What are the Annual Reporting Requirements?

Mandatory Submission

The completion and submission of an annual report are mandatory for all projects as a condition of ethical approval and governance authorisation.

The annual report is due 1 May annually.

Failure to submit a satisfactory annual report will result in the withdrawal of HREC approval and/or Governance authorisation, which leads to **study suspension**. Consequently, all study activities must be halted until the approval is granted.

Submission Timeline

The submission deadline is May 1st annually, starting from the following year of the approval date until the project completion.

Submission of final reports is required to inform the HREC about the completion or abandonment of a project.

Failure to submit progress reports within 45 days after the 01 May deadline may result in the study suspension.

Acknowledgement of a submitted annual progress report will generally be provided within 2 months of submission - *this timeline may be extended due to the significant volume of reports received.*

Types of Annual Reports

All Annual Reports and Final Reports are to be submitted under the relevant projects on SAGE.

1. **Progress/Final Report (HREC Form)**
2. **Site Report/Closure Form (RGO Form)**
3. **External Site Closure Form (HREC Form)**

Different report forms are required depending on the project types. Please refer to the following table for what report types are required for your project, and whose responsibility it is to submit.

If you believe you should have submission access but are unable to submit the form, please contact research.directorate@svha.org.au.

For further information, please contact Research Integrity and Compliance Assistance on 03 9231 6987 or email: svhm.ResearchAnnualR@svha.org.au

Project Type	Report Form Required	Where to Submit on SAGE	Whose responsibility to submit
Ethics only project - no SVHM site is involved	Progress/Final Report (HREC)	Milestone tab under the SVH Project	• Investigator-initiated study: CPI • Commercially-sponsored study: Sponsor
Governance only project - study reviewed by an external HREC, SVHM as participating site	Site Report/Closure Form (RGO) one report for each site	Milestone tab under the SSA Project for each site	PI only
Both Ethics and Governance project - **Single-site study** where SVHM is both the HREC and the only participating site	Site Report/Closure Form (RGO)	Milestone tab under the SSA Project	PI only
Both Ethics and Governance project - **Multi-site study** where SVHM is the HREC and one of the participating sites	Both HREC and RGO report forms are required	Milestone tab under the SVH Project for HREC Form; and the SSA Project for each RGO Form/s	**HREC Report:** • Investigator-initiated study: CPI • Commercially-sponsored study: Sponsor **RGO Report**: PI only
Ethics project with a closure of an external site - Closure of a non-SVHM RGO site approved under SVHM HREC	External Site Closure Form (HREC)	Form tab under the SVH Project How to submit an external site closure form	• Investigator-initiated study: CPI • Commercially-sponsored study: Sponsor