Standard Operating Procedure:

Participant Engagement and Informed Consent

# Purpose:

This Standard Operating Process (SOP) describes the processes involved in participant and public engagement, to include public involvement in the study/trial design, set up and management, the development and requirements of Informed Consent Forms (ICF) and Participant Information Sheets (PIS), participant recruitment and dissemination of study/trial results to participants.

# Scope:

This SOP applied to clinical research where the University of Birmingham (UoB) is the Sponsor, or takes on Sponsor responsibilities for participant and public engagement, development of PIS and ICF and participant recruitment. This SOP also applies to clinical research approved by UoB Research Ethics Committee (REC) that are required to follow UoB Principles of Good Clinical Practice (GCP) for Clinical Research. This SOP may be used as a guidance document in all other cases.

Where clinical research is (co-)sponsored by another institution, this procedure should be followed as far as possible, and in line with the contractual agreement between the UoB and the other institution.

# Implementation plan:

This SOP will be implemented directly after the effective date for any clinical research that are still in the set up phase. For clinical research where the ICF and PIS have already been finalised, the ICF and PIS will be reviewed within three months of this SOP effective date to ensure compliance with the General Data Protection Regulation (GDPR; effective as of 25-May-2018) as detailed under point 8. All other processes relating to PIS/ICF development will be implemented at the next PIS and/or ICF update. The processes relating to patient/public engagement will be implemented where possible.

# Stakeholders:

Note that where the UoB takes on the Sponsor responsibility for participant engagement and informed consent, the UoB will delegate the majority of these duties to the Chief Investigator (CI) and/or to a Clinical Trials Unit, who may delegate these duties further to their trials team(s). All delegation of duties will be documented using either the CI declaration and/or the Clinical Trials Task Delegation Log; see UoB-CLN-CTM-QCD-002 Clinical Trial Task Delegation Log.

* Chief Investigator (CI); the CI may delegate activities to members of their trial team, although evidence of CI involvement and approval is still expected and may not be delegated where ‘no delegation allowed’ is indicated. The SOP will state where delegation is possible. For clinical research approved by UoB REC, the role of CI may be referred to as the Principal Investigator (PI), or the supervisor for postgraduate research students.

# Background and Rationale:

For the purposes of this SOP the terms ‘clinical trials’ or ‘trial’ will cover Clinical Trials of Investigational Medicinal Products (CTIMPs), other interventional trials (e.g. surgical trials, device trials and non-CTIMP trials, and any other projects deemed to be ‘interventional’ by the Sponsor), and clinical studies.

The Health Research Authority (HRA) recommends that researchers participate in two-way public engagement, with interaction and dialogue with the public to inform their research as well as members of the public being active participants in the research. Researchers should engage with the public at the point of research concept and include them in their research journey so that they shape and assist in the research design. The public may advise on the format and content of participant-facing documents, subsequently referred to in this SOP as participant documents, such as the PIS. In addition to the public’s assistance with the research design, researchers seek to recruit members of the public to participate in their research. Robust mechanisms are required for recruiting and identifying participants and to verify that the participant exists, that the person screened is the same person dosed and fulfils the trial eligibility criteria, including across multiple trials should they choose to participate in them.

# Process map:



# Procedure:

## Engage with the public

1. The CI (or delegate) will engage with the public as per the [HRA guidance](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/) in the design, management, conduct and dissemination of the research, unless otherwise justified. See also UoB-GCP-POL-001 UoB Principles of GCP for Clinical Research.

## Develop participant documents

1. The CI (or delegate) will develop the trial protocol; for further information see UoB-CLN-PRO-QCD-002 Protocol Template CTIMP, or UoB-CRT-NCTM-QCD-001 Protocol Template - Non-CTIMPS & Studies, as applicable.

* Include a description in the trial protocol about how the public have been involved in the trial, as detailed in the Protocol Template
* Ensure that a detailed description of the recruitment and consent procedure are written in the protocol, as detailed in the Protocol Template
* Unless justified in the protocol the participants should represent the population; e.g. by gender and age groups.

1. The CI (or delegate) will ensure that a PIS and ICF are developed, to set out in writing what taking part in the trial will involve for the participant, thereby ensuring that those that participate in the trial are adequately informed.

