
<td>Attributes Replace Remove</td>
</tr>
<tr>
<td>Summary of Changes to Protocol</td>
<td></td>
<td>Attachment</td>
<td>Completed</td>
<td>Attributes Replace Remove</td>
</tr>
<tr>
<td>Temple Formal Summary of Protocol</td>
<td></td>
<td>Attachment</td>
<td>Completed</td>
<td>Attributes Replace Remove</td>
</tr>
<tr>
<td>UPENN IRB APPROVAL DOCUMENTS</td>
<td></td>
<td>Attachment</td>
<td>Completed</td>
<td>Attributes Replace Remove</td>
</tr>
<tr>
<td>Who Form</td>
<td></td>
<td>Attachment</td>
<td>Completed</td>
<td>Attributes Replace Remove</td>
</tr>
<tr>
<td>Who Form Proxy</td>
<td></td>
<td>Attachment</td>
<td>Completed</td>
<td>Attributes Replace Remove</td>
</tr>
</tbody>
</table>

6. The form will open in a new window. Uncheck the Complete box. The form will then refresh and will be editable. Make any edits you wish, and then check the Complete box when finished. The form will close automatically. This may take several moments.
7. You will be returned to the Components page of the Modifications Required to Secure Approval submission. Click on Add Institution Forms/Supporting Documents to upload new documents to include with your response submission (see the section entitled Adding Supplemental Documents).

- When the IRB requests changes to documents, please ensure that you include a clean copy and a tracked changes copy of the document, indicating where the changes were made.
- You should also include a point-by-point response memo with all Modifications Required to Secure Approval (response) submissions. Upload this as a new document.
- Give your document a name. Ensure that it is descriptive of the document you are uploading.
- Click Browse to locate the document on your computer.
- Choose a document Category.
- Click Upload.
- **Note:** you do not have to fill out the Folder, Document ID, Document Version Number, or Document Version Date if you are adding a new document.
- Click close to complete the upload of all documents.
8. To remove documents that you do not wish to include in your Modifications Required to Secure Approval submission, click Remove to the right of the document. For example, since I revised my Investigator Protocol, and have included a clean and tracked changes of the revised protocol, I will remove the Investigator Protocol that I had included in my initial submission.

**Note:** You should never remove documents that you want included in your overall, approved submission. You will not ever remove an eForm (i.e. Application), only edit it if necessary. Think of your Modifications Required to Secure Approval submission as encompassing all of the documents that you ultimately want the IRB to approve.

9. Once you have submitted your Response to the modifications requested by the IRB by editing all eForms, uploading new or edited documents, and removing any documents you do not want to include, your Response is ready to submit. The status of each Form/Document should read “Completed”. Click on Submit.

10. You will receive a pop up message asking you to certify that you will conduct your research in accordance with all applicable rules, laws, and regulations. Click Accepted and continue.

11. The submission route will display. PIs are required to acknowledge all submissions, even if the PI makes the submission directly. For detailed instructions on editing the submission route, see the section entitled “Viewing and Editing the Submission Route and Submitting”.

---

**Modifications Required to Secure Approval**

<table>
<thead>
<tr>
<th>Document/Form</th>
<th>Add</th>
<th>Type</th>
<th>Status</th>
<th>Attributes</th>
<th>Replace</th>
<th>Remove</th>
</tr>
</thead>
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<tr>
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<td>IRB Application</td>
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<td>Replace</td>
<td>Remove</td>
</tr>
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</tr>
<tr>
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<td>Attributes</td>
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<td>Remove</td>
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<td>Sponsor Study Protocol</td>
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<td>Attributes</td>
<td>Replace</td>
<td>Remove</td>
</tr>
<tr>
<td>Summary of Changes to Protocol</td>
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<td>Remove</td>
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<td>Replace</td>
<td>Remove</td>
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<td>Who Form</td>
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<td>Attributes</td>
<td>Replace</td>
<td>Remove</td>
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<td>Who Form Proxy</td>
<td></td>
<td>Attachment</td>
<td>Completed</td>
<td>Attributes</td>
<td>Replace</td>
<td>Remove</td>
</tr>
</tbody>
</table>

Show Existing Protocol Attachments
The submission will not reach the IRB until every individual on the route acknowledges it. Click Continue to start the submission on the route.

