For Office Use Only: EHSREC No: EHSREC10-RA02.

UNIVERSITY OF LIMERICK RESEARCH ETHICS COMMITTEE

RISK ASSESSMENT FORM – PROCEDURES INVOLVING HUMAN SUBJECTS

Procedure No	EHSREC10-RA02.
Title of Procedure	Blood sampling by cannulation of a superficial arm vein.
Name of Assessors	Prof. P. Jakeman/ and Dr J. Cooke
Assessment date	10 / 06 / **2010**
Does this procedure already have ethical approval?	**Yes**
If so, enter ethical number and expiry date	**Approval No: ULREC 09/07** **Date expires: 31 / 12 / 2010**

1	**Please provide a brief description of the procedure**

1. The subject is pre-screened by the clinician.
2. The subject lies supine with the head supported on an incline couch
3. A superficial arm vein is located
4. A 19-21 gauge cannula is inserted into the vein by the clinician
5. Normal saline (0.9%) is flushed to maintain patency
6. Blood samples are withdrawn (4ml) at prescribed intervals

2	**Location in which the procedure may take place**	
	√	Project Laboratory (PG034)
	√	Research Laboratory (PG050)
3	**Eligibility of subject(s) to be used**	
	√	UL student (U.G. or P.G.)
	√	University staff or campus personnel
	√	Members of the general public engaged in research projects granted ethical approval.
4	**Potential risks. To be explained <u>before</u> obtaining consent**	
	√	Minimal discomfort only

Risk to the subject:

The risk to the subject is considered to be minimal. The subject may feel some discomfort. This discomfort may include feelings of nausea and light-headedness. The subject remains supine for the insertion of the cannula. Once stable the subject remains seated. Venepuncture can leave a bruise that normally clears within 2-3 days.

Risk to the experimenter:

The objective is to decrease the risk of exposure to blood borne diseases, such as hepatitis B and AIDS. Standard operating procedures are appended. The following are precautions specific to this procedure:

1. Care must be taken to avoid accidental wounds from sharp instruments contaminated with potentially infectious material. This means that sharps are promptly placed in puncture-resistant containers used solely for such disposal. These containers are biohazard labelled and disposed of by incineration.
2. Gloves are to be worn. Gloves are to be worn when handling blood specimens or items that could have been contaminated with blood or other body fluids. Gloves are to be disposed in clinical waste containers and disposed of by incineration.
3. Hands are to be washed thoroughly following completion of this procedure. Other skin surfaces are to be washed immediately if they become contaminated with blood.

5	**Action to be taken in the event of a foreseeable emergency**

Please provide a clear statement of appropriate action including contact names and telephone numbers.

Action to be taken with reference to the subject fainting:

1. Check vital signs airways, breathing and circulation (ABC). Subjects are placed supine with lower limbs raised to improve blood flow and counteract the vasovagal influence. Check blood pressure.
2. Apply CPR if required.
3. First aid personnel would be contacted, and an ambulance would be requested if necessary.
4. The University Medical Centre number is 2534 (9:00 am to 5:00 pm)
5. The University emergency number is 3333

Action to be taken if researcher is punctured with contaminated sharp

1. Immediately wash the punctured site in running water
2. Contact health centre or medical doctor to assess risk

6	**Level of supervision required for procedure**

√	Named researcher who is trained and experienced in the performance of this procedure

7	**Other documentation required for this assessment?**

√	Standard Operating Procedure

Others, please specify

Standard Operating Procedure

Cannulation of a Peripheral Arm Vein

June 2010

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Background

Venous cannulation is the insertion of a flexible tube containing a needle into a blood vessel. This document has been constructed to provide general guidance to study personnel on how to conduct the procedures involved in the repeated sampling of venous blood from a cannula inserted into a superficial arm vein.

Personnel

For the purposes of this document, a medic is defined as a doctor with full registration provided by the Irish Medical Council. An “appropriate delegated person” is one who has received training and is experienced in the performance of the specified procedure.

Immunisation

Current and effective immunisation against Hepatitis B is required for all research and ancillary staff who undertake cannulation or handle/process blood samples.

1. Insertion and Management of a peripheral venous cannula

Venous cannulation is the insertion of a flexible tube containing a needle into a blood vessel.

Procedure

1. The Medic is responsible for inserting a peripheral venous cannula. This duty cannot be delegated.
2. Prior to the procedure the medic must ensure the correct participant is identified.
3. The medic will then explain the procedure to the participant.

