SOP 11 Management of Investigational Product

1.1 Purpose

To describe the procedures related to managing all aspects of Investigational Product (IP), either medicinal product or device. Management includes but is not limited to the receipt, storage, accountability, preparation and administration, shipment and destruction of IP.

Note: Relabelling of IP is not covered here as it will follow the procedures sent to the sites by the Sponsor or follow the Institution's pharmacy procedures for relabelling.

1.2 Scope

This Standard Operating Procedure (SOP) applies to all relevant employees including, but not limited to, visiting health professionals, contractors, consultants and volunteers who propose to undertake, administrate, review and/or govern human research involving patients/participants and staff. All study personnel involved in the clinical study must operate within their scope of practice.

Records supporting the provision of IP (Medicinal Product or Device) should permit the reconstruction of accountability so that it is possible to demonstrate that trial participants received the correct IP(s), at the correct dose, at the correct time.

The responsibility for IP accountability at a trial site lies with the Principal Investigator (PI). The task of maintaining IP accountability may be delegated to a pharmacist and/or other appropriately qualified staff in accordance with legislation and medication handling policies.

IP should be transported and stored according to specified conditions and local policy. Approaches to management of IP varies across different jurisdictions.

Investigational Medicinal Products (IMP) should not be destroyed without prior written authorisation by the Sponsor.

The PI or delegate should assess the need for emergency unblinding and only unblind if it is essential for the ongoing medical management of the participant. Wherever feasible, the PI or delegate should discuss the case with the Sponsor/Coordinating Principal Investigator. Where a participant is withdrawn from a trial, the withdrawal should be recorded.

1.3 Procedure

11.1 Management of Investigational Product (Medicinal Product or Device)

Responsibility for IP management and accountability at the trial site rests with the PI. However, the PI may delegate responsibility for IP management to the site pharmacist or, where a pharmacist is not available or involved, to an appropriately qualified person (as per SOP 03 Site Staff Qualifications, Training Records and Capability).

The site pharmacist or the appropriately qualified person will undertake management of the IP at the Primary Site and/or the Satellite Site.

Where the delegation of this activity requires supervision (e.g. pharmacist or appropriately qualified person new to the role), the delegated activity is to be clearly documented on the Supervision Plan, the Delegation and Training Logs (see SOP 03 Site Staff Qualifications, Training Records and Capability).

The task of prescribing IP should only be delegated, as appropriate and within a health practitioner's scope of practice, to medical practitioners, dentists or nurse practitioners. The task of administering IP should only be delegated to medical or clinical staff and within their scope of practice (e.g. registered nurses).

The Investigator, Pharmacist or appropriately qualified non-pharmacist must:

- Ensure the IP is used only in accordance with the approved Protocol.
- Confirm IP certification and all relevant trial approvals/notifications are in place before releasing IP for dispensing to participants (i.e. ethics and governance approval, CTN/CTA, drug committee approvals and product compliance with guidance documents and legislation).
- Maintain records of all aspects of the management of the IP. These records at a minimum should include: shipping documents; date of each transaction; quantities; batch/serial numbers; expiration dates/retest dates (if applicable); temperature logs showing the storage conditions of IP throughout the trial period; the set of unique code numbers assigned to the IP and to the trial participant; and record of destruction/return. See *Appendix 9 for Individual Participant IP Accountability Record Example*.
- Provide maintenance and calibration records for storage equipment (e.g. refrigerators, thermometers) in accordance with Sponsor requirements.
- Ensure that the IP is received, stored respecting correct temperature control, prepared, administered, shipped and destroyed as specified by the Sponsor in accordance with the Protocol, pharmacy manual and applicable regulatory requirement. Consideration must be given to security of the IP, with restricted access to approved personnel.
  - IP should be transported, stored and supplied according to jurisdictional and Institutional policies.
  - The majority of IP will be received, stored and managed within a pharmacy. However, exceptionally, it may be necessary for IMP to be stored in a ward or facility (e.g. for trials where IP is administered in the emergency setting or outside of pharmacy opening hours). Arrangements for IP storage outside of the pharmacy should only occur following

consultation with the local pharmacy service. Where organisational policy allows delivery directly to storage areas outside pharmacy, these should be assessed by staff (e.g. pharmacy) to ensure storage conditions are adequate, temperature monitoring is in place and accountability (including an area for returns) meets Protocol/pharmacy manual requirements.