12. You will be returned to the Modification page. The Submit has been replaced with the Scroll icon, which will display the Routing Progress, also displayed on the Components screen. For detailed instructions on checking on the status of your submission, see the section entitled “Viewing Progress of a Submission”.

<table>
<thead>
<tr>
<th>Document/Form</th>
<th>Type</th>
<th>Status</th>
<th>Show Route</th>
<th>(Route History)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modification of Approved Human Research</td>
<td>Modification</td>
<td>Completed</td>
<td>PDF</td>
<td>(Mandatory Form)</td>
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</table>

**Active Routing Progress**

<table>
<thead>
<tr>
<th>Route Name</th>
<th>Route Type</th>
<th>Step Number/Name</th>
<th>Who</th>
<th>Notified</th>
<th>Decision</th>
<th>Insert</th>
<th>Remov</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modification of Human Research</td>
<td>Final Review</td>
<td>Step 1 - PI Acknowledgement</td>
<td>JAVIAH N. SMITH</td>
<td>28-Sep-2016 12:34:38 PM</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Modification of Human Research</td>
<td>Final Review</td>
<td>Step 3 - IRB Check-In: Received by IRB MS. MARILYN LEWIS</td>
<td>MR. RYAN BENNETT</td>
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<tr>
<td>Modification of Human Research</td>
<td>Final Review</td>
<td></td>
<td>MR. LASHAY COBB</td>
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<tr>
<td>Modification of Human Research</td>
<td>Final Review</td>
<td></td>
<td>MAUREEN MCILHINNEY</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
13. To continue a Response in progress, but not yet submitted, utilize either the Search For or Show/List function in the My Human Subjects tab. Click Modifications Required to Secure Approval if you wish to continue.

<table>
<thead>
<tr>
<th>Type</th>
<th>Submission Number</th>
<th>Investigator Submitted On Date</th>
<th>Management Submitted On Date</th>
<th>Internal ID</th>
<th>Determination Date</th>
<th>Date From</th>
<th>Date To</th>
<th>Access</th>
<th>Log</th>
<th>Log</th>
<th>Delete</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Submission</td>
<td>N/A</td>
<td>20-Nov-2015</td>
<td>24-Nov-2015</td>
<td>N/A</td>
<td>Deferred</td>
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<td>Delete</td>
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</tr>
<tr>
<td>Modifications Required to Secure Approval</td>
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<td>12-May-2016</td>
<td>15-May-2016</td>
<td>N/A</td>
<td>Modifications Required to Secure Approval</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Log</td>
<td>Delete</td>
<td></td>
</tr>
</tbody>
</table>
Responding to Deferrals

If you have submitted an item to the IRB, and the IRB has responded with a Deferral memorandum, you can respond to the requested changes by logging into eRA.

1. Find and open your protocol by searching in the fields provided on the home screen in My Human Subjects (see instructions for Searching for an Existing Protocol). You can also see all of your existing protocols by clicking on Show/List in the My Human Subjects tab. Refer to the Protocol Number listed in the memo you received from the IRB office.

2. When you open your protocol, you will see the Submissions screen that will show you the status of your submission(s). If the submission has been deferred, you will see a blue hyperlink next to the applicable submission that says Respond. Click on Respond.

   Note: You can only use this link once. If you or another person on the research team has hit the link, but not completed the response submission, the Respond link will disappear and be replaced with a “Previously Deferred” submission with the status “Under Development” (as below). To resume this response, click on Previously Deferred to open the Response you wish to continue.

3. In the drop down box under Select Submission, choose Previously Deferred. Click Save and Close.
4. A new window will open displaying the Submissions screen. This is your Previously Deferred, or response, submission. Here you can edit your eForms or submit any additional documents or edits requested by the IRB.