4. The medic must ensure constant attention to an appropriate aseptic technique whilst procedure is being performed.
5. The medic or appropriate delegated person will clean and prepare trolley/work area.
6. The medic or appropriate delegated person will prepare all equipment required ensuring all study specific equipment is obtained.

Equipment required:

- Sharps bin
- Appropriate sized cannula (20 gauge)
- Sterile bung
- Micropore tape
- Non sterile gloves
- Mediswab
- Tourniquet
- Sterile dressing
- Sterile Gauze
- Trolley or work tray
- Sterile Syringe(s) 2 and 5ml
- Flushing agent (Sterile Normal (0.9%)Saline checked for expiry date)

7. The medic or delegated person must prepare the working environment to ensure comfort, light, room to manoeuvre, position and privacy of the participant.
8. The medic should wash his/her hands and check for any visible broken areas of skin and apply waterproof dressing if required.
9. The medic must apply non sterile gloves.
10. The medic will apply the tourniquet and select a vein.
11. The medic must slightly relax the tourniquet.
12. The medic must prepare the participants skin at the selected insertion site with a mediswab, for at least 30 seconds and allow the area to dry.
13. The medic must not re palpate the vein or touch the skin.
14. The medic will re tighten the tourniquet.
15. The medic must remove the needle guard and inspect the cannula for any faults. If any faults are identified dispose of the cannula in an appropriate sharps container.
16. The medic must hold the participant's hand/wrist/forearm using the thumb, to keep the skin taut. Care must be taken not to contaminate the site.
17. The medic must place the needle about ¼ inch below the proposed site for cannulation, with the bevel facing up.
18. The medic must elevate the angle of the cannula to 15-25 degrees and insert the cannula into the skin (fragile veins require a lower angle of insertion).

19. Once the vein has been located with the needle the medic must level the angle for insertion.
20. The medic should note a back flow of blood into the cannula chamber, unless the vein is small.
21. The medic must ensure the line of the vein is followed, whilst withdrawing the needle slightly. If there is any sign of swelling, haematoma, pain or resistance the vein wall may be ruptured. The tourniquet must be released and the cannula and needle must be removed immediately and pressure applied with cotton wool.
22. When flash back is seen along the length of the cannula the medic will advance the cannula until it is fully inserted into the vein.
23. The medic will release the skin tension and relax the tourniquet.
24. The medic must apply digital pressure to the distal end of the cannula to prevent blood spillage.
25. The medic will remove the introducer needle and discard into an appropriate yellow sharps container.
26. The medic must secure a sterile bung to the end of the cannula.
27. The medic must secure the cannula to the participant using a sterile dressing.
28. The medic must test the patency of the cannula with a minimum of 2mls of sterile sodium chloride 0.9% for injection and then cap it off.
29. The medic must ensure the participants feels no discomfort, and observe the cannula site for signs of swelling or redness.
30. The medic must dispose of all equipment used safely. The medic must keep accurate records regarding the cannula. The following Information must be recorded:
    i. The length & gauge of the cannula
    ii. Date and time of insertion
    iii. Number and location of attempts
    iv. Identification of the site
    v. Name and person placing the device
    vi. Type of dressing
    vii. Patient's tolerance of the device
31. The medic or appropriate delegated person must visually inspect the cannula site prior to any use, observing for signs of swelling, redness, or tenderness. If any symptoms are noted the cannula must be removed and the symptoms documented in the record.

2. Obtaining a blood sample from a peripheral venous cannula

Purpose

Venous access in this case is required for serial sampling in a research setting. Multiple blood samples are obtained from a peripheral venous cannula to avoid repeated venepuncture to the research participant.

Procedure

The principal investigator is responsible for ensuring that blood is obtained from a cannula according to study protocol. The duty of blood draw can be delegated to other appropriately qualified members of the research team.

1. The investigator or delegated person will ensure all study specific documentation is prepared and signed by subject according to informed consent
2. The investigator or delegated person must ensure that blood vials are labelled correctly according to the study protocol.
3. The investigator or delegated person will explain the procedure to the participant. Explaining what samples are being collected and why they are being collected.
4. The investigator or delegated person must wash their hands.
5. The investigator or delegated person will clean and prepare the work area.
6. The investigator or delegated person will prepare all equipment required ensuring all study specific equipment is obtained.