* Refer to the guidance provided by the HRA on [Informing participants and seeking consent](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/)
* Refer to UoB-CRG-QCD-001 Sponsor Review Tool for the UoB specific requirements to be included in the PIS and ICF
* Refer to the guidance provided by UoB Legal Services on [Data Protection Law resources for University researchers](https://intranet.birmingham.ac.uk/legal-services/What-we-do/Data-Protection/Data-Protection-resources.aspx) (UoB login required), which includes the development of text relating to the University’s Data Protection Policy for the PIS and ICF
* Assess how close the proposed trial follows standard practice, i.e. the closer the research is to standard practice the less need there is to provide the potential participant with detailed and lengthy information
* Ensure that all participant related assessments and procedures detailed in the protocol are included in the PIS/ICF, e.g. if protocol states that 50 ml blood sample will be collected at the baseline visit, the same information is captured in the PIS
* Where participants receive payments, ensure this is clearly described in the PIS, see also the [HRA’s Guidance on Participant Information Sheet](http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html). For further guidance on appropriate levels of payments see the [HRA’s Guidance on Payments and Incentives in Research (PDF - 305 KB)](https://www.hra.nhs.uk/documents/274/hra-guidance-payments-incentives-research.pdf)
* Ensure that the process and timelines for informing participants of the results in a suitable format (unless justified in the protocol) is defined, and clarified in the PIS.

1. The CI (or delegate) will ensure that the PIS and ICF use appropriate language, abbreviations are explained and terminology is consistent so that a lay person can easily understand the PIS and ICF.

* Refer to the [HRA Consent and Participation Information Guidance](http://www.hra-decisiontools.org.uk/consent/) when the trial involves the following participant groups:
* Incapacitated participants
* Minors
* Emergency situations
* Pregnant or breastfeeding women
* Cluster trials.

1. The CI (no delegation allowed) will document their approval of the final version of PIS and ICF in writing and the CI (or delegate) will file the written approval in the Trial Master File.
2. The CI (or delegate) will develop a variety of appropriate tools to recruit potential trial participants. The procedures proposed should be outlined in the protocol and tools may include:

* Adverts (in newspapers, websites or on local radio) or letters
* Social Media advertising, e.g. Twitter, Facebook, blogs
* Retention initiatives, e.g. vouchers, travel expenses.

1. The CI (or delegate) will ensure that any written information provided to participants will be reviewed and approved in writing by the Sponsor, HRA, REC and other parties (e.g. the Competent Authority for Clinical Trials of an Investigational Medicinal Product (CTIMPs) as required. For further information see UoB-CLN-SMA-SOP-001 Site Management.
2. For existing trials, the CI (or delegate) will ensure that the University’s Data Protection Policy requirements for transparency are met (to ensure compliance with GDPR; effective as of 25-May-2018), using the latest suggested text available from the [UoB Intranet](https://intranet.birmingham.ac.uk/legal-services/What-we-do/Data-Protection/Data-Protection-resources.aspx).

* For all new studies not submitted for approvals before 25-May-2018 amend PIS with transparency text from UoB Legal Services as detailed in point 3 above
* For studies approved and recruiting new participants after 25-May-2018 provide separate document with transparency information and via websites
* For studies approved and participants are still in the study including follow up and where data is being processed after 25-May-2018 provide the University’s transparency information (Data Protection Essentials) at next contact point or on an ad hoc basis
* For completed studies where no further data is being collected or processed after 25-May-2018 no further action is required.\*

\*If issues are noted with the wording during HRA approval (where required) please liaise with the Research Governance Team.

1. If there are changes to the trial design, medication used or risks associated with participation, the CI (or delegate) will ensure that the PIS and ICF will be updated to reflect this and ensure the amended documents will be reviewed and approved by the Sponsor, HRA, REC and other parties as required through the defined process for amendments, before participants are notified and re-consented as applicable, while ensuring that the University’s Data Protection Policy requirements for transparency are met, using the latest suggested text available from the [UoB Intranet](https://intranet.birmingham.ac.uk/legal-services/What-we-do/Data-Protection/Data-Protection-resources.aspx) and against the criteria detailed in point 8 above.
2. The CI will ensure participants are given the option to re-consent if an urgent safety measure has been instigated.

## Participant Recruitment

1. The CI (or delegate) will ensure that Principal Investigators (PIs) at site are fully aware of their responsibilities and are trained in the processes for participant recruitment and consent, that this has been delegated correctly and that oversight is maintained by the CI and evidenced; see UoB-CLN-SMA-SOP-001 Site Management for further details.

