What is an Institutional Review Board (IRB)?
Under federal regulations (see the Code of Federal Regulations, §46.102 at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102), an IRB is an appropriately constituted group that has been formally designated to review and monitor research involving human participants. See Section I (“General Policies and Procedures”) of the IRB Manual.

What does the IRB do?
It is the responsibility of the IRB to review research protocols involving human participants to ensure that the rights of the participants are protected, that they are not subjected to unreasonable harm (physical and emotional), and that information about them is kept confidential. See Section I (“General Policies and Procedures”) of the IRB Manual.

How can I tell if my project requires IRB approval?
If your project is research and involves human participants, you must file an IRB protocol with the IRB for review and approval. See Section II (“Research Requiring IRB Approval”) of the IRB Manual, for information on research requiring IRB approval, including Chart 1, “Is My Project Considered Research Involving Human Participants?” Both “research” and “human participant” are defined in Section II of the IRB Manual, and also in the Code of Federal Regulations, §46.102 http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm.

What is research?
Section II (“Research Requiring IRB Approval”) of the IRB Manual provides a detailed segment on this.

What does the IRB look for in a submitted protocol?
The IRB needs to be assured that the research is 1) of sound design, given the proposed use of human participants; 2) that there is equitable selection of subjects; 3) that there is a reasonable balance in the risks and benefits to the participants; and, 4) that the informed consent process is appropriate and comprehensive.

What does the IRB consider to be a “sensitive topic”?
While this is not an exhaustive list, some common examples are sexual activity, domestic or sexual violence, drug use/abuse, child abuse and other illegal activities.
Why did the UWP IRB decide to eliminate the "exempt" category, and who gave the IRB authority to make that decision?

Since the 2005-06 revision of the IRB Manual, the IRB requires all protocols be submitted for either expedited review or full board review. In that revision, the IRB eliminated the “exempt” category by collapsing the “exempt” and “expedited” categories of research together. This is not an uncommon practice among IRBs, and is addressed in a report from the Office for Human Research Protection (formerly known as the Office for Protection from Research Risks):

The concept of exempt research and the practice of expedited review of research can come together, as some institutions choose to provide an additional measure of protection for human subjects by reviewing what would be exempt under §46.101(b) in an expedited manner. This is acceptable, since expedited review of that which is exempt exceeds the minimum requirements for both in 45 CFR Part 46. [“Exempt Research and Research That May Undergo Expedited Review,” May 1995, available online at http://www.hhs.gov/ohrp/humansubjects/guidance/hsdc95-02.htm]

In addition, the members of the IRB have found that it is beneficial to have more than one set of eyes review a protocol. This led to the decision to have two reviewers (minimum) review each project.

What does “exempt” mean?

Before the IRB eliminated the “exempt” level of review, confusion had existed with the references in the federal guidelines to “exempt” research (see the Code of Federal Regulations, §46.101 at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subparta).

“Exempt” research is a category requiring minimal review by at least one IRB member. The level of human subjects research—exempt or otherwise—has never negated the need for the PI to complete and submit documentation of his/her research; in other words, the researcher is not the appropriate person to determine if his/her own research is exempted (at UWP, that decision was assigned to the IRB Chair).

The UWP IRB eliminated that confusion by requiring all protocols of research involving human participants be submitted for either expedited review or full board review.

Process

If I have questions about the IRB forms, where do I go?
For questions about the IRB forms, please contact the IRB Chair.

How do I find out who the IRB Chair is?
See the IRB web site at http://www.uwplatt.edu/committees/irbhsr/index.html.

Who do I need to turn the protocol in to?
Protocols must be submitted to the IRB Chair. See the IRB web site at http://www.uwplatt.edu/committees/irbhsr/index.html for contact information.
Do protocol continuations just need to go through the IRB chair, or do they need to go out to other reviewers as well?
Only the IRB Chair needs to review continuations or modifications. Complete the request for Continuation/Modification/Termination form and submit to the IRB chair. See the IRB Manual, Section V (“Requesting a continuation, modification or termination of a protocol”).

