Change of Investigator Work Instructions for Commercially Sponsored Trials

Contents

For **single-site** studies approved by the RCH HREC

PI change (Permanent change)

- **Submission type:** ERM 'Ethics Amendment Request VIC' form
- **Instructions:**
    - Notify the Sponsor/CRO of permanent PI change.
    - Under the '*Summary*' section within the ERM form, select '*Change investigator or personnel*'. This will populate further options, select '*Add member(s) of research team*' > '*Principal Investigator*'.
    - Permanent change of PI requires the following documents to be amended and submitted:
        - Indemnity – initiated by the site
        - CTRA – initiated by the site
        - ICFs – initiated by the site
        - CTN – arranged by the sponsor
        - Principal Investigator Declaration – initiated by site
    - Include new PI's CV, GCP certificate and medical registration in the submission.
    - Include completed 'RCH HREC Fee Payment Form' with submission.
    - Study team to maintain training log.
    - Study team to update Delegation Log end/start dates of each PI.
    - Study team to update trial record in EPIC – 'Study Maintenance'.
    - RGO submission ('Site Governance Amendment Request' form) is <u>not</u> required for RCH HREC approved single site studies following Ethics approval.

PI change (Temporary change)

- **Submission type:** ERM 'Ethics Amendment Request VIC' form
- **Instructions:**
    - Notify the Sponsor/CRO of permanent PI change.

- For temporary changes, i.e. sabbatical and long service leave, etc., refer to 'Investigator Length of Leave' table below to ensure it is <9 months that the PI is absent to meet temporary change requirements.
- Under the '*Summary'* section within the ERM form, select '*Change investigator or personnel'*. This will populate further options, select '*Add member(s) of research team*' > '*Principal Investigator*'.
- Include new PI's CV, GCP certificate and medical registration in the submission.
- [Principal Investigator Declaration](#) form to be completed and uploaded in 'Documents' section.
- No payment is required for this temporary change (<9 months) of PI amendment alone .
- Study team to maintain Training Log.
- Study team to update delegation log according to both PIs start/stop dates.
- Study team to update record in EPIC – 'Study Maintenance'.
- Study teams must submit another 'Ethics Amendment Request VIC' form in ERM when the original PI returns.
- The returning PI is required to complete and document trainings missed in their absence.
- Study team to update delegation log according to both PIs start/stop dates.
- If the PI does not return within 9 months and there is no official date of return, an additional amendment for permanent change of investigator needs to be submitted as detailed above – see PI change (permanent change) instructions.

AI change

- **Submission type:** ERM 'Ethics Amendment Request VIC' form
- **Instructions:**
  - Under the '*Summary'* section within the ERM form, select '*Change investigator or personnel'*. This will populate further options, select '*Add member(s) of research team*' > '*Associate Investigator*'.
  - Within the '*Documents'* section, upload the AI's CV, GCP certificate and medical registration.
  - Associate Investigator Declaration form to be completed and uploaded in '*Documents'* section.
  - Study team to maintain Training Logs for the AI.
  - Study team to update Delegation Log start/end dates.
  - Study team to update the trial's EPIC record (within '*Study Maintenance'*).
  - No fee (RCH HREC Payment Form) is required for this amendment change alone.
  - RGO submission ('Site Governance Amendment Request' form) is **not** required for RCH HREC approved single site studies following Ethics approval of the 'Ethics Amendment Request VIC' form.
  - RCH REG do **not** require notification of removal of an AI. NB: The 'Ethics Amendment Request VIC' form has the option to remove members of research team should the study team choose to do so. Under the '*Summary'* section select '*Change investigator or personnel'*, select '*Remove member(s) of research team'*.

Other team member changes

- **Submission type (not mandatory):** Email to rch.ethics@rch.org.au
- **Instructions:**
  - Study team to maintain Training Log.
  - Study team to update Delegation Log reflecting changes.
  - Study team to update trial record in EPIC – '*Study Maintenance'*.
  - ERM '*Project/Site Notifications'* are not required. If the study team does want to submit staff changes, other than PI and AI, please do so by email only.

