

WORK INSTRUCTION

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Document History

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1.0	Jade Sheppard		New Issue
2.0	Jade Sheppard	07/08/2026	Review of original document. Moved into current WI template. Updated system processes and instructions.



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1. PURPOSE

This work instruction (WI) outlines the requirements and procedures for initiating a Change of Investigator in commercially sponsored trials. It specifies the parties to be notified, the method of notification, and the applicable circumstances at the Melbourne Children's Campus.

2. BACKGROUND

This work instruction was developed by the Melbourne Children's Trial Centre (MCTC) in collaboration with the Royal Children's Hospital (RCH) Human Research Ethics Committee (HREC). Additional details on both the permanent and temporary change of Principal Investigators can be found in [MCTC025a Work Instruction | Completing Signature and Delegation Logs at Melbourne Children's](#) for wet ink and digital Signature and Delegation logs.

3. SCOPE

This work instruction applies to all commercially sponsored trials run at the Melbourne Children's Campus. This work instruction does not detail the process for notifying RCH HREC of changes to Investigators for Investigator-Initiated Trials.

4. RESPONSIBILITY

It is the responsibility of the site Principal Investigator (PI) to ensure the study team follows the process as detailed in this work instruction. Ethics/Governance submissions and acknowledgements must be filed in the ISF/eISF.

5. RELATED DOCUMENTS

[MCTC025a Work Instruction | Completing Signature and Delegation Logs at Melbourne Children's](#)

[MCTC221 Form | Change of Principal Investigator Acknowledgement](#)

Principal Investigator Declaration form - found on RCH HREC website as 'SSA - Principal Investigator Signature'

Associate Investigator Declaration form - found on the RCH HREC website as 'SSA - Associate Investigator Signature'

RCH HREC Fee Payment Form - found on RCH HREC website



6. FOR SINGLE-SITE STUDIES APPROVED BY THE RCH HREC

6.1 Permanent Principal Investigator (PI) Change

- 6.1.1 Notify the Sponsor/CRO of permanent PI change.
- 6.1.2 Submission type required is the 'Ethics Amendment Request VIC' form within the Ethics Review Manager (ERM).
- 6.1.3 Under the 'Summary' section within the Ethics Amendment Request form of ERM, select 'Change investigator or personnel'. This will populate further options.
- 6.1.4 Select 'Add member(s) of research team'.
- 6.1.5 Select 'Principal Investigator'.
- 6.1.6 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
 - Change of PI Acknowledgement Form (MCTC221) - initiated by site
- 6.1.7 Include incoming PI's CV, GCP certificate and medical registration in the submission.
- 6.1.8 Include completed 'RCH HREC Fee Payment Form' with submission.
- 6.1.9 Study team to maintain training log for incoming PI.
- 6.1.10 Study team to update Delegation Log end/start dates of each PI.
- 6.1.11 Study team to update trial record in EPIC – 'Study Maintenance'. The new PI requires ERM account to review and sign submissions.
- 6.1.12 RGO submission ('Site Governance Amendment Request' form) is not required for RCH HREC approved single site studies following Ethics approval.

6.2 Temporary Principal Investigator (PI) Change

- 6.2.1 Notify the Sponsor/CRO of temporary site PI change.



- 6.2.2 For temporary changes, i.e. sabbatical, annual and long service leave, etc., refer to the 'Investigator Length of Leave' table (see Appendix 1) to ensure length of absence is <9 months, in order to meet temporary change requirements.
- 6.2.3 Submission type required in ERM is 'Ethics Amendment Request VIC' form.
- 6.2.4 Under the 'Summary' section within the 'Ethics Amendment Request VIC' form, select 'Change investigator or personnel'. This will generate further options.
- 6.2.5 Select 'Add member(s) of research team'.
- 6.2.6 Select 'Principal Investigator'.
- 6.2.7 Include temporary PI's CV, GCP certificate and medical registration in the submission.
- 6.2.8 Principal Investigator Declaration form (found on RCH HREC website as 'SSA - Principal Investigator Signature') must be completed and uploaded in 'Documents' section.
- 6.2.9 Change of PI Acknowledgement Form (METIS: MCTC221) - initiated by site
- 6.2.10 No fee (RCH HREC Payment Form) is required for this type of amendment change alone.
- 6.2.11 Study team to maintain Training Log for incoming temporary PI.
- 6.2.12 Study team to update delegation log according to both PIs start/stop dates.
- 6.2.13 Study team to update 'Study Maintenance' record in EPIC.
- 6.2.14 Study teams must submit a subsequent 'Ethics Amendment Request VIC' form in the ERM when the original PI returns.
- 6.2.15 If applicable, the returning PI is required to complete and document training missed in their absence.
- 6.2.16 Study team to update delegation log according to both PIs start/stop dates.
- 6.2.17 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 Permanent PI Change (Section 6.1) instructions.

