Title	Preparation of Participant Information Sheets and In Consent Forms
Version number	5.0
Document category	SPONSOR GUI
Index number	SPONSOR GUI 14
Author(s)	Magdalena Laskawiec Szkonter and Matthew Goff
Authorised by	Bannin Jansen
Authorised date	02-Jul-2025
Effective Date	02-Jul-2025
Next Review Date	30-Jun-2027

1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to provide instructions for the development and review of Participant information Sheets (PIS) and Informed Consent Forms (ICF).

2. INTRODUCTION

Participants in clinical research must be provided with information on which to base an informed decision on initial and continued participation. Information provided should be balanced, proportionate and comprehensible. Potential participants should be given appropriate time to read and understand the content prior to consenting, including the opportunity to ask, and have answered, questions and concerns

3. SCOPE

The scope of this procedure is for all clinical research studies sponsored by the University of Oxford, but may also be used for other clinical research studies at the discretion of the unit.

4. DEFINITIONS

Informed Consent Form (ICF)
An approved form on which a participant's informed consent to take part in a study is recorded and which will reference the current approved version of the PIS.

Participant/Patient Information Sheet (PIS)
An approved document which provides detailed information on the study, and to which the participant can refer in order to make an informed decision about participation. Where there are additional participant-facing documents (e.g. Invitation letter), these should be treated in the same manner as the PIS.

Submission Package
Protocol and relevant supporting documents needed for submission to the Sponsor, Research Ethics Committee, and the Regulatory/Competent Authority (if applicable). A list is provided on the RGEA website, see Section 8.

5. RESPONSIBILITIES

Chief Investigator
Compilation of the study PIS and ICF, and their submission to Research Ethics Committee (REC). This responsibility may be delegated to a member of the study team.

Sponsor
Review and approval of PIS and ICF with reference to the protocol and ethical guidelines.

6. SPECIFIC PROCEDURE

6.1. Generation of the Participant Information Sheet and Informed Consent Form

The study team will work on the development of the protocol (see University of Oxford SPONSOR GUI 13 - Protocol Development), Participant Information Sheet (PIS), Informed Consent Form

(ICF) and other associated documents which form the Submission Package (a list is provided on the RGEA website).

Both the PIS and ICF will be produced according to the guidance provided by the Health Research Authority (HRA) in the UK, or country-specific equivalent. Additional guidelines are available, and these are referenced in section 8. Information provided will include clear identification of the name of the study, name of Sponsor, name of the Chief Investigator, local site address, Study Team contact details, version number and date as approved by the named REC. Where there are external funders or collaborators, these should be acknowledged within the PIS. Information should be written in a style appropriate for the target population, avoiding coercive language, and in such a way that is easily understood by a lay person. All participant procedures covered within the protocol, together with relevant safety information, must be presented within the PIS.

In the event that a study intends to recruit participants with a range of understanding (e.g. children or young people, adults without capacity), alternative approved versions should be constructed. Additionally, older children who are capable of assent should be provided with a separate and approved version of the PIS and an approved assent form. If the target population includes participants with limited facility in English, validated translations of approved documents should be used.

Where samples are collected, consideration should be given to gifting of samples to the University of Oxford, or other Sponsor, as appropriate. If applicable, the consent form should include agreement that the participant foregoes commercial interest, may be transferred to locations outside of the UK, and/or be used in future studies.

Where identifiable data is to be transferred, consideration should be given to the information in the PIS detailing safeguards for the transfer. If identifiable data is to be sent out of the UK, the consent form should include agreement for this. It is good practice to inform participants in the PIS anonymous data sharing plans, but this data can be shared without explicit participant consent.

A QC check for consistency and coherence should take place before submission to the Sponsor. The PIS, ICF along with the protocol and other associated documents (i.e. Submission Package) should be sent together for Sponsor review (see University of Oxford SPONSOR SOP 11 - Registration, Applications, Amendments and Reporting). A list of documents required for submission is provided on the RGEA website, see Section 8

7. RGEA RELATED DOCUMENTS

RGEA related documents listed below are correct at the time of SOP release. Refer to the RGEA website/RGEA internal iPassport master document list for latest versions.

