



Central University Research Ethics Committee (CUREC)

Approved Procedure: IDREC_24_Version 2.0

Title: Taking Urine, Saliva and/or Venous Blood Samples from Healthy Adult Volunteers

TAKING URINE, SALIVA AND/OR VENOUS BLOOD SAMPLES FROM HEALTHY ADULT VOLUNTEERS

1. SCOPE

A number of studies performed in the University involve taking samples of urine, saliva and/or venous blood from participants. A wide variety of tests may be performed on these samples, which can be used to address a range of research questions.

This approved procedure is intended for use by researchers operating in an appropriate clinical facility (see below for definition) within the University of Oxford, who wish to collect samples of urine, saliva and/or venous blood from study participants. The approved procedure covers the taking of the samples - it **does not** cover the subsequent tests performed on those samples, which must be specifically justified in the CUREC application.

As certain tests will de facto require an HRA REC approval rather than CUREC application:

Before submitting a CUREC application for a study involving the testing of urine, saliva and/or blood samples, details of the samples being taken, the tests carried out on the samples, storage and disposal of the samples, and the procedures which will be followed in the case of identifying abnormal results should be sent to the IDREC committee officer (ethics@medsci.ox.ac.uk). The committee officer will then seek the advice of a suitably qualified member of the committee about whether the application is likely to be suitable for review via the CUREC system.

This approved procedure does not cover the administration of any drug (or other substance) intravenously, intramuscularly or sub-cutaneously.

This approved procedure is intended for use when the following criteria are met (n.b. the CUREC application must explicitly demonstrate how these criteria are met):

- The study involves healthy adults (over the age of 18) who are able to provide informed consent
- Where blood samples will be taken, a maximum of 50ml of peripheral venous blood will be taken from the anti-cubital fossa, lower arm or back of the hand by a member of staff trained in phlebotomy (see section 3 below)
- Where blood is taken, this is done in an appropriate clinical facility (see below)
- The subsequent samples are not stored for more than 7 days before being rendered acellular or destroyed (this is a requirement of the Human Tissue Act)
- Staff involved in the collection, handling, transport or storage of samples have received appropriate training (e.g. training may be provided as part of professional training or specific courses within the University, see: <https://www.admin.ox.ac.uk/safety/oxonly/biosafe/biotrain/>)



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1.1 Phlebotomy

Persons drawing blood must perform the procedure as per the guidelines issued by Oxford University Hospitals NHS Trust:

http://www.who.int/injection_safety/1card_labTesting_web.pdf?ua=1

1.2 Appropriate Clinical Facilities for Phlebotomy

Appropriate clinical facilities contain the required levels of equipment, staff and services to safely perform phlebotomy. Specifically this includes:

Equipment

tourniquet, latex gloves, vacutainers, sterile needles including butterfly needles, cotton wool, alcohol wipes, plasters, clean equipment trays and medical tape. The facility must have an appropriately private clinical room with clean, wipeable surfaces, in which phlebotomy can be performed and which contains a comfortable chair or bed for participants with a cushion/pillow/arm brace to support participants' arms while blood is being drawn. Lastly, basic facilities for dealing with participants who faint (or feel faint) during phlebotomy should be provided—somewhere they can lie down (with their legs raised if necessary) and equipment for monitoring blood pressure.

Staff

Phlebotomy will be performed by a trained member of staff (see section 3 below). There must always be one other staff member within the building (who is readily contactable) when phlebotomy is performed.

Services

An appropriate sharps disposal service must be in place (i.e. there should be sharps disposal bins which are regularly checked and safely disposed of). The facility must have a needle stick policy in place, which includes a clear statement about who to contact in the event of a needle stick injury. There must also be an appropriate laboratory for processing the blood samples, or an established safe system for transporting the samples to such a laboratory.

