STANDARD OPERATING PROCEDURE

STORAGE & TRANSPORTATION OF CLINICAL SAMPLES (LOCAL SITE & DRY ICE) - S42

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DISCLAIMER

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

Once printed this is an uncontrolled document.

VERSION HISTORY LOG

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

VERSION	Date Implemented	Details of significant changes
1.1	20 March 2014	Minor formatting changes to table on front page.

CONTENTS

1. BACKGROUND

Samples for clinical trials may include peripheral blood, sputum, nasal washes, mouth swabs, and urine. The integrity of such samples may be affected by the conditions in which they are collected, transported and stored. Along with this standard operating procedure, staff must also refer to the study protocol for more detailed guidance on the conditions required for the storage and transportation of samples for specific trials. Guidance for the handling of samples must also be compatible with UK Health and Safety Executive regulations.

For most clinical trials involving healthy volunteers, samples will be classified as UN3373 'diagnostic specimens. The procedures described in this standard operating procedure are applicable to samples categorised as UN3373. Even though the majority of samples will be collected from healthy volunteers, there is always a risk that any sample may contain an unknown pathogen. Therefore staff must always adhere to the principles of 'universal precautions' whenever they are handling clinical samples.

This standard operating procedure provides general guidance for the storage and transportation of clinical samples.

2. PURPOSE

2.1 To ensure all clinical samples are stored safely and according to local hospital trust policy and within accordance with the UK Health and Safety Executive and UN legislation.

2.2 To ensure all clinical samples are transported safely according to trust policy from the point of collection to the point of initial processing (centrifuge) and local site storage.

2.3 To ensure that the optimum integrity of clinical samples is maintained.

2.4 To ensure the safety of staff whilst handling clinical samples.

3. SCOPE

This document covers the procedure which is to be used by all research staff when transporting and storing clinical samples (local site and dry ice).

4. RESPONSIBILITIES

4.1 It is the responsibility of staff handling bio-hazardous materials to ensure that they are properly trained in the safe handling of such items and know what to do in the event of a spillage.

4.2 It is the responsibility of all staff to work according to trust policies and procedures regarding the handling and transportation of bio-hazardous materials and to be fully compliant with trust spillage procedures.

4.3 It is the responsibility of all staff to work according to local hospital trust policies and procedures and to be fully compliant with UK legislation regarding the safe handling and transport of clinical samples.

5. PROCEDURES

Please refer to R&D/Storage & Transportation of Clinical Samples/W42.

6. Supporting Documents

R&D/Storage & Transportation of Clinical Samples/W42