Middlebury Institutional Review Board

Quick Start Guide for Researchers

To find out more about Middlebury Institutional Review Board, please visit the [Middlebury IRB website](#).

Who this is for:

Students, faculty, and staff at Middlebury College conducting human subjects research.

What this guide covers:

This guide covers the essentials of:

Required Training

Ensure your human subjects research training is up to date before starting your application. Middlebury IRB requires the **CITI Social/Behavioral Research Course** or other equivalent training approved by Middlebury IRB. This training is only required for members of the research team who will interact directly with participants or who will have access to (or the ability to access) identifiable participant data.

- New to CITI? Follow these instructions for guidance.

- Training records are imported from CITI nightly into Mentor.

- CITI training is valid for four (4) years from the completion date.

- If your training records are not shown as updated, email the IRB with your CITI username and the email address used for your CITI account.

IRB Application Process Summary

Creating and submitting an IRB application involves several steps. Details for each of these are provided in the remainder of this guide.

1. **You will first access the Mentor system**, which is the platform we use for submitting, approving, and tracking IRB protocols. You will login using your Middlebury credentials.
2. **You will create a new blank IRB protocol application by clicking "Create New Protocol"** once you are logged into Mentor. This will prompt you to answer some questions about your project and basic information including the title, start date, and type of IRB review requested. There is a pre-protocol survey you can complete to help determine the level of IRB review. Ultimately, the IRB is responsible for determining the level of IRB review, and we will adjust as needed.
3. **You now have an empty IRB protocol application, and you need to fill in each of the sections with details about your study**. The View Protocol Page shows the basic information about the study and has links to application sections. You will click "Add Personnel" to add additional PIs or research assistants, and you will click "Application Sections" to fill in all the details about your study.
4. **The Application Sections page is where you will provide all the necessary details and supplementary documentation about your study.** There are seven sections (Personnel, Proposal Basics, Recruitment and Consent, Methods, Privacy and Confidentiality, Risks and Benefits, and Physiological Data Collection). Within each section, there are several questions to answer. To answer the questions, you will click "Answer" above each question, provide your answers, and then save. As you work through the sections, you will be prompted to upload any required materials, such as your consent form.
5. You can return to your protocol at any time before submitting to edit. **To submit it, you will click "Sign Electronically" on the View Protocol Page**. If you are a student, the application will be routed to your faculty PI for an electronic signature. Once the required signatures are provided, the protocol is submitted.
6. **Once submitted, the IRB will review it, and you will be notified of its progress via email**. You cannot make any changes once submitted unless the IRB sends you a request for revision.

How to Apply for Middlebury IRB Approval

Navigate to Mentor and log in.

Mentor is the IRB management system the Middlebury IRB uses. Please log in using your Middlebury account information. If you are asked to enter an Institutional ID, enter "middlebury."

Once logged in, you will be on the Mentor home page. This is where you can navigate to your protocols, your students' protocols, your training status, and access additional guidance and instructions.

- **Drafting Your Protocol:**
  You can edit your protocol any time before submitting it. Feel free to save a draft, review it, or consult with others as needed. To return to your draft, go to the *My Protocols* page.

- **For Students:**
  When you submit the protocol (by requesting your faculty advisor's electronic signature), it will be routed to your faculty advisor for review. Once your faculty advisor electronically signs the protocol, it will be submitted for review.

- **For Faculty and Staff:**
  Your protocol is considered submitted once you electronically sign it. After submission, you cannot make further changes unless:

  - The IRB requests revisions, or

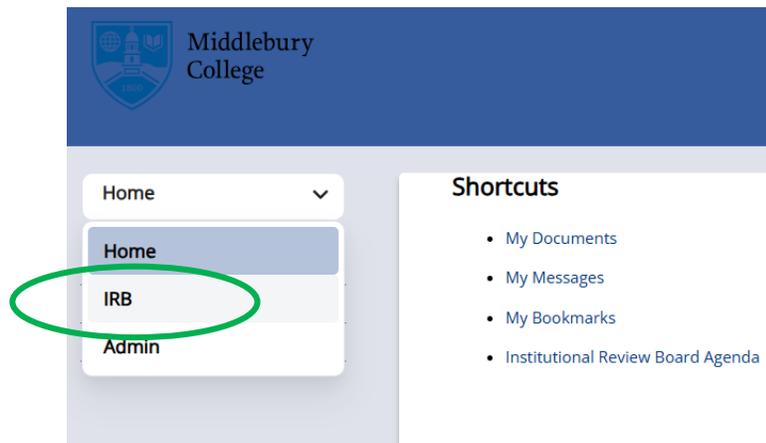 - You amend the protocol after approval.

