Standard Operating Procedure

MANAGEMENT OF INVESTIGATIONAL MEDICINAL PRODUCTS (IMP)

SETTING Trustwide for research conducted within UHBristol and/or sponsored by UHBristol

AUDIENCE All staff involved in the handling, administration or management of investigational medicinal products within clinical trials.

ISSUE

- Investigational Medicinal Products must only be used in the context of approved clinical trials and handling/management must be carried out by authorised individuals.
- Relevant to the management of Advanced Therapy (Investigational) Medicinal Products

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Standard Operating Procedure (SOP)

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Approved by:	Trust Research Group		
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Review date	Version number	Version Date	Effective Date	Reason for change	Author/Responsible person	Authorised by
Original SOP	1.0	27/07/2015	17/08/2015	n/a	Diana Benton	Diana Benton
20/08/2015	1.1	20/08/2015	14/09/2015	Minor change to formatting	Genna Nicodemi	Diana Benton
07/12/2015	1.2	07/12/2015	23/12/2015	Addition of Pharmacy SOP: CT 12 01 Raising An Income Due Advice invoice	Catherine Down	Diana Benton
26/10/2016	1.3	26/10/2016	27/10/2016	Addition of Pharmacy SOPs: CT1 06 CT1 07 CT1 08 CT1 09 CT 13 01 CT 14 01 Minor amendments to wording in Pharmacy SOP list	Jess Bisset	Elinor Griffiths
28/11/2016	1.4	28/11/2016	19/12/2016	Clarification on processes and minor updates to wording	Jess Bisset	Diana Benton

1. Purpose

The purpose of this document is to describe what processes researchers should follow in handling and managing investigational medicinal products within the context of a clinical trial. Advanced Therapy (investigational) Medicinal Products are also within scope of this SOP.

2. Scope

In scope: Clinical trials of Investigational Medicinal products and Advanced Therapy (Investigational) Medicinal Products hosted by, and/or sponsored by UHBristol.

Out of scope: All other research.

3. Definitions/Abbreviations

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
R&I	Research & Innovation
SOP	Standard Operating Procedure
UHBristol	University Hospitals Bristol
IMP	Investigational Medicinal Product
AT(I)MP	Advanced Therapy (Investigational) Medicinal Product
PI	Principal Investigator
ISF	Investigator Site File
TMF	Trial Master File
DMS	Document Management System

4. Procedure

4.1 CTIMPs and AT(I)MP trials

Clinical trials of investigational medicinal products must comply with the current applicable legislation that is SI 2004/1031.

Advanced therapy (investigational) medicinal products fall under the responsibility of the Chief Pharmacist. For that reason, Principal/Chief investigators conducting ATMP trials must engage with the pharmacy department in order to carry out a joint assessment with pharmacy to determine to what degree the pharmacy SOPs apply.

4.2 Engagement with pharmacy

The UHBristol pharmacy departments hold a wealth of experience and expertise to support CTIMPs. CI/PI and research teams should engage at an early stage in the development or setup of trials to ensure proper input is gained. Expert knowledge, for example about the way a pharmaceutical is presented or its shelf life, may contribute to changes in trial design that make the trial easier or more pragmatic to deliver.

UHBristol has a number of different pharmacy departments, encompassing the Pharmacy Trials Unit (Dispensing Pharmacy), Parenteral Services Unit, Production and Radiopharmacy. The Pharmacy Trials Unit should be contacted in the first instance, in the absence of other named contact people. Each pharmacy department has a lead Pharmacist responsible for the trials activity taking place. Contact details can be provided by the R&I department (research@uhbristol.nhs.uk; 0117 342 0233) if required.

Discussions and agreements relating to specific trials should be documented and placed in the ISF/TMF as relevant.

4.3 Pharmacy SOPs

UHBristol R&I department has delegated responsibility for developing a range of SOPs relating to the handling and management of investigational medicinal products to the UHBristol Pharmacy Department. The key contact in relation to SOP preparation is the lead pharmacist in the Pharmacy Trials Unit, based in the BRI.

Pharmacy SOPs will be developed, reviewed and updated in accordance with the pharmacy department's own internal SOP guidance to ensure UHBristol's compliance with the applicable legislation. UHBristol R&I department will ensure the suite of SOPs covers all the topics required under the applicable legislation. The pharmacy department will ensure there is no conflict between the pharmacy and R&I SOPs.

Pharmacy will upload the SOPs to the Trust's Document Management System. It will provide a full list of pharmacy SOPs to be referenced in this SOP. Researchers should then locate the Pharmacy SOPs on the Trust's Document Management System as applicable. Pharmacy will agree and document a mechanism to ensure the list of pharmacy SOPs within this SOP and on the R&I website are kept up to date following review /amendment /creation of new SOPs.