- Where IP is logged out of pharmacy and transferred to a department/facility/area (or other location) for administration to the patient/participant (e.g. IV infusion in a ward or administration of a vaccination at a participant's home), appropriate chain of custody records should be maintained. Where IP (compounded or reconstituted in pharmacy or for immediate use by nursing or other qualified staff) has limited stability/short half-life, records should be able to demonstrate that it was transported and administered within the specified timeframe.
- IP should not be destroyed without prior written authorisation by the Sponsor. IP that is unused, expired or returned by patients/participants should be stored in an appropriately controlled area, until ready for return to the Sponsor (usually at intervals) or disposal at site. Returned IP should be stored separately to unused IP. Where IP is to be returned to the Sponsor, all patient/participant-identifiers must be removed beforehand.

- Ensure any deviation to required temperature, storage conditions, potential defect/issue with IP is notified to the Sponsor in a timely manner and in accordance with the study Protocol. Follow study site quarantine process as applicable.
- Explain the correct use of the IP to each participant and check, at intervals appropriate for the trial, that each participant is following the instructions properly. Instruct participants where relevant to return empty and partially used medication containers at their next visit. Extra counselling by the Investigator or delegate, for study participants regarding poor medication compliance, may be required.
- Ensure all staff follow the trial's randomisation procedures, if any.
  - The Primary Site will normally be responsible for the randomisation of Satellite Site participants and for the notification of the result of randomisation to the Satellite Site. The Satellite Site should be provided with the randomisation codes or access to Interactive Response Technology (IRT) (and appropriate training) for trials where emergency unblinding may be required.

- Ensure, for blinded studies, the blind is broken only in accordance with the Protocol. For a blinded study, the Investigator must promptly document and explain to the Sponsor any premature unblinding (e.g., accidental unblinding, unblinding due to a serious adverse event) of the IP.
- Where the IP is shipped to, and/or returned from, a Satellite Site, a written working instruction or procedure documenting the manner in which this process is to occur must be in place at the Primary Site pharmacy. The Sponsor will require evidence of this document for the Primary Site to manage the Satellite Site stock. The document must address, at a minimum, aspects of IP shipment such as: the appropriate transfer method, respecting temperature control and monitoring thereof; clear identification of what is being shipped; that the IP is to be used according to the Sponsor's guidelines; relevant documentation to

accompany the shipment; acknowledgement of receipt by Satellite Site or Primary Site; delivery information of IP from or to the Primary Site; filing of relevant documentation at both sending and receiving sites.

- File all relevant trial related documentation in the SMF/SSSF as per *SOP 07 The Study Master File*

Appendix 9

Individual Participant Investigational Product (IP) Accountability Record Example

INVESTIGATOR NAME:	CLICK OR TAP HERE TO ENTER TEXT.	SITE ID:	CLICK OR TAP HERE TO ENTER TEXT.
PARTICIPANT NUMBER:	CLICK OR TAP HERE TO ENTER TEXT.	STUDY CODE:	CLICK OR TAP HERE TO ENTER TEXT.
PARTICIPANT INITIALS	CLICK OR TAP HERE TO ENTER TEXT.	CONTAINER DEFINITION (IF APPLICABLE):	CLICK OR TAP HERE TO ENTER TEXT.

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DISPENSING INFORMATION									RETURN INFORMATION				COMPLETED BY THE MONITOR			
INVESTIGATIONAL PRODUCT (IP)	BATCH NO.	LOT NO.	EXPIRY DATE	STUDY PROTOCOL NO.	VISIT NO.	DATE DISPENSED	AMOUNT DISPENSED (STRENGTH/UNIT)	INITIALS	USED IP	DATE RETURNED	AMOUNT RETURNED	VERIFIED BY	VERIFIED	DATE	INITIALS	COMMENTS
Blank	Blank	Blank	Blank	Blank	Blank	Blank	Blank	Blank	Blank	Blank	Blank	Blank	Blank	Blank	Blank	Blank

Appendix 10

Bulk Investigational Product Accountability Log Example

INVESTIGATOR NAME:	CLICK OR TAP HERE TO ENTER TEXT.	SITE ID:	CLICK OR TAP HERE TO ENTER TEXT.
PROTOCOL NUMBER	CLICK OR TAP HERE TO ENTER TEXT.	PROTOCOL SHORT TITLE	CLICK OR TAP HERE TO ENTER TEXT.

