RDSOP27 Implementing a Drug Recall for IMP/NIMP

Greater Manchester Mental Health NHS Foundation Trust
Title of Standard Operating Procedure: RDSOP27 Implementing a Drug Recall for IMP/NIMP

Document Summary: This standard operating procedure (SOP) describes the process for implementing recalls of trial medication when Trust pharmacy staff are notified about the recall / drug alert. Trial medication can include investigational medicinal products (IMPs) and / or non-investigational medicinal products (NIMP's).

Document Author: Maxine Syme R & I Pharmacist

Target Audience: Trust-wide, Research Community, Internal and External Researchers

Consultation: R & I Office, research community and R & I Committee members

Approval Committee: R & I Committee

Cross Reference Document(s): Research Approval Policy All Trust R & I SOPs

Contact details for further information: Sarah Leo Head of R & I Office 0161 271 0076 researchoffice@gmmh.nhs.uk

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1. Introduction

When a defect of a licensed product is considered to be a risk to public health, the marketing authorisation holder withdraws the affected product from use and the Medicines and Healthcare products Regulatory Agency (MHRA) issues a 'drug alert' letter. This alert is classified from 1 to 4 depending upon the risk presented to the public health by the defective product.

Classification of Drug Alerts

❖ Class 1:
  • Action now (including out of hours).
  • The defect presents a life-threatening or serious risk to health.

❖ Class 2:
  • Action within 48 hours.
  • The defect may cause mistreatment or harm to the patient, but it is not life-threatening or serious.

❖ Class 3:
  • Action within 5 days.
  • The defect is unlikely to cause harm to the patient, and the recall is carried out for other reasons, such as non-compliance with the marketing authorisation or specification.

❖ Class 4:
  • This alert advises “caution in use”.
  • This is where there is no threat to patients or no serious defect likely to impair product use or efficacy. (These alerts are generally used for minor defects in packaging or other printed materials).

Drug alerts to recall can be issued by the MHRA, the Royal Pharmaceutical Society or trial sponsors. Drug alerts can be received via the NHS Central Alerting System (CAS). In addition to the national CAS, Stepping Hill Quality Control laboratories (QCNW) and the National Medicines Information Centre in Liverpool manage a drug defect reporting system in the North West of England. QCNW is in place to ensure drug alerts are managed outside of working hours.

2. Purpose

This standard operating procedure (SOP) describes the process for implementing recalls of trial medication when Trust pharmacy staff are notified about the recall / drug alert. Trial medication can include investigational medicinal products (IMPs) and / or non-investigational medicinal products (NIMPs).

This SOP may not always be followed exactly as trial sponsors will usually have their own drug recall procedures which need to be followed. Also for Trust sponsored trials, the trial team and / or Chief Investigator (CI) in conjunction with the Trust, may decide to adapt the drug recall procedure for individual trials.
3. Roles and Responsibilities

3.1 Duties within the organisation

It is the responsibility of the Research & Innovation Office to make Trust R & I SOPs available to all research active staff working on Trust-approved research studies.

It is the responsibility of the study Chief Investigator (CI) or local Principal Investigator (PI) to ensure that up-to-date copies of Trust R & I SOPs are available to research staff.

It is the responsibility of the study Chief Investigator or local Principal Investigator to ensure up-to-date SOPs are filed in the Investigator Site File and are available to research staff, and to inform the Research Support Co-ordinator of the names of all research staff involved on a study so that copies of SOPs can be distributed appropriately.

It is the responsibility of the study Chief Investigator or Principal Investigator to designate if the SOPs of another organisation are to be followed for a study. For example those of a Clinical Research Network or commercial sponsor. If there is significant conflict between the external SOP and the Trust R & I SOP it is the responsibility of the CI or PI to resolve these with the Research Office prior to starting the study.

It is the personal responsibility of all staff to follow Trust (or the designated alternative organisations) procedural documents.

The Research & Innovation Office is responsible for managing Trust R & I SOPs including their approval, dissemination and archiving. All Trust R & I SOPs must be made available via Q-Pulse and published on the Trust website.