- Please note that when a Previously Deferred submission is initiated, the system will automatically include all of the documents that were a part of the submission to which you are responding. For example, my Initial Submission included the Application form, child assent, HIPAA Authorization, Investigator Protocol, Parental Consent, and Sponsor Protocol documents. The user must choose which documents to include, remove, or replace based on the changes that the IRB requested. Do not just re-submit what you already submitted!
- This page will also list Existing Protocol Documents that are a part of the protocol as a whole, but not a part of this particular submission.

5. To edit an eForm, click Modification of Approved Human Research (see red arrow below)

6. The form will open in a new window. Uncheck the Complete box. The form will then refresh and will be editable. Make any edits you wish, and then check the Complete box when finished. The form will close automatically. This may take several moments.
7. You will be returned to the Components page of the Previously Deferred submission. Click on Add Institution Forms/Supporting Documents to upload new documents to include with your response submission (see the section entitled Adding Supplemental Documents).

- When the IRB requests changes to documents, please ensure that you include a clean copy and a tracked changes copy of the document, indicating where the changes were made.
- You should also include a point-by-point response memo with all Previously Deferred (response) submissions. Upload this as a new document.
- Give your document a name. Ensure that it is descriptive of the document you are uploading.
- Click Browse to locate the document on your computer.
- Choose a document Category.
- Click Upload.
- **Note:** you do not have to fill out the Folder, Document ID, Document Version Number, or Document Version Date if you are adding a new document.
- Click close to complete the upload of all documents.
8. To remove documents that you do not wish to include in your Previously Deferred submission, click the Remove button to the right of the document. For example, since I revised my Investigator Protocol, and have included a clean and tracked changes of the revised protocol, I will remove the Investigator Protocol that I had included in my initial submission.

**Note:** You should never remove documents that you want included in your overall, approved submission. You will not ever remove an eForm (i.e. Application), only edit it if necessary. Think of your Previously Deferred submission as encompassing all of the documents that you ultimately want the IRB to approve.

9. Once you have submitted your Response to the changes requested by the IRB by editing all eForms, uploading new or edited documents, and removing any documents you do not want to include, your Response is ready to submit. The status of each Form/Document should read “Completed”. Click on the Submit icon.

10. You will receive a pop up message asking you to certify that you will conduct your research in accordance with all applicable rules, laws, and regulations. Click Accepted and continue.

11. The submission route will display. PIs are required to acknowledge all submissions, even if the PI makes the submission directly. For detailed instructions on editing the submission route, see the section entitled “Viewing and Editing the Submission Route and Submitting”.

The submission will not reach the IRB until every individual on the route acknowledges it. Click Continue to start the submission on the route.

You will be returned to the Components page of the submission. The Submit icon has been replaced with the Scroll icon, which will display the Routing Progress, also displayed on the Components screen. For detailed instructions on checking on the status of your submission, see the section entitled “Viewing Progress of a Submission”.

12. To continue a Response in progress, but not yet submitted, utilize either the Search For or Show/List function in the My Human Subjects tab. Click Modifications Required to Secure Approval to open the Response you wish to continue.
<table>
<thead>
<tr>
<th>Type</th>
<th>Submission Number</th>
<th>Investigator Submitted On Date</th>
<th>Management Submitted On Date</th>
<th>Internal ID</th>
<th>Determination</th>
<th>Determination Date</th>
<th>Date From</th>
<th>Date To</th>
<th>Access Log</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Submission</td>
<td>N/A</td>
<td>29-May-2018</td>
<td>03-Jun-2018</td>
<td>N/A</td>
<td>Modifications Required to Secure Approval</td>
<td>N/A</td>
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<td>N/A</td>
<td>Log</td>
</tr>
<tr>
<td>Modifications Required to Secure Approval</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Under Development</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>Log</td>
</tr>
</tbody>
</table>


Acknowledging a Submission in eRA

Every individual listed on the submission route on an IRB submission is required to acknowledge the submission before it can reach the IRB for review. The electronic acknowledgement takes the place of a hard copy signature. **Pls are required to acknowledge every submission on which they are listed as PI – this applies even if the PI made the submission.** Department Heads and all research personnel are required to acknowledge Initial Submissions. For Modifications adding a new researcher to the protocol, the new research personnel must be added to the submission route and must acknowledge their role in the study. Individuals can also be manually added to the submission route.