6.3 Associate Investigator (AI) Change

- 6.3.1 Submission type required in ERM is the 'Ethics Amendment Request VIC' form.
- 6.3.2 Under the 'Summary' section within the ERM form, select 'Change investigator or personnel'. This will populate further options.



- 6.3.3 Select 'Add member(s) of research team'
- 6.3.4 Select 'Associate Investigator'.
- 6.3.5 Within the 'Documents' section, upload the AI's CV, GCP certificate and medical registration.
- 6.3.6 Associate Investigator Declaration form (found on the RCH HREC website as 'SSA – Associate Investigator Signature') to be completed and uploaded in 'Documents' section.
- 6.3.7 Study team to maintain Training Logs for the AI.
- 6.3.8 Study team to update Delegation Log start/end dates.
- 6.3.9 Study team to update the trial's EPIC record (within 'Study Maintenance').
- 6.3.10 No fee (RCH HREC Payment Form) is required for this type of amendment change alone.
- 6.3.11 Research Governance Office (RGO) submission (i.e. 'Site Governance Amendment Request' form) is not required for RCH HREC approved single site studies following approval of the 'Ethics Amendment Request VIC' form.
- 6.3.12 RCH Research Ethics & Governance (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'.

6.4 Other team member changes

- 6.4.1 Notification to the RCH RGO for addition or removal of other team members is not required.
- 6.4.2 Study team must maintain Training Log/s for new staff.
- 6.4.3 Study team must update Delegation Log start/end dates, as applicable.
- 6.4.4 Study team to update trial 'Study Maintenance' record in EPIC,



7. FOR MULTI-SITE STUDIES APPROVED BY THE RCH HREC

7.1 Permanent Principal Investigator (PI) or Coordinating Principal Investigator (CPI) Change, including PIs at other sites

- 7.1.1 Notify the Sponsor/CRO of permanent CPI/PI change.
- 7.1.2 Submission type required in ERM is the 'Ethics Amendment Request VIC' form.
- 7.1.3 Under the 'Summary' section within the ERM form, select 'Change investigator or personnel'. This will populate further options.
- 7.1.4 Select 'Add member(s) of research team'.
- 7.1.5 Select 'Principal Investigator'.
- 7.1.6 Permanent change of RCH PI/CPI 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 form (found on RCH HREC website as 'SSA – Principal Investigator Signature) – initiated by the lead site
 - Change of PI Acknowledgement Form (METIS: MCTC221) - initiated by site



- 7.1.7 Include new CPI/PIs CV, GCP certificate and medical registration in the submission.
- 7.1.8 Include completed 'RCH HREC Fee Payment Form' (found on RCH HREC website) in the submission.
- 7.1.9 Study team to maintain training logs for incoming investigator.
- 7.1.10 Study team to update Delegation Log end/start dates of each investigator.
- 7.1.11 Study team to update trial 'Study Maintenance' record in EPIC.
- 7.1.12 The incoming investigator requires an ERM account to review and sign submissions.
- 7.1.13 RGO submission ('Site Governance Amendment Request' form) is not required for an RCH CPI/PI.
- 7.1.14 Permanent change of PI at a participating site requires the following documents to be submitted:
- HREC Indemnity
 - Principal Investigator Declaration form (found on RCH HREC website as 'SSA – Principal Investigator Signature')
 - RCH HREC Fee Payment Form (found on RCH HREC website)
 - New PIs CV, GCP and medical registration



