Procedure for Dealing with Biological Sample Spillage in the King's Clinical Research Facility

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Authorised by	Professor James Galloway, CRF Deputy Director
Related documents	CRF-HS-COP-1: King's CRF Health and Safety Code of Practice KCH Waste Management Policy KCH COSHH – Hazardous Chemicals Policy
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Change History		
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19th December 2013	1. Amended text in SOP title from "Clinical Research Facilities" to "King's Clinical Research Facility" 2. Amended name of Director to reflect new Director 3. Amended logos to update to current CRF letterhead template 4. Amended document number from CRF SOP007 to CRF-LAB-SOP-2 to comply with QPulse document numbering system	E Giemza
January 2016	1. Updated related documents 2. Minor administrative amendments to text 3. No changes to the procedure required	E.Giemza
February 2018	1. Minor administrative amendments to text 2. No changes to the procedure are required	E.Giemza
March 2020	1. NIHR logo updated 2. No changes to procedure	E Giemza
October 2022	1. Change of text in sections 5.10 and 5.14	D. Nebres

	2. Infection Control Policies, Protocol and guidance added as a reference in section 6.0.	
October 2024	1. Addition of sections 4.2, 5.4 and 5.5 2. Change of text in section 5.2 3. Removal of Wellcome Trust logo 4. Updated King's Health Partners logo 5. Updated images under section 5.2	D. Nebres

Review History		
Date	Review details	Approved by
18th December 2013	Review of v1.0 conducted by Lara Edwards, CRF QA Manager, superseded by v2.0 (effective date 03rd January 2014)	E Giemza
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October 2024	Review of v6.0 conducted by Amy Sutarz, CRF Laboratory Technician, and Bidisha Chakraborty, CRF Quality Assurance Manager as per review date. Changes made as per 'Change History' and re-issued as v7.0.	D. Nebres

1.0 Background

1.1. The King's Clinical Research Facility (CRF) provides facilities to support researchers, both KCH (King's College Hospital) and non-KCH, who need to collect and process biological samples for their research studies.

1.2. Samples are collected from study participants in the clinical areas of the CRF and processed in the sample processing areas.

2.0 Purpose

2.1 The purpose of this Standard Operating Procedure (SOP) is to describe the procedure which must be followed following a spillage of bodily fluid (such as blood, urine, plasma) within the clinical and sample processing areas of the CRF.

3.0 Scope

3.1 The CRF encompasses the Clinical Trials Facility (CTF), the Experimental Medicine Facility (EMF) and the Cell Therapy Unit (CTU). CRF SOPs will apply to the CTF and EMF only and staff working in those areas should work to all relevant CRF SOPs. The CTU will continue to control and use its own policies and SOPs to ensure compliance with Good Manufacturing Practice (GMP).

3.2 Although it is likely that this SOP will be most relevant within the sample processing areas, it is also applicable to any area within the CRF where a spillage occurs.

4.0 Responsibilities

4.1 All CRF core staff and users of the CRF who are collecting and processing biological samples in the EMF and CTF are bound to adhere to the procedures defined in this SOP.

4.2 For any study specific sample spillage instructions provided by the sponsor, guidelines stipulated in the protocol shall take precedence.

5.0 Procedure

5.1 Biological samples are defined as those collected from study participants in the clinical areas of the CRF and processed in the sample processing areas.

5.2 Spillages of bodily fluids in the CRF must be decontaminated promptly by a suitably trained member of CRF core staff. Biohazard Spill Kits, Clinell Spill Wipes and Cytotoxic Spill Kits are available in the sample processing areas in both the EMF and CTF.

5.3 In case of a spillage, other staff must be informed promptly of the spillage and asked to leave the area until the spillage has been removed.

5.4 For spillage of bodily fluids up to 350ml, Clinell Spill wipes can be used. Follow the instructions for use provided on the packet. Any spillage greater than 350ml requires use of the BioHazard Spill Kit.

5.5 The cytotoxic spill kit is to be used in the event of spilt cytotoxins. Follow the user manual instructions provided in the kit.

5.6 Only core CRF staff who have been trained in the use of the BioHazard spill kit and have read this SOP may deal with the spillage. Any core CRF staff member or user of the CRF who has not been trained should notify a member of the CRF clinical team, or the CRF Manager, of the spillage immediately.

5.7 The core CRF staff member responsible for clearing the spillage must wear disposable gloves, a disposable apron and also eye protection as required.

5.8 Check the product's expiry date and read the COSHH (Control of Substances Hazardous to Health) information on the product label.

5.9 Sprinkle Haz-Tab granules over the spillage until all of the moisture is completely absorbed and leave it for at least 2 minutes.

5.10 Remove the yellow clinical waste bag from the kit and peel the backing away from the adhesive strip. Attach the adhesive strip/bag to a table/wall and allow to hang open. Retain the backing to use as a tie later.

5.11 Collect the absorbed spilt material and granules with the orange scoop and scraper and discard all into the yellow bag. Tie the bag securely and discard as clinical waste as per the KCH Waste Management Policy.

5.12 Clean the entire area with Trust approved disinfectant as per the Infection Control Policy.

5.13 For splashes and drips on verticals walls, curtains etc, make up a chlorine solution by placing 4 Haz-Tab tablets into the diluter container and fill to the line with cold water. Leave for two minutes to dissolve and then mix gently by inversion. DO NOT SHAKE THE DILUTER.

5.14 Clean the surfaces with paper towels and the solution and dispose of the paper towels in the yellow bag supplied with the kit, tie securely, and dispose of as clinical waste.

5.15 Dispose of any unused solution down the sink or sluice and replace the diluter back in the Bio Hazard Spill kit box for re-use.

5.16 Clean the affected area again with Trust approved disinfectant as per the Infection Control Policy.

5.17 In the event that a spillage is made over clothing or shoes, remove immediately and drench skin with water. Seek medical advice from the KCH Occupational Health department (ext. 33387). Outside office hours it may be necessary to report to the Emergency Department.

5.18 It may be necessary to discard the clothing or shoes if appropriate cleaning cannot be implemented.

6.0 Related documents & References

6.1 KCH Waste Management Policy http://kingsdocs/Pages/Home.aspx

6.2 KCH COSHH – Hazardous Chemicals Policy http://kingsdocs/Pages/Home.aspx

6.3 KCH Infection Resources http://kweb/kwiki/Infection_Control#Infection_Control_Handbook

6.4 Infection Control Policies, Protocol and guidance Infection Control Policies, Protocols and Guidance - Kwiki

6.5 KCH Health and Safety Management

http://kweb/kwiki/Health_and_Safety_Management

6.6 CRF-HS-COP-1: King's CRF Health and Safety Code of Practice for King's CRF

7.0 List of Appendices

N/A

8.0 Approval and sign off

Approval and sign off are performed via Q-Pulse as described in *CRF-QA-SOP-3: Preparation, Review, Approval and Release of Standard Operating Procedures in the King's CRF*, version 7.0 dated 10 August 2023. All approval record are captured in the Document module section of the relevant SOP on Q-Pulse.

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