

SVHM HREC Digital Signature Guidelines

- **Mandatory:** Adherence to these guidelines are a mandatory requirement for researchers, CROs and Sponsors.
- **Preferred methods:** SVHM prefers legal agreement execution via direct PDF signing, Adobe Sign or DocuSign.
- **Partial execution requirement:** All agreements must be partially executed by all parties, except the SVHM Director of Research, prior to submission.
- **Details for completion:** Instructions for filling in a HREC Review Only Indemnity template are provided on page 2 and the website dropdown bars.
- **Contract submission form:** This document is mandatory when using Adobe Sign or DocuSign. The protocol number must be included in the subject title.
- **Final approval:** Agreements will not be signed/returned until the submission is approved.

Important notes

1. Do **not** send reminders to the Director. The agreements will be signed only when approval is granted. Please ensure that email reminders are turned **OFF**.
2. Do **not** contact the Director directly. The RGU is responsible for the facilitation of executing agreements.
3. Please ensure that the Subject title provided on the Contract Submission Form matches **exactly** that of which is sent to the Director. **It must include the protocol number.**

Process overview

1. A draft of the agreement/s is submitted within an application to the Research Governance Unit (RGU) for review.
2. If the agreement is to be signed using DocuSign or AdobeSign, the contract submission form must be submitted within the application.
3. The agreement will be reviewed by the RGU.
4. When final approval is ready to be issued, the RGU will advise the Director of Research that the agreement may be fully executed. The details provided on the Contract Submission Form will be used to locate the request for signature.
5. Approval will be issued by the RGU, with fully executed agreements provided in conjunction with the approval letter.

Submitting partially executed agreements via DocuSign/Adobesign

A request for signature must **not** be sent via DocuSign/Adobe Sign unless an application or request for amendment has been submitted to the RGU. The legal documents must be partially executed by all parties except the SVHM Director of Research at the time of submission.

A Contract Submission Form must be submitted with the corresponding application.

***Please note that legal documents will not be fully executed until final approval is granted.**

- Send the request for signature to Dr Megan Robertson, Director of Research: megan.robertson@svha.org.au

Submitting PDF agreements for direct PDF signing

Legal documents may be submitted in conjunction with new applications and amendments via the usual submission pathway if DocuSign/Adobesign is not required. In this case, the agreement must be in **PDF** format. The legal documents must be partially executed by all parties except SVHM at the time of submission.

Please ensure that the document is **not** locked as locked documents cannot be signed.

A Contract Submission Form does *not* need to be submitted.

- Provide a PDF copy of the legal agreement to the RGU via the usual submission pathway within a new application or amendment to: research.ethics@svhm.org.au

Instructions to complete HREC Review Only Indemnity

1. Fill in the Indemnified Details as follows: **St Vincent's Hospital (Melbourne) Limited, 41 Victoria Parade, Fitzroy, VIC 3065, ABN 22 052 110 755 ("the Indemnified Party")**.
2. Fill in the Sponsor Details.
3. Add the *full* Protocol Title.
4. Fill in Name of *all* Hospitals and Names of Investigators.
5. Make sure that '**DATED the XX day of XX in the year XXXX**' is filled in prior to initiating the electronic signature request.
6. Initiate an electronic signature request in Adobesign or Docusign for the authorised representative of the sponsor and the authorised representative of the Indemnified Party (**Dr Megan Robertson, Director of Research**).
7. Complete Contract Submission Form (appendix below or available in the [Forms](#) page of the website).
8. Include a PDF copy of the partially executed HREC Indemnity signed by the authorised representative of the sponsor and completed Contract Submission Form within the submission for review.

Resources

- [SVHM Human Research Ethics Webpage](#)
- [Contract Submission Form](#)
- [DocuSign eSignature User Guide](#) – page 20
- [Adobe Sign Get Started guide](#)

Legal Contract Submission Form for DocuSign/Adobesign Requests

Please utilise the following contact details:

megan.robertson@svha.org.au

[PH: \(03\) 9231 6970](tel:(03)92316970)

Study Title:
Protocol Number:
Sponsor:

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Contract 1

Contract type (e.g. CTRA, indemnity, etc.)	
Email Subject title (including protocol number)	
Date sent	
Sent via DocuSign or Adobesign? (please specify)	

Contract 2 (if applicable)

Contract type (e.g. CTRA)	
Email Subject title (including protocol number)	
Date sent	
Sent via DocuSign or Adobesign? (please specify)	

