

# Alfred Hospital Ethics Committee Update

February 2009

## Injury and Compensation Clauses in Clinical PICFs

A number of changes have been made to the wording of the injury and compensation clauses in the two clinical Participant Information and Consent Form (PICF) templates. These changes address inadequacies in the previous wording and provide a clearer and fuller explanation to potential participants about their options for seeking compensation.

The new wording is incorporated into the templates on the Ethics website. Please note that this wording is specific to Alfred Health and is not included in the Common Application Form templates on the DHS website. The new wording is being trialed for 3-4 months at Alfred Health before being considered for wider use. Any feedback from researchers, sponsors and participants is welcome.

Clinical Drug/device PICF: [www.alfredresearch.org/ethics/applicat/picf\\_drug.doc](http://www.alfredresearch.org/ethics/applicat/picf_drug.doc) (see pp.12-13)

Clinical Non-drug/device PICF: [www.alfredresearch.org/ethics/applicat/picf\\_nondrug.doc](http://www.alfredresearch.org/ethics/applicat/picf_nondrug.doc) (see p.10)

### *Things to note:*

#### **Injury clause in both clinical PICFs**

- The new injury wording clarifies that free hospital care and treatment will be provided if the injured participant is eligible for public health care (Medicare). Note: It is Alfred Health policy that people who are ineligible for Medicare benefits should not be enrolled into clinical trials unless explicit arrangements are in place between the sponsor and the hospital for indemnifying any health provider who is required to provide medical assistance in consequence of their participation.
- The changed injury clause is in both clinical PICF templates. (There is no injury clause in the Health & Social Science PICF template.)

#### **Compensation clause in drug/device PICF**

- The new compensation wording (for commercially sponsored research) clarifies the avenues available for seeking compensation.
- ALL participants in Phase 1 & 2 studies MUST be given a copy of the Medicines Australia compensation guidelines. For all other clinical trials, the MA compensation guidelines should be made available on request.
- Participants in Phase 1 first-in-human studies must also be given the opportunity to discuss the MA compensation guidelines with someone in the department who is capable of explaining them. *This means that the department/institution is responsible for ensuring that a suitably qualified person is available.*
- Compensation queries for studies which are not first-in-human should be directed to Rowan Frew, Ethics Manager, who will advise participants of the most appropriate source for further information depending on the query.
- If the study is not commercially sponsored, the compensation clause should be deleted. Some collaborative group studies may be an exception.

Please contact the Ethics Office on 9076 8825 (Angela Henjak), 9076 2281 (Nicole Rosenow) or 9076 2935 (Kordula Dunscombe) if you need help or advice.