## CORE STANDARD OPERATING PROCEDURE

**SOP No:** 001  **Version:** 3.0

**SOP Title:** Generation, Issue and Control of Standard Operating Procedures

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
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<tbody>
<tr>
<td>Author</td>
<td>Simon Kerridge</td>
<td>Quality Assurance Manager Oxford Vaccine Centre</td>
<td>[Signature]</td>
</tr>
<tr>
<td>Reviewer</td>
<td>Richard Miller</td>
<td>Senior Quality Assurance and Compliance Manager, Clinical Trials and Research Governance</td>
<td>[Signature]</td>
</tr>
<tr>
<td>Authoriser</td>
<td>Heather House</td>
<td>Head of Clinical Trials and Research Governance</td>
<td>[Signature]</td>
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### Effective Date
24 June 2014

### Review Date
23 June 2017

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1. **PURPOSE**
   The purpose of this Standard Operating Procedure (SOP) is to describe the procedures for creation, approval, issue, review and control of SOPs to ensure that they are consistent, current and effective.

2. **INTRODUCTION**
   SOPs are controlled documents which describe the procedures that must be followed to achieve uniformity in the performance of specific functions. They should be clear, concise and must be adopted by the users.

   Staff performing the activity must be trained in the process described within the SOP.

   The term 'SOP' is used throughout this document but incorporates all dependent lower level controlled documents (such as Work Instructions) that are used to maintain the conduct and quality of clinical research. The control of lower level documents will be described in local procedures, but must be subject to the principles of this SOP.

3. **SCOPE**
   This SOP applies to all SOPs, including University of Oxford Core SOPs and those produced by units within the University of Oxford, for the management of clinical research, but may also be used for other research studies at the discretion of the unit and the Sponsor.

4. **DEFINITIONS**
   **Standard Operating Procedures (SOPs)**
   Detailed, written instructions to achieve uniformity of the performance of a specific function, communicate procedures to those who will undertake them, underpin training, and form a permanent record of the methodology employed.

   **University of Oxford Core SOP**
   Generic SOPs issued by the University, and reviewed by an SOP Committee which represents trial units, for use in clinical research operating under the auspices of the University of Oxford. These SOPs must be followed where the University is Sponsor for such research, and may also be used where the University of Oxford acts as the host institution.

   **Unit SOP**
   SOPs generated and issued by individual units within Oxford University that provide instruction that is specific to the unit's operations.

   **Work Instruction**
   A Work Instruction is a controlled document to be used when an SOP is not sufficiently detailed, eg for a specific role.

   **Author**
   Individual who prepares and writes the SOP. The author should be an individual who is appropriately qualified and experienced to ensure that it is a workable record of what actually happens.
Reviewer
A person who is appropriately qualified and experienced to provide constructive, critical review and help ensure the SOP is fit for purpose.

Authoriser
A senior individual with designated experience and authority to approve the SOP for use.

Quality Assurance (QA) Manager (or equivalent)
A person designated to oversee the unit’s document control and quality management systems.

Must/required/shall refers to a process that is a legislative requirement. The process has to be performed/documented to comply with a particular regulation.

Should refers to guidance related practices.

Recommended/Suggested refers to activity that is considered best practice.

5. RESPONSIBILITIES

Author
Generates the draft SOP using the approved template.
Ensures that appropriate individuals review the SOP.
Ensures that review comments are incorporated into the SOP as appropriate.
Receives comments from users of the SOP and assesses the need for revision.

Reviewer
Provides expert input into the SOP and supports the author as necessary to ensure that the SOP delivers accurate, clear, concise and feasible instructions to the intended users.
The reviewer of the first version of the SOP must be independent from the author. Subsequent reviews may be performed by the author.

Authoriser
Authorises the SOP for issue and use by the unit.
The authoriser may also be a reviewer or author, however, at least two individuals must have input into producing or updating the SOP.

Quality Assurance Manager (or equivalent)
Assesses the need for the unit-specific SOPs when identified.
Provides support in the development and issue of SOPs.
Ensures that SOP is finalised, approved and signed off by the author, reviewer (where appropriate), and approver.
Ensures the document is correctly formatted, issues controlled reference number and version number.
Ensures that the SOP complies with relevant applicable University of Oxford Core SOPs, and submits related SOP to Clinical Trials and Research Governance (CTRG) for review.

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Ensures that all copyholders receive and maintain the current version.

Controls documents and ensures timely review.

**CTRG**
Generates and coordinates review of updates of University of Oxford Core SOPs. Reviews SOPs submitted by units for compliance with the University of Oxford Core SOPs.

**All staff**
Follow the procedure described in the SOP

Inform the author or QA manager if errors or deviations from current/best practice are identified within the SOP that will require a review to be undertaken.

Comply with the Core and unit's SOP training and implementation instructions.