3.2 R&I Governance Co-ordinator

The R&I Governance Co-ordinator is responsible for managing Trust R&I SOPs including their approval, dissemination and archiving. All Trust R&I SOPs must be published on the Trust intranet (link via R&I site).

3.3 Specific to this SOP

It is the duty of the Chief Pharmacist to ensure that Service Level Agreements are in place with Acute Trusts allied to GMMH.
4. Procedure

**Drug Recall for non-Trust Sponsored Clinical Trials of an Investigational Medicinal Product (CTIMPs)**

**Flow Chart 1: Cascade of Information – Out of Hours – Class 1 Drug Recall – Action Now - IMP/NIMP**

**Key:**
- **Pink = Immediate Action**
- **Yellow = Action to be Taken the Next Day**
- QCNW = Quality Control North West (Stepping Hill Quality Control laboratories)
- GMMH = Greater Manchester Mental Health NHS Foundation Trust
- CAS = NHS Central Alerting System

![Flow Chart 1: Cascade of Information – Out of Hours – Class 1 Drug Recall – Action Now - IMP/NIMP](image)

4.1 Out of hours procedure – Class 1 Drug Recall - Notification
For some trials the sponsor will contact the PI directly to manage the drug recall and so it might not be necessary to contact the on-call pharmacy service.

If the on-call pharmacy service is contacted about a drug recall for trial medication, the on-call should check the information in the on-call file or sent via email by GMMH’s R & I Pharmacist or proxy to check whether:
- the recall is to be managed by the PI;
- the Acute Trust’s pharmacy on-call needs to be contacted, or
- if the on-call pharmacist is required to go into the clinical trials pharmacy at Park House to manage the recall.

**Checking Stock**

GMMH’s on-call pharmacist must check the records in the on-call file to see if the affected drug is being used in any of the trials.

If the affected drug is being used, the on-call pharmacist must check which pharmacy or pharmacies are involved with dispensing IMP/NIMP for the trial.

If any of the Acute Trust pharmacies are involved, GMMH’s on-call pharmacist must contact the Acute Trust’s on-call pharmacist to check they are implementing the drug recall – the Acute Trust’s on-call pharmacy team can be contacted via the Acute Trust’s switchboard.

If the clinical trials pharmacy at Park House is dispensing the IMP/NIMP, then GMMH’s on-call pharmacist must check whether they need to go into the pharmacy or if the recall is to be managed by the PI. This can be decided by checking the information in the on-call file or sent by email from the R & I Pharmacist or proxy. If the PI is to manage the recall, the on-call pharmacist must use the information in the on-call file or in emails to contact the PI.

If the on-call pharmacist needs to go into the clinical trials pharmacy at Park House, they must enter the pharmacy, disable the alarm (instructions for opening the trials pharmacy are in the on-call file and the alarm code has been provided to the relevant pharmacy staff) and locate the pharmacy file for the trial, and then:

Check the pharmacy shelves, and / or the delivery notes/receipt documentation and drug accountability logs to identify if any affected batches of IMP/NIMP have been received.

If affected batches have been received and the stock is in pharmacy, GMMH’s on-call pharmacist must place the affected IMP/NIMP in quarantine (please see quarantine section below).

If affected batches have been received and the affected IMP/NIMP has been stored outside the pharmacy department, for example on a ward, community mental health team or treatment suite, GMMH’s on-call pharmacist must arrange for the affected IMP/NIMP to be returned to pharmacy as soon as possible. When the affected IMP/NIMP is returned to pharmacy, it should be placed in quarantine (please see quarantine section below). The location of the...
affected IMP/NIMP prior to quarantine should be recorded on the Drug Recall Form (Appendix A).

GMMH’s on-call pharmacist must check if any of the clinical trial participants have received affected IMP/NIMP and the date the affected IMP/NIMP was dispensed. Dispensing information must be documented on the Drug Recall Form (Appendix A).

If no participants have received affected IMP/NIMP, the on-call pharmacist must record this on the Drug Recall Form (Appendix A).

If affected IMP/NIMP has been dispensed to a participant and requires immediate recall, GMMH’s on-call pharmacist must contact the site investigator by telephone. (Contact telephone numbers for investigators will be listed in the pharmacy file for the trial).

The investigator will then determine when and how to contact the participants and the research team.