Creating a New Protocol

If you have a new research project that may require IRB approval, you should create a new protocol to describe the project to the IRB and request approval.

Navigate to Mentor and log in using the appropriate credentials. After you log in, the homepage should appear.
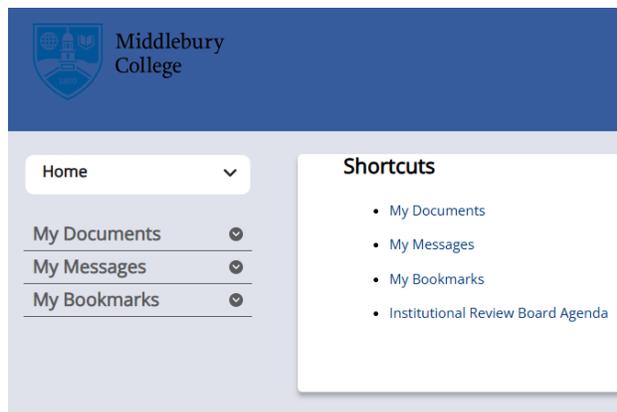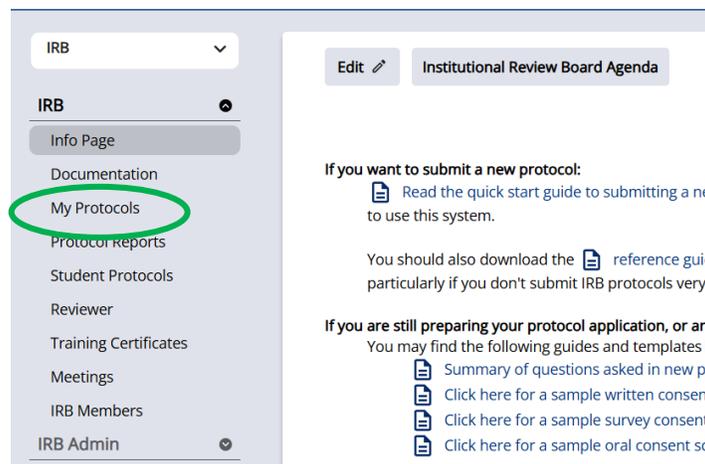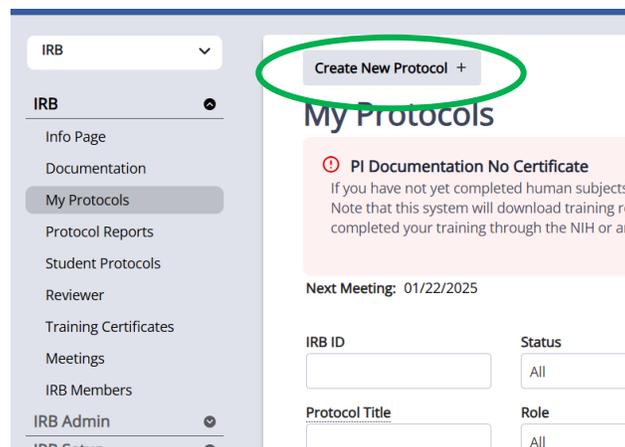
In the Home menu, click **IRB**.

Click on **My Protocols**.

Click **Create New Protocol +**.

You will be given the option to complete a Pre-Protocol Survey. We strongly recommend completing the survey, as this will guide you through the process of deciding what kind of review your project needs and will pre-populate parts of the new protocol application.

Select New Protocol Method

Use Pre-Protocol Survey

Go Directly to New Protocol Page

Answer the new protocol question. Then click **Save Answers** to move to the next question. For more information regarding the Pre-Protocol Survey questions, please refer to the Reference Guide for the Pre-Protocol Survey.

Is the study activity a systematic investigation designed to develop or contribute to generalizable knowledge? [45 CFR 46.102(l)]

○ 1. Yes, this project meets the definition of research

○ 2. No, this project does not meet the definition of research, or I'm not sure if my project meets the definition of research

Save Answers ✓   Cancel ⊗

Once on the New Protocol Page, you will see several required fields. Fill out the required information.

