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| **TGHN-256x151px****Standard Operating Procedure** | **SOP No:** **Version: 1****Effective Date:**  |
| **Title: Assessing Protocol Amendments**  |
|  | NAME | **SIGNATURE** | **DATE** |
| **PREPARED BY** |  |  |  |
| **REVIEWED BY** |  |  |  |
| **QA UNIT****AUTHORITY** |  |  |  |
| **APPROVAL****AUTHORITY** |  |  |  |

1. **Purpose/scope**

To describe the procedure for how the [group/institution] assesses amendments to the protocol in accordance with the [institution] Research Ethics Committee (HREC) criteria.

1. **Templates/forms**

AD010.1 Protocol amendment assessment form

1. **Glossary/definitions**

**Protocol amendment**

A written description of a change(s) to, or formal clarification of, a protocol

**Investigator Site File (ISF)**

Files of Essential Documents held by the Investigator. NB on occasion the [group] may also hold the Sponsor's Essential Documents in a Trial Master File, where the Principal Investigator (PI) assumes a Sponsor-investigator role.

1. **Responsibilities and procedure**
	1. According to the FHS HREC SOP "Protocol Amendments", amendments may be deemed major or minor**.** Major amendments are substantial changes that result in an increased risk to participants and / or significantly affect the study design. A revised protocol must be submitted on the appropriate form with relevant supporting documents, and may result in a full committee review. In addition, as the HREC contends that they cannot rely on a study sponsor’s description of the proposed revisions (as it seldom provides adequate contextual detail to assess the changes), the Principal Investigator (PI) must prepare a synopsis/justification of any major amendment.Minor amendments, conversely, are changes that would not materially affect the assessment of risks and benefits in the study, or substantially affect the study’s aims or design. These changes do not necessarily need to be incorporated into the protocol text and review may be expedited by the Chairman. Various examples of major and minor amendment, as determined by the HREC, are given in Appendix 1.
	2. It is important that the [group] assesses the category of an amendment accurately on the amendment application form so that the correct documentation is compiled. The PI, or other suitably qualified/experienced member of the team, should therefore prepare form AD10.1 for review within the team to aid in this categorisation process.
	3. Before submission to the HREC all proposed amendments must also be discussed with and/or reviewed by the sponsor.
	4. Form AD10.1 will be filed in the Investigator Site File together.
2. **Document history:**

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| --- | --- | --- | --- |
| **Version No.** | **Date** | **Reviewer** | **Details of changes** |
| 1 |  | NA | NA - first version of SOP |

**Appendix 1: UCT FHS HREC examples of major and minor amendments**

**Major Amendments**

* Adding a new activity that may increase risk to participants.
* Changing drugs or medications, alterations in the dosage or route of administration.
* Changing levels of radiation exposure.
* Adding a vulnerable population.
* Adding or changing invasive procedures.
* Adding a research arm to the study.
* Substantially extending the duration of exposure to the test material or intervention.
* Broadening the range of inclusion criteria
* Narrowing the range of exclusion criteria.
* Extending significantly the duration of a study.
* Removal of laboratory tests, monitoring procedures or study visits directed at gathering safety information.
* Appearance of new, serious unexpected adverse events or significant risks.
* New study documents to be distributed to or seen by participants that include information or questions substantively different from materials already approved by the HREC.

**Minor Amendments**

* Administrative or informational amendments:
* Changing the study title or telephone numbers.
* Addition or removal of qualified investigators, study sites.
* Revision of format of consent documents, recruitment materials or questionnaires.
* Correction of typographical errors.
* Editorial changes that clarify but do not alter the existing meaning of a document.
* Translations of materials already reviewed and approved by the HREC.
* Procedural amendments
* Drawing slightly different amounts of blood, changing frequency at which blood is drawn.
* An increase or decrease in proposed number of participants supported by a statistical justification.
* Narrowing the range of inclusion criteria.
* Broadening the range of exclusion criteria.
* Changing the amount of compensation, within reasonable limits.
* Revisions to the informed consent documents to improve clarity, to include missing elements or to revise lay language.
* Decreasing drug dosage or frequency of administration.
* Decrease in number of study visits provided such a decrease does not affect collection of relevant safety-related data.
* Alterations in oral forms of administration of a drug e.g. tablet to capsule or liquid, as long as the dose remains constant.
* Changing data collection points or amounts of data collected as long as it does not alter safety evaluations.
* An increase in safety monitoring resulting in more frequent visits or an increase in the length of hospitalisation.
* An increase or decrease in sample size, supported by a statistical justification.
* Changes in compensation with adequate justification.