SUBMISSION REQUIREMENTS FOR SPECIFIC AMENDMENTS

Barwon Health

Please see below submission requirements for commonly submitted amendments.
Please ensure all documents are named in accordance with the REGI Unit's Document Naming Guidelines.

Addition of New Research Personnel

- A signed Amendment Request/Site Notification Form (completed via ERM)
- CV of the new researcher (if not received in the last 3 years)
- Updated PICFs (if the new personnel will be involved in consenting participants, please consider adding the new investigator to the PICF)

Change of Sponsor/Principal Investigator (PI)

- A signed Amendment Request/Site Notification Form (completed via ERM), and invoicing details (if the project is commercially sponsored)
- If the amendment is to change the Sponsor, a letter from the new Sponsor is required
- CV of the new PI (if not received in the last 3 years)
- Updated PICFs with updated Sponsor/PI name
- If commercially sponsored, updated indemnities, CTN and CTRA are required
- If not commercially sponsored, state on the Amendment Request/Site Notification Form that no other updated documents are required

Addition of New Site (Study Site)

If a study is currently a single-site clinical trial and the intention is to amend this to become a multi-site clinical trial under the SERP process, researchers will need to contact the Department of Health (03 9096 7395).

For non-clinical trials, please contact the REGI Unit for advice. In general, the addition of a new study site for non-clinical trials will require:

- A signed Amendment Request (completed via ERM), and invoicing details (if the project is commercially sponsored)
- CV of the new PI (if not received in the last 3 years)
- If converting from a single-site to a multi-site project, please submit a new Master PICF
- If commercially sponsored, updated indemnities, CTN and CTRAs are required
- If radiation is involved, please submit a Medical Physicist's Report from the new site, Section 4 of VSM (if site is in Victoria), and site specific PICF with Medical Physicist's wording as outlined in Report
- If new site is a Catholic institution, please submit appropriate site specific PICF

Addition of New Site (Recruitment Site)

The definition of a recruitment site is where the new site is providing only information or data regarding a study occurring at another site. If the site intends to consent participants or conduct any study procedure, then they are not a recruitment site but a study site and the instructions above apply.

- A signed Amendment Request/Site Notification Form (completed via ERM), and invoicing details (if the project is commercially sponsored)
- A statement of approval from the Head of Department of the new recruitment site

- Any recruitment materials to be sent out to participants

Protocol Change

A study protocol should contain up to date information regarding all study processes including recruitment, consent and study procedures. Therefore, if an amendment will change any of these study processes, an updated protocol (tracked and clean) must be submitted. This is to ensure that any new investigators can pick up the latest protocol and be able to conduct the study as per the approved protocol.

- A signed Amendment Request/Site Notification Form (completed via ERM), and invoicing details (if the project is commercially sponsored)
- A clear description of the rationale for the changes (including a summary of changes) to the protocol and whether this warrants PICF changes – if PICF changes are required, consider if/how participants will be re-consented
- Tracked and clean versions of the protocol/PICF
- If there is an increase in the number of tests/visits, submit:
    - Updated statement of approval from relevant service departments
    - Updated budget for sign off by Management Accountant
    - Updated CTRA

Investigator Brochure (IB) Update

- A signed Amendment Request/Site Notification Form (completed via ERM)
- A clear description of the changes (including a summary of changes) and whether this warrants changes to the PICF
- If updating the risk statement on the PICF, ensure that the changes are in lay language

New Collaborator – Samples/Data Sent Off Site

This is for an investigator-initiated study which would like to have additional tests/data sent to a new collaborator (e.g. blood samples to Deakin for extra/new testing).

- A signed Amendment Request (completed via ERM)
- CV for new collaborator
- Updated protocol including details of the new collaborator's role (e.g. how new samples/data will be sent (must be de-identified), for how long, and how/when will they be destroyed)
- Updated PICF updating participants with details on how their data/samples are going off-site if required, whether they are coded, how long they will be kept, and how they will be destroyed
- An agreement between the BH PI and the collaborator (the type of agreement depends on the nature of the collaboration – please contact the REGI Unit's Research Governance Officer to discuss before submission). As a rough guide, the following should be submitted:
    - Material Transfer Agreement (if you are giving the samples to a third party and have no further involvement)
    - MOU/Research Collaboration Agreement (if you are giving the samples to a third party and obtaining results back from them e.g. the research is now jointly badged)

RGO Amendments for Multi-Site Projects under the NMA Scheme

- Following the above advice, please also include the central HREC's approval of the amendment, and all documents listed in the central HREC approval letter of amendment as part of your submission.