Title	Index Number	RGEA website (W) or internal to RGEA (I)
Protocol Development	SPONSOR GUI 13	W
Registration, Applications, Amendments and Reporting	SPONSOR SOP 11	W

8. REFERENCES

ICH Harmonised Tripartite Guideline for Good Clinical Practice (ICH GCP), https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf

World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects, https://www.wma.net/policies-post/wma-declaration-of-helsinki/

Information Sheets & Consent Forms. Guidance for Researchers and Reviewers. HRA https://www.hra.nhs.uk/planning-and-improving-research/research-planning/participant-information-design-and-review-principles/

MHRA Good Clinical Practice Guide, https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials

FDA guide to informed consent 2023 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/informed-consent

List of documents required for sponsorship review: https://researchsupport.admin.ox.ac.uk/clinical-trial-research-governance/preparation/documents#collapse396651

9. CHANGE HISTORY

Version No.	Effective Date	Significant Changes
2.0	19 June 2017	Changes to remove references to NRES, add reference to the HRA and update websites links. Also to add consideration around data transfer and Sponsor review of PIS and ICFs on multinational studies.
2.0-rev01	28 Oct 2020	SOP text unchanged – effective and review date updated
3.0	4 Feb 2022	Added requirement of Submission Package to be sent for sponsorship review on section 6.1. Replaced Competent Authority with Regulatory/Competent Authority. Replaced CTRG with RGEA. Removal of sections 6.2 Sponsor review, 6.3 REC review and 6.4. Ongoing review and Amendments. Alignment with SOPs 002 and 011. Updated into new Core SOP template (v3.0).
4.0	16 Dec 2024	Updated for CC-1 to update the index and category in iPassport (RGEA) and brought in line with updated SOP template. References amended.
5.0	30 Jun 2025	Updated references and links. Added link to SPON TEM 3 Associated Guidance Document.

Links

Please note: links are only correct at time of printing

Controlled Document links:

Changes In This Version

o Updated links in references sectionChange requested by Kate ONeill on 05-Feb-2025 Add guidance on translation requirements (agreed by Leads 29 Jan 2025): The study team should decide whether PIS translation is appropriate/feasible for the study - bearing in mind regard for EDI - and make it clear in their application whether translation will be done or not. If translation is employed, this should be done by a verified translation service. Back-translation should also be carried out. For high risk studies, this should also be carried out by a verified translation service. For low risk studies, a validated service is not necessary, but the process followed should be documented in the study file. Approved by Paul Davison on 30-Jun-2025 Approver Comments: Approved on behalf of owner - Bannin Jansen - see attached email.

Document Revision History

Superseded on 02-Jul-2025 14:10 by Bannin Jansen

Version 4.0 superseded by version 5.0

Document Published on 02-Jul-2025 14:10 by Bannin Jansen

The document was published and is ready to be used.

Authorised on 02-Jul-2025 14:10 by Bannin Jansen

Authorised version 5.0 - . The following users will be notified when a review is due for this document: Document was scheduled to be released on 2025-07-02 The document was originally due for review on 03-Feb-2025

Authorisation Approved on 02-Jul-2025 14:10 by Bannin Jansen

The user Approved the authorisation request.

Set Pending Authorisation on 30-Jun-2025 13:51 by Paul Davison

Document was set as Pending Authorisation and authorisation requests were sent to: Bannin Jansen

Authorisation requested on 30-Jun-2025 13:51 by Paul Davison

Authorisation request sent to Bannin Jansen by Paul Davison on 30-Jun-2025 13:51.

Change Request Rejected on 30-Jun-2025 13:43 by Paul Davison

Paul Davison rejected change request: "Will be taken into account on next review when new regulations and HRA advice are finalised. See attached email."

