

Tips & FAQs for SSA submission at RMH

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1. Acronyms used in this document

AI	Associate Investigator
CTRA	Clinical Trial Research Agreement
ERM	Ethics Review Manager – the online ethics and governance submission platform
HOD	Head of Department
HREC	Human Research Ethics Committee
MAR	Management Accountant - Research
OFR	Office for Research
PI	Principal Investigator
PICF	Participant Information and Consent Form
RMH	Royal Melbourne Hospital
SOA	Statement of Approval
SSA	Site Specific Authorisation. The terms SSA and Governance are interchangeably used in this document. Obtaining Governance approval is the same meaning as obtaining SSA approval.

2. Preparing for your governance application

- Read all of the points in the process on the website, including information drop-downs, before commencing with your application
- Note that the numbering system of each step in the process is arbitrary and that multiple steps can be undertaken in parallel to save you time
- You can start preparing the SSA application alongside the ethics application
- Governance approval will only be issued *after* ethical approval has been obtained

3. Submitting the application

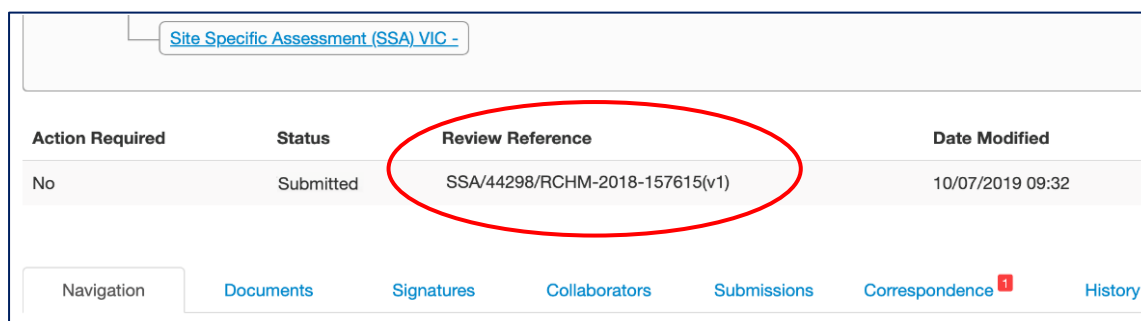
Submit as complete an application as possible – meaning submit all documentation at the one time. This will ensure the review process is timely and efficient.

Q. *I have uploaded the SSA form in ERM – do I still need to email it as well?*

- Yes, you need to submit via both ERM and email.
- The email alerts the OFR that an application has been submitted.
- If you do not submit your email, we will not know that your application has been submitted.

Q. *How do I check that the SSA form has been fully submitted in ERM?*

- Login to ERM to check if your SSA form has been submitted.
- On the project screen of ERM* check the **Status** and the **Review Reference** fields. Project screen is where you find the project tree, visible at the top of the picture below.
- As shown in the image below, this SSA status is “**Submitted**” and the Review Reference is “**SSA/44298/RCHM-2018-157615(v1)**”, which means it has been submitted.



The screenshot shows a web interface for a Site Specific Assessment (SSA) form. At the top, there is a breadcrumb trail: "Site Specific Assessment (SSA) VIC -". Below this is a table with the following columns: "Action Required", "Status", "Review Reference", and "Date Modified". The table contains one row with the following data: "Action Required" is "No", "Status" is "Submitted", "Review Reference" is "SSA/44298/RCHM-2018-157615(v1)", and "Date Modified" is "10/07/2019 09:32". The "Review Reference" cell is circled in red. Below the table is a navigation bar with the following items: "Navigation", "Documents", "Signatures", "Collaborators", "Submissions", "Correspondence" (with a red notification icon), and "History".

Action Required	Status	Review Reference	Date Modified
No	Submitted	SSA/44298/RCHM-2018-157615(v1)	10/07/2019 09:32

- If the form hasn't been submitted, the Status will read “**Not Submitted**” and the Review Reference will be “**N/A**”.
- The other place you can look is the SSA form itself. Check the SSA reference number has been added to the second line of the footer titled “*Review Reference*”

Q. *When can I submit my governance application?*

A research governance application can be submitted *at the same time* as the ethics application or even before you receive ethical approval.

