The University of Toledo
Human Research Protection Program
Office of Research Compliance
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Frequency of IRB Review; Verification Regarding Material Changes

Written Guidance Document

Purpose: Each IRB must follow written procedures for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review [45 CFR 46.108(3)(ii), 21 CFR 56.108(a)(2)].

Operational Details

1. **IRB approval period:** The calculation of the approval and expiration dates is as follows:

   1.1 For initial review the date that the research is approved, or if modifications are required (to secure approval), the date that the modifications/conditions are met by the investigator (date of approval) is the " start date" for the approval period.

   1.2 For continuing review the date that the research is re-approved, or if modifications are required (to secure approval), the date that the modifications/conditions are met by the investigator (date of approval) is the " start date" of the re-approval period.

   1.3 The expiration date of convened research, and expedited research when applicable, is the last date of the approval period. Unless the IRB determines an earlier expiration date, the expiration date is one year (minus one day) from the date of approval.

   - For example, the expiration date for research that was approved on June 1, 2019, with a continuing review frequency of one year is May 31, 2020. Therefore, the last date that the research can be performed (unless the study is re-approved) is May 31, 2020.

2. **Determining frequency of IRB review:** The IRB Member(s)/Committee conducting the initial or continuing review (or as otherwise warranted) will determine continuing review at intervals appropriate to the research, but not less than once per year for convened research. Should the IRB Member(s)/Committee determine that expedited research requires continuing review, the reasons continuing review is required must be clearly documented. An approval period of no more than six months can be granted for Phase I Clinical Trials or research in which there is more than minimal risk involving a vulnerable population with no prospect of direct benefit to the individual participants. Examples of criteria used to make a determination on the frequency of review include, but is not limited to:

   2.1 The nature of the study
   2.2 The risks posed by the study and any minimization of those risks
   2.3 The degree of uncertainty regarding the risks involved
   2.4 The vulnerability of the subject population
   2.5 The experience and qualifications of the research team
   2.6 The projected rate of enrollment
   2.7 Whether the study involves novel therapies
   2.8 Any previous non-compliance or misconduct by the researcher(s)
   2.9

2.11 For FDA regulated studies, the trial phase assigned by the FDA
2.12 Other criteria as determined by the IRB

3. **Documenting the approval period:** The approval period will be documented in the following locations by HRPP staff:

3.1 IRB meeting minutes
3.2 IRB study records
3.3 IRB approval letter

4. **Communicating the IRB's determinations regarding the approval period to the researcher(s):** Principal Investigators are notified of the approval period5.2 -8.El2MCIDx)-8 (a.2 (nut)-p 0-12(..2 (i)3Tw ((he)](w)902(d [(pe)11.n2.2 (i)