1.3 Collection of Urine and/or Saliva Samples

Urine and/or saliva samples will be collected by the participant following explanation of the collection process by a researcher. Appropriate equipment must be provided to participants (i.e. sealable containers for Urine samples or saliva collection tubes for saliva samples). Samples may be taken at the research site or elsewhere (e.g. the participant's home) as required by the study. In studies involving the transport of samples (e.g. samples taken in a participant's home which must be transported to the research site) it is the Principal Investigator's responsibility to ensure that this is done in line with regulations for the transport of hazardous materials (University courses covering this topic are provided: <https://www.admin.ox.ac.uk/safety/oxonly/biosafe/biotrain/>).

2. TRAINING OF RESEARCH STAFF

It is the responsibility of the study Principle Investigator to ensure that all researchers involved in collecting samples have been adequately trained in the procedures used to collect, handle, transport and store samples. Researchers who will take blood must have completed formal training in



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phlebotomy. This may have been during broader clinical training (e.g. doctors, nurses, trained phlebotomists) or, for non-clinical staff, the phlebotomy training course provided by various NHS Trusts or external agencies. As some of these courses involve training on mannequins, staff who complete them must only take blood from participants under direct clinical supervision until a fully trained clinician (i.e. doctor, nurse, phlebotomist) is satisfied that they may perform the procedure safely on their own. As participants may sometimes faint before, during or after the taking of blood, at least one member of staff (present in the building) must be trained in basic life support. Lastly all staff performing phlebotomy must have evidence of Hepatitis B immunity following immunisation and be fully up to date with the standard vaccination schedule, including tetanus.

3. METHODS FOR RECRUITING PARTICIPANTS

Potential participants will be recruited as per existing CUREC guidelines.

4. INFORMATION PROVIDED TO PARTICIPANTS

Participants should be fully informed of all procedures involved in the research study. For studies involving the taking of biological samples the Participant Information Sheet should describe the number and timing of the samples as well as a brief description of the reason for the sample(s). For blood samples, the volume to be taken must be stated. The PIS should also contain information about what will be done with the samples (i.e. whether they will be stored for any length of time, when they will be destroyed). The information sheet should include a statement that, before the sample is taken, consent will be sought to enable the researchers to forward the results to the participant's GP in the case of a clinically significant abnormal result. Lastly, for studies involving phlebotomy, the Information Sheet should contain a brief section on the possible risks, most commonly fainting, pain and bruising.

Example sections of the Participant Information Sheet are provided below:

“What will happen during the study?

A total of ___ blood/saliva/urine samples will be taken during the study. These samples will be used to check the levels of ___ in the blood/saliva/urine.

What are the risks of taking part in the study? - example for studies including phlebotomy

Although taking blood is a very safe procedure, it can be uncomfortable and may result in fainting, localised pain, or bruising.

What will happen to my samples?

Your blood/saliva/urine samples will be analysed in the laboratories of _____. The samples will be kept for a maximum of 7 days and will then be destroyed (*NB the samples may be kept for longer if the cells within them are destroyed*). Only the named researchers of the study will have access to the results of the tests.”

The Information Sheet is written in simple but non-patronising language. Most word-processing packages provide readability statistics for a document, and one should aim for a 12-year-old (Year 7) reading level for adults.



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Current guidelines for the [Information Sheet for Participants](#) can be found on the CUREC website.

5. CONSENT OF PARTICIPANTS

The informed consent of participants should be recorded on a form which includes explicit consent for the taking, storing and testing of the samples. The form must also contain an item in which explicit consent is obtained for contacting the participant's GP in the event of a clinically significant abnormal result (researchers may also consider restricting recruitment of participants to those already registered with a GP) and an explicit statement that the participant understands that they will be informed in advance if findings are to be forwarded.

Example items are provided below:

I understand that a blood/saliva/urine sample will be taken during the study and that this sample will be tested for _____. I understand that the sample will be destroyed after completion of this test or if I withdraw my consent for the test.

I consider these samples a gift to the University of Oxford and I understand I will not gain any direct personal benefit from this.

