

Signature on the VIC SSA Form

The Victorian Site Specific Assessment (SSA) form is created, completed, signed and submitted using ERM <https://au.forms.ethicalreviewmanager.com>.

The SSA form is designed to be signed digitally. If a signatory is unable to digitally sign a SSA form, it can be printed for ink signature.

If there are multiple signatories on a SSA form, any ink signatures must be sought *first*, followed by digital signatures. Once digital signature is requested or applied, the SSA form is locked to prevent changes.

Ink Signature

Step 1: Obtain Signature

1. In the SSA application, select the signature section for the person that is applying ink signature.

The screenshot shows the ERM Applications interface. The main content area displays the 'Site Specific Assessment (SSA) VIC' form. The 'Signatures' section is highlighted with a red box, and a red circle with the number '1' is placed over it, indicating the step to select the signature section. The form is organized into sections and questions, with the 'Signatures' section being the focus of the instruction.

Form Status	Review Reference	Date Modified	NMA
Not Submitted	N/A	24/02/2020 14:39	Project is not for NMA

Navigation: Documents | Signatures | Collaborators | Submissions | Correspondence | History

Section: Introduction | Site Research Team | Site Impact | Participants | Regulation | Budget | Other Documents | Signature

Questions: Information | Project | Location | Ethics Review | Site Addition | Team | Documents | Impact | Conflict of Interest | Dates | Departments and Services | Summary | Recruitment | Co-enrolment | Standard Care | Admissions | Sponsor | Research Agreement | Indemnity and Insurance | Funding | Administering Organisation | Other Documents | Principal Investigator | Associate Investigator | Head of Department | Head of Supporting Department

2. Enter the signatory's details (required for Head of Department and/or Head of Supporting Department).
3. Select the **Print** action.

ERM Applications Home Contacts Help Professor Joe Bloggs (joebloggs98231@gmail.com)

Actions

Previous Next Navigate

Print Documents Signatures

Save Collaborators

Completeness Check Submit

Site Specific Assessment (SSA) VIC

Signature of Head of Department

- A Head of Department may delegate responsibility to an appropriate staff member.
- An investigator must **not** approve their own research on behalf of their department. If an investigator is also Head of Department, certification must be sought from the person to whom the Head of Department is responsible.

Who is providing signature?

Head of Department
 Head of Department's Delegate

Declaration by Head of Department

Name: Prof. A. Hart
Department: Cardiology

I certify that:

- I have read the research project application named above.
- I have discussed this research project, and the resource implications for this department, with the Principal Investigator.

4. A PDF of the SSA application form is generated. Print the form and obtain ink signature on the page, then scan the signed page.

Step 2: Upload Evidence of Signature

5. In the SSA application, select the **Other Documents** section.

ERM Applications Home Contacts Help Professor Joe Bloggs (joebloggs98231@gmail.com)

Work Area

Home Notifications

Actions

Project Duplicate Form Delete Form

Create Sub-form Share Transfer Form

Completeness Check Submit Refresh

NMA Project Print Correspond

Testing Another New Investigational Product

Project Tree

- Testing Another New Investigational Product
 - HREA
 - Site Specific Assessment (SSA) VIC - Administrator Use Only

Form Status	Review Reference	Date Modified	NMA
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Navigation Documents Signatures Collaborators Submissions Correspondence History

Site Specific Assessment (SSA) VIC

Section

Introduction: Information Project Location Ethics Review Site Addition

Site Research Team: Team Documents Impact Conflict of Interest

Site Impact: Dates Departments and Services Summary

Participants: Recruitment Co-enrolment Ward Care Admissions

Regulation: Sponsor Research Agency Community and Insurance TGA Notification Safety

Budget: Funding Administering Organisation

Other Documents: Other Documents

Signature: Principal Investigator Associate Investigator Head of Department Head of Supporting Department

6. Select Upload Document.

ERM Applications Home Contacts Help Professor Joe Bloggs (joebloggs98231@gmail.com)

