POST APPROVAL STEPS FOR PROTOCOL AMENDMENTS AND OTHER TRIAL RELATED DOCUMENTS FOR SPONSORS AND SITES

These steps apply to the following documents:

- Protocol Amendments - Major and Minor, Investigator Brochures, PICF, Annual reports, Certificate of Currency, DSUR, SUSAR, IDMC, Notifications, CTRA, Indemnity
- Updated patient information e.g. patient diaries, QoL etc

Sponsor:

1. Sends primary site the HREC approved amendment or other HREC approved documents.

Primary Site:

2. If master PICF(s) have been updated, amend cluster PICF(s) and send back to sponsor for approval.

Sponsor:

3. Approves updated cluster PICF (s) if applicable and notifies primary site investigator

Primary site:

4. Submit all documentation for the amendment, or other HREC approved documents including cover letter with brief synopsis of amendment and list of documents to be authorised, electronically through ERM (via ERM post approval amendment tab) and provide one hard copy of all documentation to primary site RGO for authorisation.
5. Primary Site RGO undertakes full review and authorisation for amendment/ documents on behalf of all cluster sites and provides authorisation letter and a cover letter for satellite site RGO(s). Authorisation letter states whether there will be an impact on satellite site(s) e.g. change in funding; change in conditions of study; change in roles.
6. On receipt of primary site RGO approval all HREC approved documentation for amendment (and updated cluster site specific PICF(s) if required), with primary site RGO authorisation, is sent to the satellite sites.

Satellite site:

7. Receives primary site RGO authorised amendment documents, or other HREC approved documents including primary site RGO cover letter, from the primary site investigator and submits all documentation for the amendment electronically through ERM (via ERM post approval amendment tab). Provides one hard copy of all documentation to satellite site RGO for authorisation at the satellite site.
8. Satellite site RGO receives amendment documentation, or other HREC approved documents and if there is no significant impact on satellite site(s) authorises the amendment without further RGO review and submits the authorisation to the satellite site investigator. If a significant impact on a satellite site is identified the RGO undertakes a full amendment review.
9. A copy of the satellite site RGO authorisation is sent to primary site investigator who submits all RGO's authorisations to the sponsor.

Additional Considerations

- If required all staff involved in the clinical trial at the primary and satellite site(s) must complete training in the updated clinical trial protocol and this must be documented in the training logs.
- The primary site will assist the Sponsor with satellite site training as required.
- The Sponsor will check that all staff conducting trial related activity at primary and satellite site(s) have completed all required training and this is recorded in the training logs. The PI at the Primary Site will also share this responsibility as part of their oversight.
- The primary site investigator must update the Supervision Plan in collaboration with each satellite site if required.
- For documents requiring additional information, i.e. An HREC approved Annual report which requires information to be added for each site within a cluster prior to RGO submission. Primary site collates the information from each satellite site to include in the annual report site specific details.
- Each satellite site can add their own additional information before submission to their RGO if required.