3. Consent to participate in research

The primary purpose of the policy is to ensure that for any participant taking part in research consent is considered both legal and ethical. Researchers should be able to demonstrate that the consent process is:

- Given by a person with capacity;
- Voluntarily given, with no undue influence;
- Given by someone who has been adequately informed;
- A fair choice.

This Policy should be read and acted upon in conjunction with the Trust's policy on Consent to Examination and Treatment[1] and JRMO SOP 25 Informed Consent.

Throughout this policy, the use of 'participants' means someone taking part in research, such as healthy volunteers, patients, consultees on behalf of patients etc.

3.1 Standards for 'All' types of research

Before applying to the Barts Health or Queen Mary for Sponsorship or QMERC, all researchers should:

- Ensure that template information, such as a participant information sheet, is in an accessible form (for example, that it responds appropriately to language, literacy and capacity needs). The cost of producing information in these formats should be included in the overall project costing;
- Consider the specific language and cultural needs of the study population. Queen Mary and Barts Health would particularly encourage researchers to seek advice from local community groups and Barts Health Advocacy Service. Failure to engage local ethnic minority groups may have implications for the validity of the research sample;
- Read and adhere to the current National Research Ethics Service (NRES) guidelines and templates on writing a participant information sheet and consent form;
- Read the HRA and MHRA joint statement on seeking and documenting consent using electronic methods (e-consent), if applicable.
- Should it not be feasible to contact individual participants to obtain consent, the REC must confirm that it is acceptable for the research to proceed without it. This may require SECTION 251 exemption from the Confidentiality Advisory Group (CAG).

3.2 Procedures for obtaining consent to participate in clinical research

The Health Research Authority (HRA) website and the Information Commissioner's Office (ICO) contains a range of guidelines on obtaining an individual's consent to participate in health and social care-related research which Barts Health and Queen Mary researchers must adhere to.

[1] Barts Health Policy on Consent to Examination and Treatment, 26 March 2012: https://weshare.bartshealth.nhs.uk/trust-wide-policies

They include but are not limited to, ensuring that:

- Protocol(s) for research involving participants, human tissue, participant data or healthy volunteers are submitted for Research Ethics approval.
- Templates (such as participant information sheets and consent forms) satisfy standards set by the National Research Ethics Service.
- Research is conducted openly and transparently, by:
    (i) Informing participants of, and clearly identifying, any conflict of interest and/ or personal benefit to be gained from the research (including financial) and/ or any involvement with a commercial entity that might constitute a conflict of interest
    (ii) Ensuring that consent covers 'consent to participate', 'consent to process personal data', 'consent to transfer personal data outside the Sponsor organisation' and 'consent to use images and tissues gathered during research', where relevant.
    (iii) Seeking approval for the study from the sponsor and having local confirmation of capacity and capability before any participant being informed of the study or approached.

Chief Investigators and Principal Investigators leading health and social care-related research at our sites are required to ensure that all research staff working on a research project abide by the standards set by the HRA.

The following applies to all research where it is assumed that the potential participant has the legal capacity to consent.

- Consent for research should always be obtained in writing, be signed and dated by the person taking consent, the participant/ their representative and, for health and social care-related research, a witness. The same principles would apply for e-consenting but any platform/system used would need to be validated using SOP 38a first.
- The participant should receive one copy of the signed consent form, a second copy should go on the site file and, where relevant (i.e., where the research is health and social care related), a third copy should be kept in the medical notes.
- The researcher should ensure that the original consent form is stored securely.
- Written consent should be sought from the participant at the earliest opportunity.
- The best practice procedures for written consent and records storage should be followed.

More information concerning groups requiring Special Consideration is contained in Section 3.5 below).

To be able to demonstrate compliance with Good Clinical Practice & UK Policy Framework requirements the researcher must be able to show that:

- Consent was sought by someone fully trained and able to explain the nature of the research, the risks and benefits of taking part and capable of answering any questions the participant may have;
- The version of the consent form and participant information sheet used to obtain

consent is the same version approved by the REC;

- The participant had ample time to consider whether to take part in the research. Time allocated should be proportionate to the level of complexity and risk of taking part in the study;
- Appropriate advocacy or interpretation arrangements or translated documents are made available during the consent process and clearly documented. Ideally, all participants requiring advocacy or interpretation should have this provided in person;
- The participant has been made aware that they may withdraw at any time without their routine care being affected;
- The participant has a contact point for further information about the study;
- Participants have not been offered inducements (financial or otherwise). Reimbursement of expenses and moderate inconvenience allowances are permitted if declared and approved by the REC.

3.3 Research on Human Tissue

The Human Tissue Act (HTA) 2004 regulates the storage and use of human organs and tissues from the living and the removal, storage and use of organs and tissue from the deceased. Certain uses (scheduled purposes) require appropriate consent. Please refer to the separate policy on consent under the HTA held within the Trust/University HTA designated Individual policies.

3.4 Groups for special consideration

There are several groups of potential participants whose inclusion in research requires special consideration. These include but are not limited to:

- Children
- Adults lacking the capacity to consent
- Participants in emergency situations
- frail elderly people,
- those living in institutions
- pregnant women

When planning research involving these populations, researchers should seek advice from the Governance section, JRMO and JRMO SOPs, all applicable regulations and guidelines and ensure the use of guardians, parents, personal, legal and professional representatives, as appropriate.

Individuals lacking the capacity to consent may be included in research only if it relates to their condition and the relevant knowledge could not be gained through research on persons able to consent. Please see the Mental Capacity Act (2006), for further information. Where possible and appropriate if a participant regains capacity their consent should be sought and wishes respected.

Where participants lack the legal capacity to consent, REC-approved procedures for seeking consent from professional/personal consultees should be followed.

Further Information may be obtained from:

1) JRMO Governance Section via research.governance@qmul.ac.uk
2) HRA website: www.hra.nhs.uk/
3) Medicines & Healthcare Products Regulatory Agency: www.mhra.gov.uk

This policy applies to both Queen Mary and Barts Health.