For **multi-site** studies approved by the RCH HREC

CPI or PI change (permanent change, including PIs at other sites)

- **Submission type:** ERM 'Ethics Amendment Request VIC' form
- **Instructions:**
    - o Notify the Sponsor/CRO of permanent PI change.
    - o Under the '*Summary'* section within the ERM form, select '*Change investigator or personnel'*. This will populate further options, select '*Add member(s) of research team*' > '*Principal Investigator*'.
    - o Permanent change of PI requires the following documents to be amended and submitted:
        - ▪ Indemnity – initiated by the site
        - ▪ CTRA – initiated by the lead site
        - ▪ ICFs – initiated by the lead site
        - ▪ CTN – arranged by the sponsor
        - ▪ Principal Investigator Declaration – initiated by the lead site
    - o Include new CPI/PIs CV, GCP certificate and medical registration in the submission.
    - o Include completed '[RCH HREC Fee Payment Form](#)' in the submission.
    - o Study team to maintain training logs.
    - o Study team to update Delegation Log end/start dates of each CPI/PI.
    - o Study team to update trial record in EPIC – 'Study Maintenance'.
    - o RGO submission ('Site Governance Amendment Request' form) is <u>not</u> required for a RCH CPI/PI.

AI change

- **Submission type:** ERM 'Site Governance Amendment Request' form
- **Instructions:**
    - o Within the ERM form under the 'Overview' section, select '*Notify the site RGO of a governance-only amendment that **does not** require ethical approval*'. Under '*Site Governance-only Amendment*' select 'Acknowledged', '*Change site investigator or personnel*', '*Add member(s) of the site research team*' and '*Associate Investigator*'. NB: In order to detail the AI information, the submission needs to be created as described in this point. It cannot be combined in an amendment that requires ethical approval.
    - o Upload new AI's CV, GCP certificate and medical registration.
    - o 'Declaration of New Associate Investigator' (Associate Investigator Declaration) is completed by the new AI within ERM. Follow the '*Request Signature*' prompt in ERM on the '*Declaration*' page.
    - o Study team to maintain training logs for the AI.
    - o Study team to update Delegation Log start/stop dates.
    - o Study team to update trial's EPIC record (within '*Study Maintenance'*).
    - o No fee (RCH HREC Payment Form) is required for this 'Site Governance Amendment Request' for AI change alone.
    - o AI removals do not require notification to REG.
    - o RCH REG office does <u>not</u> need to be notified of AI changes for other sites.

Other team member changes

- **Submission type (<u>not</u> mandatory):** Email to rch.ethics@rch.org.au
- **Instructions:**
    - o Study team to maintain Training Logs.
    - o Study team to update Delegation Log reflecting changes.

- Study team to update trial's EPIC record (within *'Study Maintenance'*).
- ERM *'Project/Site Notifications'* are not required. If the study team does want to submit staff changes, other than PI and AI, please do so by email only.

For **governance only** studies, approved by an external HREC

PI change (Permanent change)

- **Submission type:** ERM 'Site Governance Amendment Request' form
- **Instructions:**
  - Notify the Sponsor/CRO of permanent PI change.
  - Per lead site ethics requirements, submit necessary documentation.
  - Once ethics approval has been granted, create a 'Site Governance Amendment Request' form in ERM.
  - Within the ERM form under the 'Overview' section, select the option *'Notify the site RGO of an amendment that has been approved by the reviewing ethics committee'*.
  - Upload evidence of external HREC Amendment Request <u>submission</u> and <u>approval</u> documentation.
  - Within the form, under '*Documents*' section, '*Are there any amended documents to be provided to the site RGO?*' select '*Yes*', '*Which documents are amended?*' select '*Other*' and upload the new PI's CV, GCP certificate and medical registration.
  - Permanent change of PI requires the following documents to be amended and submitted:
    - Indemnity – initiated by the site
    - CTRA – initiated by the lead site
    - ICFs – initiated by the site
    - CTN – arranged by the sponsor
    - Principal Investigator Declaration – initiated by the lead site
  - Upload completed '[RCH HREC Fee Payment Form](#)' to the submission.
  - Study team to document training of new PI.
  - Study team to update Delegation Log according to start/stop dates.
  - Study team to update trial's EPIC record (within *'Study Maintenance'*).

PI change (Temporary change)

- **Submission type:** ERM 'Site Governance Amendment Request' only
- **Instructions:**
  - Notify the Sponsor/CRO of permanent PI change.
  - For temporary changes, i.e. sabbatical and long service leave, etc., refer to 'Investigator Length of Leave' table below to ensure it is <9 months that the PI is absent to meet temporary change requirements.
  - If the sponsor **does** require temporary change of investigator notification to the lead site ethics, on the ERM form under 'Overview', select the first option *'Notify the site RGO of an amendment that **has** been approved by the reviewing ethics committee'*.
  - Upload evidence of external HREC Amendment Request submission and approval documentation.
  - If the sponsor **does not** require notification be submitted to lead ethics, under 'Overview' within the form, select the second option '*Notify the site RGO of a governance-only amendment that **does not** require ethical approval*'.
  - Include new PI's CV, GCP certificate and medical registration in the submission.
  - Study team to amend Delegation Log according to start/stop dates.