GMMH’s on-call pharmacist must document that they have contacted the investigator on the Drug Recall Form (Appendix A).

GMMH’s on-call pharmacist must ensure they have completed all the relevant sections of the Drug Recall Form (Appendix A) and scan and email it to GMMH’s R & I Office, either straightaway or the next working day. The R & I Pharmacist will arrange to collect the original form as soon possible.

The next day, GMMH’s on-call pharmacist must contact GMMH’s R & I Pharmacist on telephone number 07918 755 235 (or GMMH’s R & I Office on telephone number 0161 271 0607 if the R & I Pharmacist is unavailable) to ensure GMMH are aware of the drug recall and the action taken.

GMMH’s R & I Pharmacist must follow up any action taken by the on-call pharmacist and ensure that affected batches of IMP/NIMP and any affected IMP/NIMP supplied to participants are returned to pharmacy and placed into quarantine (please see quarantine section below).

GMMH’s R & I Pharmacist must complete the Drug Recall Form (Appendix A) and make sure it is filed, along with a copy of the drug alert, in the electronic R & I folder for the trial and the trial pharmacy file, as appropriate.

GMMH’s R & I Pharmacist (or R & I Manager if the R & I Pharmacist is unavailable) must complete a Trust incident form on Datix. If the affected drug is not being used in any CTIMP, GMMH’s on-call pharmacist must write on the Drug Recall Form (Appendix A) –“Drug not currently used as an IMP/NIMP. No action required.” The form should be scanned and emailed to GMMH’s R & I Office (researchoffice@gmmh.nhs.uk), either straightaway or the next working day. The R & I Pharmacist will arrange to collect the original form as soon possible.

If the drug could have potentially been involved in a CTIMP but was not (for example, if an affected batch had been received, but was not supplied from pharmacy):

GMMH’s on-call pharmacist must complete the relevant sections of the Drug Recall Form (Appendix A).

The next day, GMMH’s on-call pharmacist must contact GMMH R & I Pharmacist on telephone number 07918 755 235 (or GMMH R & I Office on telephone number 0161 271 0607 if the R
& I Pharmacist is unavailable) to ensure GMMH are aware of the drug recall and the action taken.

GMMH’s on-call pharmacist must ensure they have completed all the relevant sections of the Drug Recall Form (Appendix A) and scan and email it to GMMH’s R & I Office, email address: researchoffice@gmmh.nhs.uk, either straightaway or the next working day. The R & I Pharmacist will arrange to collect the original form as soon possible.

GMMH’s R & I Pharmacist must complete the Drug Recall Form (Appendix A) and make sure it is filed, along with a copy of the drug alert, in the electronic R & I folder for the trial and the trial pharmacy file, as appropriate.

GMMH’s R & I Pharmacist (or R & I Manager if the R & I Pharmacist is unavailable) must complete a Trust incident form on Datix to record this near miss.

### 4.2 Quarantine of Stock

GMMH’s on-call pharmacist must segregate affected IMP/NIMP stock and label it ‘in quarantine’. The affected IMP/NIMP should be stored at the correct temperature, even though it has been quarantined.

### 4.3 Further Action

The next working day GMMH’s R & I Pharmacist must check that the actions specified in the drug alert have been completed, for example that affected IMP/NIMP has been returned to pharmacy and has either destroyed, is being returned to the sponsor or is being kept in quarantine until further instructions have been received. The R & I Pharmacist must record this information on the Drug Recall Form (Appendix A).

The R & I Pharmacist must check that replacement IMP/NIMP has been ordered if stocks have depleted and there is a possibility that participants could go without treatment.

The R & I Pharmacist must contact the CTIMP sponsor to inform them of the action taken and to request further stock if necessary.

If the recall is likely to cause an interruption to supply and likely to interrupt participants treatment, the R & I Pharmacist must inform the investigator and research team.

The R & I Pharmacist must ensure a Drug Recall Form (Appendix A) has been completed and filed in the electronic R & I folder for the trial and the trial pharmacy file, as appropriate.

