

DocuSign Process

Sponsor sets up the automatic DocuSign process for signatures.

See page 2 for Adobe option.

CRC

CONTRACT NEGOTIATIONS COMPLETED:

CRC to submit SSA, fully signed RCASE + attached draft of either:

- Medicines Aust CTA (preferred: Site Indemnity embedded if possible)

OR

- Relevant contract

1

RGO

RGO REVIEWS DOCUMENT:

RGO provides

- comments for a contract amendment

OR

- approval for uploaded contract

RGO unlocks ERM submission and requests "Further Information"

2

CRC

CRC TO ADVISE SPONSOR:

- CTA reviewed and not approved then

→ CRC sends CTA to sponsor

OR

- CTA reviewed by RGO and ready for DocuSign signature process to begin

3

SPONSOR

SPONSOR:

- Addresses RGO comments in CTA amendment and send to CRC for uploading against SSA

OR

- Emails approved CTA to PI for signing, ensure **5 digit study ERM reference number is in subject line**, cc CRC

4

CRC

CRC TO EITHER:

- Uploads amended CTA into SSA and resubmit
→ Go back to Step 1

OR

- Advise PI to expect e-mail and apply electronic signature

5

SPONSOR

SPONSOR (PI HAS SIGNED):

- Emails approved CTA to RGO for DocuSign process to continue
- Ensures **5 digit study ERM reference number is in subject line**

MSH-RGO@health.qld.gov.au

6

RGO

RGO COMPARES CTA WITH DRAFT CTA IN ERM:

- Reviews against approved draft and Signs DocuSign Agreement as reviewed
- E-mails Signatory (cc Sponsor, PI & CRC) notifying agreement has been approved for Signatory to sign

7

SPONSOR

SPONSOR:

- Sends Contract via DocuSign to Institute's Signatory for review and approval

8

SIGNATORY

MSH SIGNATORY SIGNS CONTRACT:

- Signatory Signs DocuSign Agreement which automatically returns to Sponsor upon signature being provided by Signatory

9

SPONSOR

SPONSOR:

- Signs Agreement
- E-mails fully executed agreement to CRC

NB: Time stamp is date of RGO Approval Letter.

10

CRC

CRC:

- Uploads fully executed CTA into the SSA and resubmits

OR

- Uploads via Study Correspondence if SSA locked

RGO approval will progress as per standard practices

11

Adobe Sign-off Process

The Adobe sign-off process is initiated by the Sponsor via the CRC

See page 1 for DocuSign option.