Change Request Approved on 30-Jun-2025 13:41 by Paul Davison

Paul Davison approved change request: "Approved on behalf of owner - Bannin Jansen - see attached email."

Change Requested on 30-Jun-2025 11:50 by Paul Davison

Elena Villarreal Requested Change: 'Include Core Templates in references, also add HRA templates and guidance from CT toolkit: http://www.hra-decisiontools.org.uk/consent/'

Draft Created on 30-Jun-2025 11:50 by Paul Davison

Reason:

Change Requested on 30-Jun-2025 11:50 by Paul Davison

Kate ONeill Requested Change: 'Add guidance on translation requirements (agreed by Leads 29 Jan 2025): The study team should decide whether PIS translation is appropriate/feasible for the study - bearing in mind regard for EDI - and make it clear in their application whether translation will be done or not. If translation is employed, this should be done by a verified translation service. Back-translation should also be carried out. For high risk studies, this should also be carried out by a verified translation service. For low risk studies, a validated service is not necessary, but the process followed should be documented in the study file. '

Change Requested on 05-Feb-2025 17:27 by Kate ONeill

Kate ONeill Requested Change: 'Add guidance on translation requirements (agreed by Leads 29 Jan 2025): The study team should decide whether PIS translation is appropriate/feasible for the study - bearing in mind regard for EDI - and make it clear in their application whether translation will be done or not. If translation is employed, this should be done by a verified translation service. Back-translation should also be carried out. For high risk studies, this should also be carried out by a verified translation service. For low risk studies, a validated service is not necessary, but the process followed should be documented in the study file. '

Superseded on 16-Dec-2024 09:54 by Paul Davison

Version 3.0 superseded by version 4.0

Document Published on 16-Dec-2024 09:54 by Paul Davison

The document was published and is ready to be used.

Authorised on 16-Dec-2024 09:54 by Paul Davison

Authorised version 4.0 - . The following users will be notified when a review is due for this document: Document was scheduled to be released on 2024-12-16 The document was originally due for review on 03-Feb-2025

Change Requested on 11-Dec-2024 16:56 by Paul Davison

Elena Villarreal Requested Change: 'Include Core Templates in references, also add HRA templates and guidance from CT toolkit: http://www.hra-decisiontools.org.uk/consent/'

Draft Created on 11-Dec-2024 16:56 by Paul Davison

Reason: Up-versioned for CC-1

Change Request Approved For Future Version on 15-Sep-2022 18:50 by Pati Shayler (Inactive)

Pati Shayler approved for future version change request: "This request was reviewed by the QA group on 15Sep2022 and it was decided that making reference to RGEA templates might be helpful, however the RGEA website is currently under restructure. This will be taken into consideration at the next SOP review."

Change Request Rejected on 15-Sep-2022 18:47 by Pati Shayler (Inactive)

Pati Shayler rejected change request: "This request was reviewed by the QA group on 15Sep2022 and was rejected due to the content being too specific. Core SOPs must be high-level in order to be applicable across multiple research groups in the university."

Change Request Rejected on 15-Sep-2022 18:47 by Pati Shayler (Inactive)

Pati Shayler rejected change request: "This request was reviewed by the QA group on 15Sep2022 and was rejected due to the content being too specific. Core SOPs must be high-level in order to be applicable across multiple research groups in the university."

Change Request Rejected on 15-Sep-2022 18:46 by Pati Shayler (Inactive)

Pati Shayler rejected change request: "This request was reviewed by the QA group on 15Sep2022 and was rejected due to the content being too specific. Core SOPs must be high-level in order to be applicable across multiple research groups in the university."

Change Request Rejected on 15-Sep-2022 18:46 by Pati Shayler (Inactive)

Pati Shayler rejected change request: "This request was reviewed by the QA group on 15Sep2022 and was rejected due to the content being too specific. Core SOPs must be high-level in order to be applicable across multiple research groups

in the university."

