

Electronic Signing Platform(s) Information

As of 30 March 2020, CALHN Research Services will no longer be accepting hard copy/wet-ink documents for signing.

Our preference is to send agreements for signing via our DocuSign account which has 21 CFR Part 11 compliant signing.

If signing via our DocuSign account is not acceptable to the contracting party, the preferred method is via platforms such as DocuSign and AdobeSign as this complies with external parties' workflows. Most sponsors require signatures to be '21 CFR Part 11 Compliant', the document will need to be sent via DocuSign or AdobeSign to ensure the audit trail is available and not as a 'PDF' document. Signing using Adobe Certificates is not considered to be compliant.

Where parties have sent documents via electronic platforms, CALHN Research Services will require Principal Investigators to sign via the electronic platform, to ensure consistency within the process and reduce mixed media signatures. For ease of reference, please see links available on how to sign via these electronic platforms on page 2.

Please ensure that you have passed on the correct and relevant details to the sponsor/contracting party for execution by the CALHN delegate. The details are as follows:

Commercially Sponsored Clinical Trials	Amendments	Name:	Bernadette Swart
		Title:	Manager, CALHN Research Services
		Email:	Health.CALHNClinicalTrials@sa.gov.au
	CTRA/Agreement	Name:	Liz Sutton
		Title:	CALHN Director Research
		Email:	Health.CALHNClinicalTrials@sa.gov.au
	Forms of Indemnity	Name:	Bernadette Swart
		Title:	Manager, CALHN Research Services
		Email:	Health.CALHNClinicalTrials@sa.gov.au

Investigator Initiated Research (IIR)	Amendments	Name:	Bernadette Swart
		Title:	Manager, CALHN Research Services
		Email:	Health.CALHNResearchGovernance@sa.gov.au
	Agreement	Name:	Liz Sutton
		Title:	CALHN Director Research
		Email:	Health.CALHNResearchGovernance@sa.gov.au

All documents are to **be sent to the generic email addresses** to ensure they are the correct version for signing. Platforms such as DocuSign/AdobeSign have the function to delegate the document to the correct authoriser/signer. If the external party/Sponsor requires information on how this will work from CALHN Research Services perspective the information below outlines this.

Preferred signing order:

1. Sponsor to sign
2. PI to acknowledge / sign (via electronic method not wet-ink)
3. CALHN Research Services to review and delegate
4. CALHN Delegate to sign
5. Clinical Trial Manager and Health.CALHNClinicalTrials@sa.gov.au(or Health.CALHNResearchGovernance@sa.gov.au for IIR) added as "cc Receives a Copy". This is

particularly important if delegation is not possible and documents are sent directly to the CALHN Delegate for signing.

How to sign via electronic platforms:

AdobeSign

<https://helpx.adobe.com/au/sign/using/esign-document.html>

DocuSign

<https://support.docusign.com/articles/How-do-I-sign-a-DocuSign-document-Basic-Signing>

Work Flow - Sending to generic mailboxes for delegate to sign:

AdobeSign

1. CALHN Research Services receives email notification that document is ready to be signed
2. Document is opened and reviewed against last agreed on draft
3. If document is acceptable, 'Alternative actions' will be selected, then 'Someone else should sign'. This can also be completed by clicking, 'Delegate' on the original email and putting in the delegates details.
4. The document will then be sent to the correct delegate with a message to advise the document is ready for signing.
5. Once the delegate has signed a completed copy will be available for both the generic mailbox (for filing) and for the delegate.

If the Sponsor/Party would like clarification on how this method will be undertaken, a demonstration is viewable on the provided link - <https://helpx.adobe.com/sign/how-to/adobe-delegate-signing.html>

DocuSign

1. CALHN Research Services receives email notification that document is ready to be signed
2. Document is opened and reviewed against last agreed on draft
3. If document is acceptable, 'Other actions' will be selected, then 'Delegate to another signer'. The delegate's email address will then be entered in with a message.
4. The document will then be sent to the correct delegate to advise the document is ready for signing.
5. Once the delegate has signed a completed copy will be available for both the generic mailbox (for filing) and for the delegate.