7.2 Temporary Principal Investigator (PI) Change

- 7.2.1 Notify the Sponsor/CRO of temporary PI change.
- 7.2.2 For temporary changes, i.e. sabbatical, annual and long service leave, etc., refer to 'Investigator Length of Leave' table (see Appendix 1) to ensure it is <9 months that the PI is absent to meet temporary change requirements.
- 7.2.3 Submission type required in ERM is the 'Ethics Amendment Request VIC' form.
- 7.2.4 Under the 'Summary' section within the ERM form, select 'Change investigator or personnel'. This will populate further options.
- 7.2.5 Select 'Add member(s) of research team'.
- 7.2.6 Select 'Principal Investigator'.
- 7.2.7 Include temporary PI's CV, GCP certificate and medical registration in the submission.
- 7.2.8 [Principal Investigator Declaration](#) form (found on RCH HREC website as 'SSA – Principal Investigator Signature') to be completed and uploaded in 'Documents' section in ERM.
- 7.2.9 Change of PI Acknowledgement Form (METIS: MCTC221) - initiated by site
- 7.2.10 No payment is required for this temporary change (<9 months) of PI amendment alone.
- 7.2.11 Study team to maintain Training Log for incoming PI.
- 7.2.12 Study team to update delegation log according to both PIs start/stop dates.
- 7.2.13 Study team to update 'Study Maintenance' record in EPIC.
- 7.2.14 Study teams must submit another 'Ethics Amendment Request VIC' form in ERM when the original PI returns from temporary leave.
- 7.2.15 If applicable, the returning PI is required to complete and document training missed in their absence.
- 7.2.16 Study team to update delegation log according to both PIs start/stop dates.
- 7.2.17 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 above Permanent PI Change (6.1) instructions.



7.3 Associate Investigator (AI) Change

- 7.3.1 Submission type required in ERM is the 'Site Governance Amendment Request VIC' form.
- 7.3.2 Within the ERM form under the 'Overview' section, select '*Notify the site RGO of a governance-only amendment that **does not** require ethical approval*'.
- 7.3.3 Under '*Site Governance-only Amendment*' select 'Acknowledged', '*Change site investigator or personnel*',
- 7.3.4 '*Add member(s) of the site research team*'.
- 7.3.5 Select '*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.
- 7.3.6 Upload new AI's CV, GCP certificate and medical registration.
- 7.3.7 '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.
- 7.3.8 Study team to maintain training logs for the AI.
- 7.3.9 Study team to update Delegation Log start/stop dates.
- 7.3.10 Study team to update trial's 'Study Maintenance' record in EPIC.
- 7.3.11 No fee (RCH HREC Payment Form) is required for this 'Site Governance Amendment Request' for AI change alone.
- 7.3.12 AI removals do not require notification to RCH REG.
- 7.3.13 RCH RGO does not need to be notified of AI changes at participating sites.

7.4 Other team member changes

- 7.4.1 Notification to the RCH RGO for addition or removal of other team members is not required.
- 7.4.2 Study team to maintain Training Logs.
- 7.4.3 Study team to update Delegation Log reflecting changes.
- 7.4.4 Study team to update trial's EPIC record (within '*Study Maintenance*').

8. FOR GOVERNANCE ONLY STUDIES, APPROVED BY AN EXTERNAL HREC

8.1 Permanent Principal Investigator (PI) Change

- 8.1.1 Notify the Sponsor/CRO of permanent PI change.
- 8.1.2 Per lead site ethics requirements, provide all required documentation to the Sponsor/CRO.



- 8.1.3 Once ethics approval has been granted, create a 'Site Governance Amendment Request' form in ERM.
- 8.1.4 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*'.
- 8.1.5 Within the form, under 'Documents' section, '*Are there any amended documents to be provided to the site RGO?*' select 'Yes', '*Which documents are amended?*'
- 8.1.6 Select 'Other' and upload the new PI's CV, GCP certificate and medical registration.
- 8.1.7 Upload evidence of external HREC Amendment Request submission and approval documentation.
- 8.1.8 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 (found on RCH HREC website as 'SSA – Principal Investigator Signature') – initiated by the lead site
 - [Change of PI Acknowledgement Form \(METIS: MCTC221\)](#) – initiated by site
- 8.1.9 Upload completed 'RCH HREC Fee Payment Form' (found on RCH HREC website) to the submission.
- 8.1.10 Study team to document training of new PI.
- 8.1.11 Study team to update Delegation Log according to start/stop dates.
- 8.1.12 Study team to update trial's 'Study Maintenance' record in EPIC.
- 8.1.13 New PI requires an ERM account to review and sign submissions.

