Research Ethics and Governance – Site initiation and close out Procedure

TARGET AUDIENCE and SETTING

Principal Investigator and all staff conducting research.

PURPOSE

To describe the procedures related to site initiation and close out of a clinical trial.

PRECAUTIONS/CONTRAINDICATIONS

All researchers at Monash Health must conduct research in the manner indicated in the Human Research Policy and the Research Governance Procedure.

STANDARD REQUIREMENTS

All investigators must abide by relevant legislation, the Australian code for the responsible conduct of research (NHMRC, 2018), the National Statement on Ethical Conduct in Human Research (NHMRC 2018), the Safety monitoring and reporting in clinical trials involving therapeutic goods (NHMRC 2016) and the International Council on Harmonisation Guidance for Good Clinical Practice E6(R2) (2016)

PROCEDURE

Site Initiation

Prior to initiation the investigator(s) must:

- Arrange with the monitor the scheduled date, time and location of the study initiation visit.
- Review the Investigator's Brochure and any up-to-date information on the investigational product. The Investigator(s) must be familiar with the product, including pre-clinical toxicology, pharmacology, pharmacokinetics and up-to-date clinical data if applicable.
- Ensure that the procedures stated in the study protocol are applicable in their site and fully understood.
- Ensure that sub Investigator(s), pharmacist(s), research coordinators and any other relevant staff involved with the study have been advised of the study initiation visit / meeting and are able to attend.

During the initiation the investigator(s) or delegate(s) must:

- Establish that the Investigator's Site Mater File contains all the required regulatory documents.
- Provide a list of study personnel and functions in the study to the clinical monitor.
- Provide curricula vitae of the sub Investigators involved.
- Ensure that the names and contact numbers of the relevant medical and study personnel of the sponsor are available and documented clearly.
- Ensure that all relevant study site personnel fill out the Site Personnel/Signature Log.

- Check that the procedures and plans for storage, dispensing and return of investigational product have been agreed and finalised with the Sponsor and Pharmacist (if applicable).
- Review the documents used in the shipment of the investigational products to the study site.
- Check that the quantities of Case Report Forms that have been requested or shipped to the study site are sufficient for the number of participants/patients that are likely to be recruited into the study.
- Check that other related supplies are available, or are to be shipped to the study site at a later date, and that they are available in sufficient quantities.
- Check that laboratory facilities and arrangements for the dispatch of samples to the laboratory are organised and that any specialised equipment that may be required will be available throughout the period of the trial, e.g. centrifuge freezer, etc.
- Establish who will be responsible for Case Report Form completion and clarify the procedure for entering data in the Case Report Form, as well as making changes and corrections.
- Ensure an understanding of the requirements that source documents and raw data will need to be available during monitoring visits to enable the monitor to perform source data verification at each monitoring visit.
- Review the arrangements for organising and maintaining study files.
- Ascertain that the procedures relating to the archiving of study records at the end of the study is agreeable to the sponsor.
- Establish the next monitoring visit with the Monitor.

Premature Termination or Suspension of a Trial

If the trial is prematurely terminated or suspended for any reason, the investigator/institution must:

- Promptly inform the trial participants, should assure appropriate therapy and follow-up for the participants, and, where required by the applicable regulatory requirement(s), should inform the regulatory authority(ies).

In addition:

If the investigator terminates or suspends a trial without prior agreement of the sponsor, the investigator must:

- Inform the institution where applicable, and the investigator/institution should promptly inform the sponsor and the Human Research Ethics Committee.
- Provide the sponsor and the Human Research Ethics Committee with a detailed written explanation of the termination or suspension.

If the sponsor terminates or suspends a trial, the investigator must:

- Promptly inform the institution where applicable and the investigator/institution should promptly inform the Human Research Ethics Committee and provide the Human Research Ethics Committee a detailed written explanation of the termination or suspension.

If the Human Research Ethics Committee terminates or suspends its approval/favourable opinion of a trial the investigator must:

- Inform the institution where applicable and the investigator/ institution should promptly notify the sponsor and provide the sponsor with a detailed written explanation of the termination or suspension.

4.3 Site close-out

The investigator(s) must:

- Provide a summary report of the trial outcome to the ethics committee and or research governance office and the regulatory authorities, if required.
- Keep documentation and correspondence in the trial master file.
- Inform the sponsor of the completion of the study.
- Ensure arrangements for archiving of trial documents are clarified (see section on Record Keeping and Archiving in relevant Procedure)
- Ensure appropriate final disposition of any investigational product. This may include return to the sponsor or destruction of remaining materials. Refer to "Receipt and Handling of Investigational Product" procedure.
- Provide a final report from the sponsor or Principal Investigator to Research Support Services.

KEY STANDARDS, GUIDELINES OR LEGISLATION

Australian code for the responsible conduct of research (NHMRC, 2018),

National Statement on Ethical Conduct in Human Research (NHMRC 2018)

Safety monitoring and reporting in clinical trials involving therapeutic goods (NHMRC 2016)

International Council on Harmonisation Guidance for Good Clinical Practice E6(R2) (2016)

KEYWORDS

Case report form, source documents, site initiation, close out, final report

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