Taking Blood Samples from Colleagues or Students for Research and Teaching

OHS Policy Document 1/03

Appendices in Word and PDF format

This policy document provides guidance to be followed when blood samples are taken from colleagues or students. It has been drafted in consultation with other universities g. It should be read in conjunction with Appendix 2 (Work with Blood and Human Tissue) of the University Guidance Note S5/09 – Biological Health and Safety, and the Occupational Health Policies Immunisation (OHS 1/01), and Needlestick Injuries (OHS 2/03).
The same legal and good practice requirements apply to samples from colleagues as they would to any other participant in blood donation or research. Consideration should be given to the processes for obtaining appropriately informed, and freely given, consent; feedback of any clinically significant findings; and protection of colleagues' confidentiality.

Ethical review and approval should be obtained (from either a University or NHS Research Ethics Committee) for the taking and use of human tissue samples (including, but not restricted to, blood, urine, saliva and faeces), except in the following cases:

- where, as part of their training or employment, students/staff are being taught how to take blood (phlebotomy training), and the blood will not subsequently be stored or used for another purpose;
- where samples will be used for evaluation or assessment of established diagnostic devices or in-vitro diagnostic kits then destroyed (performance assessment). (n.b. use of tissue in the development of new diagnostic devices/kits would be classed as research requiring ethical review);
- where material is used in a programme for systematic monitoring/evaluation of a clinical project, service or facility to ensure that standards of quality are being met (Quality assurance);
- where the tissue sample is being used in research 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 tissue itself);
- where blood is to be taken as part of a practical class and will not subsequently be stored or used for another purpose.

In such cases, consent should still be obtained from the tissue donor, but if the sample is being taken for any of the above purposes, this use will not require formal review and approval by either a University or NHS Research Ethics Committee. **The Central University Research Ethics Committee (CUREC) webpage http://www.admin.ox.ac.uk/curec /provides full information on how to apply for ethical review and approval as appropriate.**

Collection of blood samples from students or colleagues presents the same potential risks to the health and safety of the person taking or using the blood sample as does the collection of samples from patients or volunteers. The same risk assessment and safety procedures for the person taking or using the blood should, therefore, be followed, and consideration must also be given to the health and safety of donors, and to important ethical considerations which may arise.

The University requires that all individuals working with or handling unscreened blood be registered with the University Occupational Physician. Such registration is compulsory. The information on the registration form will be used by the Occupational Health Service to initiate and maintain appropriate health surveillance. As required, this will include Hepatitis B immunisation and associated immune response checking. Individuals who do not respond to immunisation will be further advised by the University Occupational Physician. (UGN S1/95 Appendix 8.6).
Negative tests for known blood-borne viruses do not rule out the possibility of infectious agents being present in a sample. All blood and serum samples must be treated as potentially infectious. Users should read the relevant University policy documents (OHS 1/01 Immunisation Policy, OHS 2/03 Needlestick Policy; UGN S1/95) - in summary:

use Vacutainer™ collection equipment whenever feasible;

wear gloves;

never recap needles;

used equipment should be discarded immediately after use;

discard syringes and needles as a unit; never carry used sharps;

sharps disposal containers should be available at the point of use;

never re-use equipment;

discard sharps containers when three-quarters full;

report all accidents to the Safety Office on an accident form and seek advice from the Occupational Health Service. [ref. Sharps, Splash & Bite Injury Policy (329kb)].
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 (Appendix 3a, Appendix 3b, and Appendix 3c, appended).
If blood from the NBS is not used, volunteers should not donate if they may be infected with a blood-borne virus and should not become a regular donor if they may be at risk of infection from, for example, sexual partners. The information sheet (Appendix 1-Donor Information sheet, appended) can be used to give this information to potential volunteers to avoid embarrassment or inadvertent breach of confidentiality. The sheet lists exclusion criteria relating only to infection control and donor protection. Depending on the project, the investigator may need to add specific additional exclusion criteria to avoid use of samples that may affect results, eg the donor taking drug treatment or suffering from a specific disease.