Actions

Previous Next Navigate

Print Documents Signatures

Save Share Collaborators

Completeness Check Submit

Site Specific Assessment (SSA) VIC

Supporting Documents

7.1 Are any other supporting documents provided (in addition to the documents already uploaded within this SSA)?

Yes

No

Upload Document

7. Browse for the scanned document, enter details and select Upload.

Documents - Other

Please attach your Other here:

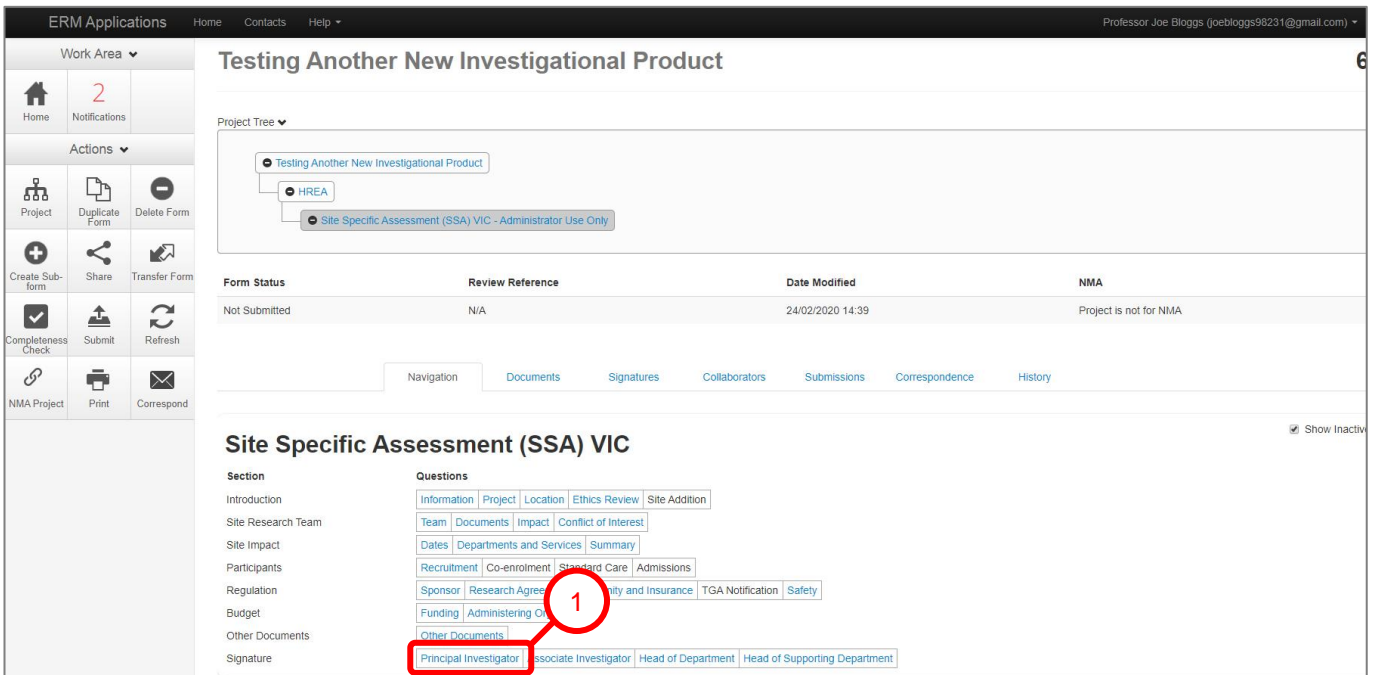
Document Name	Version Date	Version	
SSA signed by hand <input type="text" value="SSA signed by hand"/> <input type="button" value="Browse"/>	<input type="text" value="24/02/2020"/>	<input type="text" value="Prof Hart"/>	<input type="button" value="Upload"/>
SSA signed by hand.pdf			

