Tips for Ethics and Governance Submission

Barwon Health

General Ethics & Governance

- For investigator-initiated projects – ensure the researcher completes the protocol template from the Research Ethics Governance and Integrity (REGI) website before commencing the application in Ethics Review Manger (ERM). https://www.barwonhealth.org.au/research/for-researchers/research-ethics-governance-and-integrity-unit
- Use the PICF template required for research that can be found on the Coordinating Office home page and follow the guidelines for completion.
- https://www2.health.vic.gov.au/about/clinical-trials-and-research
- Ensure the documents have correct names / dates / versions in the footers to assist with HREC / RGO approval letters
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Ethics Submission

If you are involved in a multi-centre clinical trial research project, you are either acting as lead site and submitting the project on behalf of all sites involved nationally, or are a participating site which means another site is submitting on your behalf.

- If you are acting as lead site, request a complete list of site names (as required on approval letter) and PI name, these should match the submission
- If lead site, request the sponsor provide any advertising materials prior to HREC submission if available
- If you are not lead site request the lead site gives you read only access to the HREA in ERM to assistance with the completion of your SSA
- Make sure all investigators have ERM accounts for timely sign off
- If lead site check with sponsor regarding other sites to be involved and the systems they require for their state. As lead you are required to generate SSAs for all other sites and may need access to these other systems. For example
  - NSW REGIS: https://regis.health.nsw.gov.au/
  - SA Online forms: https://au.ethicsform.org/SignIn.aspx
  - WA RGS: https://rgs.health.wa.gov.au/Pages/Home.aspx

Ethics Review Manager (ERM)

- Request sponsor / lead site adds the correct study title to ERM when creating projects. This initial entry cannot be altered and is copied through every aspect of the project i.e. future amendments and governance submissions.
- Ensure all documents to be uploaded to ERM are correctly labelled with dates / version on the file name that match the footer of the document.
- Ensure the notifications and access you are given (by lead sites) or giving (if you are lead) is correct, otherwise you will receive all notifications for other sites SSAs and they will receive yours. If this occurs contact the lead site to change the permissions. These options include read, write, submit, share, create all sub forms and receive notifications. These are accessible from the Share tab in each of the documents.

- Once you receive HREC or RGO approval of the main forms (HREA AND SSA) ensure it is also acknowledged in the ERM system by the Lead Site Ethics or Governance Officer respectively, otherwise you cannot generate other sub forms and submit items during your trial.
- Have the researcher complete the ERM training provided by the coordinating office prior to commencing a submission. This will provide an overview of the system, how to use it and where to get help.
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- **Governance**
  - Make sure you obtain your Barwon Health Project number from the REGI website
  - Identify the key research team members and supporting departments, specifically, Principal Investigator should designate a minimum of two supporting investigators.
  - A primary and back up coordinator should be allocated to each project at a resourcing Full Time Equivalent (FTE) appropriate to the study requirements.
  - Provide the protocol and other associated study documents to supporting departments for review early in the study set up process. Supporting departments should have the opportunity to review the study and impact on their area, resources required and any additional costs to include in the study budget.
  - Consider additional training needs for your research team. Do they have current Good Clinical Practice (GCP) training? Is IATA dangerous goods training required? Who will provide protocol specific set up training, when will it occur and how will it occur? How will training be documented?
  - Study documentation management: Are you being provided Investigator Site Files? If not, you should implement your own site files form standard templates. How will source data be captured? Where will data be entered, what system? How will its integrity be ensured? How will you monitor and evaluate its quality? Who will be responsible for this?
  - At the end of the study, how will data be stored, where will it be stored and for what period?