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**To plan your responses to the pre-protocol survey or to the application forms, see the file Pre-Protocol Survey and Application Forms, found in IRB Mentor on the Info Page and under Documentation.**
Log in to IRB Mentor

Option 1: Using a Bryn Mawr email address
Go to IRB Mentor log in page: https://shib.axiommentor.com/pages/irb/info.cfm
In the Institution ID box, type (all one word): brynmawr

That will take you to the Bryn Mawr College log in page. For the Username, enter the first part of your Bryn Mawr email address.

You will be asked to certify your login with dual authentication.
Option 2: Using a non-Bryn Mawr email address

If you do not have an email address ending in brynmawr.edu, you will need a Form Code to log in to IRB Mentor. Email irb@brynmawr.edu and request a Form Code. The Form Code will be emailed to you with a link where you can create a User Account. Supply the requested information.

After you hit Submit, you will see a confirmation message.

You will receive an email containing a link where you must set a password. The link will only be good for 24 hours. Create a password, and upload your human subjects training certification.
You will see a confirmation page.

When the IRB administrator has approved your profile in IRB Mentor, you will receive an email containing your username and a link where you can access the system. The link will only be good for 24 hours. Log in to IRB Mentor.

When you log in, you will reach the landing page.

To proceed, go to the section IRB Mentor landing page in this guide.
IRB Mentor instructions for students, faculty, and staff

IRB Mentor landing page
You will start in IRB Mentor on the Info Page. The templates for the Consent Form and Waiver of Consent Form are found here.

INTRODUCTION: The Bryn Mawr College Institutional Review Board is charged by the Federal Government with protecting human subjects involved in research. The IRB performs prospective and continuing review of protocols, the informed consent process, and the procedures used to enroll subjects in order to ensure that the human subject research is conducted ethically and in compliance with the Belmont Report, and with applicable federal, state, local, and institutional requirements.

If you have any questions about the process of IRB review, please contact either Gary McDonogh, the IRB Chair, or your departmental reviewer. Either person will be glad to assist you. In addition, you can find a variety of documents related to the IRB process. For example, check the Documentation tab on the left navigation menu for a link to the federal regulations and some foundational documents on the ethics of research involving human subjects.

For complete information on the protocol submission and review process, please see the Policies and Procedures on the Sponsored Research Office website.

Procedure for Submitting a Protocol
This document will walk you through the steps to create a protocol and submit it to the IRB. (Screen shots included.)

What Constitutes Human Subjects Research and What Research Needs to Be Reviewed?
Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to the generalization of knowledge. The following activities, as well as some others not listed here, are not considered research for the purposes of IRB review: scholarly and journalistic activities (e.g., art, history, journalism, blog-posting, literary criticism, legal research, and historical scholarship). Human subjects means a living individual about whom an investigator conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual; and, uses, studies, analyzes, or otherwise uses the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

How to Determine What Your Category of Research Is and What Application Forms to Use
When you go to the My Protocols page and click on the "Create a New Protocol" button, Mentor will launch a diagnostic survey that will assist you in determining the proper forms for submission. At the completion of this survey, you will be prompted to either continue the protocol submission process or to cancel out and return to submit your protocol at a later date. See below for documents containing blank versions of the application forms, the survey questions, and the survey and all forms compiled as one document.

Informed Consent Templates
The IRB offers the following templates as guides to writing your consent forms. Please see the consent documents in the Documentation section available in the menu on left. Not all protocols require an consent form, and some protocols may require a very truncated consent form (see below). We recommend using the templates here when full informed consent is required. You may still write your own consent form, but be sure to cover all the elements outlined in the template. The federal regulations outline the elements of informed consent in Section 116: General Requirements for Informed Consent

- Application Forms Required of All Protocols: Consent Form
- Pre-Protocol Diagnostic Survey: 471 K 03/10/2020
- Supplemental Form: Expedited Review Protocol: 156 K 03/10/2020
- Supplemental Form: Full Review Protocol: 377 K 03/10/2020
- Survey and All Forms Compiled.pdf: 3 M 03/10/2020

Please note: The IRB does not review the consent process for exempt protocols. It is up to the investigator to decide if informed consent is appropriate. In most cases, the exemption criteria anticipate that informed consent would not be appropriate.

