

Document Title: Emergency Trolley in CTBI

Document Number: R&D SOP044

Staff involved in development: <i>Job titles only</i>	Senior R&D Manager, R&D Administration Manager, Clinical Project Managers
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Department:	Research and Development
For use by:	NHS Staff Trust-Wide
Review due:	May 2019
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Summary of Significant Change(s) (for this version only)

Section(s):	Modification:
	Minor administrative changes throughout.

Key Points of this Document

- This document sets out the procedures to be followed to promote good clinical practice in research and maintain a safe environment for research participants.
- It provides guidance on the steps involved in the maintenance of the Emergency Trolley in the CTBI.

1 Purpose and Contents

- a. This document defines the Trust's research SOP for the checking and maintenance of the emergency trolley located in the Clinic Room of the R & D Department. It is not intended to cover the Resuscitation Procedure which can be found on the hospital intranet under Trust Documents – DN309 Resuscitation Procedure (CPR Procedure). All staff who are potential users of the emergency trolley in the R&D clinic room should ensure that they are familiar with the Resuscitation Procedure.

2 Roles & Responsibilities

- a. This Policy applies to all personnel that are conducting research at the Trust.

3 Policy

- a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with may result in disciplinary procedures.

4 Procedure

- a. The emergency trolley, located on the ground floor of the CTBI must be maintained in a fully functioning and workable order, at all times.
- b. This is the only emergency trolley located within the CTBI and as such, needs to be easily accessible at all times. Therefore, it is essential that the location of the trolley remains constant, and access is maintained at all times by ensuring furniture/apparatus do not obstruct the trolley.
- c. It is the responsibility of the Clinical Research Nurses to ensure that a rota is maintained for checking of the emergency trolley on a weekly basis. Any nurse who is not able to complete checks on dates assigned to them, must ensure that another nurse is willing and able to perform all relevant checks, and any personnel changes must be recorded on the rota and signed. This is necessary in order to provide an audit trail of responsibility.

- d. A complete inventory of all items required on the emergency trolley must be maintained and kept up-to-date according to trust policies. This will detail all items and equipment that need to be present on the trolley in order to ensure it is fully operational for basic life support. See FRM014 Resuscitation Trolley Weekly Checklist for full crash trolley inventory.
- e. The defibrillator performs a daily self-test. The corresponding test print out must be checked and initialled each day by a designated individual when the CTBI building is in use. The preceding days print out can then be discarded. If in the event that the defibrillator test fails this must be reported to the maintenance and ALERT teams immediately for repair and for the unit to be replaced.
- f. The emergency trolley must be checked at least weekly and confirmation of the check recorded by the person performing the checks signing and dating FRM014 located in drawer 1 of the resuscitation trolley. FRM014 can also be found in S:\shared\Clinical Research Workers Group\Crash trolley docs and it is the responsibility of the person who completes the previous checklist to ensure that a new checklist is edited with the correct dates, printed and in place ready for the next period.
- g. Weekly checks undertaken must ensure the following:
 - 1. All items and equipment detailed on the emergency trolley inventory are present on the trolley.
 - 2. Expiry date: any items exceeding their expiry date should be removed from the trolley and disposed of in the appropriate manner. Any items removed from the trolley must be replaced immediately and a record of any changes recorded on the checklist where the expiry date is required. It is suggested that items due to expire are removed from the trolley and put into the clinical areas where they can be used prior to their expiry to minimise waste.
 - 3. Evidence of tampering: all items on the trolley must be checked in order to ensure that they are suitable for use and do not show any signs of damage/tamper.
 - 4. The defibrillator on the trolley is in date for electrical safety testing.

- h. Once a month all items should be removed from the trolley and the trolley thoroughly cleaned. The check must be recorded on FRM014.

5 Risk Management / Liability / Monitoring & Audit

- a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

- b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

- c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

- d. The Research and Development Directorate is responsible for the ratification of this procedure.


Further Document Information

Approved by: <i>Management/Clinical Directorate Group</i>	Research and Development Directorate						
Approval date: <i>(this version)</i>	[Current active version approved date]						
Ratified by Board of Directors/ Committee of the Board of Directors:	STET						
Date:	N/A						
This document supports: <i>Standards and legislation</i>	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. Research Governance Framework for Health and Social Care (2005)						
Key related documents:	Trust Research Policy [Insert list of linked or relevant documents to this SOP]						
<p>Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.</p>							
Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative							
Review date:	May 2019						

Version Control

Version	Date effective	Valid to	Approved by	Date of approval
1.0				
2.0				
3.0				
4.0				

I certify the contents of this SOP has been reviewed and ratified


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Signed by Dr Ian Smith, Clinical Director of R&D

31st Jan 2017
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Date

SOP release date: 7th February 2017

