INTRODUCTION

What is an Institutional Review Board (IRB)?
The IRB is a committee established to review and approve applications for research projects involving human subjects. The primary purpose of the IRB is to protect the rights and welfare of the human subjects.

What is an Exempt Determination Official (EDO)?
An EDO can determine if your research protocol is “exempt.” Some research protocols are “exempt” and do not need to be reviewed by an IRB. As a researcher, you cannot determine whether your research is “exempt.” Only an EDO can make that determination.

What are examples of research that may require an Exempt Determination or Institutional Review Board (IRB) approval?
- Determining if a change in classroom practice contributes to improved academic outcomes.
- Determining whether changes in the food provided in the cadet mess hall are associated with improved athletic performance.
- Identifying associations between cadet gait and ACL injuries.
- Administering a survey to learn about academy schedule preferences.

What if I am only trying to improve the class or course?
If you are not disseminating the work (this includes cadet Projects Day presentations and Master Teacher Projects) and are only using information for internal administrative purposes, this is not classified as human subjects research and you do not need to submit your research protocol for review.

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<td>Check with the Human Research Protections Program (HRPP) Staff whether your study/project will need to be submitted for HRPP review. Pose your question in an email, <a href="mailto:hrpp@westpoint.edu">hrpp@westpoint.edu</a></td>
<td>Run your study/project and present/publish your findings at a conference/Project’s Day/as a Master Teacher Project without HRPP review.</td>
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<td>Try to obtain HRPP review after the data is collected.</td>
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STEPS FOR PREPARING YOUR PROTOCOL APPLICATION

1. Write a layman’s description of your project and e-mail it to HRPP.
   Doing this step first will save you a lot of time and unnecessary headache. The HRPP Staff reviews every single protocol application and attends all IRB full board meetings. The HRPP Staff will be able to help you craft your protocol and have insight into issues of coercion and risks to subjects that you may not think of. They will also know if you need to obtain documented informed consent. HRPP Staff may also set up a call with you if they need more information or do not understand your project description. This is helpful for when you write your protocol. Finally, HRPP Staff can help you decide whether you select “Exempt Determination” or “Non-Exempt Research” within Cayuse.

2. Obtain a Cayuse Account.
   Protocol applications are submitted digitally using Cayuse. To obtain your Cayuse username and login details, email HRPP. Guidance on submitting your application through Cayuse can be found here. In Cayuse, under Products and Human Ethics, select “New Study” (see guidance and screenshot on left) and you will receive prompts.

   Before you conduct a human subjects study, you will need to fulfill human subjects training. The training takes 2-3 hours. Guidance on how to access the required CITI training modules can be found here.
4. Prepare all HRPP forms and research team member documents

Your research team members will need CVs, mini-biosketches for cadet investigators, proof of valid human subjects (CITI) training, command support letter (instructions), and signed conflict of interest disclosure forms. Let your study team know what is required sooner rather than later. For your study, if you need documented informed consent (e.g., if cadets in your class are being studied, you may need documented informed consent), this document needs to be prepared and uploaded. If you are using a device, you will need a departmental instrumentation policy (see example). You will need a scientific review by someone not on your team. This can be a colleague or an external investigator. You will be prompted for the upload of these documents as needed.

5. Conduct a thorough literature search.

HRPP assesses the risk versus benefits of your study. Part of this is placing your study in terms of the field.

BEST PRACTICES FOR PREPARING YOUR PROTOCOL APPLICATION

You may have heard stories about IRB applications “slowing down research”. IRB approval is not in the way of human subjects research, it is a part of human subjects research. Preparing your protocol will help you think through your study and support successful execution of your plan. You will have completed a literature search and described your proposed research to reviewers.

Reviewers are not your enemy. They are volunteers who serve on the IRB because they believe in protecting human subjects and believe in research. However, if the reviewers have questions, they will ask you to respond. This adds time to your review because the reviewers will take up to a couple weeks to review your application and revisions. Then you will need time to respond to the comments. The back and forth delays your application’s approval. If you adhere to some best practices, the time it takes to review and approve your proposal will shorten and the reviewers will thank you for it.

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| Write your background, recruitment methods and step by step protocol so reviewers from any background can understand it. Work on the writing so that it flows. **Example** Students learn to count with numbers in the usual order. For example, children count like this: 1, 2, 3, 4 and so on. There are other ways to order numbers in mathematics. We wanted to know how students respond to these alternative ways to order numbers. | Don’t use jargon and technical language. **Example** Consider the Sharkovsky ordering of \( \mathbb{N} \):
\[
3 < 5 < 7 < 9 < \cdots < 3 \cdot 2 < 5 \cdot 2 < 7 \cdot 2 < 9 \cdot 2 < \cdots \]
\[
< 3^2 < 5^2 < 7^2 < 9^2 < \cdots < 2^3 < 2^2 < 2 < 1
\]
Let \( I \) be either the real line or an interval. If \( f: I \to I \) is a continuous map, then a set \( P = \{x_1, x_2, \ldots, x_n\} \) such that \( f(x_1) = x_2, f(x_2) = x_3, \ldots, f(x_n) = x_1 \), is called a cycle or a periodic orbit. |
| Add all details in your protocol. Anyone should be able to read your protocol and have enough information to execute the research. **Example** Cadets will be invited during class to hear about the study in TH120 during Dean’s Hour. Professor Frink who is not an officer or teaching a class in the study will explain the study to the cadets. Professor Frink will pass out the consent forms and ask the cadets to read the consent forms. The cadets will be given time to ask questions. If they are prepared to sign the consent form, the signed forms will be collected by Professor Frink. If cadets want to think about it, they can email questions and bring a signed form to Professor Frink at a later date. Cadets can also choose not to sign the form and will be reminded verbally that there will not be consequences if they choose not to participate. | Do not leave out details. The following leaves many questions in the reviewer’s minds. How are you going to collect consent forms? Who will administer them? Where will they be administered? How will coercion be mitigated? And so forth. **Example** We will consent all cadets before collecting surveys. |

REFERENCES