New Exempt Study- Submission Guide

You will need to submit your protocol for IRB review using the online IRB submission system, called Mentor.

This guide includes information to help you to prepare and submit a new human subject research proposal that qualifies for Exempt Review under the federal regulations and Ascension Wisconsin policies and procedures.

Research Personnel Training and Account Access

Before you can submit a protocol to the IRB, you an all of the research personnel must have a Mentor account.

Research personnel includes all persons responsible for the design or conduct of the research, including the Principal Investigator and Sub-Investigators, research coordinators, individuals named on a grant/contract or FDA form 1572, or who are obtaining informed consent or individually identifiable health information. For more information about these requirements or who should be added to the study, see the IRB Guidance Investigators and Research Personnel.

All research personnel must complete the following before they can be added to the study. If they already have an active research account, nothing else is needed now.

Directions and links for completing the below are found on the New Researcher Account Activation page.

- ☐ **Human Subject Protection Training (CITI)** The IRB requires Human Research Protection Training for all study personnel before they can be involved in study activities.
- ☐ **COI Research Conflict of Interest Questionnaire:** Study staff must complete this ONLY IF they will be involved in any research that: receives funding OR where they may have a financial interest, regardless of funding
- ☐ **Mentor Account** All study staff need a Mentor account *before they can be added to a study*. You only need to request an account once.

IF you will have a Research Coordinator who will submit information on your behalf: You must give permission to each person that you would like to be able to use Mentor to submit to the IRB on your behalf.

To designate a Research Coordinator the PI must:

- Log into Mentor IRB and go to "Research Coordinators" on the left navigation bar
- Click the "Designate a New Research Coordinator" button
- Start typing the coordinator's last name. If the coordinator has a Mentor IRB account, their name will appear. Choose the name and click "Designate"
- If the Coordinator does not have a Mentor account yet, they must have one before they can be added
- The Research Coordinator's name will now appear on the PI's "Research Coordinator" page and is available in any study with that PI. Designated coordinators can prepare and submit items for that PI.

Prepare Submission Materials

Before you enter the study submission into Mentor, it will be helpful to prepare the information and documents that you will need to complete the submission.

Complete and gather the applicable items

Save each document below as a separate electronic file. IRB forms and templates are in Mentor.

Research Protocol or Outline:

- ☐ **Sponsor-written or multi-site protocol** OR,
- ☐ **Investigator-written protocol** *(Protocol template is on the Mentor IRB Info Page)*

Additional Documents Depending on the Research: Upload all that apply.

- ☐ **Consent documents** If you are obtaining informed consent for this research, upload proposed form or handout. *(templates are in Mentor)*

Research Using Protected Health Information, include all applicable (*forms are in Mentor)*:

- ☐ HIPAA Authorization
- ☐ Request to Waive/Alter HIPAA Authorization
- ☐ Data Use Agreement for a Limited Data Set
- ☐ Request to Access PHI from Decedents.

- ☐ **Advertisements to Recruit Subjects** Any advertisements to be used, including flyers, letters, etc.
- ☐ **Data Collection Sheet** or list of data collection points (for use during a chart review for example).
- ☐ **Questionnaires** Upload copies of any questionnaires, surveys, interview questions or diaries.
- ☐ **Grant application** Upload one copy of the complete grant application.
- ☐ **Other document(s)** Any other supporting documents that may be relevant for this submission.

Complete the Mentor Submission

Below is a general guide for the Mentor submission process. Step-by- step instructions for new study submissions are in the Mentor User Manual, available on the IRB Info Page in Mentor.

1) **Create the IRB Application in Mentor** in Mentor IRB, Click on “My Protocols” and then “Create New Protocol”. A brief protocol summary form will open.
2) **Adding Research Personnel to a New Study**: Researchers must have a Mentor eIRB account to be added to a study. See “Research Personnel Training and Account Access” above for details.
3) **Principal Investigator:** Choose the PI name from the drop-down menu.
4) **Research Coordinator:** If the PI has designated research coordinators, a “Research Coordinator” field will appear. Choose the Research Coordinator’s name from the drop-down menu. The Research Coordinator will be copied on all eIRB correspondence sent to the PI. See above for instructions on designating a Research Coordinator.
5) **Sub-I or Research Associate**: Type the first few letters of the individual’s last name. Choose the name from the list and click “Add”.
6) **Review Type**: Choose Exemption requested.
7) **Upload Protocol and Consent**: The protocol and main consent document (if applicable) can be uploaded at the bottom of the protocol summary. If the study has multiple consent documents, upload in Step #4.
8) **Save the Completed Protocol Summary.** Click “Save” when the summary is complete. After saving, an “Upload Documents” button will appear on the top of the protocol summary.
9) **Click the “Upload Documents” Button**. In “Upload Documents”, **choose a file type** from the drop down menu (IRB application, questionnaire, advertisement, additional consent, etc.) and attach and save all applicable items.
10) **Complete and Upload the signature page** (next page)
11) When the submission is complete, click the "**Submit Protocol for Review**" button. IRB staff will be notified of the new submission and will contact you with any questions.

Signature Page

Required signatures must be submitted in Mentor eIRB prior to IRB review; they don't need to be on the same page.

All other information is entered directly into Mentor, there is no additional form to complete.

Project Title
Click here to enter text.

PRINCIPAL INVESTIGATOR'S ASSURANCE STATEMENT

I understand that as Principal Investigator, I have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to the study protocol and any stipulations imposed by the Ascension Wisconsin Institutional Review Board.

I agree to comply with all Ascension Wisconsin policies and procedures, as well as with all applicable federal, state, and local laws, regarding the protection of human subjects in research, including, but not limited to:

- Ensuring all investigators and key study personnel have completed the human subjects training program;
- Ensuring the project is conducted by qualified personnel following the approved IRB application and study protocol;
- Maintain accurate and complete research records, including, but not limited to, all informed consent documents if used;
- **Report any changed to the IRB that may affect the study's exempt status determination;**
- **Promptly report to any new information involving risks to research subjects, including adverse experiences and all unanticipated problems involving risks to human subjects** or others, in accordance with IRB policies and procedures;
- **Maintain signed HIPAA authorization documents for 6 years from the date authorization is obtained or the date it was last in effect, whichever is later;**
- Notify the IRB of study closure.

Links to policies and regulations for the protection of human research subjects are on the IRB website and Mentor.

Principal Investigator Signature Signature certifies that the information provided in this document is complete and accurate.	
PI Name (printed):	
PI Signature:	**Date:**

Department/Service Line Leader Approval Signature certifies that I have reviewed this protocol and approve its submission to the IRB. The investigator is credentialed, has appropriate training to conduct the research, and has adequate resources and staff to perform procedures outlined in this study. *This signature is required for all new studies prior to IRB review.* *It is the PI's responsibility to identify the appropriate person to provide this approval.*	
☐ *PI is also Department/Service Line Leader (do not need to sign again)*	
Name (printed):	
Signature:	**Date:**

Advisor/Mentor Signature (required if project lead is a student) Signature certifies that I have reviewed this protocol and approve its submission to the IRB. The investigator is credentialed, has appropriate training to conduct the research, and has adequate resources and staff to perform procedures outlined in this project. *This signature is required for prior to IRB review where a student is the Project lead.* *Advisor's will need to be identified in Mentor eIRB (request an account here)*	
Name (printed):	Click here to enter text.
Signature:	**Date:**