- o Study team to document training of new PI.
- o Study team to update trial's EPIC record (within '*Study Maintenance'*).
- o No fee (RCH HREC Payment Form) is required for this Site Governance Amendment change alone.
- o Study teams must submit a 'Site Governance Amendment Form' in ERM when the original PI returns.
- o Study team to amend Delegation Log according to start/stop dates of both staff.
- o The returning PI is required to complete and document trainings missed during their absence.
- o If the PI does not return within 9 months and there is no official date of return, then an amendment with COI needs to be submitted as detailed above – see PI permanent change instructions.

AI change

- **Submission type:** ERM 'Site Governance Amendment Request' only
- **Instructions**:
  - o Within the ERM form under the 'Overview' section, select '*Notify the site RGO of a governance-only amendment that **does not** require ethical approval*'. Under '*Site Governance-only Amendment*' select '*Acknowledged*', '*Change site investigator or personnel*', '*Add member(s) of the site research team*' and '*Associate Investigator*' . NB: In order to detail the AI information, the submission needs to be created as described in this point. It cannot be combined in an amendment that requires ethical approval.
  - o Upload new AI's CV, GCP certificate and medical registration.
  - o 'Declaration of New Associate Investigator' (Associate Investigator Declaration) is completed by the new AI within ERM. Follow the '*Request Signature*' prompt in ERM on the '*Declaration*' page.
  - o Study team to maintain training logs for the AI.
  - o Study team to update delegation log according to leave start/stop dates.
  - o Study team to update the trial's EPIC record (within '*Study Maintenance'*).
  - o Change (addition/deletion) of an AI does not require external HREC approval.
  - o RCH REG office does not need to be notified of removal of AIs. NB: The 'Site Governance Amendment Request' form has the option to remove members of research team should the study team choose to do so. Under the '*Summary'* section select '*Change investigator or personnel'*, then select '*Remove member(s) of research team'*.

Other team member changes

- **Submission type (not mandatory):** Email to rch.ethics@rch.org.au
- **Instructions:**
  - o Study team to maintain Training Logs.
  - o Study team to update Delegation Log.
  - o Study team to update trial's EPIC record (within '*Study Maintenance'*).
  - o ERM '*Project/Site Notifications*' are not required. If the study team does want to submit staff changes, other than PI and AI, please do so by email only.

Investigator Length of Leave

Refer to when PI change is temporary

Period of temporary change	New PI's current status	Process
<9 months	Existing AI	Submit amendment form within ERM. Associate Investigator Declaration should be completed if not previously provided. If the PI does not return within 9 months and there is no official date of return, submit an amendment per 'Permanent Change' instructions detailed above. Ensure staff member training is current, update delegation log to reflect roles and start/stop dates. Payment to RCH HREC is not required where the change is <9 months. If the sponsor requires the indemnity to be amended for the period of leave taken by the PI, this can be done although it is not mandated by RCH REG.
<9 months	Non-existing AI	Submit Amendment form within ERM as detailed in the section above that is relevant to the site. Upon return of the initial PI, another amendment submission is required to reflect the change. The returning PI is required to complete and document trainings missed in their absence. Update the delegation log accordingly. Payment to RCH HREC is not required where the change is <9 months. If the sponsor requires the indemnity to be amended for the period of leave taken by the PI, this can be done although it is <u>not</u> mandated by RCH REG.

>9 months	Existing AI or not-existing AI	Change to be completed according to 'Permanent Change of Investigator' requirements detailed in the main section of this document. Submit amendment form within ERM as detailed in the relevant section above. Upon return of the initial PI, another amendment submission is required to reflect the change. The returning PI is required to complete and document trainings missed in their absence. Update the delegation log accordingly. Evidence of payment to RCH HREC is required to be uploaded to the amendment submission.

Payments: RCH HREC Fee Payment Form

Fee payments: Permanent CPI/PI change $880

                         Governance only PI change $660

No fee payment: Temporary CPI/PI change, any AI or study team change.