Portsmouth Hospitals NHS
NHS Trust

CREATION OF CRIB SHEETS FOR CLINICAL DATA COLLECTION

For Completion by SOP Author	
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Document Reviewer(s)	Laura Marshall

For Completion by Research Dept., SOP Controller	
Name of Responsible Committee	Research Governance Group 05 September 2016
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The definitive versions of all Portsmouth Hospitals Trust SOPs, Templates and Forms for Research are online at http://www.porthosp.nhs.uk/research-department

If you are reading this SOP in printed form then you are reading an uncontrolled document. You must therefore verify that the version number and date given below are the most recent, by cross-checking with the Trust research website before proceeding with implementation.

Portsmouth Hospitals NHS Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds. This SOP has been assessed accordingly

INTRODUCTION

Source data is defined as all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Put simply, source data is the first record of any interaction with participants and any data relating to them.

Clinical trial data originate from a variety of sources such as a patient notes, laboratory notes, x-rays, reports from instruments, etc which are collectively called source documents. Occasionally, data is first recorded into data collection tools such as CRF, patient diaries, questionnaires, etc. In these cases the data collection tools become source documents and should be reviewed and agreed with the sponsor and documented at the site initiation or in the form of a source data agreement unless it is clearly defined in the protocol.

Crib sheets are a data collection tool used in clinical research. One situation when a crib sheet is used, for example, is when the study employs electronic CRFs or the CRF is too long therefore it is not practical to use during all stages of a trial. Crib sheets can also be used as prompt sheets for research teams so that they can quickly pick up and see what research activities and information is needed for a study visit and record the relevant data. As a document where an individual piece of data could potentially be first captured, a crib sheet is considered a source document. Therefore, a process for developing and reviewing crib sheets must be documented and described as a Standard Operating Procedure.

1. PURPOSE

The purpose of this document is to describe the Standard Operating Procedures for creating crib sheets used as a clinical data collection tool.

2. SCOPE

This SOP applies to all members of staff using crib sheets as a data collection tool in clinical research. This SOP applies to data collected for both hosted and sponsored studies.

The Trust recognises that some external sponsors, networks, funders and employers may require the use of their own SOPs for the good governance of research. In such cases it is the responsibility of the Portsmouth Hospitals Trust user (including those individuals contracted to work on behalf of the Trust), to ensure that the external SOP is compatible with the procedure outlined below. If the external SOP contradicts the Trust's procedure then approval must be sought in writing from the Director of Research.

In the event of an infection outbreak, flu pandemic or major incident, the Trust recognises that it may not be possible to adhere to all aspects of this document. In such circumstances, staff should take advice from their manager and all possible action must be taken to maintain ongoing patient and staff safety

3. ABBREVIATIONS & DEFINITIONS

SOP: Standard Operating Procedure
CRO: Clinical Research Organization
CRA: Clinical Research Associate
CTIMP: Clinical Trial of an Investigational Medicinal Product
PHT: Portsmouth Hospitals NHS Trust
Hosted: Refers to an externally sponsored study for which Portsmouth Hospitals NHS Trust are acting as a site.
Sponsored: Unless otherwise specified, this refers to a study for which Portsmouth Hospitals NHS Trust are the sponsor.

4. DUTIES AND RESPONSIBILITIES

Role	Responsibilities
All studies Research team member	• To ensure this SOP is followed when designing a crib sheet • To seek the sponsor's agreement or approval for the use of the crib sheet • To ensure the latest version of the crib sheet is used
Sponsor	• To review the crib sheet, ensuring is version controlled, dated and added to the list of source documents.

5. PROCESS

Each crib sheet should have a header/footer section containing key information. As a minimum, the information should provide; version number, study identifier, site identifier, participant ID, visit number and date.

Crib sheets should be version and dated and listed on the study version log, if there are changes to be made to these documents, the version number and date should be updated accordingly and added to the version log, especially in the case of protocol amendments which may lead to changes in the information that needs to be collected. Any updates to the crib sheets throughout the study should be notified to the Sponsor or the PHT R&I office, where PHT is the Sponsor. Crib sheets should be consistent with the protocol.

Data fields should be clear, logical and user friendly. All pages should be paginated, with the document version and date in the header or footer.

For hosted studies: please make sure the sponsor is aware that you intend to use a crib sheet to facilitate data collection by sending the document to the trial manager, CRO/CRA or study monitor. This is so that the crib sheet is included as a source document during monitoring visits.

For sponsored studies: If a crib sheet is required, it must be provided to R&I facilitator, methodologist or trial manager (where appropriate) for review and approval. After the sponsor is satisfied then the crib sheet must be version controlled, dated and listed as a source document in the protocol or as part of the study document pack in the version control log.

6. TRAINING REQUIREMENTS

Self directed training must be carried out by all research staff required to use crib sheets. Evidence of training shall be required for all CTIMP studies and Research Office staff.

"The Research Dept., will endeavour to notify staff of SOP developments that may be relevant to them. Updates on SOPs will feature in Research newsletters and communications. It is the responsibility of all research active staff to ensure that they read the issued updates that may be relevant to them.

When a new SOP is authorised, or when an existing SOP is revised, self directed training must be carried out by all staff to which the SOP is relevant and this training documented in their training record. A template is provided to support this process. A study specific SOP training plan will be developed for investigators on high risk PHT Sponsored studies.

Staff should take time to read and fully understand the SOP and relevant documents, ensuring that they are able to implement the SOP when required. If clarification is needed then the trainee should approach their line manager and the SOP Controller who will arrange additional training. All staff should complete their training prior to the published implementation date which will normally be between 2-6 weeks after publication.

All staff are responsible for maintaining their own SOP Training Records and copies must be made available to line managers, the SOP Controller or study monitors on request."

7. REFERENCES AND ASSOCIATED DOCUMENTATION

MHRA good Clinical Practice Guide. Tso. 542 pages

8. 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	Date Implemented	Details of Significant Changes
1.0	05 Sep 2016	Approved by RGG 05 September 2016

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CONFIRMATION OF SOP TRAINING RECORD

A copy of this record may be kept in your personal training file to confirm your training in a specific SOP. If required by a study Sponsor a record may also need to be kept in the Trial Master Files (TMF) or Investigator Site Files (ISF)

SOP Details: To be completed by the SOP Controller	
Title of SOP	CREATION OF CRIB SHEETS FOR CLINICAL DATA COLLECTION
Reference Number	PHT/RDSOP/017
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Implementation Date	05 September 2016

Personnel Details	
Name	
Job Title & Research Role	
Date of Training	
Nature of Training	Self Directed/Delivered by etc
Records of any meetings to clarify details in SOP	

Signatures
I confirm that I have read and consider myself to be sufficiently trained in the above Standard Operating Procedure with regards to my individual roles and responsibilities Signature of Trainee …… Date ……
I confirm training in the above SOP was delivered as recorded above and that the trainee may be considered sufficiently trained in their roles and responsibilities Signature of Trainer …… Date ……

Additional Notes & Signatures

Signature of Trainer (where appropriate)

I confirm training in the above SOP was delivered as recorded above and that the trainee may be considered sufficiently trained in their roles and responsibilities

Signature of Trainer …… Date ……..