Further action may include checking the PI has completed the drug recall or that the Acute Trusts’ pharmacies have completed the drug recall – all of which needs to be documented.
Flow Chart 2: Cascade of Information – During Normal Working Hours –

Class 1 Recall – Action Now - Licensed IMP/NIMP
Key: **Pink = Immediate Action**

- QCNW = Quality Control North West (Stepping Hill Quality Control laboratories)
- GMMH = Greater Manchester Mental Health NHS Foundation Trust
- CAS = NHS Central Alerting System

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MHRA sends drug alert via QCNW and / or CAS

GMMH

Lead Pharmacists for Mental Health, including GMMH’s R & I Pharmacist

Site Investigator

Research Team

Clinical Trial Participant (if required)

Site/Acute Trust Pharmacy Clinical Trials Pharmacist/Team
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Flow Chart 3: Cascade of Information – During Normal Working Hours –

Class 1 Recall – Action Now - Unlicensed IMP/NIMP

Key: Pink = Immediate Action
GMMH = Greater Manchester Mental Health NHS Foundation Trust

1. Trial Sponsor Notification of Recall
2. GMMH R & I Pharmacist/R & I Office / Site Investigator
3. Site Investigator
4. Research Team
5. Clinical Trial Participant (if required)
6. Site/Acute Trust Clinical Trials Pharmacist/Team
4.4 During normal working hours

Receipt of drug alerts for licensed IMP/NIMP used in CTIMPs and the initial response.

Drug alerts can be received via the CAS and / or from Stepping Hill Quality Control laboratories (QCNW) and the National Medicines Information Centre in Liverpool.

GMMH must ensure the Lead Pharmacists for GMMH, including the R & I Pharmacist, are aware of the drug alert. A copy (email version) of the MHRA alert and IMP/NIMP details, (which will state the urgency of the alert and the necessary action to be taken, including the recall of the affected batches) must be cascaded to the R & I Pharmacist.

GMMH’s R & I Pharmacist will co-ordinate the recall if the affected drug is being dispensed from GMMH’s own pharmacy or liaise with the relevant Acute Trust clinical trials pharmacist or pharmacy team to ensure they have received the drug alert, are co-ordinating a response in-line with directions on the drug alert and documenting information on the Drug Recall Form (Appendix A). A lead person responsible for implementing the drug recall must be identified and their name documented on the Drug Recall Form (Appendix A).

4.5 Receipt of drug alerts for unlicensed IMP/NIMP and initial response

If the manufacturer of an unlicensed product initiates a recall of an IMP/NIMP this information will be issued direct from the sponsor of the CTIMP. This drug alert may be received by letter, telephone call, email or via an Interactive Web Response System (IWRS), by the site investigator, GMMH’s R & I Office or R & I Pharmacist or to a member of the Acute Trust clinical trials pharmacy team. (The person informed of the drug recall must ensure the other parties have been informed).

GMMH’s R & I Pharmacist will co-ordinate the recall if the affected drug is being dispensed from GMMH’s own pharmacy or liaise with the relevant Acute Trust clinical trials pharmacist or pharmacy team to ensure they have received the drug alert, are co-ordinating a response in-line with directions on the drug alert and documenting information on the Drug Recall Form (Appendix A). A lead person responsible for implementing the drug recall must be identified and their name documented on the Drug Recall Form (Appendix A).
4.6 Checking Stock

GMMH’s R & I Pharmacist or proxy must check the CTIMP log (circulated to the pharmacists by email and stored electronically) to determine if the drug alert is relevant to any of the CTIMPs GMMH is participating in or sponsoring.

If the drug being recalled is not used in any CTIMPs taking place within GMMH, then the R&I Pharmacist must write on the hard copy of the alert, “Drug not currently used as an IMP/NIMP. No action required.” The R&I Pharmacist must file the endorsed drug alert in the R&D Drug Alert file, which is kept in GMMH R&D Office.

If the affected drug is used in a CTIMP being conducted within GMMH, the R & I Pharmacist or proxy must contact the relevant clinical trials pharmacy team to ask them to check the drug delivery/receipt and drug accountability sections in the relevant CTIMP pharmacy file(s) to determine if any affected batches have been received/used. The R & I Pharmacist or proxy will ask the clinical trials pharmacy team to scan and email copies of the delivery/receipt documentation and drug accountability logs to GMMH’s R & I Office (researchoffice@gmmh.nhs.uk) - patient identifiable data/information would need to be removed from these logs.