★ PI

Ann Hudson

★ Protocol Title

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★ Proposed Start Date ⊗

📅 02/10/2025

End Date ⊗

📅

★ Federally Funded

No

Funding Source

Grant Number

★ Review Type

Exemption

Please choose the option(s) that you think best fits your project:

- [ ] (1) Educational Research
- [ ] (2) Tests, Surveys, Interviews
- [ ] (3) Benign Behavioral Interventions - Adults
- [ ] (4) Secondary Research Uses of Data or Specimens
- [ ] (5) Evaluation of Public Benefits & Service Programs
- [ ] (6) Taste and food quality evaluation and consumer acceptance studies

Message to IRB Staff

ⓘ ★ Subjects

- [ ] Children (17 years or younger)
- [ ] Cognitively Impaired Persons
- [ ] Prisoners
- [ ] Pregnant Women
- [ ] Elected officials or candidates for public office
- [ ] None of the above

There may be supplemental questions, depending on your responses in the pre-protocol survey or the review category chosen, similar to below. Complete all required questions.

> **(2) Tests, Surveys, Interviews Questions**

Save ✓   Cancel ⊗

After you click **Save,** the View Protocol Page will open. You have now created an empty protocol application. You will now add the details about your study to each of the sections of the application. Here is what the View Protocol Page will look like:

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ⓘ If you have not yet started or submitted this protocol
First, click the Application Sections link below (see the green arrow, below) and make sure you answer all required questions.

Then, you should either Submit Protocol to Faculty Advisor (if you're a student) or Sign Electronically
The button to **Submit Protocol to Faculty Advisor** is below and to the left
The button to **Sign Electronically** is to the right of your name, below (and is only available once all required questions have been answered)

If any of that isn't clear, please 📄 **Read the quick start guide to submitting a new protocol**, or email the IRB for help.

⚠ Required Questions Not Answered
1 Signature Missing

PI	Approval Status	Created	01/09/2025	Approved	Set Date
Ann Hudson	Exemption	Received			
Staff	Exemption Requested	Date of Completion	Set Date		

To add personnel, on the View Protocol Page, under the Personnel section, click **Add/Edit Personnel**.
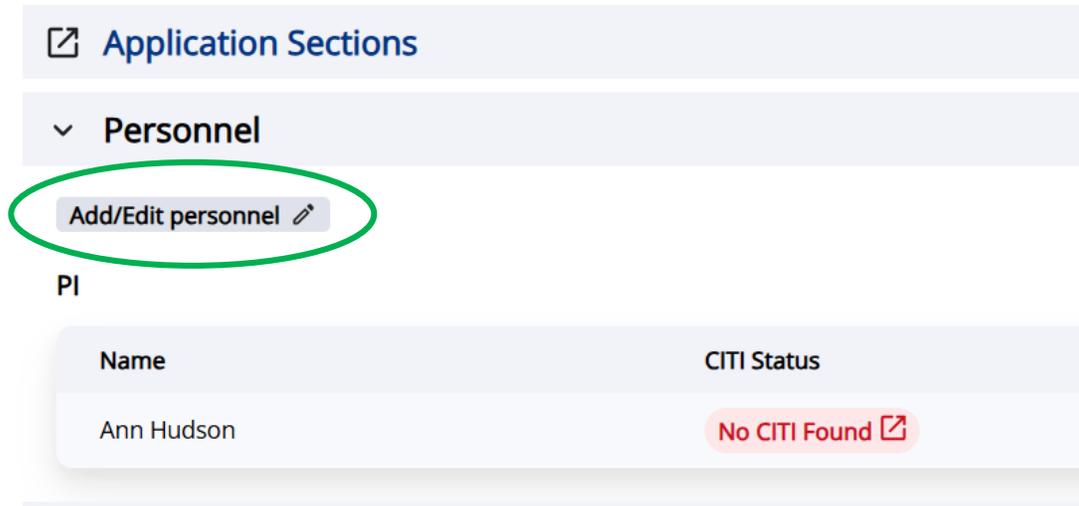
This is where you can add any Co-PIs, Research Assistants, or External Collaborators. If you can't locate a Co-PI, research assistant, faculty sponsor, or other collaborator in the Personnel section, ask them to log into Mentor. Once they log in, their account will be created, allowing you to add them to your protocol.

If your collaborator is not affiliated with Middlebury, please add them as an External Collaborator. External Collaborators are subject to the same training requirements listed above. They will need to have completed either the CITI Social/Behavioral Research Course or another equivalent approved by Middlebury IRB in the last 4 years.

Click **Application Sections** to fill out the IRB Application.

PI	Approval Status	Created	01/09/2025	Approved	Set Date
Ann Hudson	Exemption	Received			
Staff	Exemption Requested	Date of Completion	Set Date		
	(2) Tests, Surveys, Interviews				
	Withdraw Protocol from Review				

⧉ Application Sections	Required Questions Unanswered: 30
⌄ Personnel	

To answer a question, click the **Answer** box above each question. Please answer the required protocol questions as thoroughly as possible. All answers should be complete and not simply a reference to an attachment.

