NHS, Invasive or Clinical Research (NICR) Committee

Physiology, Exercise & Nutrition

Research Group



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

# TAKING URINE, SALIVA 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 laboratory within the University of Stirling, 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.

This approved procedure is intended for use when the following criteria are met (n.b. the NICR 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 50 mL of peripheral venous blood will be taken per visit from an arm or hand vein by a trained phlebotomist
* Researchers involved in the performance of phlebotomy have received appropriate training

## Appropriate Laboratory Facilities for Taking Venous Blood Samples

Appropriate laboratory facilities contain the required levels of equipment, staff and services to ensure the procedures conform to the SOP and participant safety is guaranteed. Specific equipment includes:

Equipment

tourniquet, latex gloves, vacutainers (if necessary), 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).

Staff

A trained phlebotomist will perform the procedure. There must always be at least one other, readily contactable, staff member within the building when phlebotomy is performed.

Services

An appropriate sharps disposal service and biohazard waste management system must be in place (i.e. there should be sharps disposal bins and biohazard waste bags available 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.

## 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 transport is done in line with regulations for the transport of hazardous materials.

# 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 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 immunization and be fully up to date with the standard vaccination schedule, including tetanus.

# PROCEDURES

All required equipment should be prepared prior to the procedure. Appropriate hand hygiene procedures should be adhered to (i.e. washing hands with soap). An appropriate, palpable vein is located, preferably at the bend of the elbow. A tourniquet is applied ~1-3 inches above the selected site. The participant is asked to squeeze their fist a few times to increase the prominence of the vein. The site is disinfected with 70% isopropyl alcohol (alcohol wipe) and allowed to dry. The vein is anchored by holding the patients arm and placing the thumb below the venipuncture site. The vein is then swiftly entered with the needle at a small angle to the skin. The blood sample(s) is/are collected. The needle is removed AFTER releasing the tourniquet, and the participant is given a clean folded tissue or dry cotton wool ball to apply pressure to the site to reduce bruising. The participant is asked to keep their arm straight while doing this for a couple of minutes, or until bleeding at the puncture site has stopped. Needles will be disposed of in the sharps bin immediately after removing from the arm. Any other potentially contaminated materials, including tissues and gloves, are disposed of in the appropriate way (sharps bin or biohazard waste bag). After finishing the procedure, hands are washed.

# POTENTIAL RISKS TO PARTICIPANTS/RESEARCHERS/OTHERS AND WHAT WILL BE DONE TO MINIMISE THE RISKS

## 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. An adequately equipped facility for performing the procedure (see above) and having a staff member trained in basic life support will reduce these risks.

Although phlebotomy is a very safe procedure, it does create a puncture wound on the skin that may very rarely lead to infection around the puncture site. Ensuring strict hygiene during the procedure and not recruiting participants who are at increased risk of infection will minimize this risk. 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.

There are no known risks of saliva or urine sampling for the participant.

## Risk to Researchers/Other Staff

Taking venous blood samples carries a risk of needle stick injury to the researcher, which in turn carries a risk of exposure to blood borne infections. This risk will be minimised by a) ensuring staff are adequately

trained, b) ensuring staff have been vaccinated against, and show immunity to Hepatitis B. 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 and disposal of waste is provided.

# METHODS FOR RECRUITING PARTICIPANTS

Potential participants will be recruited as per existing NICR guidelines and the inclusion and exclusion criteria of the particular study.

# 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.

Current guidelines for the Information Sheet for Participants can be found on the NICR website.

# CONSENT OF PARTICIPANTS

The informed consent of participants should be recorded on a form that 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.

Guidance on the informed consent process can be found on the NICR website.

# 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 NICR

Committee also will be notified of such events.

# FINANCIAL AND OTHER REWARDS TO PARTICIPANTS

Compensation for time commitments, travel and parking may be offered to participants in line with existing PENRG policy and will be determined separately for each individual protocol.

# COMMUNICATION OF RESULTS

Results of the study will be communicated via the normal channels as per existing PENRG practice.

# 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, but it is expected that each study will have a system in place 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 NICR guidelines.