**FHS016hlp: Annual Progress Report – Pointers for Researchers**

The Principal Investigator (PI) is responsible for submitting an annual progress report to the Human Research Ethics Committee (HREC) in a timely manner before the approval period for the study expires. The HREC has the authority to suspend or terminate research which does not comply with annual reporting requirements. Review of an amendment to a protocol does not alter the specified date for annual review.

Use the current version of the Annual Progress Report Form (FHS016) available on the Administrative Forms website. In the case of qualitative studies, complete all the questions and insert ‘not applicable’ where questions are inappropriate for this kind of research. If the research is categorised as a record review, an audit, a collection of biological specimens, a repository or a database, use the Annual Progress Report form (FHS017) customised for these types of research.

All HREC forms can be found on the following link: <http://www.health.uct.ac.za/fhs/research/humanethics/forms>

**Points to Consider**

* Has participant enrolment proceeded as anticipated?
* Have risks and benefits been consistent with those originally anticipated?
* Based on findings to date, has the relationship between risks and benefits changed in the past year?
* Have any serious adverse events occurred that were different from those originally anticipated?
* Have there been any unanticipated problems to participants or others?
* Have there been any protocol deviations or exceptions?
* Are any protocol changes needed to prevent similar events in the future? If necessary, complete an Amendment Form.
* Are there any significant new findings that reasonably might affect participants’ willingness to continue taking part in the research?
* Have participants been informed of these findings or should they be?
* Are current information sheets and informed consent forms complete and accurate?
* Have any complaints been raised about the research? If yes, have these been resolved satisfactorily in a way that protects participants’ rights and wellbeing?
* What, if any, are the findings from recent DSMB reports?

**US Federally-funded Research (e.g. NIH, CDC)**

In the case of US Federally-funded research the PI must make sure he or she is familiar with the US regulatory (i.e. legal) reporting requirements for continuing review. Guidance produced by the Office of Human Research Protections (OHRP) is available on its website: <http://www.hhs.gov/ohrp/humansubjects/guidance/contrev0107.pdf>.

There is no grace period extending the approval period beyond the expiry date. Therefore, continuing review and re-approval of a study must occur on or before the date when the HREC approval expires. If the PI has failed to provide continuing review information to the HREC or the HREC has not reviewed and approved a study by the continuing review date specified by the HREC the research must stop unless the Committee decides it is individual participants’ best interests to continue taking part in the research-related interventions and/ or interactions. The PI may not enrol new participants after the expiry of HREC approval.

If the initial review of a US federally-funded study was undertaken by a full Human Research Ethics Committee meeting and the PI now believes the research is and is likely to remain minimal risk, he or she may request that future annual reviews be completed using an expedited procedure. See ‘Eligibility for Expedited Review of US Federally-funded Research — Pointers for Researchers of US’ on the website for further information.