Do I have to have my cover page re-signed if I make requested changes/revisions to the protocol?
No, the Chair usually keeps the original cover page, with the signatures, and attaches that to the copy of the revised protocol. The revised protocol is then sent to the Office of Sponsored Programs, where protocols are kept on file for three years.

If I already obtained protocol approval, but I wanted to make some substantial changes, do I need to submit a whole new protocol?
Perhaps. Submit a Continuation/Modification/Termination form to the IRB chair – if the changes are determined by the chair to be extensive, the chair will request a new protocol. See Section V (“Requesting a Continuation, Modification or Termination of a protocol”) of the IRB Manual.

Can I submit a protocol via email?
No. The protocol must be submitted in hard copy because of the required signatures.

Can I turn in a protocol without my department chair’s signature? Can I get the signature after I’ve gotten the protocol approved by the IRB?
No. The IRB will not accept any protocol without all required signatures. See Section IV (“Preparing a Protocol”) of the IRB Manual.

What’s the difference between the standard form and the teaching improvement form?
The Standard Form is appropriate for the majority of research projects. The Teaching Improvement Form is appropriate for many teaching improvement projects. For more information, see Appendix A (“IRB Review Protocol Samples and Instructions”) of the IRB Manual.

How long does it take to get feedback from the reviewers?
Upon receiving the protocol, the IRB has 10 business days to provide feedback to the PI. See Chart 2, “Summary of the Review Process” located in Section IV (“Preparing a Protocol”) of the IRB Manual.

The forms available online, and the forms in the IRB Manual appear to be slightly different. Why is that? Which version of the forms am I supposed to use?
The forms, both the standard form and the teaching improvement form, are available online. These are the forms you fill out and submit to the IRB Chair for IRB review. The versions of the forms available in Appendix A (“IRB Review Protocol Samples and Instructions”) of the IRB Manual include extra, detailed instructions to aid in filling out the forms. Both forms, on the 2nd page (after the cover page), advise the researcher to refer to those detailed instructions in the IRB Manual. The cover pages of both forms are reproduced in the IRB Manual.
I need to spellcheck my protocol, but the protocol forms do not allow me to do this. How can I spellcheck my protocol?
The forms have been locked so the researcher(s) is able to fill in the sections of the form. Although this feature is convenient, the spellcheck function in Word does not work on locked forms. One alternate solution to spellcheck your content is to do the following:

- Open a new Word document,
- Cut and paste a section(s) of text you want to spellcheck into the new Word document
- Run spellcheck
- Cut and paste revisions as necessary back into the form

If that doesn't work, try this: cut and paste the text first into a Notepad or Wordpad file, then copy into a new Word document to run spellcheck.

Consent

Do I have to have consent forms signed by participants?
Perhaps not, if you are applying the principle of “implied consent” (see below). However, all participants need to have some kind of consent form including, but not limited to, an explanation of the research project and a statement that by filling out a survey, etc., that they are agreeing to participate in the research. See Section VII (“Informed Consent”) of the IRB Manual for more information on consent and Appendix B (“Sample Consent Forms”) for sample consent forms.

What is “implied consent”?
This is when consent is secured without having a signature. “Implied consent” (referred to in the IRB Manual as “unsigned consent”) is when the participants know that by completing a research task, such as filling out a survey, etc., they are agreeing to participate in the research. The action of filling out the survey serves as the participants’ consent. See Section VII (“Informed Consent”) of the IRB Manual for more information on consent and Appendix B (“Sample Consent Forms”) for sample consent forms.

Why do I have to use a consent form for educational projects and for projects that are “minimal risk”?
Participants have the right to decide if they want to take part in a research project. It is the responsibility of the IRB to review research protocols involving human participants to ensure that the rights of the participants are protected, that they are not subject to unreasonable harm (physical and emotional), and that information about them is kept confidential. “Minimal risk” is defined in Section III (“Determining the Appropriate Level of Review”) of the IRB Manual.

