Helpful Hints: Ethics Applications

PRIMARY CARE COLLABORATIVE CANCER CLINICAL TRIALS GROUP

Acknowledgement

These Hints were generated from discussion by members of our Coordinators Network and other participants in PC4 workshops who were willing to share their experience.

Ethics application tips

- Familiarise yourself with the NHMRC National Statement on Ethical Conduct in Human Research[1] and use this to inform your application: most ethics committees review applications against this framework.
- Search Clinical Trials registries for examples of similar trials, such as the Australian Cancer Trials Registry[2], the Australian New Zealand Clinical Trials Registry[3] and ClinicalTrials.gov[4].
- Seek Good Clinical Practice (GCP) courses and workshops through your local University or Hospital Human Research Ethics Committee (HREC) to keep up to date.
- Institutions may accept ethics registration from another body – if you are conducting a trial at multiple sites, you may be able to reduce the number of applications you make by submitting as a multi-site trial to a primary site.
  - If GPs are involved, the RACGP has a national ethics committee[5] that is quick and efficient and other sites may accept RACGP ethics registration.
- Check your institution's submission requirements before submission to make sure you have provided all the necessary documentation (i.e. data collection tools, consent form, privacy documentation, protocol and participant form). Institutions will list the documents required on their website and may provide templates.
- Gather as much feedback as possible: you're seeking differing points of view that you may not have considered so approach a number of people with different perspectives to review the application.
- Allow a generous timeline that includes re-submissions. Applications may need to be submitted 2-3 weeks before the committee meets, after which you will have up to three months to re-submit the requested changes.
  - An ethics committee's Executive Officer or Research Governance Officer is often the first point of contact and usually does not sit on the committee. They may be able to assist you with your application before submitting it to the committee.
- Ensure that the protocol is well explained by anticipating and addressing potential queries.
  - Develop or access 'answer templates': some organisations build a 'bank' or database of previously accepted ethics applications, enabling them to reuse acceptable language.
  - Similarly, source a high quality ethics application from another investigator and look at the language that was used.
- It is acceptable to request a signature from each Investigator for collation for the application, rather than having all Investigators signing the completed application.

1. https://www.nhmrc.gov.au/book/national-statement-ethicalconduct-human-research
2. http://www.australiancancertrials.gov.au/
3. http://www.anzctr.org.au/
4. https://clinicaltrials.gov/
5. http://www.racgp.org.au/yourracgp/organisation/committees/national-committees/nreec/

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