

## Student Guidance

The steps and topics listed below are provided as a Quick Start, please review the information on the website for a full listing of guidance, policies and forms.

1. View the Getting Starting page of the website for information on training, pre-submission requirements, and submitting the protocol application in WVU+kc.

*Note that if the research involves scrolling into a school, a letter of permission to conduct research with the School or the board of education is required to be submitted with the protocol application.*

<https://human.research.wvu.edu/get-started>

2. Minimal risk projects that are not federally funded should consider the WVU Flex submission type

Find guidance for WVU flex here:

<https://human.research.wvu.edu/files/d/f3b4af33-4d8e-41cb-a1b0-18661f8c742d/flexnew.pdf>

This 6 minute Youtube video provides information on how to enter a protocol application; the example in the video is for an Exempt protocol; however, the instructions are the same for WVU Flex, just be sure to enter the Protocol type are Flex/NHSR.

<https://www.youtube.com/watch?v=HJxkXadmXTQ>

3. This page contains the Informed Consent for templates: <https://human.research.wvu.edu/forms>
4. For guidance on Advertising, visit: <https://human.research.wvu.edu/recruitment-and-advertisement-guidance>
5. Personnel:

Student researchers cannot be a Principal Investigator

Conflict of Interest – Institutional policy requires individuals listed on the Personnel tab in WVU+kc as a Principal Investigator or a Co-Investigator to complete COI disclosures. It is recommended that students be listed under Study Personnel unless they must be listed as Co-Investigators for other reasons.

6. Submitting the Protocol Application

The application will be routed to the Principal Investigator for the final approval before it is routed to WVU OHRP for review. To decrease the time required, we recommend that you prompt the PI to review and approve the application (bottom of the protocol summary or Protocol actions tab). The PI can be a professor, department chair, advisor, etc

## FREQUENTLY ASKED QUESTIONS

### General Questions:

- 1. I am doing an electronic survey. Do I need a cover letter?** Yes. You will need to provide a cover letter that mentions the participant can choose not to participate in the survey at any time. Include this text in question form at the end of the cover letter. The option must be provided for the participant to indicate agreement to take the survey or to opt-out.
- 2. When is a telephone script needed?** A telephone script is required when you are conducting either a telephone survey or a telephone interview. You must inform the participant that participation is voluntary, and they can choose to stop at any time during the survey. You must use the script for all verbal communication with the participant, and a copy of the script must be submitted with your protocol application for review and approval.
- 3. I am conducting a retrospective chart review that has PHI, will I need a HIPAA waiver of research authorization form?** Yes, you will need to complete this form if you/anyone on the study team is accessing the medical record.
- 4. I am listed on the WVU+kc Personnel Tab for Protocol Application; what training will I need?** CITI Human Subjects Protection Ethics training is required for everyone listed on the protocol application. Either the Biomedical Research Investigators or Social & Behavioral Research Investigators course is required. For more information, visit: <https://human.research.wvu.edu/get-started/training/citi-ethics-training>
- 5. What is Informed Consent?** Potential participants must give their informed consent before participating.
- 6. What is Informed Assent?** Potential participants are often unable to give consent for reasons of mental state, legal restrictions, or age (under 18). In this situation, a parent or legal guardian must provide consent.
- 7. Do research projects conducted by students require IRB approval?** Yes. If the project fits the definitions of research and human subjects. The level of review and approval is dependent upon the submission type. If the project is to be used in a classroom setting only to teach research methods, the project may not constitute human participant research.
- 8. What is minimal risk?** Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- 9. What is the faculty advisor's role in a student's research project?** The faculty advisor is an active mentor to the student researcher. *Ultimately, the faculty advisor is responsible for the conduct of the research as the Principal Investigator.* The advisor is expected to be familiar and discuss with the student researcher the ethical and regulatory requirements of human subjects research before the initiation of any project involving human subjects; help students determine whether their project requires Institutional Review Board (IRB) review and guide students through the protocol application process. The advisor must support the student in the conduct of the research project after approval is attained, giving special attention to maintaining participant protections (including privacy, confidentiality, and informed consent), minimizing risk and ensuring voluntary participation and withdrawal.
- 10. I am an undergraduate or graduate student. May I be the Principal Investigator (PI) on a project?** No, while students are encouraged to write and submit research protocols, a responsible faculty member must act as PI and certify the application review of a protocol application.

11. **What are the core requirements for Advertisements?** Clearly state that this is research, the name, address, and department of the Principal Investigator, eligibility criteria are clearly summarized, benefits are concise, the time or commitment for participation is clearly explained, the location of the research is provided, indicated that WVU IRB review is on file.

### WVU+kc Questions:

1. **I'm using Internet Explorer, and the WVU+kc system is not working?** The best browser to use with WVU+kc is Mozilla Firefox or Google Chrome.
2. **How do I create a Protocol?** Login to WVU+kc. Scroll to the top of the page, on the IRB tab select "Create IRB Protocol" answer all required fields as directed.
3. **How can I find out the status of my Protocol application?** Select "Protocol Actions" scroll to the bottom to "Route Log" and look for pending action requests to see who is responsible for moving the application forward
4. **How do I submit my Protocol for review?** Once you enter the required fields, scroll to "Protocol Actions" tab of the Protocol; under available actions, there will be an option for Review. Press submit.
5. **If I am not the Principal Investigator, can I submit a Protocol?** Yes, however, the application will be routed for the PI for review and approval. Scroll to the "Protocol Actions" tab of the Protocol under available actions will be an option for review. Press submit.
6. **I need a copy of the approval letter for a Protocol where is it located?** Scroll to "Protocol History" tab. Scroll to History and press show. Scroll to the "Correspondence tab" and press Show. Scroll to Actions and press View and then print the letter.
7. **Where do I complete my Conflict of Interest form?** In WVU+kc. Scroll to the top of the page and press the "COI" tab and complete the form.
8. **I need to make revisions; however, I cannot edit?** Logout of WVU+kc, log in and re-enter the Protocol number. On the left, under Action, there is an option for Edit, Copy, View. Select edit to edit your Protocol.
9. **Who can make corrections on the Protocol or add additional information?** Anyone that is an "aggregator" on the Permissions tab for the Protocol
10. **I received a revision letter. Where do I find it in WVU+kc?** Scroll to "Protocol History" tab, select on "History," select "Correspondence," and select "Show."