STANDARD OPERATING PROCEDURE FOR HANDLING PRODUCT RECALLS OF CLINICAL TRIAL INVESTIGATIONAL MEDICINAL PRODUCTS OR OTHER TRIAL RELATED DRUGS

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1. PURPOSE

This document describes the procedure for dealing with notification of drug alerts or recalls in medicinal products used in Clinical Trials of Investigational Medicinal Products (CTIMP) which are sponsored or co-sponsored by the University of Dundee (UoD) and/or NHS Tayside (NHST). These medicinal products may be investigational medicinal products (IMPs), non-investigational medicinal products (NIMPs) or routine drug products supplied through Pharmacy stores. Medicinal products may be recalled either because of a defect in the product's quality or because of a serious and unexpected adverse drug reaction.

2. SCOPE

This Standard Operating Procedure (SOP) applies to members of staff associated with and managing research studies that are sponsored by UoD or co-sponsored by NHST.

3. RESPONSIBILITIES

This SOP complies with the requirements of the Medicines for Human Use (Clinical Trial) Regulations 2004, and subsequent amendments.

4. PROCEDURE

4.1 Types of medicinal product defect notifications

4.1.1 An official notification of defects in products can be issued from the following:

- Manufacturer/Distributor
- Scottish Government (Health Department)
- Scottish Government (Health Department) via the Specialist in Pharmaceutical Public Health at NHS Tayside
- Medicines and Healthcare Products Regulatory Authority (MHRA) drug alert department.

4.1.2 The Scottish Government (Health Department) gives Drug Alerts the following classifications:

Class 1 Action Now (including Out of Hours)
Class 2 Action within 48 hours
Class 3 Action within 5 days
Class 4 Caution in use.

4.1.3 Drug Alerts Classes 1 to 3 will be augmented with the words “Medicines Recall” in the title.

4.1.4 An additional classification, “Drug Safety Information” has been introduced for Pharmacovigilance alerts. Drug Safety Information messages should be disseminated immediately upon receipt during working hours to the health professionals specified.

4.1.5 An email notification (followed by a hard copy in the post) is sent to the Area Pharmaceutical Office (APO) in Ninewells Hospital, who will cascade it by email to all hospital dispensaries in NHS Tayside. The APO must receive confirmation of receipt and action from all the dispensaries. The Clinical Trial (CT) Pharmacy staff are also sent the email notification.

4.2 Official notification of drug alerts or product recall

4.2.1 Ninewells CT Pharmacy can be notified of a drug alert or product recall in one of the following ways:

- by email from the APO
- directly from a commercial CTIMP Sponsor or their delegate *i.e.* Clinical Research Organisation (CRO) or CT Monitor, for IMPs or NIMPs supplied solely for the purpose of a CTIMP.
- by the supplier of a drug specifically supplied for a CTIMP
- by a Chief Investigator (CI) , Principal Investigator (PI) or delegate
- by the TASC office.

4.3 Commercial product used in single centre/site studies

4.3.1 On receiving a drug Recall/Alert Notice, Ninewells CT Pharmacy staff will check whether the product is, or has ever been, held in stock for CTIMPs by checking the drug accountability records in the Pharmacy Site Files (PSF) of trials using the product and the clinical trials storage area in CT Pharmacy.

4.3.2 Any affected product held in CT Pharmacy will be removed to an appropriate quarantine area in the CT Pharmacy room and be clearly marked as “in quarantine / do not use.” CT Pharmacy staff will document quantity, reason for and location of quarantined drug on the appropriate accountability log in the study PSF.

4.3.3 The CI or PI of any affected CTIMP will be informed of the alert or recall by the CT Pharmacy staff using the Recording Form for Product Recalls or Alerts affecting CTIMPs Sponsored by UoD or NHST (Doc Ref 094) and a copy of the recall/alert notice.

4.3.4 If affected IMP is being stored out with pharmacy, the CI, PI or delegate will quarantine any affected stock held in the IMP Storage and Supply Site that is being used. The quantity of quarantined IMP, reason for the quarantine and location of quarantined drug should be documented on the drug accountability log in the Trial Master File or Investigator Site File. The CI or PI or delegate will notify CT Pharmacy and TASC when this action has been taken by returning the completed Recording Form for Product Recalls or Alerts affecting CTIMPs Sponsored by UoD or NHST (Doc Ref 094).

4.3.5 Where the notification dictates that product recall is to patient level and if the drug accountability logs are kept in the PSF in CT Pharmacy, then CT Pharmacy will identify any affected trial participants and pass this information to the CI with the Recording Form for Product Recalls or Alerts affecting CTIMPs Sponsored by UoD or NHST (Doc Ref 094). The CI, PI or delegate will be responsible for contacting the participants.

