

H&SS PROJECT REVIEW INSTRUCTIONS

Dear Reviewers

Please refer to the document labeled 'H&SS projects' on the CD for your allocated projects. (Primary Reviewers should get 'their' projects in hard copy but there is sometimes a hiccup!)

Primary reviewers:

- Briefly summarise the project at the start of your review. It is expected that the primary reviewers will introduce/summarise 'their' projects at the meeting.
- Phrase any concerns/questions you may have as direct questions to the researchers
- If you have issues that you want to raise with/run by the Committee *rather than* asking the researchers directly, please make this clear in your comments
- For projects requesting a "privacy waiver", one primary reviewer will be nominated as the Privacy Spokesperson and emailed a Privacy Report to complete and speak to at the meeting.
- If you have no changes to recommend, please use the following wording: "I have read this proposal and have no changes to make".

All H&SS Members:

- To ensure an informed discussion at the meeting, please read the Participant Information sheets and/or the Lay Summary at the start of the ethics application for all the H&SS projects.

**PLEASE RETURN YOUR REVIEWS BY
MIDDAY ON THURSDAY 11th NOVEMBER**

to

s 47F

&

s 47F

Your comments will be sent to the researcher(s) for further action and/or the Ethics Committee for its meeting on **25th NOVEMBER 2010**.

A Checklist of common ethical issues is provided below as a reference, for those who find it helpful. There is no need to complete it or submit it with your review.

CHECKLIST OF ETHICAL ISSUES REQUIRING SPECIAL ATTENTION**Privacy Issues**

- ☐ Collection of identified information *without* gaining participant/guardian consent
- ☐ Use of identified information *without* gaining participant/guardian consent
- ☐ Disclosure of identified information *without* gaining participant/guardian consent

What is the researcher's justification and is it adequate?

Minors

- ☐ Involves participants under 18 years **without** parental/guardian consent

*Is the researcher's justification adequate?
Are processes to determine competence and gain consent appropriate?*

Participants with impaired capacity to consent

- ☐ Highly dependent on medical care
- ☐ Mentally or intellectually impaired
- ☐ Emergency situations

Consent procedures involve:
 - Person Responsible consent **Y / N**
 - Procedural Authorization **Y / N**
 - Emergency Enrolment **Y / N**

Is the researcher's justification adequate? Are the consent procedures appropriate?

Sensitive Issues

- ☐ Questionnaire-based research involving sensitive or highly personal information
- ☐ Collection of specific and substantial sensitive data about third persons without their consent
- ☐ Genetic analysis of medical or social* significance to relatives (*eg. paternity)
- ☐ Subject matter or conduct that may give rise to legal vulnerability of participants or researchers
- ☐ Contact with relatives of deceased patients
- ☐ Deception of participants
- ☐ Indigenous populations

*a) Is it necessary to the research, and/or
b) are the approach to participants, procedures and researchers suitable?*

External Sites

- ☐ Alfred Hospital Ethics Committee is responsible for sites external to the hospital, eg. GPs

Are recruitment procedures a) adequately explained, and b) appropriate?

External Data Collector

- ☐ Data collection being outsourced eg. conducted by a research company
- ☐ Data collection from medical records not being done by an Alfred staff member

Are credentials and data security adequate? Are participants informed in the PICF?

Other ☐

Are there any other SIGNIFICANT issues that should be raised at the meeting?