Waiver or Modification of Informed Consent
Under special circumstances the IRB may permit a modification of the requirements for informed consent or a complete waiver of informed consent. The criteria for modification or waiver should be reviewed by the investigator.

The IRB may also waive the requirement for documentation of informed consent, that is, getting a signed consent form for each participant. The criteria for this waiver are spelled out in section 117(c) of the federal regulations. Documentation of Informed Consent:

- Consent Form
- Waiver of Consent Form
- Certificates of Confidentiality:
- When research involves particularly sensitive information (e.g., drug use, genetic information, etc.) that is linked to subjects, the IRB may require that the investigator secure a "Certificate of Confidentiality" from the NIH. To obtain that certificate, click on this link.
- Annual Reports/Continuing Review:
- Exempt protocols are not required to file continuing reviews on an annual basis, but all protocols approved by expedited or full board review processes are required to submit a continuing review report or termination. Mentor will automatically notify you of an impending report due date. Just go to the View Protocol page, and scroll down to the set of tabs at the bottom. The Annual Report tab is the first tab visible. Click on the Context menu, select Edit, and complete the resulting form.
- Adverse Events:
- In the event that a human subject is harmed as a result of participation in your project, you must immediately inform the IRB.

03/15/2021
IRB Mentor instructions for students, faculty, and staff

Additional information can be found under Documentation at the left.

Create new protocol
Click on “My Protocols” (third down the list on the left of the screen).
Click the grey button “Create New Protocol.”

If you do not know the protocol’s level of review (Exempt, Expedited, Full), click “Use Pre-Protocol Diagnostic Survey – 2019,” and go to the section **Option 1: Pre-Protocol Diagnostic Survey** in this guide. If you know the protocol’s level of review, click “Go Directly to New Protocol Page,” and go to **Option 2: New protocol page**.

**Option 1: Pre-Protocol Diagnostic Survey**
The survey is a series of Yes/No questions that will help you determine your protocol’s level of review (Exempt, Expedited, Full).

**Pre-Protocol Diagnostic Survey - 2019**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Research</strong></td>
<td><strong>Type: Multiple Choice</strong></td>
<td></td>
</tr>
<tr>
<td>The following questions will help you determine your protocol’s level of review (Exempt, Expedited, Full). When you have finished this survey, you will be routed to the Application Forms that you will need to fill out and submit to the IRB.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the study activity a systematic investigation designed to develop or contribute to generalizable knowledge? [45 CFR 46.102(l)]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Options:</td>
<td>1. Yes</td>
<td>2. No</td>
</tr>
</tbody>
</table>

To plan your answers, consult the complete survey in the file Pre-Protocol Survey and Application Forms, found in IRB Mentor on the Info Page and under Documentation. You will not need to answer all the questions. If your research is Exempt or Expedited, you will probably answer fewer than 10 of them.

After completing the survey, student PIs are routed to the section **Select faculty advisor** in this guide. Other PIs are routed to the **Create IRB Protocol page** section.
Select faculty advisor
Student PIs who complete the Pre-Protocol Diagnostic Survey are prompted to select the faculty advisor. Type the first few letters of their last name and hit Continue.

Create IRB Protocol page
Some information, such as your name, populate automatically. If Review Type is assigned and you think it is incorrect, you may change it. Enter the required data. Undergraduates should enter the end of the academic year for the Proposed End Date: 05/30/20XX. When you click Save, your protocol record is created, and a protocol number is assigned.