* No trial specific screening can take place until informed consent is obtained from the participant. Pre-screening is permitted by the care team to ensure that the trial is appropriate for the intended participant. This can include reviewing medical notes and associated imaging and laboratory results that are part of the participant’s standard care. Other ways of identifying potential participants may include:
* Identification through a database or review of records, followed up by an invitation to attend a clinic to discuss the trial
* Discussion during a multi-disciplinary team meeting where treatments are reviewed
* Attendance at a site, e.g. surgery or hospital department undertaking the trial
* Responding to advertisements
* Identification and contact of individuals under [Section 251 of the NHS Act 2006](http://www.legislation.gov.uk/ukpga/2006/41/section/251).
* For CTIMPs, the decision as to whether a potential participant is eligible for the trial is considered to be a medical decision and must therefore be made by a medically qualified doctor or when appropriate a qualified dentist.
* There may be unique instances when it is appropriate for other Good Clinical Practice (GCP)-trained non-physician healthcare professionals to confirm eligibility providing the eligibility assessments and process are detailed in full in the trial protocol.
* In this case, the protocol must define who should perform the eligibility assessments and a clear explanation provided of how any potential risks associated with a non-physician healthcare professional determined eligibility would need to be mitigated
* Delegation of eligibility assessment must be incorporated into the delegation of responsibilities log
* The risk management of the eligibility process and the impact on any subsequent administration and monitoring of the Investigational Medicinal Product (IMP) must be considered as part of the trial risk assessment, and the outcome documented in the trial risk assessment.
* The participant should be given adequate time to consider their decision to participate in the clinical trial
* The informed consent of the participant should be in writing. Where the participant is unable to write, it may be recorded through appropriate means such as audio or video recorders. Informed consent must be dated and signed by the participant and by the person delegated to take consent
* In certain emergency situations it may not be possible to obtain informed consent prior to the intervention and in such cases clear rules must exist as to when a participant may be enrolled, providing it relates directly to their medical condition and there is a therapeutic window. Informed consent from the participant or their legal designated representative should be sought as soon as possible
* The participant should sign and date the consent form, and indicate their approval of the various statements by initialling against them. The ICF should also be counter-signed by the person delegated to take consent
* If the participant is unable to sign or mark to indicate their consent, it may be given orally in the presence of at least one witness and recorded in writing
* The original consent form must be filed in the Investigator Site File (ISF), with a copy provided to the participant together with the PIS and where applicable a copy sent to the coordinating centre
* Following updates to the consent process the participant may need to be re-consented, which should be done at the next scheduled visit
* Consent documentation should be available for inspection by the relevant regulators and sponsor representatives.

## eConsent

1. Where consent is being taken electronically, the CI (or delegate) will follow the [Joint statement on seeking consent by electronic methods (PDF - 209 KB)](https://www.hra.nhs.uk/documents/1588/hra-mhra-econsent-statement-sept-18.pdf) issued by the MHRA and HRA.

## Disseminate Results

1. The CI (or delegate) will ensure that the results of the trial are made accessible in a timely fashion and that a summary is available in lay language.

# List of expected outputs:

* A Public Involvement section in the protocol, detailing which aspects of the research process have actively involved or will involve patients, service users, and/or their carers, or members of the public
* Evidence of public involvement in the design of the trial e.g. Trial Steering Committee membership, meeting notes from focus groups etc.
* PIS (including previous archived versions)
* Blank ICF (including previous archived versions)
* Advertisements (if applicable)
* Documented evidence within the Trial Master File (TMF) confirming the CI’s approval of the PIS and ICF and for any subsequent amendments
* Evidence of internal and external approval (if applicable) of participant-facing documents
* Evidence of training of PIs by the CI in responsibilities and processes for recruitment and consent, where applicable
* Evidence of delegation to obtain consent and that the person is qualified to do so; .e.g. Site Signature and Delegation Log (SS&DL) and Investigator CV
* Completed trial ICFs, with the originals in the ISF and copies (where explicit consent has been obtained) at the coordinating centre
* Evidence of ongoing oversight by the CI of processes and duties undertaken at site for recruitment and consent
* For trials using eConsent, evidence that the MHRA and HRA ‘Joint statement on seeking consent by electronic methods’ has been followed

