Research Ethics and Governance – Documentation of Investigation Site Qualifications, Adequacy of Resources and Training Procedure

TARGET AUDIENCE and SETTING

Principal Investigator and all staff conducting research.

PURPOSE

To describe the procedures related to the appropriate documentation of investigational site qualifications and training records as well as the provision of resources to perform research appropriately.

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. Documentation of Investigational Site Qualifications and Training Records

The investigator(s) will:

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

1.2 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.

1.3 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.

1.4 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 authority(ies).

1.5 Maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

1.6 Maintain a delegation log that must be completed, signed and dated by the investigator on a per person basis, and kept in the study document file.

1.7 Undertake appropriate Good Clinical Practice (GCP) training as documented in the Good Clinical Practice Training procedure.

2. Adequacy of Resources.

The investigator(s) will:

2.1 Be able to demonstrate (if possible based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period. This may be in the form of de-identified subject recruitment listings or other documented written evidence.

2.2 Have sufficient time to properly conduct and complete the trial within the agreed trial period and have available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.

2.3 Adequacy of resources is normally determined by a site feasibility assessment for commercially-sponsored studies.

3. Training Records.

The investigator(s) will:

3.1 Ensure that all persons assisting with the trial are adequately informed about the procedure, the investigational product(s), and their trial related duties and functions. An initiation meeting may be held where all required staff are present and written evidence of study specific training is developed.

3.2 Ensure that documentation of this training be kept current and available for review on request throughout the entire trial period.

3.3 Record the delegation of tasks to study staff using the delegation log and study specific training records where appropriate.

3.4 An internal Training Record will be completed, signed and dated by the investigator on a per person basis. This will be kept in the Study Master File.

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)

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KEYWORDS

Research documentation, human research, Principal Investigator, site qualifications, training records, delegation log, resources, curriculum vitae.

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