

## Standard Operating Procedure (SOP)

# MANAGEMENT OF INVESTIGATIONAL MEDICINAL PRODUCTS (IMP)

<b>SETTING</b>	Trustwide for research conducted within UHBW and/or sponsored by UHBW
<b>AUDIENCE</b>	All staff involved in the handling, administration, or management of investigational medicinal products within clinical trials.
<b>ISSUE</b>	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
<b>QUERIES</b>	Contact R&D department : Ext 20233 or <a href="mailto:research@uhbw.nhs.uk">research@uhbw.nhs.uk</a>

## Document History

<b>SOP number</b>	SOP_006	<b>SOP Version</b>	1.8
<b>Effective Date</b>	01/APR/2023	<b>Review Date</b>	15/NOV/2023

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

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. 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.

## 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

## 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](mailto: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 the Trust's Document Management System (DMS). 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 DMS 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.

## **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.

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 TMF or ISF 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*.

## **7. Related documents**

### **Pharmacy SOPs**

#### Setting up a Clinical Trial

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|---------|---|
| 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  |

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

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|---------|---|
| 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

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|---------|---|
| 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                                 |

#### Return, Disposal and Recall of Clinical Trial Material

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|---------|---|
| 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

### 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

<b>AUTHORISING BODY</b>	Trust Research Group
<b>SAFETY</b>	N/A
<b>QUERIES AND CONTACT</b>	Research & Development department on 0117 34 20233 or email <a href="mailto:research@uhbw.nhs.uk">research@uhbw.nhs.uk</a>