4.3.6 Where drug accountability logs are kept at a local IMP Storage and Supply Site, the CI, PI or delegate will identify affected trial participants and will contact the participant(s) to retrieve the affected product.

4.3.7 The CI, PI or delegate should supply timely and accurate information to affected participants. This may include definition of symptoms, what to do if they experience symptoms and what the arrangements are for further treatment, if any, and/or re-supply. The CI, PI or delegate will order new stock for the trial if appropriate.

4.3.8 Any further instructions issued by the CT Pharmacist regarding quarantined stock of further action should be actioned appropriately by the CI, PI or delegate.

4.4 Commercial product used in multi-centre/multi-site studies

4.4.1 The CI, PI or delegate will carry out the steps described in 4.3.1-4.3.8 and in addition the CI will send a copy of the recall/alert notice to all PIs, Trial co-ordinators and Pharmacies at each participating site explaining the nature of the recall/alert, what the implications are and the recommended action(s) at that site.

4.4.2 Any further instructions issued by the Sponsor should be actioned appropriately.

4.5 IMPs and NIMPs supplied for the sole purpose of use in a specific trial

4.5.1 The CI will carry out the steps described in 4.3.1-4.3.8 and in addition any further instructions issued by the CT Pharmacist should be actioned appropriately.

4.6 Routine drug supplies

4.6.1 The CI will carry out the steps described in 4.3.1-4.3.8 and in addition any further instructions issued by the CT Pharmacist should be actioned appropriately.

4.7 Testing the recall/alert procedure

4.7.1 A test of the recall/alert procedure (mock recall) will be undertaken by TASC approximately every 12 months and within a window of 6-18 months since the previous mock recall.

4.7.2 A UoD and/or NHST sponsored or co-sponsored CTIMP will be selected for the mock recall.

4.7.3 The pharmacy site file for the selected CTIMP will be reviewed in order to select the IMP batch number.

4.7.4 The TASC CT Monitor will send a Recall Alert Notice (Doc Ref 016) by email to the CT Pharmacy. This will be followed up by a phone call to ensure receipt.

4.7.5 The CT Pharmacy should temporarily quarantine the IMP held in pharmacy as documented in the Recall/Alert Notice and notify TASC when this action has been completed.

4.7.6 If the IMP is held out with pharmacy, the CT Pharmacy staff will notify the CI, PI or delegate of the recall and ask for the affected IMP to be temporarily quarantined.

4.7.7 The CI, PI or delegate will notify CT pharmacy when the IMP has been quarantined. The CT Pharmacy staff will notify TASC when this action has been taken.

4.7.8 The CT Monitor and CT Pharmacist will complete the IMP Mock Recall Report (Doc Ref 095) to document the mock recall process.

4.7.9 The TASC CT Monitor will check the temporarily quarantined IMP before it is returned to normal IMP stock.

4.7.10 All documentation relating to the recall will be kept by TASC.

5. ABBREVIATIONS & DEFINITIONS

APO	Area Pharmacy Office
CI	Chief Investigator
CRO	Clinical Research Organisation
CT	Clinical Trial
CTIMP	Clinical Trial of an Investigational Medicinal Product
IMP	Investigational Medicinal Product
NIMP	Non-investigational Medicinal Product
PI	Principal Investigator
PSF	Pharmacy Site File
MHRA	Medicines and Healthcare Products Regulatory Authority
NHST	NHS Tayside
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre
UoD	University of Dundee

6. ASSOCIATED DOCUMENTS & REFERENCES

Doc Ref 016: Recall/Alert Notice
Doc Ref 094: Recording Form for Product Recalls or Alerts affecting CTIMPs sponsored by UoD or NHST
Doc Ref 095: IMP Mock Recall Report

7. DOCUMENT HISTORY

History prior to 2021 is in the archived SOPs available from TASC Quality Assurance Dept.

Version Number:	Reviewed By (Job Title):	Effective Date:	Details of editions made:
7	Tracy Petrie (Quality Assurance Support Officer)	18/01/2021	Uploaded to new TASC SOP template which shows the new TASC website in the footer. Physical scan converted to electronic pdf as a requirement for upload to new TASC website
8	Shona Carson (Clinical Trials Pharmacist)	13/08/2021	Scheduled review no changes required.
9	Shona Carson (Clinical Trials Pharmacist)	13/08/2023	Scheduled review no changes required.

8. APPROVALS

Approved by:	Date:
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	08 Aug 2023