If blood is to be taken regularly, the total (including donations elsewhere) should not exceed 500ml in a 6 month period for men or 250ml in 6 months for women. No-one should work with their own blood samples if the intention is to transform lymphocytes. In the event of an accidental exposure, the immune system will not challenge the transformed cells. Similarly, individuals should not work with the blood of colleagues with whom they share work space. Measures must be in place to ensure that there is minimal risk of people feeling pressured or coerced to participate. This may take the form of advertising for volunteers outside of the immediate laboratory group or department, or putting in place a hierarchy, i.e. consent can only be sought from someone more senior than the person seeking to recruit (Post-doctoral researcher can recruit a Principal Investigator for example, but not the other way around).

Blood should be drawn only by a competent person or by someone working under the direct supervision of a competent person. A competent person is a registered medical practitioner, a trained phlebotomist, or another person who is working under the control of a University department or institution and who has been trained in the United Kingdom and certified as competent in writing by a registered medical practitioner or a recognised training phlebotomist. An individual may require refresher training if they have not practised their phlebotomy for over one year. This will depend on the individual's experience and training and further advice may be sought from the Occupational Health Service on this matter. These training criteria need not apply when only a finger prick blood sample is required.

Undergraduates should not draw blood from one another unless the procedure forms part of their clinical training and is done under direct supervision by a registered medical practitioner.

Blood should be taken only in a quiet area set aside for this purpose:

always sit, or preferably lie, the donor down before taking blood;

whenever feasible, samples of >20ml should be taken with the donor lying down on a couch;

if taking blood with the donor seated, ensure there is sufficient space immediately adjacent to lie the donor down should s/he faint;

for samples of >50ml the sample must be collected in a clinical room (as defined in The Health and Safety (First-Aid) Regulations 1981 ACOP and Guidance, sections 40 and 41) with a registered medical practitioner, registered nurse or first aider qualified in resuscitation available to assist with faints;

the Occupational Health Service may be able to assist with sample collection, other service commitments permitting;

for samples of >200ml a haemoglobin estimation should be carried out prior to collection (the Occupational Health Service can advise on this). Samples should not be taken from men if haemoglobin is lower than 13.0 g/dl. Samples should not be taken from women if haemoglobin is lower than 12.0 g/dl.

A record of donations, the total collected, and the purpose for which the blood was used should be maintained by a responsible person, such as the supervisor or course leader, together with the study reference number(s) or other personal identifiers. These records should be stored securely in the department in case of subsequent queries from donors or from the Health and Safety Executive (HSE). There are no clear guidelines on storage of this information, so the OHS recommends storage for at least 40 years, in line with the legal requirements of the HSE for health surveillance records *(Control of Substances Hazardous to Health Regulations 1999)*.

Blood donation 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. All labelling should be coded in order that donors cannot be identified by the samples. Donors of samples with desirable biological characteristics should not be unfairly targeted.

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. (Appendix 1 - Donor Information sheet, appended).

For repeat donations, consent should be re-affirmed or newly sought if the information supporting the consent has changed since the last donation. It may be necessary to go through the exclusion criteria to check that a donors circumstances haven't changed since the previous donation, i.e. new diagnosis of disease, donor taking a new drug treatment.

Verbal consent is normally sufficient, provided the donor has been given access to the information in Appendix 1 (appended). If verbal consent is obtained this should be clearly documented in laboratory records, detailing when consent was obtained and the purposes for which the consent was given. The need for written consent must be considered by the **e**thical review process. **The Central University Research Ethics Committee (CUREC) webpage http://www.admin.ox.ac.uk/curec / provides full information on how to apply for ethical review and approval as appropriate.**

Donor information sheet (19kb)	Donor information sheet (19kb)
Donor consent form (6kb)	Donor consent form (23kb)
Obtaining screened blood (20kb)	Obtaining screened blood (20kb)
Application form for supply of non-clinical materials (8kb)	Application form for supply of non-clinical materials (20kb)
Application form for supply of non-clinical materials - approved application (5kb)	Application form for supply of non-clinical materials - approved application (23kb)

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