6. **SPECIFIC PROCEDURE**

6.1 **Identification of Need**
All procedures for the conduct and quality of clinical research must be defined within an SOP or similar, controlled document.

Any member of staff may identify procedures for inclusion within an SOP and should notify the person responsible. Such requests must be assessed to determine whether the process is already covered in existing procedures or is required to be included in an SOP.

If an SOP is required, an author must be assigned to draft the new procedure.

6.2 **Numbering, Version Control and Format**
All SOPs used by individual units must be developed using an approved template, and must follow a defined indexing and versioning system, so that each version of every SOP can be uniquely identified. This will be described in the individual unit Document Control SOP.

The current status of each SOP should also be clearly marked (e.g. draft, authorised, superseded) in order to maintain a clear audit trail of versions.

6.3 **Content / Authorship**
SOPs should be written in a clear and concise manner and be as instructive as possible, so that any trained individual can complete the SOP activity effectively.

Content should not include reference to data that may change on a regular basis (e.g. phone numbers, addresses, staff names). All abbreviations and acronyms should be defined.

Wherever reference is made to an activity covered by another SOP, the SOP reference should be inserted. The version number should not be included.

Once the first draft of a new SOP has been written, a suitably qualified reviewer will be identified who will ensure that the SOP complies with all relevant regulations/guidelines, and is formatted/indexed correctly.

If the SOP is a unit SOP, and relates to a Core SOP, there are two options for preparation of the SOP:
- Request an editable version of the relevant Core SOP from CTRG in order to add further specific detail

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Write the unit SOP from scratch, maintaining compliance with the Core SOP
In either case, the SOP will be submitted to CTRG for review of compliance.

6.4 Authorisation
Once the final version of the unit SOP has been produced, it must be authorised by a senior
member of the department. The authoriser will sign and date to take overall responsibility for
the SOP. University of Oxford Core SOPs must be authorised by a senior member of CTRG.
The effective date should be agreed with the relevant senior staff and will allow time for user
notification, SOP training and implementation.

6.5 Notification and Training
SOP users must be trained as appropriate to ensure understanding and compliance prior to
performing the activity. Training must be recorded, and each unit must maintain appropriate
training records.

6.6 Storage and Access
Current SOPs must be readily available at point of use in electronic or paper format.
Unauthorised copies must not be used as these may become outdated and lead to incorrect
procedures being performed.
The original version of the University of Oxford Core SOP is the only official version. Core SOPs
copied or printed are unofficial. Units will institute a system to ensure that unit SOPs, if copied
or distributed, are appropriately tracked.
The University will make relevant material (e.g. SOP listings, individual controlled documents,
change history and archival records) easily available to authorised third parties for the purpose
of confirming that clinical research is conducted in accordance with the principles of Good
Clinical Practice and the applicable SOPs.
Original versions of SOPs, relevant controlled documents and other related quality
management records must be retained securely for as long as necessary to reconstruct the
conduct of the dependent clinical research activities. In general this will be for a minimum of 5
years from completion of the last academic protocol performed according to the SOP but will
be defined within local archiving SOPs.

6.7 SOP Change Requests and Deviations
Unauthorised changes to a current SOP are not permitted. Any amendment requires a new
version to be produced and issued.
Users will inform the author and/or QA manager without delay to request changes to an SOP.
Examples might include changes to correct errors, prevent forced deviations, improve
feasibility/effectiveness and ensure the SOP reflects current/best practice. Change requests
will be reviewed as described below.
All deviations from and/or errors within the SOP must be reported to the QA manager who
will document the error/deviation and ensure a review is performed, including implementation
of any corrective/preventive actions.

6.8 Review of Issued SOPs
All SOPs must be current and fit for purpose and as such require regular review. A routine
review of each SOP must be carried out at least every three years.
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Earlier review may be necessary due to the introduction of new regulations or procedures, or in response to SOP change requests or deviations.

New SOPs may have shorter first review dates, to allow refinement of content.

The reviewer will usually be the author or another suitably qualified and experienced individual.

If the SOP requires updating, a new version must be created and issued as above. If no change is required, the review date must be renewed.

If a new version is required, an editable copy of the SOP and current SOP template (if different) should be made available to the author for updating. Changes should be tracked and the significant changes recorded for ease of reference.

In case of amendment, the revised, related SOP will be submitted to CTRG for review of compliance with University of Oxford Core SOPs.

7. RELATED DOCUMENTS
Template-SOP001-Core SOP

8. REFERENCES
MHRA Good Clinical Practice Guide (2012)

9. CHANGE HISTORY

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<tr>
<th>Version No.</th>
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<tr>
<td>2.0</td>
<td></td>
<td>Redrafting of Work Instruction section Addition of Core SOP template to Related Documents Additional instructions in Content/Authorship</td>
<td>1.0</td>
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<tr>
<td>3.0</td>
<td></td>
<td>Amended wording in section 6.3 regarding use of Core SOPs</td>
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