Next, fill out the application forms that the IRB will review. To plan your answers, see the file Pre-Protocol Survey and Application Forms, found in IRB Mentor on the Info Page and under Documentation. When ready to submit, go to Fill out Application Forms in IRB Mentor.
Option 2: New protocol page
Enter the required data. For External Co-PIs, enter their email addresses. Research Assistants are people who are neither PIs nor students. They will have read-only access to the protocol. If you have Research Assistants external to BMC, their information can be entered later.

When you select your “Review Type,” subsequent options will appear. The questions that appear will confirm whether or not your selected Review Type is correct.
When you click Save, your protocol record is created, and a protocol number is assigned.

Next, fill out the application forms that the IRB will review. To review the forms, see the file Pre-Protocol Survey and Application Forms, found in IRB Mentor on the Info Page and under Documentation. When ready to submit the forms, go to **Fill out Application Forms in IRB Mentor**.
IRB Mentor instructions for students, faculty, and staff

Fill out Application Forms in IRB Mentor
After you click Save, you may see a red error message like this one that says, “Required questions not answered.”

If you hover your cursor over the underlined red message, an explanation box will appear.
Click on either of the “Click Here for Application Forms.” They both take you to the same place.

On the next screen, red messages direct you to the sections where you need to provide information. Click on the arrows next to each section heading to see the forms. To see all of the sections at once, click Expand All Sections.
IRB Mentor instructions for students, faculty, and staff

To answer the questions, click the grey “Add/Edit Answers” button.

A pop-up window will appear for you to supply answers to the questions. When you are finished, click the “Save Answers” button at the bottom.
You will automatically be advanced to the next set of questions in that section. When you have finished the section, you will be returned to the main Application Forms page. If you still have unanswered questions in other sections, click the dropdown arrow to access the other sections.

When you have finished answering all of the questions, click “View Protocol Page.”
Before submitting, export protocol to share with faculty advisor or co-PI

On the Protocol page, the “Edit” button returns you to the original Create IRB Protocol page that you filled out. You may edit your information there if needed. The “Upload Docs” button allows you to upload (or re-upload) forms. The “Print/Zip” button allows you to print your application forms (with or without attachments) to a pdf. This option is useful for student PIs who want to email their protocol forms to their advisor for advisor review prior to submission.
Electronically sign and submit the protocol
The red message indicates this protocol is missing signatures. As PI, your signature is required.

If you need to request signatures from co-PIs, click the grey “Request Signatures” button. Otherwise, you may proceed to adding your own signature. Click the “Sign Electronically” button. **NOTE: Once you electronically sign the protocol, it will automatically be submitted to the IRB. If the protocol lists a Faculty Advisor, the Faculty Advisor will be immediately notified and asked to accept responsibility for advising on this protocol.**
On the pop-up window, click the “Sign Electronically” button. **NOTE: After you press this button, your protocol will automatically be submitted to the IRB, and your Faculty Advisor will be notified (if applicable).**

Your protocol is now submitted, and your Faculty Advisor (if applicable) has been notified. On the Protocol page, you will see that your protocol has been signed and date/time stamped.
IRB Mentor instructions for students, faculty, and staff

Log out of IRB Mentor
When you are finished, click Logout in the upper right corner.

If you receive a Stale Request message, close the browser to ensure you have exited the system.

What to expect next
The PI will receive an email notification confirming that the protocol was submitted. A student PI’s protocol will be sent to the Faculty Advisor who is asked to accept responsibility for advising. The protocol will then continue to IRB review. For staff and faculty PIs, the IRB will assign the protocol to a reviewer, and the reviewer will have a set time period in which to perform the review. You may log in at any time to check the status of your submission. You will receive an email notification when the IRB review is complete.
To get help after submitting your protocol
To contact the IRB administrators, click My Protocols on the left, and then click on your protocol name.

Click on Messages.
Click New Message.

A student PI’s default recipients (on the right) are the PI, faculty advisor, and the IRB administrators. Type your message into the text box, and click Save.
When your collection and review of data is complete
Click My Protocols on the left, and then click on your protocol name.

Click Terminate Protocol. In the window that pops up, confirm the termination of protocol.