Digital Signature

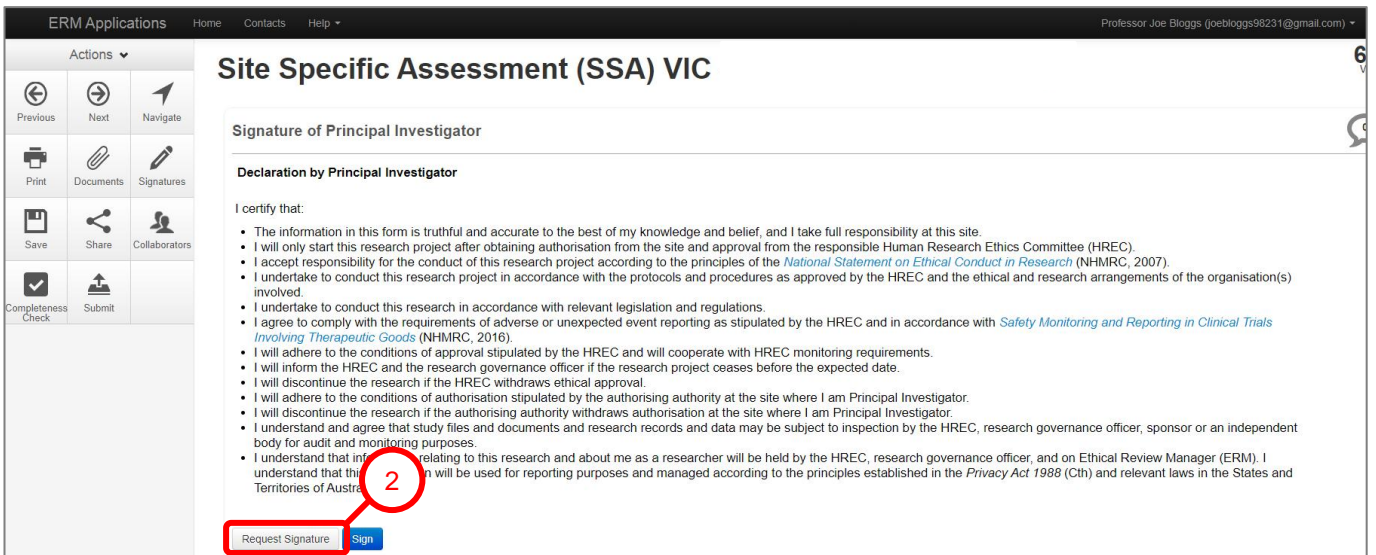
If applying ink *and* digital signatures on a SSA form, ensure the ink signatures are sought first, before digital signature. Once digital signature is requested or applied, the SSA form is locked to changes.

Option 1: Request from a Colleague

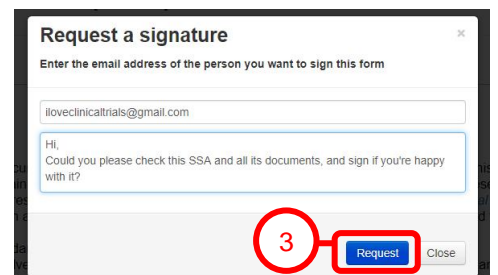
1. In the SSA application, select the Investigator or other applicable signature section.



2. Select Request Signature.



3. Enter the signatory's email address (must be the address used for their ERM account) and select Request.
4. The signatory receives an email with a link to sign the form in ERM. They can also login directly to their ERM account to sign the form.



Option 2: Apply Own Signature

1. In the SSA application, select the applicable signature section.

The screenshot shows the ERM Applications interface. The top navigation bar includes 'ERM Applications', 'Home', 'Contacts', and 'Help'. The user is identified as 'Professor Joe Bloggs (joebloggs98231@gmail.com)'. The main content area displays the project 'Testing Another New Investigational Product' with a 'Project Tree' showing 'HREA' and 'Site Specific Assessment (SSA) VIC - Administrator Use Only'. Below this is a table with columns for 'Form Status', 'Review Reference', 'Date Modified', and 'NMA'. The 'Form Status' is 'Not Submitted', 'Review Reference' is 'N/A', 'Date Modified' is '24/02/2020 14:39', and 'NMA' is 'Project is not for NMA'. A navigation bar below the table includes 'Navigation', 'Documents', 'Signatures', 'Collaborators', 'Submissions', 'Correspondence', and 'History'. The 'Site Specific Assessment (SSA) VIC' form is open, showing a 'Section' list on the left and 'Questions' on the right. The 'Associate Investigator' option is highlighted with a red circle and the number 1.

