Standard Operating Procedures (SOP) for:			
Informed Consent			
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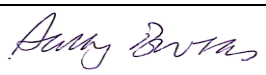
Signature:	
Date:	23rd August 2017

Purpose and Objective:
To ensure that any clinical research sponsored or hosted by Barts Health NHS Trust (BH) or Queen Mary's University of London (QMUL), is compliant with all relevant legal and ethical principles of consent. To ensure that any potential research participant is fully informed of all aspects of a study that is relevant to the subject's 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 SOP applies to all research being conducted within BH and QMUL. This SOP applies to CTIMPs and non-CTIMPs. The guidance covers consent in adults, children, young people and adults not able to consent for themselves (in both emergency and non-emergency situations), healthy volunteers and takes into account UK-wide requirements.

Abbreviations:	
BH	Barts Health NHS Trust
CI	Chief Investigator
CRS	Care Records Service
CTIMP	Clinical Trial of an Investigational Medicinal Product
HRA	Health Research Authority
HTA	Human Tissue Authority
IB	Investigator Brochure
ICF	Informed Consent Form
ISF	Investigator Site File
JRMO	Joint Research Management Office
PI	Principal Investigator
PIS	Participant information sheet

QMUL	Queen Mary University of London
REC	Research Ethics Committee
SmPC	Summary of Product Characteristics
Definitions (*if needed*):	
N/A	
Relevant SOPs:	
For guidance on Amendments for Sponsored and hosted Studies see: • SOP 17b – Process for Researchers: Amendments for Hosted Studies • SOP 17c – Process for Researchers: Amendments for Sponsored Studies	

SOP Text:		
	Responsibility	Activity
1.	Chief Investigator (CI) / Research Team	**Write a participant information sheet (PIS) and informed consent form (ICF) for the research study and seek approval.** The content and format of the PIS and ICF must adhere to the ethical principles of the most recent version of the Declaration of Helsinki, the most recent HRA guidelines and the ICH Good Clinical Practice (GCP) guidelines. The HRA templates should be used as far as possible. Obtain ethical approval for the PIS and ICF from an appropriate Research Ethics Committee (REC) prior to use in the study. For some studies additional PIS and ICF may be required which must also be approved before use.
2.	Principal Investigator (PI)	**Ensure appropriate staff take consent, are on the delegation log, and are suitably trained and qualified.** Complete the delegation log prior to starting the study. All staff delegated by the Principal Investigator (PI) as able to take consent from participants must be listed on the study delegation log which is signed by the PI. Delegated individuals should be appropriately trained and qualified. 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 CTIMPs, consent must be taken by a medically qualified individual or dentist (unless agreed by the Sponsor in advance). If consent is not taken by a medically qualified person (or dentist) for BH and QMUL sponsored studies, the ICF must be countersigned by the PI in a timely manner. See *Associated Document 1* for a template delegation log. When delegating the taking of consent, individuals must be: • Suitably trained and qualified • Familiar with all aspects of the study as described in the latest approved version of the protocol. This should include sufficient knowledge of the proposed investigation, treatment and / or condition and an understanding of the risks of the study in order to answer questions raised by the participant. • For CTIMPs, be familiar with the latest version of the IB/SmPC.

		Training in consent should be documented in the research training logs. Consent must be obtained prior to participation in the research study. For example: • Before initiation of any screening procedures, • Before any changes are made to the participant's medication, • Before any preparation for screening procedures; e.g. before fasting for blood draws. Only site staff with specifically delegated responsibility should be involved in the Informed Consent Process.
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.** Unless otherwise agreed by Sponsor, the following is deemed as best practice: • The potential study participant will be identified and approached by a member of their usual clinical care team. • A trial physician must ensure each participant meets the eligibility criteria **BEFORE** they are entered into the research study. • The research team will then contact the participant about the research study. • The potential study participant, or their legally acceptable representative, will then be informed of all aspects of the research study (including the nature, significance, implications/burdens and risks of the research) in a way that they are able to understand, both verbally and in writing, in the form of the PIS. • The potential study participant or their legally acceptable representative must be given as much time as they require to read the PIS and to ask any questions prior to making a decision to take part in the research study. The potential participant must be given a copy of the PIS to take away with them. • If the participant agrees to take part in the study, the person taking consent must ensure the participant understands the research study, that participation is voluntary, and that they know they have the right to withdraw from the study at any point without their care being affected. 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

