Policy on the collection of blood samples for research or teaching

Blood for research purposes and the Human Tissue Act

The Human Tissue Act 2004 regulates the storage and use of human tissue for research purposes. It applies to human tissue whether or not it is sourced from the NHS. **Human tissue includes blood**, human primary cells and other material, other than gametes, which consists of or includes human cells (for further information on what constitutes human tissue, see the Human Tissue Authority's list of relevant material). Failure to comply with the Act can lead to imprisonment and/or a fine.

The legislation requires that the storage of human tissue for research purposes must be done either under a licence issued by the Human Tissue Authority or as part of a project which has received ethical approval from an NHS Research Ethics Committee (NHS REC). Storage includes storage for any length of time. University research ethics committees like Greenwich's University Research Ethics Board (UREB) are not authorised to approve the storage of human tissue for research purposes.

Because the University of Greenwich does not hold an HTA licence, **you must submit an application to an NHS REC if your research project will involve the storage of human tissue for research purposes**. NHS RECs can approve applications for research involving human tissue irrespective of whether it is sourced from NHS patients. Applications should be submitted via the Integrated Research Application System (IRAS). Once your application has been approved by the NHS REC, you should submit a copy to UREB for information.

Where human tissue is stored under approval from an NHS REC, you must ensure that the material is stored for no longer than the duration of your project's approval, or apply in good time to the NHS REC to extend the approval.

There are some exceptions to the requirement that human tissue must be stored under an HTA licence or under NHS REC approval:

- Where the storage is incidental to transport to another organisation (the transportation should take place in a matter of hours or days and in less than a week);
- Where the human tissue is stored with the intention of rendering it acellular. This should take place in a matter of hours or days and in less than a week. NB this exemption does not cover using human tissue for research purposes prior to rendering it acellular;
- Where the human tissue has been received from an HTA-licenced tissue bank with generic NHS REC approval.

The taking of blood for teaching purposes (e.g. to train students in how to take blood) is not covered by the Human Tissue Act.

1. Introduction

1.1 Collection of blood samples for research or teaching requires a consideration of: (i) the health and safety of the donors, (ii) the health and safety of the collectors as well as (iii) an ethical overview of the experiments proposed. Consequently the following should be observed:

1.2 Individuals working with or handling blood should be appropriately trained.

1.2.1a Training for individuals taking blood by venepuncture will be provided annually at the expense of the faculty (when required for teaching) and at the expense of the research grant holder when for research. Training will be administered (organised) locally, through faculty liaison with the external training provider (see section 1.2.2).

1.2.1b Medically trained staff with up to date CPD records that include phlebotomy (*i.e.* a physician licensed to practice in the UK), will be exempt from additional, unnecessary training.

1.2.1c Where less than 1mL of blood is being drawn by methods not requiring venepuncture, training may be provided locally by a suitably trained academic or technician (section 1.2.1-1.2.3).

1.2.2 Training may be provided by any competent organisation that meets NHS standards (*i.e.* NHS Skills For Health CHS132).

1.2.3 Individuals taking blood will need to be able to demonstrate that they have undertaken (and where appropriate passed) this training (section 1.2.2).

1.2.4 The training for students and staff handling (but not taking) blood will be provided locally by an experienced academic or technician. Local records of this training will be maintained.

1.2.5 Non-compliance with the aforementioned training will result in cessation of the research project / teaching provision until training has been undertaken. Failure to comply with these directives will be deemed a serious breach of procedure and appropriate action taken. This may result in disciplinary action and or legal action being taken against the offender.

1.3 Blood from screened, anonymised sources such as out-of-date or surplus transfusion blood should, where practicable, be used instead of fresh blood from colleagues or students. The National Blood Service (NBS) will release blood for non-clinical purposes, subject to an initial approval process.

1.4 When blood is taken, the total (including donations elsewhere) should not exceed 500ml in a 6-month period for men or 250ml in 6 months for women. Consequently the donor should be asked about blood donated or taken over the last 6 months prior to the procedure. Local blood donations will be recorded and those records maintained locally (see section 2) by the

academic or technician in charge of either the research project or teaching provision.

1.5 No one should work with his or her own blood.

2. Records and storage

2.1 A record of donations, the total collected, the purpose for which the blood was used and accurate disposal records should be maintained by either: the academic or technician in charge of teaching provision or, in the case of research projects, the academic in charge of the project (*i.e.* the Principal Investigator (PI)).

These records should be both sufficiently accurate and detailed enough to identify the individual study being performed (by reference number(s)) as well as the donors and how much blood has been taken from each donor (cumulatively as well as on a given day). These records should be stored securely in the department for 10 years in case of subsequent queries.

As indicated above (see 'Blood for research purposes and the Human Tissue Act'), the University does not hold a licence from the Human Tissue Authority (HTA) for the storage of human tissue (including blood) for research purposes. Blood should only be stored for research if it is associated with a project which has been approved by an NHS Research Ethics Committee (NHS REC). It may also be stored where the storage is incidental to transportation to another organisation; where the material will be rendered acellular within a short space of time (provided research is not carried out on the material prior to rendering it acellular); or where it has been received from an HTA-licenced tissue bank with generic NHS REC approval.

3. Ethics

3.1 Blood donation for teaching or research must always be voluntary. Colleagues or students should not be placed under pressure to give samples. All potential donors should be able to refuse to give blood, without having to give an explanation for a refusal. Any personal information obtained in connection with collection or use of a sample must be held in confidence.

3.2 Volunteers should be told before agreeing to donate how much blood is to be taken, what the sample is going to be used for, and what tests for markers of disease, if any, are to be carried out on the sample while it remains traceable back to the donor.

3.3 Written consent, confirming that donation is voluntary and informed should be obtained. The donor should also be made aware of this policy which will be (at a minimum) available as a public document held and distributed through the University's website.

3.4 As indicated above (see 'Blood for research purposes and the Human Tissue Act'), university research ethics committees (e.g. Greenwich's University

Research Ethics Board) are not authorised to give ethical approval for the storage of human tissue (including blood) for research purposes. Ethical approval should be sought from an NHS REC through IRAS. A copy of the approval should be provided to the University Research Ethics Board.

4. Blood-borne infection

4.1 The University has a duty to protect staff and students from accidental contamination with contagious blood borne disease such as HIV, hepatitis B and hepatitis C. All people coming into contact with human blood should have been immunised against hepatitis B and have a current booster vaccination (*i.e.* less than 5 years since last booster). The cost of doing this should be covered under the same criteria applied to training (see section 1.2.1).

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