2. Select Sign.

The screenshot shows the ERM Applications interface in 'Beta Test Mode'. The user is identified as 'Professor Joe Bloggs (joebloggs98231@gmail.com)'. The main content area displays the 'Site Specific Assessment (SSA) VIC' form. A message at the top states 'This form has been locked through signatures/requests'. The 'Signature of Associate Investigator' section is visible, including a 'Declaration by Associate Investigator' section. The declaration text reads: 'I certify that: The information in this form is truthful and accurate to the best of my knowledge and belief. The research will be conducted in accordance with the National Statement on Ethical Conduct in Research (NHMRC, 2007). I undertake to conduct this research in accordance with relevant legislation and regulations. I undertake to conduct this research project in accordance with the protocols and procedures as approved by the HREC and the ethical and research arrangements of the organisation(s) involved. I will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements. I will only start this research project after obtaining authorisation from the site and approval from the responsible Human Research Ethics Committee (HREC). I will discontinue the research if the HREC withdraws ethical approval. I will adhere to the conditions of authorisation stipulated by the authorising authority at the site where I am Associate Investigator. I will discontinue the research if the authorising authority withdraws authorisation at the site where I am Associate Investigator. I understand and agree that study files and documents and research records and data may be subject to inspection by the HREC, research governance officer, sponsor or an independent body for audit and monitoring purposes. I understand that information relating to this research and about me as a researcher will be held by the HREC, research governance officer, and on Ethical Review Manager (ERM). I understand that this information may be used for reporting purposes and managed according to the principles established in the Privacy Act 1988 (Cth) and relevant laws in the States and Territories of Australia.' The 'Request Signature' button is highlighted with a red circle and the number 2.

3. Enter your login details (email and password) and select Sign.

The screenshot shows the 'Sign Form' dialog box. It prompts the user to enter their login details to sign the form. The email field contains 'joebloggs98231@gmail.com' and the password field is masked with dots. The 'Sign' button is highlighted with a red circle and the number 3.

Review Signatures

In the SSA application, the **Signatures** tab displays all information about digital signatures and requests.

The screenshot shows the ERM Applications interface. The top navigation bar includes 'ERM Applications', 'Home', 'Contacts', 'Help', and a user profile for 'Professor Joe Bloggs (joebloggs98231@gmail.com)'. The main header displays the project title 'Testing Another New Investigational Product' and a notification count of '60'. A sidebar on the left contains navigation icons for Home, Notifications, Project, Duplicate Form, Create Sub-form, Share, Transfer Form, Completeness Check, Submit, NMA Project, Print, and Correspond.

The main content area features a 'Project Tree' showing a hierarchy: 'Testing Another New Investigational Product' (parent), 'HREA' (child), and 'Site Specific Assessment (SSA) VIC - Administrator Use Only' (child). Below this is a table with the following data:

Form Status	Review Reference	Date Modified	NMA
Not Submitted	N/A	24/02/2020 16:08	Project is not for NMA

Below the table are navigation tabs: 'Navigation', 'Documents', 'Signatures' (highlighted with a red box), 'Collaborators', 'Submissions', 'Correspondence', and 'History'.

The 'Signatures' section contains a table with the following data:

Type	Signatory Email	Signed Date	Validity
Associate Investigator	joebloggs98231@gmail.com	24/02/2020 16:08	Valid

The 'Signature Requests' section contains a table with the following data:

Type	Signatory Email	Requested Date	Status	Response Date	Action
Principal Investigator	iloveclinicaltrials@gmail.com	24/02/2020 15:57	Requested		<input type="button" value="Cancel"/>