GMMH’s R & I Pharmacist or proxy will check the stock in GMMH’s own pharmacy. If affected stock has not been received, the R & I Pharmacist or proxy must write on the copy of the drug alert, “Drug used as an IMP/NIMP, but no affected batches have been received. No action required.” The R & I Pharmacist or proxy must file a copy the endorsed drug alert in the appropriate electronic R & I folder(s) and trial pharmacy file(s). If affected batches of IMP/NIMP have been used in a CTIMP, the R & I Pharmacist or proxy must ensure the affected batches are located and removed from the area(s) identified (includes any off-site storage) and placed in an area of pharmacy suitable for IMP/NIMP quarantine.

The R & I Pharmacist or proxy must ensure affected IMP/NIMP is not used. The R & I Pharmacist or proxy must ask the clinical trials pharmacy team to check the participant-specific drug accountability logs in the relevant CTIMP-specific pharmacy file to identify all participants that have received affected IMP/NIMP. The R & I Pharmacist or proxy will ask the clinical trials pharmacy team to email copies of the delivery/receipt documentation and drug accountability logs to GMMH’s R & I Office (researchoffice@gmmh.nhs.uk) - patient identifiable data/information would need to be removed from these logs.

GMMH’s R & I Pharmacist or proxy will check the participant-specific drug accountability logs for the CTIMPs being dispensed via GMMH’s own pharmacy. The R & I Pharmacist or proxy must determine the date the affected drugs were dispensed and record this information on the Drug Recall Form (Appendix A). If no patients have received affected IMP/NIMP, this should be recorded on the Drug Recall Form (Appendix A).

The R & I Pharmacist or proxy must ensure the drug recall procedure is completed and that the Drug Recall Form (Appendix A) is completed and a copy filed, along
with a copy of the drug alert, in the appropriate electronic R & I folder(s) and trial pharmacy file(s).

GMMH’s R & I Pharmacist or proxy must email the CTIMP sponsor to inform them of the actions taken following a drug alert which involved IMP/NIMP used in their CTIMP, regardless of whether affected batches were received by the pharmacy. GMMH’s R & I Pharmacist or proxy must keep a copy of the correspondence to the sponsor in the appropriate electronic R & I folder(s) and trial pharmacy file(s), as appropriate.

4.7 Quarantine of Stock

GMMH’s R & I’s Pharmacist or proxy must ensure the affected IMP/NIMP being stored in GMMH’s own pharmacy is placed in quarantine. GMMH’s R & I Pharmacist or proxy must ensure the clinical trials pharmacy team at the relevant pharmacy site have put affected IMP/NIMP in quarantine (withdrawn all affected IMP/NIMP from storage areas and isolated it so the affected stock cannot be used).

The clinical trials pharmacy team and/or GMMH’s R & I Pharmacist or proxy must segregate affected IMP/NIMP stock and label it ‘in quarantine’. The affected IMP/NIMP should be stored at the correct temperature, even though it has been quarantined. GMMH’s R & I Pharmacist or proxy must check that actions specified in the drug alert have been completed, (for example that the affected NIMP/IMP has been returned to the manufacturer or CTIMP sponsor or that the destroyed drugs have been destroyed). The R & I Pharmacist or proxy must record this information on the Drug Recall Form (Appendix A).

Where the clinical trials pharmacy team/R & I Pharmacist or proxy have been instructed to wait for further instructions, affected IMP/NIMP must be kept in quarantine until more information is received. (Replacement stock or credit may be available through the trial sponsor, the manufacturer or wholesaler).

If no action needs to be carried out, the R & I Pharmacist or proxy must record this on the Drug Recall Form (Appendix A).

The clinical trials pharmacy team must inform the R & I Pharmacist or proxy if unaffected stock is low and there is a possibility that participants may run out of IMP/NIMP.

The R & I Pharmacist or proxy must contact the CTIMP sponsor to inform them of the action taken and to request further stock if necessary.
If the recall causes an interruption to supply and likely to interrupt participants’ treatment, the R & I Pharmacist or proxy must inform the site investigator and research team.

