Joint Research Management Office Standard Operating Procedure for:			
Informed Consent			
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Purpose:

To ensure that any clinical research sponsored or hosted by Barts Health NHS Trust (Barts Health) or Queen Mary's University of London (Queen Mary) is compliant with all relevant legal and ethical principles of consent.

To ensure that consent processes are appropriate to the type of study and population to be recruited.

To ensure that where relevant any potential research participant is fully informed of all aspects of a study that is relevant to their decision to participate, before they voluntarily confirm that they are willing to participate in the research.

To ensure that the process is documented appropriately.

To ensure that participants enrolled in the study are kept informed of any new information concerning the study that might affect their willingness to continue with their involvement in the research.

Scope:

This Standard Operating Procedure (SOP) applies to all research being conducted within Barts Health and Queen Mary. This SOP applies to Medicines and Healthcare Products Regulatory Agency (MHRA) regulated, interventional studies and research studies.

Further guidance on consent can be found in *Associated Document 1: Informed Consent Guidance*.

Abbreviations:

Barts Health	Barts Health NHS Trust
CI	Chief Investigator
DCT	Direct Care Team
GCP	Good Clinical Practise
HRA	Health Research Authority
HTA	Human Tissue Authority

IB	Investigator Brochure
ICF	Informed Consent Form
ISF	Investigator Site File
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare Products Regulatory Agency
PI	Principal Investigator
PIS	Participant information sheet
Queen Mary	Queen Mary University of London
REC	Research Ethics Committee
R & D	Research and Development
SmPC	Summary of Product Characteristics

SOP Text:		
	Responsibility	**Activity**
1.	Chief Investigator (CI) / Research Team	**Establishes an appropriate consent process and that includes proportionate information for the type of study being planned.** Use HRA and MRC guidance alongside JRMO protocol templates (JRMO SOP *11a*, *12a* and *13a*) when deciding how information about the study will best be provided to the participants, how the study will be discussed and how this will be documented. There may need to be multiple PIS and ICFs within one study depending on the study population and consent process, For special consideration of taking consent please see *Associated Document 1 Informed Consent Guidance.* The HRA templates should be used as far as possible- *https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/*
2.	Principal Investigator (PI)	**Delegation Log and Training** Ensure appropriate staff taking consent, are on the delegation log, and are suitably trained and qualified. The delegation log must be signed by the PI prior to the study starting. The PI remains responsible for the consenting of participants and should have systems in place to ensure they are aware of all consents and enrolments. Please note for MHRA regulated studies, consent must be received by a medically qualified individual or dentist (unless agreed by the Sponsor in advance). Full training in all aspects of consent procedures must be given and documented in the research training logs (*SOP 34a Researcher training*).
3.	PI or person delegated by the investigator	**Ensure that all participants are approached, provided with all relevant information and are consented as per the latest REC approved protocol, Sponsor requirements, and REC application.** See *Associated Document 1* for guidance on best practice when taking consent. Consent must be obtained prior to participation in any study activity (including any screening procedures).

		The informed consent process must be fully documented in the medical records. This must include: • The date of discussions and when the PIS was given to the participant. • Who took informed consent? • The version of documents used (PIS and ICF). • Explicit information to demonstrate that the participant fully met **every** inclusion/exclusion criteria of the study . Researchers will ensure ongoing participant consent, keep participants updated and, if necessary, re-consent in a timely manner (see point 6). Research involving adults unable to consent for themselves requires **specific** REC approval from a **recognised** Mental Capacity Act Flagged REC. Research involving human tissue (from the living and/or the deceased) requires specific consent for the samples to be stored and used in research. For this, tissue samples must be transferred and stored in a Human Tissue Authority (HTA) Licensed Tissue Bank after the ethical approval has expired. See *Associated Document 1* for HTA exceptions. For further information on HTA requirements please contact Designated Individual and HTRC Manager Katie Ersapah on *k.ersapah@nhs.net*.
4.	PI or person delegated by the investigator	**Ensure that the ICF is completed correctly to accurately reflect the consent process that occurred.** If receiving consent through a face-to-face interaction, when obtaining the participant's consent, the boxes adjacent to each question/point on the ICF must be **initialled** by the participant or their legally acceptable representative. They must also print and sign their name, and write the date, in the appropriate place on the ICF. The person taking consent must print and sign their name and write the date in the appropriate place on the ICF. Please see *Associated Document 1* for alternative consent methods.
5.		**Additional considerations when receiving consent through study or participant specific methods.** **Witness:** Where an impartial witness is required, the witness must sign and date the ICF in addition to the participant if they are confident the participant has understood the information and is able to make a decision. If the participant is unable to see or to write, then the participant makes some mark on the ICF, if possible. **Professional or personal representatives**: The NHS translation service should be used when a potential participant or their legally acceptable representative do not speak and/or understand sufficient English to understand the information being given. The translator must be independent of the study team and must not be a member of the participant's family. In situations where a participant is not able to give consent, the consent of the legally acceptable representative can be sought. If this is not possible, enrolment of the participant must follow measures described in the protocol with documented approval from the NHS REC (see the *HRA website* for details).

		The participant, or their legally acceptable representative, must be informed about the study as soon as is possible, and "consent to continue" requested. **Children:** Age-appropriate information sheets and assent forms should be used when participants are classified as children and/or young people. The requirements for consent, where participants are children and/or young people depends on the type of study and where in the UK it is taking place. Generally, in England Wales and Northern Ireland, participants are classed as children when they are under 16 years of age. As the time of SOP release the below link is a good source of advice and guidance: *https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-involving-children/* **E-consenting:** The use of e-consenting must be discussed and agreed with the Sponsor and host organisation's Research and Development (R&D) during study set up. For further details please see *Associated Document 2: JRMO Guidance document on seeking consent by electronic methods* Any computerised or electronic system used for e-consenting should comply with *SOP 38a Use of computerised equipment, software and systems in clinical research* and *38b Electronic data management systems for MHRA-regulated studies*.
6.	PI or person delegated by the investigator	**The original and copies of the ICF and associated PIS must be safely filed.** After signature, the original ICF must be kept in a safe and designated place; See *Associated Document 1* for guidance on appropriate filing. A copy must always be given to the participant (along with a copy of the associated PIS). Any scans or copies must be checked for completeness and clearly labelled as a verified copy (including signature and date of person completing this check).
7.	CI / Research Team	**Amendments process – timely update of ICF and PIS.** Any change to the PIS will be deemed an **amendment**. The Sponsor must approve the amended documents prior to submission to REC. The new PIS/ICF must be approved by the REC before being used. See *SOPs 17b* and *17c* for JRMO amendments procedure guidance on amendments.
8.	PI / Research Team	**Re-consenting Participants.** The need for re-consent should be discussed with the sponsor and highlighted to the REC in the amendment. The re-consent process must be fully documented in the medical records/source documents. The researcher must re-receive consent from the participant for their involvement in the study based on the new protocol or safety information

Change control

This section outlines changes from version 7 to version 8.

Section changed	Summary and description of changes
Definitions	Removed from SOP
Throughout	Terminology changes to receive consent rather than take consent
Throughout	Links inserted for supporting documents and referred websites
Associated Document 1	Drafting of a guidance document
Associated Document 2	Addition of guidance document for consent by electronic methods.

List of associated documents

Associated Document 1	Informed Consent Guidance Document
Associated Document 2	Guidance document on seeking consent by electronic methods