8.2 Temporary Principal Investigator (PI) Change

- 8.2.1 Submission type required in ERM is the 'Site Governance Amendment Request' form.
- 8.2.2 Notify the Sponsor/CRO of temporary PI change.
- 8.2.3 For temporary changes, i.e. sabbatical, annual and long service leave, etc., refer to 'Investigator Length of Leave' table (see Appendix 1) to ensure it is <9 months that the PI is absent to meet temporary change requirements.



- 8.2.4 Per lead site ethics requirements, submit documentation as required.
- 8.2.5 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'*.
- 8.2.6 Upload evidence of external HREC Amendment Request submission and approval documentation.
- 8.2.7 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'*.
- 8.2.8 Include new PI's CV, GCP certificate and medical registration in the submission.
- 8.2.9 Principal Investigator Declaration form (found on RCH HREC website as 'SSA – Principal Investigator Signature') and Change of PI Acknowledgement Form (METIS: MCTC221) to be completed and submitted in ERM.
- 8.2.10 Study team to amend Delegation Log according to start/stop dates.
- 8.2.11 Study team to document training of new PI.
- 8.2.12 Study team to update trial's 'Study Maintenance' record in EPIC.
- 8.2.13 No fee (RCH HREC Payment Form) is required for this Site Governance Amendment change alone.
- 8.2.14 Study teams must submit a 'Site Governance Amendment Form' in ERM when the original PI returns.
- 8.2.15 Study team to amend Delegation Log according to start/stop dates of both staff when original PI returns.
- 8.2.16 The returning PI is required to complete and document training missed during their absence.
- 8.2.17 If the PI does not return within 9 months and there is no official date of return, an amendment with COI needs to be submitted as detailed above – see PI permanent change instructions (8.1).

8.3 Associate Investigator (AI) Change

- 8.3.1 Submission type required in ERM is the 'Site Governance Amendment Request' only.
- 8.3.2 Within ERM form under the 'Overview' section, select *'Notify the site RGO of a governance-only amendment that **does not** require ethical approval'*.
- 8.3.3 Under 'Site Governance-only Amendment' select *'Acknowledged'*.
- 8.3.4 Select *'Change site investigator or personnel'*.



- 8.3.5 Select 'Add member(s) of the site research team'.
- 8.3.6 Select '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.
- 8.3.7 Upload new AI's CV, GCP certificate and medical registration.
- 8.3.8 '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.
- 8.3.9 Study team to maintain training logs for the AI.
- 8.3.10 Study team to update delegation log according to leave start/stop dates.
- 8.3.11 Study team to update EPIC record – 'Study Maintenance'.
- 8.3.12 Change (addition/deletion) of an AI does not require external HREC approval.
- 8.3.13 RCH RGO 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'.

8.4 Other team member changes

- 8.4.1 Notification to the RCH RGO for addition or removal of other team members is not required. Study team to maintain Training Logs.
- 8.4.2 Study team to update Delegation Log.
- 8.4.3 Study team to update trial's 'Study Maintenance' record in EPIC.

9.0 COLLABORATORS

Name / Role	Department / Group	Affiliation
Alison Keily	Senior Research Nurse Coordinator	MCRI

10. APPENDIX

a. Appendix 1: 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 RGO.
<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 RGO.
>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.
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The CPI/PI is not required to transfer their responsibility if:

- their leave is <9 months duration
- the sponsor has been notified of the leave type and duration
- they maintain oversight of trial conduct according to GCP and the trial's CTRA
- they have regular contact with the study team (this may be in the form of weekly minuted meetings, timely responses to all communication, etc.), and where necessary, with the participant/s and sponsor)
- they have oversight of and are responsive regarding HREC submissions, reporting (including safety and protocol deviations), and participant visits (eg. results and reports)



b. Appendix 2: Payments

Where payment at submission is required, refer to the RCH HREC website to view the 'RCH HREC Submission Fees'. Download and complete 'RCH HREC Fee Payment Form' for submission.

Fee payments: Permanent CPI/PI change

Governance only PI change

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

11. DISSEMINATION AND TRAINING

This WI and any associated templates and forms will be made available via [METIS](#).

All staff with duties and responsibilities covered by this WI are required to take time to read and understand the content of this WI and 'Related Document' (section 5 of this WI).

DOCUMENT END

