Guidance on obtaining and using human blood and tissue from healthy volunteers for research purposes

Scope

Staff and students from Queen Mary University of London (Queen Mary) and Barts Health NHS Trust (Barts Health) regularly undertake work that requires the use of blood from human volunteers. It is imperative that these individuals are supported to produce high quality work whilst volunteers are protected from unnecessary risks. This document outlines the requirements staff and students of Queen Mary and Barts Health should comply with when obtaining and using blood from human volunteers.

This document applies to all work involving blood from human volunteers for research, and activity that is not defined as research (including equipment calibration, preliminary assays, and proof of concept work). It also applies to the use of any biological samples (e.g. saliva, tissue samples) which are considered "*relevant material*" under the Human Tissue Act (2004) (for more information please see here); where this document refers to blood samples this also applies to any and all relevant materials. It does not cover use or acquisition of blood from patients as part of their standard healthcare (which is covered by regulations and the procedures of the NHS or other healthcare provider). It covers all forms of obtaining blood, including pin-pricks, venepuncture or arterial puncture, self-phlebotomy, and procurement of products through tissue banks or the NHS Blood and Transplant service. It does not apply to other human tissues, samples, or non-human blood. For study set up of 'Research Tissue Bank' studies or 'Study limited to working with human tissue samples (or other human biological samples)' please refer to Joint Research Management Office Standard Operating Procedures (SOP) 12a (here) and 13a (here).

When planning work with blood from human volunteers, it is also important to consider both of the following:

- The requirement for ethical review and approval to collect, use, and / or store human blood,
- The need to meet Human Tissue Authority (HTA) regulations for storage of human blood.

Please be aware that your Institute, Department, Unit, or Group may also have SOPs or additional requirements or guidance in place that should be adhered to in addition to this guidance.

Good practice for obtaining blood

Queen Mary and Barts Health have a duty of care towards volunteers who provide blood samples, regardless of whether the work requires ethical review or the volunteer is a patient, staff member or student, or is unaffiliated with Barts Health or Queen Mary. This duty of care has its roots in the Declaration of Helsinki and the principles of Good Clinical Practice.

Sample Storage and HTA Requirements

'Relevant material' does not need to be stored in a HTA licenced facility when it is being held according to the favourable opinion granted by an NHS Research Ethics Committee, or where it is being held for no more than seven days. If relevant material is held at the end of a study, it must be destroyed or, if appropriate, transferred to a HTA licenced premises within seven days.

If you have any questions related to relevant materials and their storage, please refer to the Human Tissue Resource Centre section of the JRMO website, found here.

Research ethics approval

In the first instance it is necessary to establish whether the project is research. Please use the Health Research Authority (HRA) decision tool (here). If the work is defined as research, ethical approval is normally required before any activities can take place. If none of the criteria above apply and the work is classified as research requiring blood from healthy volunteers with no long term storage, approval from the Queen Mary Ethics of Research Committee (QMERC) is typically required (for more information please visit the QMERC webpage here). If the work requires blood from NHS patients or individuals with specific attributes (e.g. diabetic patients), or is to be stored in a premises that do not hold an HTA licence, a favourable opinion from an NHS REC is required (for more information please visit the HRA webpage here).

Research ethics review is not required:

- Where samples will be used for evaluation or assessment of established diagnostic devices or in-vitro diagnostic kits then destroyed (performance assessment).
- For a programme for systematic monitoring or evaluation of a project, service or facility to ensure that standards of quality are being met (quality assurance).
- In laboratories as a reagent – e.g. as a source of feeder cells for maintenance of cell lines or clones, or substrate for growth of virus stocks (i.e. no knowledge is being derived from the blood itself).
- For training (e.g. in phlebotomy) or for a practical class and will not subsequently be stored or used for another purpose.

If you have any questions or would like advice please contact research.governance@qmul.ac.uk.

Risk assessment

Before blood can be taken from any volunteer or research participant a risk assessment to identify potential risks and methods for mitigating them should be completed. Please see here for risk assessment templates.

Training

All individuals taking blood from a volunteer or themselves should be sufficiently qualified and competent to do so by training and experience, and able to report any safety concerns.

An individual should have their competencies confirmed by their line manager prior to undertaking any work.

Environment

Blood samples should be taken in a manner that protects the safety and confidentiality of the volunteer and ensures that any incidents can be reported appropriately and safely resolved. Please ensure familiarity with local policies and procedures prior to commencing work.

