

WORK INSTRUCTION

**STORAGE & TRANSPORTATION OF CLINICAL SAMPLES
(LOCAL SITE & DRY ICE)
W42**

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This generic R&D Standard Operating Procedure (SOP) must be followed unless;

- A study specific SOP exists
- A departmental SOP dictates a different working practice

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VERSION HISTORY LOG



This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

VERSION	Reviewer	Date Implemented	Details of significant changes
V1.0	Sian Ellard, Head of Department, Molecular Genetics	20 October 2011	
V1.1	Su Wilkins, Clinical Research Nurse	12 December 2014	No changes to content required. Minor changes to format of work instruction.

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1. WORK INSTRUCTION

1.1 Storage of Clinical Samples

- The storage of all types of clinical samples for clinical trial is regulated by the UK Human Tissues Act.
- Plasma, serum or blood clot samples are obtained from whole blood after spinning in a centrifuge and are stored in cryovials supplied by the study sponsor. Urine samples must be transferred from the collection pot in to a designated sample tube using a pipette. Sputum and whole blood samples may be frozen in the blood tube they are collected in. DNA samples collected on mouth swab sticks will be supplied with a sterile bag or pot for the swab to be placed in after collection.
- Ensure the sample storage tube or pot is correctly labelled and corresponds with the label and information given on the original sample collection tube.
- Serum or plasma samples may be stored in sample grid boxes with lids. These boxes must be clearly labelled in waterproof ink with the study name, study number, box number and contact telephone number for the local study team. Other samples must be placed within clear plastic 'marsupial' bags and sealed.

1.2 Transporting Clinical Samples (Local Site)

- Sample must be collected in plastic clinical sample tubes or pots supplied by the study sponsor. Blood sample tubes must have rubber bung tops, whilst other collection pots may have a plastic screw or click-flip lid. DNA samples collected on mouth swab sticks will be supplied with a sterile bag or pot for the swab to be placed in after collection.
- Ensure the sample tube or pot is correctly labelled. This must be done whilst still with the subject.
- Wrap sample with absorbent paper or place within absorbent bag and seal.
- Place the wrapped sample within a clear plastic bag and seal. Clear 'marsupial' bags are often used in the clinical environment as these have an outer pocket for any accompanying forms. However, these may not be necessary for some clinical trials.
- For transport from the point of collection to the centrifuge laboratory or freezer storage, place the wrapped and bagged sample within a leak proof plastic box and close the lid. Ideally, these boxes must be clear enough to see the contents inside. Alternatively, if the sample needs to be transported in a temperature controlled box, the wrapped and bagged sample may be placed in a polystyrene cool box with a protective insulation sheet and ice block.
The temperature may be monitored with a thermometer probe on the inside of the cool box connected to a meter held outside via a thin lead. For most samples, the temperature range of 2 - 8°C is required for local transport between the point of collection and the point of initial processing and, or storage but this must be checked against the specific guidelines provided in the study protocol.
- In the event of damage, the sample tube must be left inside the clear plastic bag unopened and discarded as a whole in a clinical waste bin. Loss of the sample must be recorded in study documentation.
- A spillage kit must be carried by staff when collecting and transporting samples. In the event of a spillage, staff must refer to the standard operating procedure for minor spillages of clinical samples.

1.3 Transporting Clinical Samples on Dry Ice

- Sample must be collected in plastic clinical sample tubes or pots supplied by the study sponsor. Blood sample tubes must have rubber bung tops, whilst other collection pots may have a plastic screw or click-flip lid. DNA samples collected on

mouth swab sticks will be supplied with a sterile bag or pot for the swab to be placed in after collection.

- Ensure the sample tube or pot is correctly labelled. This must be done whilst still with the subject.
- Serum or plasma samples may be transported in samples grid boxes with lids. Other samples must be placed within an absorbent bag and sealed.
- Place the boxed or wrapped sample within a strong clear plastic bag and seal.
- Put a layer of dry ice into a polystyrene insulation box using protective gloves. Place the bagged sample on top of the dry ice. Prime the digital thermometer if this is a study requirement and place this with the samples. Cover the samples and digital thermometer with dry ice still using the protective gloves. Securely close the lid of the polystyrene insulation box.
- Place the Polystyrene insulation box within a sturdy cardboard box. The polystyrene box must fit snugly in to the cardboard box. Any trial paper work that is needed to accompany the samples must be placed in an addressed envelope and located with the polystyrene insulation box inside the cardboard packaging box. Close the lid of the cardboard packaging box and seal with strong transport tape. Ensure the box has the correct address on it with details of the sender and appropriate UN 3373 'diagnostic clinical specimens' transport stickers.
- Sign and retain copies of all transport paperwork in the local study site file.