		It is good practice not to recruit anyone who could be "coerce[d] or unduly influence[d]… to participate or to continue to participate in a trial". Family members or closely associated staff (i.e. people over whom there is the potential for the CI or PI to have undue influence) should not be recruited onto a trial unless approved by the ethics committee. 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. Tissue samples must be transferred and stored in a Human Tissue Authority (HTA) Licensed Tissue Bank after the ethical approval has expired. Exceptions: 1. Consent is not required if the samples (from the living and/or the deceased) were taken before 1st September 2006. 2. Consent is not required from a living donor fully anonymised to the researcher and where the study has REC approval. 3. A HTA license is not required where samples are being stored for use in a specific REC approved study and the tissue is not retained after that study for unspecified future use.
4.	PI or person delegated by the investigator	**Ensure that the ICF is completed correctly to accurately reflect the consent process that occurred.** 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. The person taking consent must be a member of the research team delegated to take consent as stated in the delegation log. There may be situations where an impartial witness is required to be present during the entire informed consent process. For example, if the participant is unable to read or write or if they have a poor level of English. 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. When a potential participant or their legally acceptable representative do not speak and/or understand sufficient English to understand the information being given (and where insufficient English is not an exclusion criteria), a translator must be provided. The NHS translation service should be used where possible. The translator should be independent to the study team and should not be a member of the participant's family.

		In emergency situations, when 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 as detailed in the ICH GCP Guidelines section 4.8.15. Otherwise, the ICF must be signed prior to any study participation (as stated in Section 2).
5.	PI or person delegated by the investigator	**Ensure that the original and copies of the ICF and associated PIS are safely filed.** After signature, the original ICF must be kept in a safe place; either in the participant's medical notes (where applicable), with source documents, or in the study file (with a copy placed in medical notes / with source documents) and a copy must always be given to the participant (along with a copy of the associated PIS). It is acceptable to scan the PIS and ICF onto hospital electronic health records. A copy of the PIS and ICF must be filed in the medical notes/with source documents and, if possible, the Investigator Site File (ISF).
6.	CI / Research Team	**Amendments process – timely update of ICF and PIS.** If the protocol is amended in such a way that it may affect participants' willingness to consent, or if new safety information that affects the research study becomes available, the PIS/ICF must be revised to reflect these changes. For example, if new safety information arises regarding the medicinal product or the device, the information needs to be brought to the attention of the participants so that they continue to be fully aware of all aspects of the research study. Any change to the PIS will be deemed an **amendment**. Ask the study Sponsor for advice on whether changes are minor or substantial. 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 guidance on amendments. On receipt of REC approval for the amended PIS/ICF, the CI must alert all sites to the new documentation.
7.	PI / Research Team	**Re-consenting Participants.** Participants who may be affected by this new or amended information must be re-consented. The re-consent process must be fully documented in the medical records/source documents. The researcher must re-take consent from the participant for their involvement in the study based on the new protocol or safety information (as per the process outlined in Section 4).

Change Control

This section outlines changes from version **5.0** to version **6.0**

Section Changed	Summary and Description of Changes
All	Editorial revisions and streamlining of content: spelling, punctuation, grammar and general phrasing. "Consent Form" abbreviated to "ICF" throughout document.
Section 5	Reference to "CRS" changed to "hospital electronic health records"

List of Associated Documents

Document Ref.	Document Name
1.	BH/QMUL Template delegation log