Research Ethics and Governance – Study site master file and documents Procedure

TARGET AUDIENCE and SETTING

Principal Investigator and all staff conducting research.

PURPOSE

To outline documentation required to be kept in the study site master file..

DEFINITIONS

Essential Documents
Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced

Good Clinical Practice (GCP)
A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.

Principal Investigator
An individual responsible for the conduct of a research projects including clinical trials at a research/trial site and ensures that it complies with GCP guidelines.

Study Site Master File
A file that contains all the applicable essential documentation for the research project /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

1. The Study Site Master File and Essential Documents.

The investigator(s) will:
1.1. File essential documents at the site in a timely manner. All site-related materials will be made available for review by the sponsor's representatives (monitors and auditors) or regulatory authorities.

1.2. Keep a minimum list of essential documents from before the clinical phase of the trial, during the clinical conduct of the trial and after completion or termination of the trial.

1.3. Maintain documentation for a minimum of 15 years for adult studies or 25 years for paediatric studies after completion of the clinical trial. For legal reasons, sites may consider indefinite archiving periods.

2. Documentation of Investigational Site Qualifications and Training Records.

The investigator(s) will:

2.1 Maintain an up-to-date Curriculum vitae and review on a yearly basis.

2.2 Be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial. This will be evidenced in the Curriculum vitae.

2.3 Meet all the qualifications specified by the applicable regulatory requirement(s). Current medical practitioner registration details and similar documentation will be referenced in the Curriculum vitae.

2.4 Provide evidence of such qualifications through up-to-date Curriculum vitae and/or other relevant documentation requested by the sponsor, the Human Research Ethics Committee, and/or the regulatory authorities.

2.5 Maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties. A delegation log will be completed, signed and dated by the investigator on a per person basis. This must be kept in the study document file.

3. The Site File.

3.1 The site file will contain all the essential documentation referred to in Section 8 of the International Council on Harmonisation Guidance for Good Clinical Practice E6(R2) (2016). https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf

3.2 For commercially sponsored studies, sponsoring companies will normally provide site file complete with tab separators for ease and consistency of filing.

3.3 Financial documentation such as the clinical trial agreement may be filed in a separate location to the Master Site File.

3.4 The site pharmacy will usually keep investigational product shipping, receipt and accountability documents. The site itself does not have to replicate these documents. The records must be made available to sponsors, monitors and auditors.

KEY STANDARDS, GUIDELINES OR LEGISLATION

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

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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

Study site master file, source documents, site file, Principal Investigator, International Council on Harmonisation Guidance for Good Clinical Practice E6(R2) (2016).

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