



NF/SGVHS Research Service

Standard Operating Procedure:

HRPP Annual Status Report - Workflow for Researchers

Updated: 12/24/22

Every VA-approved study must submit an annual VA Research and Development (R&D) Status Report, regardless of IRB classification (e.g., full board, expedited, exempt). IRBNet/VAIRRS lists an “expiration” date and a “report due” date in the Project Overview section of your study. The Human Research Protections Program (HRPP) is now applying the following definitions for these dates when each Annual Status Report is processed. However, until your current Status Report has been processed, your study dates may not yet follow these definitions. If you have questions about this, please contact VHANFLResearchStudy@va.gov.

- The NF/SGVHS **HRPP Expiration** will be set to be the same as your IRB expiration date. If the study is exempt or expedited, there will be no HRPP expiration date listed. Exempt studies do not expire. For expedited studies, refer to the IRB approval letter to determine the expiration date.
- The NF/SGVHS **R&D Report Due** will be the next Annual Status Report due date. For full board studies, this date should match the new HRPP Expiration date (i.e., the next IRB expiration date). For exempt or expedited studies, this date should match the initial approval date, but be adjusted to the appropriate year. The Report Due date is not a “hard” deadline, and your study activities may continue uninterrupted even if the deadline passes. However, please make every effort to submit the Annual Status Report on time.

1. *Document: Annual Status Report coversheet*

Download and review the Annual Status Report coversheet from the Forms and Templates section of IRBNet/VAIRRS (the library called NF/SGHVS Research Administration Members – Gainesville, FL – Documents for Researchers). The Coversheet provides guidance on the required forms/documents needed.

2. *Update Conflict of Interest*

All investigators (Principal and Co-Investigators) must complete a Conflict of Interest (COI) submission electronically in IRBNet/VAIRRS using the “My COI” portal. Instructions can be found on the Research Service [website](#) under the heading “IRBNet (VAIRRS) Tutorials for Researchers”. COI submissions must be reviewed every year, even if that COI was already reported/approved in a prior year. This is due to the possibility that laws changed, or that the nature of the conflict of interest evolved over the past year.

If your IRB required a continuing review submission (annual renewal) or a UF IRB status report*, then download that submission as a PDF file from the website of the external IRB. Upload that file to your IRBNet/VAIRRS Annual Status Report package, along with the IRB approval letter.

**UF IRB status reports are required every three years for expedited studies*

3. *Update study staff*

If you have added/removed study staff since the last VA Annual Status Report, update the staff list in IRBNet using the “**Share this Project**” link under the Project Administration menu. New study staff must upload their TMS Privacy and HIPAA certificate to their IRBNet profile, and link their CITI training account to IRBNet. For instructions, view the section called “IRBNet (VAIRRS) Tutorials for Researchers” on the NF/SGVHS Research Service website:

<https://www.nffre-research.org/va-research-resources>

4. *Ensure all trainings are current*

Required training cannot be expired for any staff member listed on the IRBNet project. These include:

- TMS Government Ethics
- TMS Privacy and HIPAA Focused Web-Based Training
- CITI Human Subjects Protection.

If the study involves the collection/shipment of human biospecimens, ensure that appropriate staff members have completed CITI trainings for Biohazard Shipping and for Bloodborne Pathogens. These staff members should be listed on the Annual Status Report Coversheet.

5. *Cover Sheet Wizard*

Make sure that your study has completed the VA Cover Sheet Wizard in IRBNet/VAIRRS. If necessary, update the Cover Sheet Wizard document to account for any changes to your study (such as adding or removing co-investigators). For questions or assistance please contact VHANFLResearchStudy@va.gov.