The R & I Pharmacist or proxy must ensure a Drug Recall Form (Appendix A) has been completed and filed, along with a copy of the drug alert, in the appropriate electronic R & I folder(s) and trial pharmacy file(s), as appropriate.

4.8 Informing Investigators and Clinical Trial Participants

If an alert is received in normal working that concerns a drug that has been used as part of a CTIMP or if the drug must be retrieved from clinical trial participants, GMMH’s R&I Pharmacist must notify the investigator and sponsor promptly (timescale as dictated by the alert).

The R&I Pharmacist must contact the investigator and sponsor by telephone and by email and print a copy of the email to file in R&I CTIMP file and Drug Alert file.

When required, the R&I Pharmacist must follow up out of hours contact by the on-call pharmacist with a telephone call and email.

The R&I Pharmacist must document this communication on the Drug Recall Form (Appendix A).

The R&I Pharmacist must ensure a Trust incident form (via Datix) is completed.

The investigator will determine when and how to contact the research team and clinical trial participants.

4.9 Drug Recall for Trust Sponsored CTIMPs

This involves drugs (IMP/NIMP) that are the subject of drug alerts cascaded by QCNW, the CAS or drugs that GMMH have decided to recall. A qualified person (QP) must be involved in the decision to recall drugs and advise on appropriate action. The R&I Pharmacist or proxy will liaise with the QP and the trial’s CI when a trial drug recall is necessary.

Before a recall for a trial is initiated it is recommended that the MHRA (the Clinical Trials Unit and the Defective Medicines Report Centre) is notified, as discussions could lead to a different decision for the trial-related product (for example, the decision to continue use and keep the trial going rather than recall).
4.10 Out of Hours

GMMH's on-call pharmacist must determine if the affected drug has been dispatched to other sites, using the dispatch log provided by GMMH, filed in the on-call file or in individual trial files kept in pharmacy.

If affected IMP/NIMP has been dispatched to other sites, GMMH's on-call pharmacist must contact the on-call pharmacist at the other sites to action the recall or check the recall is being implemented. The on-call pharmacists at other sites can be contacted via the hospital switchboards.

If affected IMP/NIMP has been dispensed to clinical trial participants and requires immediate recall, the on-call pharmacist, covering the site where affected IMP/NIMP has been supplied to participants, must contact the site investigator by telephone. (Investigators' contact telephone numbers will be listed in the CTIMP pharmacy file).

The investigator will then determine when and how to contact the participants and the research team.

The on-call pharmacist at each site must complete the GMMH Sites Drug Recall Form (Appendix B) and scan and email this form to GMMH R&I Office. The on-call pharmacists must leave the original form for the attention of the clinical trials pharmacist/pharmacy team at that particular site so that the form can be posted to GMMH's R&I Office (3rd Floor, Rawnsley Building, Manchester Mental Health and Social Care Trust, Hathersage Road, Manchester, M13 9WL).

The GMMH's R&I Office must file this form in the R&I CTIMP file and Drug Alert file and pharmacy trial file if appropriate.

The GMMH's R&I Office must complete a Trust incident form on Datix.

The R&I Pharmacist must follow up any outstanding actions.

4.11 During Normal working Hours

GMMH's R&I Pharmacist must act as the responsible person to ensure clinical trials pharmacy staff know about the recall, are following the recall procedure and that affected IMP/NIMP is dealt with accordingly.

The R&I Pharmacist must check if affected IMP/NIMP has been dispatched to other sites using the dispatch log.

If affected stock has been despatched to other sites, the R&I Pharmacist must contact the clinical trials pharmacist (or clinical trials technician if the pharmacist is not available) at the other trial sites to notify them of the recall and advise them on
the action to be taken. The R&I Pharmacist will notify pharmacy staff at the other sites by email or fax and follow that up immediately with a telephone call.

The R&I Pharmacist must check with the clinical trials pharmacist/pharmacy team at each site to establish if affected IMP/NIMP has been dispensed to any clinical trial participants. (The R&I Pharmacist can ask for drug accountability logs to be faxed to GMMH’s R&I Office from each site if this is deemed necessary).

