Guiding Principles for Self-Experimentation

Self-experimentation in research is a data-driven approach in which the experimenter conducts the experiment on themself, using a single case, i.e. where the experimenter is also the subject.

Approval for self-experimentation is required following normal process for ethical approval. When applying for approval to undertake self-experimentation, a proposal should address the following points:

- Is there a conflict of interest in the proposal?
- Is there a mechanism by which the experiment can be observed by a peer researcher?
- Is there a mechanism by which the results are confirmed by a peer researcher?
- Are there any restrictions imposed by any future publisher which would suggest the results could not be disseminated.
- Is there any potential harm to the experimenter or others who are involved?
- Is there a legitimate reason for the study?
- Does Occupational Health need to notified?

The researchers need to know the rules of the publishers they intend to use and if this type of research is accepted by the publisher, before the research is submitted for ethics approval. All safeguards must be in place to mitigate any risks to the participant and data.

Guidance for regarding colleagues donating samples for research projects or validation of equipment or other methodologies.

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 a 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). (e.g. 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 a NHS Research Ethics Committee.

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 Trust requires that all individuals working with or handling unscreened blood be registered with the Occupational Health. Such registration is compulsory. The information on the registration form will be used by the Occupational Health 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 Trusts Occupational Health team.

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 Trust policy documents (Immunisation Policy, 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 on DATIX and seek advice from the Occupational Health team.

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.

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 should 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, e.g. 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 the Trust 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 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 they feel faint;
- for samples of >50ml the sample must be collected in a clinical room with a registered medical practitioner, registered nurse or first aider qualified in resuscitation available to assist with faints;
- the Occupational Health 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 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; the legal requirement for HSE for health surveillance records (Control of Substances Hazardous to Health Regulations 1999) is at least 40 years.

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.

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 donor's 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 information relating to the procedure in a clear and understandable format. 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 ethical review process.