Section 1 – Storage Details

ROOM/LOCATION:		STORAGE REQUIREMENTS:	☐**AMBIENT** ☐**2 – 8 ° C** ☐**OTHER**

Section 2 – Site Study IP Transaction History

DATE / TIME		TRANSACTION DETAILS				BALANCE OF IP			COMMENTS
DATE	Time	Received, Dispensed, Destroyed or Returned	Indicate Received from, Dispensed to Participant ID, Destroyed by, Returned to	Performed by (initials)	Checked by (initials)	IN	OUT	TOTAL	
		☐ Received ☐ Dispensed ☐ Destroyed							

DATE / TIME		TRANSACTION DETAILS				BALANCE OF IP			COMMENTS
		☐ Returned							
		☐ Received ☐ Dispensed ☐ Destroyed ☐ Returned							
		☐ Received ☐ Dispensed ☐ Destroyed ☐ Returned							

Glossary

TERM	**DESCRIPTION**
ADE	Adverse Device Effect
ADR	Adverse Drug Reaction
AE	Adverse Event
AHPRA	Australian Health Practitioner Regulation Agency
AI	Associate Investigator
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ARPANSA Code of Practice	ARPANSA Code of Practice for the Exposure of Humans to Ionizing Radiation for Research
CAPA	Corrective and Preventative Actions
CASA	Civil Aviation Safety Authority
CIOMS	Council for International Organizations of Medical Sciences
CPI	Coordinating Principal Investigator
CRA	Clinical Research Associate
CRC	Clinical Research Coordinator
CRF	Case Report Form
CRO	Contract Research Organisation
CTA	Clinical Trial Approval scheme (previously Clinical Trials Exemption (CTX) scheme)
CTN	Clinical Trial Notification scheme
CTPRG	Clinical Trials Project Reference Group
CTRA	Clinical Trial Research Agreement
CV	Curriculum Vitae
DSMB	Data and Safety Monitoring Board
EMR	Electronic Medical Record
GCP	Good Clinical Practice
HHS	Hospital and Health Service
HREC	Human Research Ethics Committee
IATA	International Air Transport Association
ICH	International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use
IP	Investigational Product
IMD	Investigational Medicinal Device

IMP	Investigational Medicinal Product
IVRS	Interactive Voice Response System
IWRS	Interactive Web Response System
National Statement	National Statement on Ethical Conduct in Human Research (NHMRC)
NHMRC	National Health and Medical Research Council
NMA	National Mutual Acceptance
PI	Principal Investigator
PICF	Participant Information and Consent Form
PMS	Post Registration or Marketing Surveillance Study
RGO	Research Governance Officer
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SMF	Study Master File
SSA Form	Site Specific Assessment Form
SSI	Significant Safety Issue
SSSF	Satellite Site Study File
SUSAR	Suspected Unexpected Serious Adverse Reaction
TGA	Therapeutic Goods Administration
UR	Unit Record
USADE	Unanticipated Serious Adverse Device Event
USM	Urgent Safety Measure

TERM	**DESCRIPTION**
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AI	Associate Investigator
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ARPANSA Code of Practice	ARPANSA Code of Practice for the Exposure of Humans to Ionizing Radiation for Research
CAPA	Corrective and Preventative Actions
CASA	Civil Aviation Safety Authority
CIOMS	Council for International Organizations of Medical Sciences

CPI	Coordinating Principal Investigator
CRA	Clinical Research Associate
CRC	Clinical Research Coordinator
CRF	Case Report Form
CRO	Contract Research Organisation
CTA	Clinical Trial Approval scheme (previously Clinical Trials Exemption (CTX) scheme)
CTN	Clinical Trial Notification scheme
CTPRG	Clinical Trials Project Reference Group
CTRA	Clinical Trial Research Agreement
CV	Curriculum Vitae
DSMB	Data and Safety Monitoring Board
EMR	Electronic Medical Record
GCP	Good Clinical Practice
HHS	Hospital and Health Service
HREC	Human Research Ethics Committee
IATA	International Air Transport Association
ICH	International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use
IP	Investigational Product
IMD	Investigational Medicinal Device
IMP	Investigational Medicinal Product
IVRS	Interactive Voice Response System
IWRS	Interactive Web Response System
National Statement	National Statement on Ethical Conduct in Human Research (NHMRC)
NHMRC	National Health and Medical Research Council
NMA	National Mutual Acceptance
PI	Principal Investigator
PICF	Participant Information and Consent Form
PMS	Post Registration or Marketing Surveillance Study
RGO	Research Governance Officer
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SMF	Study Master File

SSA Form	Site Specific Assessment Form
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○ Revision Chronology

Document History			
Version	**Effective Date**	**Summary of Changes**	**Author**
1.0	*13/11/2025*	Initial Version	Katie Ozdowska