5. Dissemination and training in the SOP

5.1 Dissemination of this SOP

5.1.1 New SOPs and new versions of existing SOPs: The Research Operations Manager will be responsible for ensuring authorised SOPs are uploaded to the DMS in line with Trust policy and on the R&I website as described in the SOP "Authorship, review, revision and approval of research procedural documents produced by research & innovation". Internal Trust Staff are expected use the DMS to access latest versions of SOPs and to check the website regularly for updates.

Notice of new or amended procedural documents that have undergone a major amendment will be given via the following routes:

- Inclusion in the R&I e-bulletin (monthly)
- Direct email to Research Leads, Research Unit Managers and Band 7 staff for onward cascade
- Direct email to Chief Investigators of CTIMPs sponsored by UHBristol
- Direct email to the Head of Research Governance at the University of Bristol (as relevant)

5.2 Training in this SOP

5.2.1 All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP. This will be determined by the type of research in which they are involved and their role.

5.2.2 The training log which may be held centrally or within the Site File/Trial Master File should be completed to document that members of staff have read and understood the content of the SOP and its amendments.

IMPORTANT NOTE:
This procedure has been screened for equality impact; it was not assessed as having adverse effects on any section of the community.

RELATED DOCUMENTS

Pharmacy SOPs:

Setting up a Clinical Trial

CT 1 01 Procedure for the Set-Up of a Clinical Trial in the Pharmacy Trials Unit.

CT 1 02 Pharmacy Approval of a Clinical Trial

CT 1 03 Procedure for the review of a QP batch release certificate for a clinical trial of an Investigational medicinal product

CT 1 04 Procedure for carrying out a risk assessment for storing clinical trial material outside of pharmacy

CT 1 05 Set Up and Maintaining of a Pharmacy Clinical Trial File

CT 1 06 Procedure for carrying out a risk assessment for sending Investigational Medicinal Products to trial subjects by post, courier or taxi

CT 1 07Chemocare Prescription Set Up

CT 1 08Final Check and Release of Chemocare Prescriptions

CT 1 09Amending Chemocare Prescriptions

Receipt, Re-labelling and Recording of Expiry Dates of Clinical Trial Material

CT 2 01 Receipt and Recording of the safe delivery of Clinical Trial Material.

CT 2 02 Relabelling of clinical trial material for commercial and non-commercial clinical trials

CT 2 03 Procedure for recording and updating expiry dates for clinical trial medication

CT 2 04 Pharmacy Trials Unit Clinical Trial and Drug Expiry Date Database

Safe Handling, Storage and Transfer of Clinical Trial Material

CT 3 01 Safe Handling and Storage of Clinical Trial Material in Pharmacy Trials Unit (PTU)

CT 3 04 Procedure for the transfer of bulk clinical trial material within the Trust

CT 3 05 Procedure for the transfer of patient specific clinical trial medication within the Trust hospitals

Return, Disposal and Recall of Clinical Trial Material

CT 4 01 Return and Disposal of Unused Pharmacy Trials Unit Clinical Trial Material

CT 4 02 Procedure for Recall of Trial Medication

CT 4 03 Quarantine of Trial Medication

Code Break Situations

CT 5 02 Emergency Code Break Procedure.

Clinical Trial Pharmacy Staff Training

CT 6 01 Training of Clinical Trial Pharmacy Staff

Close Down of Clinical Trials and Archiving of Clinical Trials Documentation

CT 7 01 Close down of a Clinical Trial set up by the Pharmacy & Archiving of Pharmacy Clinical Trial Documentation.

Checking Clinical Trial Prescriptions

CT 8 01 Final Accuracy Checking of Clinical Trial Prescriptions in the Pharmacy Dispensary at Bristol Royal Infirmary

Premises & Equipment

CT 9 01 Critical Equipment List

CT 9 02 Permit to Work

Substantial Amendments

CT 10 01 Review of Protocol Amendments

Safe Handling of Dry Ice

CT 11 01 Procedure for the Safe Handling of Dry Ice

Income Due Advice

CT 12 01 Raising An Income Due Advice/Invoice

Review of SOPs

CT 13 01 Authorship, review, Revision and approval of Standard Operating Procedures

CD Cupboard and Fridge Keys

CT 14 01 Safe Keeping of Controlled Drug cupboard and Fridge Keys

QUERIES Research Operations Manager or Research Management Facilitators - Research & Innovation Department via 0117 342 0233