Equipment required:

- Sharps bin
- Mediswab
- Non-sterile gloves
- Sample tray
- 2 and 5ml sterile syringes
- 10 ml 0.9% Sterile Normal saline (check expiry date)
- Virkon™ or 1:10 dilution of bleach (to treat spillages)

7. The investigator or delegated person must prepare the working environment to ensure comfort, light, room to manoeuvre, position and privacy of the patient.
8. The investigator or delegated person must check the cannula site for swelling or redness.
9. If the investigator or delegated person notes any redness, tenderness or swelling around the cannula site, the cannula should be removed and re-sited by the medic. The investigator or delegated person must document this in the study record. (Including information on the time the cannula was removed and the alternative location where it was re-sited.)
10. The investigator must wear the appropriate protective clothing (disposable gloves & apron) when there is a risk of contamination.
11. The investigator or delegated person must remove the white cap from the end of the cannula, attach a 2ml Plastipak syringe to the female luer fitting, release the clamp from the lead line to the cannula and withdraw a 2ml blood sample and discard as clinical waste. Discarding this sample will ensure accurate analysis of the results.
12. The investigator or delegated person must now draw the required blood sample into a Plastipak 5ml syringe.
13. The investigator or delegated person must then insert the sample into the appropriate blood vial.
14. The investigator or delegated person must draw up 1-2 mls of 0.9% normal saline using a sterile Plastipak syringe. The solution and expiry date of the syringe contents must be verified by a second delegated person before injection

15. The investigator or delegated person must flush the cannula using a sterile Plastipak syringe with 1-2mls of 0.9% normal saline. This will prevent blood from clotting and confirm patency on completion of blood collection.
16. The investigator or delegated person must clean the female luer fitting with an alcohol wipe. This is carried out by wiping the luer fitting with the alcohol wipe in one direction and then discarding into the appropriate clinical waste container. The luer fitting should be allowed to dry for approximately one minute, then replace the white cap.
17. The investigator or delegated person must ensure that all sharps are disposed of immediately into a sharps container.
18. The investigator or delegated person must wash their hands.
19. The investigator or delegated person must ensure all the samples are correctly labelled.
20. If any blood spillage occurs the investigator or delegated person should clean up the spillage using Virkon™ or a 1:10 dilution of bleach.
21. **When obtaining further samples from the smart site port for serial sampling at timed intervals please repeat the above steps**
22. The medic must remove the cannula when no longer indicated. The time and date that cannula was removed must be documented in the study record. The state of the cannula site should be recorded.
23. The medic must dispose of the cannula in a yellow sharps bin.
24. The investigator or delegated person must remove gloves and discard into appropriate clinical waste bag.
25. The principal investigator or delegated person must ensure that if samples are to be shipped off-site they are prepared, stored and couriered according to the study protocol.
26. If the samples are to be stored in PESS the principal investigator must ensure that PESS health and safety policy is adhered to.

3. Removal of a peripheral venous cannula

Background

The cannula should be removed as soon as possible when no longer required for the experimental trial.

Procedure

It is the principal investigator's or delegated person's responsibility to monitor a participant with a peripheral venous cannula. The medic is responsible for removing it once the cannula is no longer needed, has associated signs of inflammation or before the participant leaves the PESS building
The medic or delegated person should collect all equipment required to remove the peripheral cannula safely.
The equipment necessary is:

- Appropriate receptacle, e.g. a kidney dish
- Sterile gauze
- Sterile dressing
- Tape
- Non sterile gloves
- Sharps bin

1. The medic must wear the appropriate protective clothing (disposable gloves & apron) when there is a risk of contamination.
2. The medic must ensure the correct person is identified for removal of the cannula.
3. The medic will explain the procedure to the participant.
4. The medic should wash his/her hands.
5. The medic must remove the dressing from the cannula site and perform a visual inspection, observing for redness, swelling or tenderness. If any symptoms are observed these must be documented in the research record.
6. The medic should prepare a piece of sterile gauze ready to place over the site upon removal of the cannula.
7. The medic must remove the cannula carefully and slowly and immediately apply firm pressure.
8. The medic will check the integrity of the cannula to ensure the device remains complete and discard into an appropriate yellow sharps container.
9. The medic must ensure that bleeding has stopped before applying a sterile dressing to the cannula site.
10. The investigator or delegated person must dispose of all equipment used safely.
11. The medic must wash his/her hands.
12. The medic must complete the relevant study source documentation and record in the research record that the cannula has been removed as appropriate.