I understand that my General Practitioner may be informed if the result of the blood/saliva/urine test is significantly outside the normal range expected for that test and that I will be notified in advance if any findings are to be forwarded to my GP

Guidance on the informed consent process can be found at:

<http://www.admin.ox.ac.uk/curec/resources/informed-consent/>

6. FINANCIAL AND OTHER REWARDS TO PARTICIPANTS

Compensation to participants may be offered in line with existing CUREC guidelines.

7. POTENTIAL RISKS TO PARTICIPANTS/RESEARCHERS/OTHERS AND WHAT WILL BE DONE TO MINIMISE

7.1. Risks to participants

Common risks associated with phlebotomy are pain during the procedure and bruising (with associated pain afterwards). These risks will be minimised by ensuring that all staff are fully trained in phlebotomy. Bruising after the event will also be reduced by promptly applying pressure on the puncture site after the needle is withdrawn. All participants will be fully informed about these risks in the Participant Information Sheet.

The worry associated with taking blood may cause some participants to feel unwell or faint before, during or after the procedure. The risk associated with this will be reduced by having an adequately



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equipped facility for performing the procedure (see above) and having a staff member trained in basic life support.

Although phlebotomy is a very safe procedure, it does create a puncture wound on the skin which may very rarely lead to infection around the puncture site. The risk of this will be minimised by ensuring strict hygiene during the procedure and by not recruiting participants who are at increased risk of infection. In the event that a participant reports symptoms of an infection (local redness, swelling, pain or discharge of pus) they should be referred to their GP or to A&E urgently.

7.2. Risk to Researchers/Other Staff

Taking blood carries a risk of needle stick injury to the phlebotomist, which in turn carries a risk of exposure to blood borne infections. This risk will be minimised by a) ensuring staff are adequately trained in phlebotomy, b) ensuring staff have been vaccinated against, and show immunity to Hepatitis B and c) having a local policy for needle stick injury which describes the process of being assessed for and receiving post exposure prophylaxis. The risk of exposure to infection is increased in all those involved in the collection, transport, storage or processing of any biological material. This risk will be minimised by ensuring all staff involved in these procedures are adequately trained and that the appropriate equipment and facilities for the safe handling of samples is provided.

7.3. Organisational Risk

If samples are kept beyond 7 days prior to being rendered acellular then the University would be in contravention of the Human Tissue Act. This risk is minimised by requiring all applicants to specify in their application the procedures in place for either a) destroying the sample within 7 days or b) rendering it acellular within this time period.

8. MONITORING AND REPORTING OF ADVERSE OR UNFORSEEN EVENTS

Adverse or unforeseen events will be reported to the departmental safety officer in the first instance and may be followed up by the University Safety officer if deemed necessary. The Research Ethics Committee will also be notified of such events.

9. COMMUNICATION OF RESULTS

Results of the study will be communicated via the normal channels as per existing CUREC guidelines.

10. DUTY OF CARE ISSUES / CONFIDENTIALITY

Duty of care and confidentiality issues arise largely due to the results of tests on the samples, rather than taking of the samples per se. This approved procedure does not cover issues concerned with the testing of the samples, although it is expected that studies will have in place a system by which the results of the tests performed are reviewed and, where necessary, further investigations or referrals are made. The confidentiality of the results are also expected to be maintained as per CUREC guidelines.



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11. DATA PROTECTION ISSUES

Data protection issues arise from the tests performed rather than sampling procedures. The CUREC guidelines on data protection should be followed.

12. FURTHER INFORMATION

WHO guidelines on drawing blood:

http://whqlibdoc.who.int/publications/2010/9789241599221_eng.pdf

13. CHANGE HISTORY

Version No.	Significant Changes	Previous Version No.
1.0	Incorporates reference to the University Safeguarding Code of Practice and related requirements. Retitled 'Approved Procedure' (previously 'Protocol'). Approved by CUREC, 19 November 2015	N/A
2.0	Expanded to include urine and saliva samples in addition to venous blood	1.0