Standard Operating Procedure (SOP)

MANAGEMENT OF INVESTIGATIONAL MEDICINAL PRODUCTS (IMP)

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

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

QUERIES Contact R&D department : Ext 20233 or research@uhbw.nhs.uk

Document History

SOP number	SOP_006	**SOP Version**	2.0
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Review date	Version number	Version date	Effective date	Author/ Reviewer	Authorised by
Original SOP	1.0	27/JUL/2015	17/AUG/2015	Diana Benton	Diana Benton
20/AUG/15	1.1	20/AUG/2015	14/SEP/2015	Genna Nicodemi	Diana Benton
07/DEC/15	1.2	07/DEC/2015	23/DEC/2015	Catherine Down	Diana Benton
26/OCT/16	1.3	26/OCT/2016	27/OCT/2016	Jess Bisset	Elinor Griffiths
28/NOV/16	1.4	28/NOV/2016	19/DEC/2016	Jess Bisset	Diana Benton
12/JAN/18	1.5	12/JAN/2018	15/FEB/2018	Trusha Rajgor	Jess Bisset
21/JUL/20	1.6	14/AUG/2020	14/AUG/2020	Liz McCullagh	Jess Bisset
13/JAN/21	1.7	13/JAN/2021	15/NOV/2021	Katharine Wale	Jess Bisset
FEB/2023	1.8	16/FEB/2023	01/APR/2023	Lucy Riddolls	Jess Bisset
NOV/2023	1.9	13/NOV/2023	13/NOV/2023	Liz McCullagh	Jess Bisset
SEP/2025	2.0	13/OCT/2025	21/NOV/2025	Liz McCullagh Jess Bisset Sarah Bishop	Diana Benton

Version Number	Reason for change
Original V1.0	N/A
1.1	Minor change to formatting
1.2	Addition of Pharmacy SOP: CT 12 01 Raising An Income Due Advice invoice
1.3	Addition of Pharmacy SOPs: CT1 06, CT1 07, CT1 08, CT1 09, CT 13 01, CT 14 01 and Minor amendments to wording in Pharmacy SOP list
1.4	Clarification on processes and minor updates to wording
1.5	Update in line with annual review
1.6	Minor updates for 2 yearly review and addition of Pharmacy SOP CT 3 06 Monitoring of clinical trials stored and dispensed outside pharmacy
1.7	Minor update to section 5.1 to include the Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019
1.8	Departmental name change from Research & Innovation to Research & Development. Updated throughout SOP as a minor amendment.
1.9	Addition of 2 pharmacy SOPs in section 7 as part of biennial review and minor updates in line with updated Trust SOP template requirements.
2.0	Updates to list of Pharmacy SOPs in section 7, addition of sponsor pharmacist role, clarification on requirements of an IMP management plan and other minor clarifications.

1. Purpose

The purpose of this document is to describe what processes researchers should follow in handling and managing investigational medicinal products (IMPs) 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 (CTIMPs) and Advanced Therapy (Investigational) Medicinal Products hosted by, and/or sponsored by UHBW.

Out of scope: All other research.

3. Responsibilities

- Researchers who handle and manage investigational medicinal products are responsible for ensuring that they discuss arrangements with UHBW pharmacy and follow all applicable SOPs.
- UHBW Pharmacy is responsible for the management of investigational medicinal products and producing applicable SOPs.
- The R&D department is responsible for ensuring all studies involving investigational medicinal products have been reviewed and authorised by UHBW Pharmacy.
- Where R&D have delegated IMP management of sponsored studies (or some aspects of this) to another department or external body, this will be clearly documented in an IMP management plan.

4. Abbreviations and Definitions

Abbreviations	
ATIMP	Advanced Therapy Investigational Medicinal Product
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
DMS	Document Management System
IMP	Investigational Medicinal Product
ISF	Investigator Site File
PI	Principal Investigator
R&D	Research & Development
SOP	Standard Operating Procedure
TMF	Trial Master File
UHBW	University Hospitals Bristol and Weston NHS Foundation Trust
UoB	University of Bristol
Definitions	
Sponsor pharmacist	Pharmacist delegated by UHBW as sponsor with the appropriate expertise to provide advice on all aspects of IMP management to ensure sponsor obligations under clinical trials regulations are met.

