Protocol Submission Prep Checklist

Use this checklist as you prepare to submit your protocol to the WVU Office of Human Protections, the support office for the WVU IRB.

Prepare ahead of time

- ☐ Use WVU OHRP's Getting Started webpage to determine if your project needs IRB review (Step 1) and if so, what type of protocol to submit (Step 2).
- ☐ Consider the average turnaround time for approval. Reference the average approval times when preparing your submission. *Remember:* Turnaround time is a collective effort. Be sure to return your protocol submission promptly after receiving any requested revisions.
- ☐ Complete the required human subjects protection training. All study personnel must maintain up-to-date human subjects protection training. It is the responsibility of the PI to ensure all study staff members are trained. *(Hint:* You can check study personnel's training before submitting your protocol by clicking the "Personnel" tab at the top of the WVU+kc submission and looking at "Person Details" for each study team member.)

Submission guidance

- ☐ Select the correct protocol type in WVU+kc (NHSR/flex, exempt, expedited, full board, or cIRB). (*Hint*: Select "IRB" and then "Create IRB Protocol" in WVU+kc. Do not click/create a new "proposal.")
- ☐ Complete all listed sections and provide as much detail as possible so the IRB can understand and evaluate your study.
- ☐ Use WVU OHRP's Forms to create any informed consents or information sheets that will be utilized for the project.
- ☐ Be sure to delineate any procedures done specifically for research purposes from those that are occurring independently of the study. The IRB should be able to identify any standard of care procedures versus those done solely for research purposes.
- ☐ Double check your submission to ensure congruency in the application. Information like the number of subjects to be enrolled, the procedures, study objectives, timelines, locations, etc. must be consistent throughout your submission and the attached documents.
- ☐ If you are creating and submitting a protocol and you are not the principal investigator, follow up with the PI to ensure the protocol is submitted. When someone other than the PI clicks "Submit the Protocol," it is directed to the PI for final submission in WVU+kc.
- ☐ You can track the review process and see where your protocol is by clicking the "Protocol Actions" tab in your WVU+kc submission. Click "Route Log" and navigate to "Pending Actions Request" to see who has the submission.

Attachments

- ☐ Ensure you have uploaded any consent documents as PDF so they receive the appropriate watermark after approval.
- ☐ Attach your data protection certificate in your WVU+kc submission. (*Hint:* Ensure you label this document correctly because there is a hard stop in the system if this document is not included.)
- ☐ Attach any participant-facing material for IRB review (e.g., recruitment materials like emails, phone scripts, flyers as well as any surveys, handouts, etc.).

Screening comments or IRB revisions

- ☐ Respond promptly and fully to any WVU OHRP screening comments or IRB revisions and return the submission to WVU OHRP.

☐ If you are guided to change the category of the protocol in the review stage, go to the "Protocol" tab in WVU+kc, and change the category with the protocol type. After making this change, be sure to answer the questions that appear in the Questionnaire tab.

Post-approval considerations

Full board and Expedited

☐ Full board only: Be sure to submit your continuing renewal with enough time to be assigned to a meeting, reviewed, and approved before the expiration date.

☐ Submit any changes via an amendment for IRB review before implementing any change.

☐ When submitting amendments for full board or expedited studies, delete any attachments that are no longer being used, including old consent forms if you are uploading new ones. If the document is still being used and was not changed, do not delete or re-upload; leave it as is.

☐ Be sure to adhere to any reporting requirements. See WVU OHRP's Reporting Events webpage for further guidance.

☐ When you have finished your study, close your protocol in WVU+kc. Complete a protocol closure form and submit a closure request in WVU+kc with the form attached.

NHSR, Flex, Exempt

☐ Contact WVU OHRP if any changes are made to the protocol that may change its risk level or protocol type. If you are unsure, call or email for guidance.

All

☐ To obtain a copy of your approval or acknowledgment letter, open the WVU+kc submission and click the "Protocol History" tab. Then click the "History" tab and navigate to "Correspondence" to extract your letter.

Other Considerations

☐ If you need to copy a protocol to a new protocol, navigate to the "Protocol Actions" tab in your submission. There you will see "Copy to New Document." This will only copy the WVU+kc questionnaire. The attachments will not transfer and must be uploaded again before submitting for review.

☐ To print your WVU+kc questionnaire, open the protocol and click the "Protocol Summary" tab and click "Print."

Request Assistance

Contact WVU OHRP at any point during the submission process. We are here to help!

irb@mail.wvu.edu
(304)293-7073
Submit a Support Request
https://human.research.wvu.edu/