You can also submit your Governance application before you receive your MAR approval. As we know it can take several weeks to obtain signed SOAs and budget review.

- If the budget review has not been completed, please confirm in your SSA application email or cover letter that you have started the budget review process.

Q. *Do I need to include all of the HREC approved documents in the application?*

YES - you need to do this for projects where RMH HREC did not undertake the ethical review of the project.

Provide a copy of all of the HREC approved documents and their corresponding HREC approval letter(s).

4. Signatures

Q. *Do I need to get signed declarations for everyone on the SSA form?*

All Investigators involved in a study must be listed on, and must sign, the SSA. This includes all the AIs as well as the PIs. The options for signing an SSA are:

- Using the ERM online signature function (**preferred option**).
- E-signing a pdf copy of the completed SSA (via DocuSign, AdobeSign, etc). Include the signed .pdf of the SSA in your email submission
- Printing the signature pages from the SSA once it is completed, signing and scanning the hard copies, and including the scanned copies in your email submission
- Copy the text of the relevant declaration into an email, documenting your acceptance in writing at the bottom, and including the email in your email submission

If you choose to sign outside of ERM, you need to ensure that all SSA signatures have at least one study identifier on them (Protocol Number, HREC Reference Number, Local Reference Number, Study Title, etc.) and the full text of the most up-to-date version of the relevant declaration (PI, AI, Head of Department) is visible.

Q. *What does the RMH PI's Head of Department signature.*

The RMH PI's HOD will need to sign multiple forms. We recommend that you complete all of the forms and submit them in one package for signing.

- SSA – to confirm that they support the research project being carried out in the department and that the research staff have the appropriate experience to do it.
- SOA (funded) OR simple budget spreadsheet (for \$0 in/out funding) – to accept financial responsibility for the project.

5. Employee affiliation and information if RMH is the study sponsor?

Q. *I work at several organisations – which one do I list as my organisation on the SSA form?*

For each person listed, only list the organisation that is relevant to the project. If this is an RMH only project, do not include your University of Melbourne (UoM) details in the contact section as this complicates our review, and leads to further questions regarding the involvement of UoM.

Note: Only RMH affiliated persons (employee or honorary appointment) can access RMH patients or data.

Q. *What information do I include if RMH is the sponsor?*

You can enter "NA" or include your own details in the sponsor contact section.

6. MAR Budget Review

Q. *How long does it take to get the budget reviewed?*

Budget review can take several weeks so plan to submit the documents for review as early as possible.

Also note that you will need the **signed** SOAs for the budget review so allow 1-2 weeks to obtain these prior to submitting for budget review.

7. Site specific PICFs for a multi-site study

Q. *How do I create site specific PICFs for multi-site studies?*

- Base the site specific PICF on the most recently approved Master version
- Do not change any wording in the body of the PICF adding your site details only in the prompted sections, i.e. <insert hospital name>
- The footer must include:
 - » The date and version number of the *site-specific PICF*; and
 - » date and version number and date of the *Master PICF* that the PICF is based on.
- In the site specific PICF include the RMH clinical contact and complaints contact details as instructed on the OFR Governance website.
- The person to talk to about the guidelines should be a member of the study team, not a member of the OFR.

8. Radiation information

Q. *Do I need to submit Radiation information?*

YES if your study involves *any ionising radiation* even if it is standard of care.

This includes CT, X-ray, MRI. It is RMH standard practice to have a MRI pre-screening chest X-ray.

9. Indemnity and Insurance

Q. *Do I need to complete an Indemnity form for my project?*

It depends on the research to be conducted:

- Investigator initiated clinical research projects – **No**
- Commercially sponsored clinical trials – **Yes**.

10. Agreements

Identify if you require an agreement early in the application preparation process and start drafting it. Provide the **unsigned draft** agreement in the research governance application

Check if there are any Special Conditions in the CTRA?

If the CTRA for your project has special conditions in Schedule 4 or 7 of the agreement, ask your sponsor to send you the SEBS (South Eastern Border States) approval letter for that wording and include the letter as part of your governance submission package.