If affected IMP/NIMP has been dispensed to participants and requires immediate recall, the R&I Pharmacist must contact the relevant investigator(s) by telephone. (Investigators’ contact telephone numbers will be listed in the CTIMP-specific pharmacy file or R&I file).

The R&I Pharmacist must ensure a GMMH Sites Drug Recall Form (Appendix B) is completed and filed in the R&I CTIMP file.

GMMH’s R&I Office must complete a Trust incident form on Datix. GMMH’s R&I Pharmacist must follow up any outstanding actions.

### 4.12 Testing the Drug Recall Procedure

This recall procedure must be tested periodically as stipulated by the R&I Office. The recall procedure should be tested for a Trust sponsored CTIMP and a non-Trust sponsored CTIMP, (depending on the type of CTIMPs being conducted within GMMH at that time).

A test drug recall email will be sent by the R&I Pharmacist to the relevant site/Acute Trust pharmacy department during normal working hours stating ‘test recall’.

This test recall must be treated as a class 1 drug alert, stating the time frame in which the recall must be completed and requiring drugs to be recalled from clinical trial participants. (It is not necessary to contact the actual participants).

The personnel contacted, the action taken and the outcome of the test must be documented on the Test Drug Recall Form (Appendix C).

Findings from the test recall should be discussed with the sponsor of the trial. Where GMMH is the sponsor, the R&I Pharmacist should discuss the findings with the Chief Pharmacist, R&I Manager and Governance Co-ordinator. If deemed necessary, the drug recall procedure should be reviewed and changes made where appropriate. Any further actions to be put in place should be agreed and documented on the Test Drug Recall Form (Appendix C).

The Test Drug Recall Form must be filed in the R&I Drug Alert file and the relevant R&I file kept in GMMH R&I Office (and in the relevant pharmacy trial file if applicable).
5. Equality Impact Assessment

This SOP has been equality impact assessed by the author using the Trust's Equality Impact Assessment (EqIA), which has been submitted to the Equality and Diversity Department for ‘Service Equality Team Sign Off’.

No significant issues in relation to equality, diversity, gender, colour, race or religion are identified as raising a concern.

6. Consultation, Approval and Ratification Process

6.1 Consultation and Communication with Stakeholders

Trust R&I SOPs are written by a member of the R&I Office or MMC staff with relevant expertise and experience. Additional advice is sought from members of the research community within the Trust, including the R&I Committee, or external advisors when this is appropriate.

6.2 SOP Approval Process

All Trust R&I SOPs are subject to approval by the R&I Committee. This SOP is also subject to approval by the MMC. The SOP will then be sent to the Trust Management Board for ratification.

7. Dissemination and Implementation

7.1 Dissemination

When approved, this SOP will be posted on the Trust R&I Office Intranet site; only the current version will be available. A list of current versions will also be posted on the public Trust website; researchers who do not have access to the intranet should refer to this list and request copies from the R&I Office accordingly.

All researchers listed on the Research Office ‘active researcher’ mailing list will be notified by email when an updated version of an SOP is available.

7.2 Implementation of Procedural Documents

Support and advice on the implementation of this SOP can be obtained via the Research Office.
8. Review, Monitoring Compliance with and the Effectiveness of Procedural Documents

8.1 Process for Monitoring Compliance Effectiveness

Review will be undertaken by the Research Office Management. Compliance with the Trust R&I SOPs by researchers will be monitored via the Trust’s Research Governance Monitoring Programme where appropriate.

SOP contents will be reviewed against any changes to the applicable guidelines and regulations and taking into account any feedback received from researchers or via the Monitoring Programme.

Review and monitoring will be conducted based on an initial risk assessment of the project. This process may change based on results on any monitoring visit.

The outcome of the review – and any resulting amendments - will be reported to the R&I Committee and the MMC.

8.2 Standards and Key Performance Indicators KPI’s

This SOP will be available on the Trust intranet.

This SOP must be reviewed at least every three years or when there are significant changes to the document.

9. References and Bibliography

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ICH Topic E6 (R1) Guideline for Good Clinical Practice.