# Related documents:

* UoB-CLN-CTM-QCD-002 Clinical Trial Tasks Delegation Log
* UoB-CLN-CTM-SOP-001 Clinical Trial Management
* UoB-CLN-ESD-QCD-004 Guideline for consenting procedure for site staff
* UoB-CLN-ESD-SOP-001 Essential Documents development and maintenance
* UoB-CLN-PRO-QCD-002 Protocol Template CTIMP
* UoB-CLN-SMA-SOP-001 Site Management
* UoB-CRG-POL-001 UoB Principles of GCP for Clinical Research
* UoB-CRG-QCD-001 Sponsor Review Tool
* UoB-CRT-NCTM-QCD-001 Protocol Template – Non-CTIMPs & Studies
* UoB-GCP-POL-001 UoB Principles of GCP for Clinical Research

Note the UoB QMS documents can be found on the [Clinical Research Compliance Team website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx). The RGT can be contacted via [researchgovernance@contacts.bham.ac.uk](mailto:researchgovernance@contacts.bham.ac.uk) and the CRCT can be contacted via [crct@contacts.bham.ac.uk](mailto:crct@contacts.bham.ac.uk) for a copy of their internal Work Instructions.

# References and Frameworks:

* EU Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing. Directive 2001/20/EC: [https://ec.europa.eu/health//sites/health/files/files/eudralex/vol-1/reg\_2014\_536/reg\_2014\_536\_en.pdf](https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf)
* Good Clinical Practice Guide compiled by the Medicines and Healthcare products Regulatory Agency (MHRA). First edition published in 2012. UK: TSO Information and publishing solutions
* HRA Consent and Participation Information Guidance: <http://www.hra-decisiontools.org.uk/consent/>
* HRA Guidance on Best Practice in Public Involvement: <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/>
* HRA Guidance on Informing Participants and Seeking Consent: <https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/>
* HRA Guidance on Participant Information Sheet: <http://www.hra-decisiontools.org.uk/consent/content-sheet-involved.html>
* HRA Guidance on Payments and Incentives in Research: <https://www.hra.nhs.uk/documents/274/hra-guidance-payments-incentives-research.pdf>
* ICH GCP Guidelines with Integrated Addendum E6 (R2): <http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf>
* INVOLVE website. National Institute for Health Research: <http://www.invo.org.uk/>
* MHRA and HRA Joint statement on seeking consent by electronic methods (2018): <https://www.hra.nhs.uk/documents/1588/hra-mhra-econsent-statement-sept-18.pdf>
* NHS Act 2006 Section 251; <http://www.legislation.gov.uk/ukpga/2006/41/section/251>
* The Medicines for Human Use (Clinical Trials) Regulations 2004 and amendments: <http://www.legislation.gov.uk/uksi/2004/1031/contents/made>
* UK Policy Framework for Health and Social Care Research: <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>
* UoB Legal Services – Data Protection Resources: <https://intranet.birmingham.ac.uk/legal-services/What-we-do/Data-Protection/Data-Protection-resources.aspx>

# Abbreviations and Definitions:

| Term | Description |
| --- | --- |
| **Informed Consent Form (ICF)** | The Informed Consent Form is the form which is used to document the voluntary confirmation of a participant’s willingness to take part in a trial after having being informed of all aspects of the trial that are relevant to their decision. The form must be signed and dated. |
| **Participant** | An individual who participates in a clinical research project. This may involve being the target of observation of research, a recipient of an investigational product(s) or as a control. |
| **Participant Information Sheet (PIS)** | The Participant Information Sheet describes in lay (clear and easy) language a research project, explaining its purposes and methods, and outlining the risks and benefits of participation. Information sheets are also referred to as ‘Patient Information Sheet’. |
| **Public** | The general public. Includes carers, relatives of patients and service users and healthy volunteers. |
| **Public Engagement** | Working in collaboration with patients, service users or the public to disseminate information and knowledge about research, for example; science festivals, open days and media coverage. |
| **Public Involvement** | Public involvement in research refers to the public being involved in the research process so that the work, or elements of it, is done with or by the public and not 'to', 'about' or 'for' them.  Public involvement does not refer to taking part in research as a research participant. |
| **Research Ethics Committee (REC)** | An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human participants involved in clinical research and to provide public assurance of that protection, by, among other things, reviewing and approving/providing favourable opinion on, the protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the participants. |

See also the [Glossary of Terms](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/Glossary-of-Terms.aspx).