

Dear VT Researcher,

October 19, 2018

Research initiatives and opportunities continue to grow throughout the Virginia Tech campus and community. The division of Scholarly Integrity and Research Compliance (SIRC) facilitates scholarly excellence by fostering ethical decision-making and ensuring research regulatory compliance.

The Human Subjects Research Protections Program (HRPP) and the Institutional Review Board (IRB) are committed to protecting the rights of and ensuring the safety of human subjects participating in research conducted by faculty, staff, and students of the University.

Members of the HRPP Office have been working diligently to make changes to the IRB Protocol Management online system to ensure a more streamlined process and experience for researchers. Due to these efforts, new updates will be launched on October 22, 2018 to the IRB Protocol Management online system. These changes will create continuity between the other offices within SIRC, enhance the user experience, and improve the process for requesting use of the Commercial IRB review process.

The changes to the IRB Protocol Management online system will be separated into three categories:

- 1) [Changes to the system that affect all submissions](#)
- 2) [Changes to the system that affect submissions requesting transfer to WIRB](#)
- 3) [Changes to the system based on user feedback](#)
- 4) [Links to additional guidance](#)

Changes to the system that affect all submissions

When completing the online submission in Protocol Management, you will notice new questions, revised options, and updated (or new) guidance documents.

- The addition of a new question that directly asks if this study is seeking transfer to WIRB. The change is found in section (1) Project Info. If you are required or prefer to remain with the VT HRPP office for VT IRB review, please answer No. If you wish to seek transfer please answer Yes. This will remove the previous task of sending a separate email to HRPP to request transfer.
- PIs will now be required to acknowledge their responsibilities and certify that protocol applications are ready for submission, before the study can be submitted. This only applies to new submissions. The certification process will not be required for submitting amendments (unless the amendment is to change to a new PI), continuing reviews, or other submission types. This change is found in section (2) Project Personnel. PI certification ensures that the person responsible for the study (i.e., the PI) is aware of and accepts responsibility for what others are submitting on their behalf.

- A new conflict of interest question has been added to the personnel section. This change allows investigators to disclose any real or perceived conflicts related to the study and active project personnel. While anyone completing the submission can provide answers, the PI must review the responses to indicate an understanding of the required responsibilities. This change is found in section (2) Project Personnel.
- The addition of a category for project personnel: Other Study Personnel. Other study personnel include individuals who, while not considered co-investigators, interact with human subjects, obtain informed consent, or handle personally identifiable data of participants. Examples of other study personnel include, but are not limited to, project coordinators, research assistants, student researchers, and data analysts. All study personnel must complete human subjects research training. This change is found in section (2) Project Personnel.
- Revisions to the dropdown options found in the Collaboration section. The changes only apply if you are collaborating with another institution on the study. This change is found in section (2) Project Personnel.

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Changes to the system that affect submissions requesting transfer to WIRB

- The addition of a new question that directly asks if this study is seeking transfer to WIRB. This change is found in section (1) Project Info. If you are required or prefer to remain with the VT HRPP office for VT IRB review, please answer No. If you wish to seek transfer, please answer Yes. This will remove the previous task of sending a separate email to request transfer.

The following changes will only be visible if the question on transferring to WIRB has been answered Yes.

- Helpful NOTES have been added throughout the Protocol Management system to provide information and guidance when creating and uploading study documents. These changes are reflected in sections (3) and (4).
- For convenience, various WIRB documents are linked and available for immediate download. Please note that the link to the step-by-step instructions document will only be available in the formal Authorization Letter. VT researchers are not allowed to submit to WIRB without a formal Authorization Letter. These links are available in sections (4) and (5).
- The creation of a new section titled (5) WIRB Transfer. This section includes two separate acknowledgements that must be checked in order to submit. The first entry seeks project personnel's understanding that the VT IRB will provide an Authorization Letter, which does not mean IRB approval. The second entry provides details for the required amendment that must be submitted after obtaining a WIRB review letter. While anyone completing this submission can provide answers, the PI must review the response to indicate understanding and acceptance of the required responsibilities.

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Changes to the system based on user feedback

The office received valuable feedback and suggestions from our users. Based on this feedback, we have made several enhancements to the system:

- We increased the number of protocols listed in “Your Protocols” from 10 to 15 per page.
- We added a keyword(s) search bar to allow you to find a specific protocol more quickly.
- We added a revise option to the review process of an Amendment, to allow for changes or requested revisions to be addressed.
- We have revised guidance documents and links throughout.

If you have suggestions or ideas on how to enhance the user experience, please send them to irb@vt.edu.

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Here are links to additional guidance:

[Read more on the VT Partnership with Western IRB \(WIRB\) and details on determining whether your study is eligible for transfer to WIRB.](#)

[Review guidance that provides an in-depth description on the changes to the IRB Protocol Management online system \(using screenshots and more detailed guidance\).](#)

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