5. Procedure

5.1 CTIMP and ATIMP trials

- CTIMPs must comply with the current applicable legislation that is SI 2004/1031, the Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019 and any amendments.
- ATIMPs 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.

5.2 Engagement with pharmacy

- The UHBW 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.
- UHBW 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&D department (research@uhbw.nhs.uk; 0117 342 0233) if required.

- Discussions and agreements relating to specific trials should be documented and placed in the Trial Master File (TMF) or Investigator Site File (ISF) as relevant.

5.3 Pharmacy Standard Operating Procedures (SOPs)

- UHBW R&D department has delegated responsibility for developing a range of SOPs relating to the handling and management of investigational medicinal products to the UHBW 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 UHBW's compliance with the applicable legislation. UHBW R&D 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&D SOPs.
- Pharmacy will upload the SOPs to MyStaffApp which is the the Trust's current 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 MyStaffApp as applicable. Pharmacy will agree and document a mechanism to ensure the list of pharmacy SOPs within this SOP and on the R&D website are kept up to date following review /amendment /creation of new SOPs.

5.4 Role of the Sponsor Pharmacist

For UHBW sponsored trials the role of the sponsor pharmacist is to provide regulatory advice and IMP management oversight to ensure safety of participants. This will include preparing and reviewing IMP management documentation for the trial as appliable and providing regular advice throughout the life-cycle of the trial as needed. Delegation to a sponsor pharmacist will be clearly outlined in the trial Set Up and Management Plan (SUMP) and any other IMP management documentation for a particular trial.

6. Dissemination and training in the SOP

This SOP will be disseminated to applicable research staff (including R&D) and will be available on the R&D website.

Plan Elements	**Plan Details**
The Dissemination Lead is:	Research Operations Manager
Is this document: A – replacing the same titled, expired SOP, B – replacing an alternative SOP, C – a new SOP:	A- Replacing the same titled, expired SOP
If answer above is B: Alternative documentation this SOP will replace (if applicable):	N/A
This document is to be disseminated to:	All applicable research staff (including R&D)
Method of dissemination:	For major updates to the SOP dissemination will be: 1. To Chief Investigators of UHBW Sponsored CTIMPs 2. Research Unit leads across UHBW

	3. Head of Research Governance at UoB (where SOP is applicable) All updates (major and minor to the SOP) will be: 1. Updated on the trust MyStaffApp 2. Updated on the R&D website 3. Cascaded in the R&D e-bulletin
Is Training required:	All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP. The personal training log of the individual (and the Investigator Site File/Trial Master File if required) should be completed to document that the content of this SOP has been read and understood as described in *SOP_007 Research Training UHBW*

7. 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 Sending Investigational Medicinal Products to trial subjects by post or courier
CT 1 07 Chemocare Prescription Set Up
CT 1 08 Final Check and Release of Chemocare Prescriptions
CT 1 09 Amending Chemocare Prescriptions
CT 1 11 Writing, approval and use of paper clinical trial 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 performing and recording stock and expiry date checks 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
CT 3 06 Monitoring of clinical trials stored and dispensed outside pharmacy
CT 3 07 Transfer of clinical trial material offsite

Return, Disposal and Recall of Clinical Trial Material
CT 4 01 Return and Disposal of Unused Clinical Trial Material
CT 4 02 Procedure for Recall of Trial Medication
CT 4 03 Quarantine of Trial Medication
CT 4 04 IMP stock expiry and maintenance

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.

Clinical Trial Prescriptions
CT 8 01 Final Accuracy Checking of Clinical Trial Prescriptions in the Pharmacy Dispensary at Bristol Royal Infirmary
CT 8 02 Dispensing clinical trial medication

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

Incidents
CT 15 01 Incident reporting

AUTHORISING BODY	Trust Research Group
SAFETY	N/A
QUERIES AND CONTACT	Research & Development department on 0117 34 20233 or email research@uhbw.nhs.uk
AUDIT REQUIREMENTS	R&D departmental Quality Management System audits are undertaken annually.