Informed consent

Freely given informed consent should be obtained prior to taking any blood samples (see JRMO SOP 25). Potential participants should be given information regarding the nature of the intervention, significance, implications, and risks of their blood being taken and used, to allow them to make an informed decision. They should be provided explicit information in relation to all research usage and/or storage.

It is important to ensure accurate records are kept in relation to the samples given by each volunteer to avoid over-donation. The date and quantity of each donation should be recorded, and the individual taking blood should seek information from the volunteer about blood samples taken for any purpose within the preceding six months. All records should be kept for a minimum of 20 years, in line with the JRMO's Archiving SOP (20).

Restriction of volunteers

It is not appropriate to take blood samples from some volunteers:

- Anyone who could feel pressured or coerced into giving blood samples should not be approached for blood samples (please refer to JRMO SOP 25). Employees should not take blood samples from family members, friends, or anyone in their immediate group or laboratory. It is acceptable to seek consent from someone in a more senior role than the person taking consent, and it is not acceptable to seek consent from staff and students under their line management or supervision. For other blood sources see section below.
- Men should not donate more than 500ml of blood, and women should not donate more than 250ml of blood, over any six month period including samples given to other sources. Records for each individual should be maintained to track how much blood a volunteer has given within the past 6 months, to prevent over-donation from occurring.
- Where blood samples are to be used for culturing, samples from the individual conducting the work, or those who work in the same physical environment, should not be used due to the risks associated with *in vitro* transformation or genetic modification.

Unless explicitly stated in a NHS REC approved study protocol, the following individuals should not be approached for blood samples:

- Individuals who are pregnant.
- Individuals who are known to be a carrier of a contagious blood borne infection (e.g. HIV, Hepatitis B or C).
- Children under the age of 16.

- Potential participants who may lack the capacity to consent. More information related to the Mental Capacity Act and how it applies to research can be found here.
- Any underlying medical conditions. Please note this may be potentially sensitive, and asking volunteers about them could potentially breach the volunteer's confidentiality or cause the volunteer significant embarrassment or discomfort. It is therefore recommended that employees seek confirmation that all inclusion and exclusion criteria are satisfied rather than addressing each criterion individually, in a confidential environment.

Other blood sources

Institutes and Departments are responsible for implementing measures to avoid potentially coercive practices. Such measures may include:

- Purchasing excess blood donated to the NHS. An application should be submitted for each project seeking to obtain blood through NHS Blood and Transplant service (NHS BT), and needs approval from an NHS REC. More information can be found here.
- Tissue banks may hold suitable samples. They should be contacted directly to determine their requirements before samples can be released.
- Setting up a departmental or inter-departmental opt-in mailing list, to which all staff members can consent to being notified when blood samples are needed. All volunteers who then express interest in specific projects could consent for the blood samples required. Such a mailing list would be considered for approval by the QMERC, although specific projects requesting access to the mailing list would be likely to require separate QMERC or NHS REC approval to do so (please refer to the Ethical Approval section for further information).

Reporting concerns

If you become aware of any unethical behaviour (e.g. coercion of volunteers to provide samples), please follow the JRMO's Policy on Research Integrity

References and additional resources

Queen Mary University of London Occupational Health website
Queen Mary Health and Safety Directorate website

Barts Health NHS Trust Occupational Health website
Barts Health NHS Trust Resuscitation policy
Barts Health NHS Trust Venepuncture / Phlebotomy policy

Good Clinical Practice (ICH GCP E6 revision 2)

Mental Capacity Act (HRA website)

Human Tissue Authority (HTA) website
List of materials considered "relevant materials" under the Human Tissue Act 2004
Human Tissue Resource Centre website

JRMO SOP 12a (Sponsorship of Interventional Studies)
JRMO SOP 13a (Sponsorship of Research Studies)
JRMO SOP 20 (Archiving)
JRMO SOP 25 (Informed Consent)

http://www.jrmo.org.uk/performing-research/research-integrity/

Medical Research Council (MRC) ethics series - Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines

We thank the Central University Research Ethics Committee (CUREC) at the University of Oxford, the University of Birmingham, and the University of Greenwich as the primary sources for the guidance provided in this document.

Overview of Process: Obtaining and using human blood and tissue for research