1. If you are required to acknowledge a submission, you will receive an email from the IRB Office. To review and acknowledge the submission, click on the Reviewer Dashboard link. To review the submission in its entirety, click on the Open Submission Package link.

2. If entering through the Reviewer Dashboard, click on the green Review tab on the left. Open and review each document by clicking on the Form/Document. Select Reviewed or Not Applicable under Review Status. Add your Comments, if necessary, in the appropriate box. Hit Save.

3. After hitting Save, you must scroll down in the Reviewer Dashboard, and choose your decision.
4. If you are satisfied with the documents being submitted, select “Acknowledge”. This will move the submission to the next individuals in the submission route. Once you select “Acknowledge”, you will be prompted to Accept or Decline an integrity statement. Click Accept.

My Decision is:

- Acknowledge

I agree to conduct this Human Research in accordance with applicable regulations, the Temple University Investigator Manual, The Temple University Human Research Protection Program Plan, and the Organizations policies and procedures.

- Accept
- Decline

5. If you are not satisfied with the documents being submitted and would like changes to be made, select “PI clarification”. This decision will return the submission back to the PI, and changes can be made to resubmit.

**Note:** If the submission is sent back as “PI Clarification”, it will need to be resubmitted and all individuals in the submission route will be prompted to acknowledge the submission again.

My Decision is:

- PI Clarification

You have chosen a decision that will send this record back for further revision prior to your acceptance. Please complete your decision by clicking the Save icon.

6. After choosing your decision (either “Acknowledge” or “PI Clarification”), you must click Save in the upper right-hand corner. Your review is now complete.

**Save your data or it will not be recorded...**

Comments I can see...

No Comments have been recorded
Student Investigator and Study Coordinator Roles

Student Investigators and Study Coordinators can be added as personnel roles in individual protocols. This allows them to submit items to the IRB without being added as the PI’s Delegate. The Student Investigator or Study Coordinator will then have the ability to access the protocol, and will be able to submit subsequent items such as Continuing Reviews, Reportable New Information, Modifications, and Closures. The PI must acknowledge all submissions made by Student Investigators and Study Coordinators. In order to add to or remove a Student Investigator or Study Coordinator from an existing protocol, the PI must submit a Modification request to the IRB, and the personnel must have completed their CITI training. The roles apply to individual protocols and must be added individually to every distinct protocol.

To Create a New Protocol as a Student Investigator or Study Coordinator, begin by starting the process of creating a basic new protocol:

1. In the My Human Subjects tab, select Create New.

2. A pop up window will present asking you how you wish to create the protocol. By default, New Human Protocol in Human Subjects Development will be checked. Click on Continue.
3. Enter a **Title** for your new protocol, and click on **Continue**.

![Protocol Creation](image)

4. **Select your PI.** This is where the Student Investigator should choose the faculty advisor as PI, or the Study Coordinator should choose the PI. The name of the person creating the submission will populate by default. Search by PI's last name (remove your name) and type in box next to Member by PI last name. Once the drop down box populates with the correct PI name, click Continue.

![Select PI](image)
5. The protocol shell has now been created.

**Note:** At this point, the eRA system only has the PI affiliated with the submission shell. If you leave the submission, you will not be able to find it again. In order to return to the submission, you must first add yourself to the Initial Submission eForm.

6. For instructions on how to add the eForm, return to the section entitled “Adding and Filling Out the Application eForm”.

![Image of the ERA Test Protocol Creation interface with a dashed box highlighting the Submission section and an initial submission page with an Add button indicating no forms have been associated with this submission.]
For questions about this guide or submitting items to the Temple University IRB, please contact the IRB office at 215-707-3390 or irb@temple.edu.

Research Integrity & Compliance: Institutional Review Board
Office of the Vice President for Research Administration
Student Faculty Conference Center
3340 North Broad Street, Suite 304
Philadelphia, PA 19140
Phone: 215-707-3390
Web: https://www.temple.edu/research/regaffairs/irb/