CORE STANDARD OPERATING PROCEDURE
SOP No: 004   Version 1.0 – rev01
SOP Title: Training for Clinical Research

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<tbody>
<tr>
<td>Author</td>
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Effective Date 01 Jan 2017
Review Date 31 Dec 2019

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1. **PURPOSE**
   This SOP describes the processes which units will put in place to ensure that those involved in clinical research are demonstrably qualified by education, training and experience to perform their respective study roles and responsibilities.

2. **INTRODUCTION**
   The principles of Good Clinical Practice (GCP) state that each individual involved in conducting a trial should be qualified by education, training and experience to perform his or her respective task(s). Such training should be proportionate to need, in line with GCP principles, and meet applicable legal requirements.

3. **SCOPE**
   The scope of this procedure is for all interventional trials including CTIMPs and device trials conducted under the auspices of the University of Oxford, but may also be used for other research studies at the discretion of the unit and the Sponsor.

4. **DEFINITIONS**
   **Curriculum Vitae (CV)**
   A CV written, signed and dated to provide clear, comprehensive, concise evidence of education, qualifications, experience and training relevant to the researcher’s current role and responsibilities.

   **Training record**
   A record of training completed by those involved in clinical research in terms of GCP, general training, study-specific and role-specific training.

5. **RESPONSIBILITIES**
   **Relevant Manager**
   Responsible for implementing and maintaining processes and documentation that ensures that staff receive and record relevant training.

   **Chief Investigator / Principal Investigator (CI/PI)**
   Responsible for ensuring that the Study Team have received all necessary study-specific training to allow formal delegation of responsibilities.

   **All staff**
   Ensure that SOP, GCP, study-specific and role-specific training are up-to-date and adequately recorded in training records.

6. **SPECIFIC PROCEDURE**
6.1 **SOP training**
   All staff will read and familiarise themselves with SOPs that are relevant to their current duties, and document this in a training record. Additional training may be required on certain
procedures, and this will be planned and recorded when performed. Changes in SOPs and/or role may require retraining.

6.2 GCP training
All staff are required to complete initial GCP training appropriate to their role, refreshed as necessary e.g. following a significant change in GCP, or their role, on returning to research following a prolonged break, and/or at periodic intervals. Training undertaken must be recorded in a training record.

6.3 Study-specific training
The CI/PI is responsible for ensuring that study-specific training is delivered, which will be documented.

All staff will ensure that they receive relevant training on the protocol, and other study-related documents, to a level that enables them to perform their delegated duties appropriately, and that they have read and understood the content. They must complete the required training before starting study-specific activities, and training must be maintained as necessary throughout the study.

6.4 Training records
Staff training records should contain at least the following:

- A current signed and dated CV
- Evidence of GCP training appropriate to their role
- Evidence of SOP training
- A current job description / role outline
- Evidence of any relevant internal and external training
- Evidence of study-specific training

Any of the above may be stored separately so long as their location is recorded in a file note. Training documentation must be stored securely and be easily accessible for update by individuals, and review by authorised parties. Obsolete records should be archived.

7. RELATED DOCUMENTS
University of Oxford Core SOP 005 - Archiving of Essential Documents
University of Oxford Core SOP 006 - Trial Master File and Investigator Site File

8. REFERENCES
ICH Harmonised Tripartite Guidelines for Good Clinical Practice (ICH GCP) 1996

9. CHANGE HISTORY

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<td>SOP text unchanged – effective and review date updated.</td>
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