⌄ Proposal Basics	Required Questions Unanswered: 3

ⓘ Please click on the 🖼Add/Edit Answers buttons below to provide more information about your protocol.

Answer ✎

* Project summary:
(Briefly summarize your project in non-technical langauge. You will have opportunities later in this application to describe the project in detail, including uploading documents if necessary. This summary is intended to introduce your project to the IRB.)

Answer Required

Uploading Additional Documents:
There are places in the application to upload certain documents. However, if you need to upload additional documents, navigate to the View Protocol Page and scroll to the Files section. Click **Upload** and choose the file you wish to upload, as well as the appropriate file type.

⌄ Files	

Upload ⬆

Date	File name	St...
Pre-Protocol Questionnaire		
⋮ 01/09/2025	📄 Pre-Protocol Questionnaire.pdf	

Amendments	Adverse Events	Protocol Deviations

No Amendments yet.

After completing all questions in the Application Sections, return to the View Protocol Page and click **Sign Electronically**. The Sign Electronically button will highlight when all required questions have been answered. This submits your protocol to the IRB for review.

PI

Name	CITI Status	Signed Date	Date Added
Ann Hudson	No CITI Found ⧉	Sign Electronically	01/09/2025

Your protocol has been submitted! The IRB will review it, and you will be notified via email of its progress.

Amendments

Amendment approval is required *before* you deviate from your approved protocol. Please note that you need only modify the sections of your application that are being changed as a result of the amendment.

To create an amendment, navigate to the protocol and scroll to the bottom of the View Protocol Page. Click on the **Amendments** tab. Then, click **New Amendment +**.
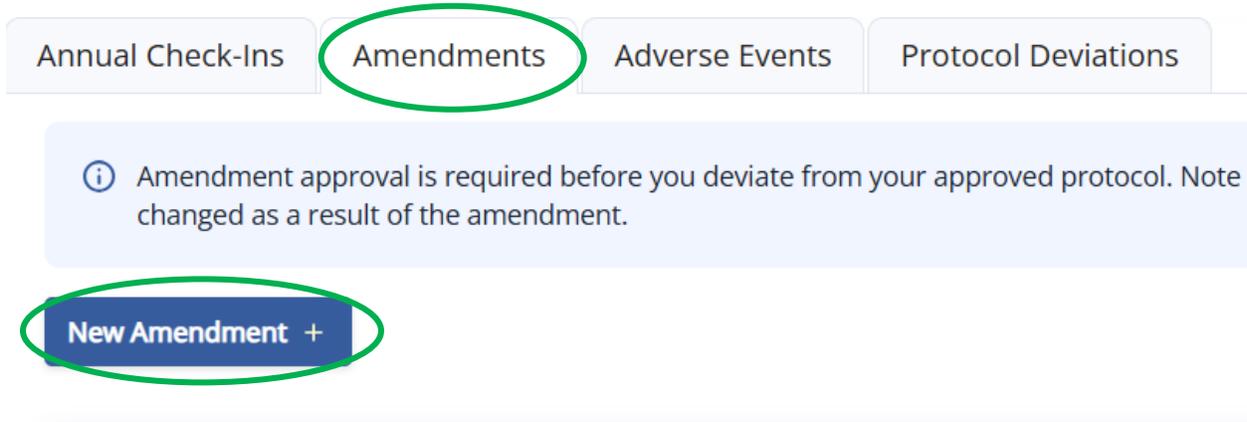
Fill out the Amendment survey.

Answer any questions pertaining to the section you are modifying in your protocol.

Navigate back to the View Protocol Page and click **Sign Electronically** to submit your amendment to the IRB for review.

#	Date	Type
⌄ ⋮ 4	01/09/2025	Personnel Changes

Submit

Edit Application Sections

Personnel Summary ✓

Required Amendment Electronic Signatures

Upload ⬆

- PI: Megan Prentice

Sign Electronically

Continuing Reviews/Annual Check-Ins

If the IRB has requested that you complete an annual check-in or continuing review, you will need to submit it by the requested deadline. To submit an annual check-in or continuing review, navigate to the protocol and scroll to the bottom of the View Protocol Page. Choose the "Annual Check-ins" tab. To start your annual check-in, click **Complete & Submit**.

If you wish to renew your protocol, choose *Continue Protocol* in the Continuation Status drop-down menu. Complete the required questions and click **Submit**.

Closing a Protocol

To close or terminate a protocol, complete the Annual Check-In process as described above and choose *Close Protocol* as the Continuation Status.

Who to Contact

For more information, or if you have any questions, please contact:

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