Why do I have to use a consent form if my students would be completing these materials in class anyway?
If your project is research and involves human participants, you must file an IRB protocol with the IRB for review and approval. Both “research” and “human participant” are defined in Section II (“Research Requiring IRB Approval”) of the IRB Manual and also in the Code of Federal Regulations, §46.102 [http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm]. Section II, Part D, of the IRB Manual also includes a detailed segment on class assignments.
Some research indicates that letting participants know they are in a research project invalidates the results; if I use a consent form they'll know they're in a study, so shouldn't I be allowed to not use a consent form?

There are some specific situations when the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent. Section VI (“Informed Consent”) of the IRB Manual contains more details on exceptions to consent requirements—including the statement that the IRB may waive informed consent if “the research could not practicably be conducted without the waiver or alteration.” It is important to note that “practicably” deals with more than inconvenience and cost. It addresses situations in which it would be impossible, or nearly impossible, to carry out the research if consent was required.

I am the students’ instructor and already know their grades, so why do I need a signed consent form to use their grades in my research?

Students would not reasonably expect their grades to be included in a research project without their consent. It is the responsibility of the IRB to review research protocols involving human participants to ensure that the rights of the participants are protected, that they are not subject to unreasonable harm (physical and emotional), and that information about them is kept confidential. See Section VII (“Informed Consent”) of the IRB Manual for more information on obtaining consent. Consult FERPA regulations.

I am the students’ instructor. I record their grades on a coded sheet and then give them to a researcher. Consequently the participants are completely anonymous to the researcher. Is signed consent still necessary?

Signed consent is not necessary in this case as long as the instructor is not a researcher in the study. See Chart 1 (at the end of Section II, “Research Requiring IRB Approval”) of the IRB Manual. Also see Section VII (“Informed Consent”) for more information on signed consent. Consult FERPA regulations.

In the Manual, it says the IRB can waive the requirement for informed consent. Why won’t you waive that requirement in my case?

The IRB considers the requirements for informed consent on a case-by-case basis. See Section VII (“Informed Consent”) of the IRB Manual for more details.

Miscellaneous Situations

Do I need a debriefing statement with an electronic/online survey?

Yes, there needs to be some kind of debriefing statement after the participants have submitted the survey. A debriefing statement provides a reasonable understanding of the project and its goals to the participant.
Do I need approval from the UWP IRB if my project has been approved by an IRB at another institution?
Usually, please contact the Chair of the UWP IRB for guidance on your project. In general, if the funds supporting the project were awarded to UWP and/or UWP personnel are involved as part of their position at UWP, then the project must be reviewed and approved by the UWP IRB. Also see Section II (“Research Requiring IRB Approval”), Part C, of the IRB Manual for more information on the role of UWP faculty and staff as researchers.

Is publishing something (like a paper, brochure, or newsletter) online considered contributing to “generalizable knowledge”?
Yes, because then anyone is able to access it electronically. “Generalizable knowledge” is defined in Section II (“Research Requiring IRB Approval”) of the IRB Manual.

Must class projects involving human participants be approved by the IRB?
Perhaps. If the class project can be categorized as research, then the answer is yes. See Section II (“Research Requiring IRB Approval”), Part D, of the IRB Manual for more details.

We’re doing a follow-up survey to see what people thought of our workshop. Does that have to come to the IRB?
If the survey is for in-house use, then IRB approval is not required. You would need to receive IRB approval only if the results of the research will contribute to generalizable knowledge. For more information and a definition of “generalizable knowledge,” see Section II (“Research Requiring IRB Approval”) of the IRB Manual.

If I want to survey my students to improve my course, do I need IRB approval?
No. This is not considered research since there is no contribution to generalizable knowledge. “Generalizable knowledge” is defined in Section II (“Research Requiring IRB Approval”) of the IRB Manual.

If I want to look at the trend of final exam scores in a particular course and share the information with my department, does this require IRB approval?
No. This is not considered research since there is no contribution to generalizable knowledge. “Generalizable knowledge” is defined in Section II (“Research Requiring IRB Approval”) of the IRB Manual.

Do I need to get IRB approval for a project with a private firm?
Perhaps. Each situation is unique; please contact the Chair of the UWP IRB for guidance on your project. Please see Section II (“Research Requiring IRB Approval”), Part C, for more information on the role of UWP faculty and staff as researchers.