Change Requested on 31-Aug-2022 14:03 by Elena Villarreal

Elena Villarreal Requested Change: 'Include Core Templates in references, also add HRA templates and guidance from CT toolkit: http://www.hra-decisiontools.org.uk/consent/'

Change Request Rejected on 31-Aug-2022 13:46 by Pati Shayler (Inactive)

Pati Shayler rejected change request: "As per Elena's request, this change request has been rejected to allow further information to be added. "

Change Requested on 31-Aug-2022 13:39 by Elena Villarreal

Elena Villarreal Requested Change: 'Include HRA templates and Core templates in references section'

Change Requested on 31-Aug-2022 13:39 by Elena Villarreal

Elena Villarreal Requested Change: 'Define coercive language/give examples of coercive vs non-coercive'

Change Requested on 31-Aug-2022 13:39 by Elena Villarreal

Elena Villarreal Requested Change: 'Reference GDPR requirements in section on data protection statements, including use of agreed wording. '

Change Requested on 31-Aug-2022 13:39 by Elena Villarreal

Elena Villarreal Requested Change: 'Include separated sections for various aspects of patient information (e.g. minimum general content, separate PISs for varying understanding, use of samples, data protection, consent form contents)'

Change Requested on 31-Aug-2022 13:39 by Elena Villarreal

Elena Villarreal Requested Change: 'Include suggestion for patient involvement/lay review when considering lay language'

Document Released on 04-Feb-2022 00:00 by Clare Riddle (Inactive)

The Document was released.

Superseded on 17-Dec-2021 11:22 by Clare Riddle (Inactive)

Version 2.0 superseded by version 3.0

Document Published on 17-Dec-2021 11:22 by Clare Riddle (Inactive)

The document was published and is ready to be used.

Authorised on 17-Dec-2021 11:22 by Clare Riddle (Inactive)

Authorised version 3.0 - Changed authorship in the system: from Clare Riddle to Pati Shayler. The following users will be notified when a review is due for this document: Document was scheduled to be released on 2022-02-04 Previous version of the document didn't have a review date set.

Authorisation Approved on 17-Dec-2021 11:22 by Clare Riddle (Inactive)

The user Approved the authorisation request.

Set Pending Authorisation on 15-Dec-2021 13:22 by Pati Shayler (Inactive)

Document was set as Pending Authorisation and authorisation requests were sent to: Clare Riddle

Authorisation requested on 15-Dec-2021 13:22 by Pati Shayler (Inactive)

Authorisation request sent to Clare Riddle by Pati Shayler on 15-Dec-2021 13:22.

Reverted to Draft on 14-Dec-2021 16:29 by Clare Riddle (Inactive)

Document was reverted to draft. Reason to revert: "Please change author"

Authorisation Rejected on 14-Dec-2021 16:29 by Clare Riddle (Inactive)

Clare Riddle rejected authorisation with the following comments: Please change author

Set Pending Authorisation on 14-Dec-2021 13:51 by Pati Shayler (Inactive)

Document was set as Pending Authorisation and authorisation requests were sent to: Clare Riddle

Authorisation requested on 14-Dec-2021 13:51 by Pati Shayler (Inactive)

Authorisation request sent to Clare Riddle by Pati Shayler on 14-Dec-2021 13:51.

Draft Created on 14-Dec-2021 13:49 by Pati Shayler (Inactive)

Reason: Added requirement of Submission Package to be sent for sponsorship review on section 6.1. Replaced Competent Authority by Regulatory/Competent Authority. Replaced CTRG by RGEA. Removal of sections 6.2 Sponsor review, 6.3 REC review and 6.4 Ongoing review and Amendements. Alignment with SOPs 002 and 011. Updated into new Core SOP template (v3.0).

Authorisation

This document was securely signed and authorised by:

Bannin Jansen: 02-Jul-2025 14:10