10. Associated Trust Documents

RDSOP4: Research Approval Process (including amendments)
RDSOP8A: Pharmacovigilance for Trust-Sponsored MHRA-regulated Clinical Trials
RDSOP8B: Pharmacovigilance for MHRA-regulated Clinical Trials not sponsored by the Trust
RDSOP 10B: IMP Management
RDSOP11: Research Governance Monitoring
RDSOP22: Approval Procedure for Clinical Trials of Investigational Medicinal Products (CTIMPs).
# Appendix A – Drug Recall Form

<table>
<thead>
<tr>
<th>Details of Alert</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(attach copy of official notification and include class of recall)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of Recall</th>
<th>Date and Time Recall Alert Received</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Details of IMP/NIMP Affected</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(include details of formulation, strength affected, batch number and expiry date)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical Trial of an Investigational Medicinal Product (CTIMP) Affected</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(include EudraCT number and protocol name/number)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name of Pharmacy Staff Member Responsible for Implementing the Drug Recall</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Location of Affected IMP/NIMP</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(before quarantine)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Location of Quarantined IMP/NIMP</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Details of Clinical Trial Participants that have Received Affected Drug</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(include dispensing dates)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Investigator(s) informed?</th>
<th>Date and Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>(include contact telephone number(s) here)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Action Completed</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>All Recalled Drugs Returned to Pharmacy?</strong>&lt;br&gt; (please circle one of the options)</td>
<td><strong>Yes / No / Not applicable</strong>&lt;br&gt; If ‘No’ please state what is outstanding and why:</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td><strong>Site/Acute Trust Pharmacy Staff Providing Information on this Form</strong>&lt;br&gt; (print name and sign)</td>
<td><strong>Date</strong></td>
</tr>
<tr>
<td><strong>Form Received by</strong>&lt;br&gt; (GMMH R&amp;I Pharmacist to print name and sign)</td>
<td><strong>Date</strong></td>
</tr>
</tbody>
</table>
## Appendix B– GMMH Sites Drug Recall Form

<table>
<thead>
<tr>
<th>Details of Alert</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(attach copy of official notification and include class of recall)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of Recall</th>
<th>Time Recall Started</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Details of IMP/NIMP(s) Affected</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(include details of formulation, strength affected, batch number and expiry date)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical Trial of an Investigational Medicinal Product (CTIMP) Affected</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(include EudraCT number and protocol name/number)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name of Pharmacy Staff Member Responsible for Implementing the Drug Recall</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sites that have Received Affected IMP/NIMP</th>
<th>Date and Time Site(s) Informed</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Location of Quarantined IMP/NIMP – List per Site</th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Details of Clinical Trial Participants that have Received Affected IMP/NIMP</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(include dispensing dates)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Investigator(s) informed?</th>
<th>Date and Time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>All Recalled Drugs Returned to Pharmacy?</strong></td>
<td><strong>Yes / No / Not applicable</strong></td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>(please circle one of the options)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If ‘No’ please state what is outstanding and why:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Site/Acute Trust Pharmacy Staff Providing Information on this Form</strong></th>
<th><strong>Date</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>(print name and sign)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Form Received by</strong></th>
<th><strong>Date</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>(GMMH R&amp;I Pharmacist to print name and sign)</td>
<td></td>
</tr>
</tbody>
</table>
## Appendix C– Test Drug Recall Form

<table>
<thead>
<tr>
<th>Details of Test Drug Recall</th>
<th>Time Test Drug Recall Started</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Test Drug Recall</td>
<td></td>
</tr>
<tr>
<td>Clinical Trial of an Investigational Medicinal Product (CTIMP)</td>
<td>C TIMP Sponsored or Hosted by MMHSCT?</td>
</tr>
<tr>
<td>(include EudraCT number and protocol name/number)</td>
<td>Document Personnel Contacted, Action Taken and Outcome of the Test</td>
</tr>
<tr>
<td>Process Reviewed and by Who?</td>
<td>Any Further Actions to be Put in Place?</td>
</tr>
<tr>
<td>Form Completed by</td>
<td>Date</td>
</tr>
<tr>
<td>------------------</td>
<td>------</td>
</tr>
<tr>
<td>(GMMH R&amp;I Pharmacist to print name and sign)</td>
<td></td>
</tr>
</tbody>
</table>

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