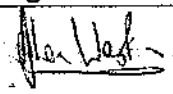
STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_009

SOP Title: Disposal/Destruction of clinical trial medication

Role	Name	Signature	Date
SOP Author	Alex Weston- Principal Pharmacist R&D		02-Mar-2018
SOP Reviewer	Victoria Croome- Clinical Trials Technician		06-Mar-2018
SOP Authoriser	Raj Parekh- Chief Pharmacist		05-APR-2018
SOP Review Date	**June 2020**		

Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	01-Nov-2012	Initial Version	01-Nov--2012
2	27-May-2016	Template updated to include additional sections and further guidance in preparation of SOPs	12-Jan-2016
3	1-June-2018	Review to ensure content still current	05-Apr-2018

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1. PURPOSE AND CONTEXT

1.1 To describe the procedures for disposal/ destruction of clinical trial medication.
1.2 Covers the procedures to follow when clinical trial medication is to be disposed of or destroyed following sponsor approval, including
- Local disposal / destruction procedures
- Procedures for returning to sponsor for destruction

2. DEFINITIONS

3. PROCEDURE and RESPONSIBILITIES

- As part of the trial review and set up process, ascertain the specific instructions for the disposal/destruction of clinical trial medication, and document the agreed process in the trial specific pharmacy instructions.

3.1 General steps

3.1.1 Locate the relevant pharmacy site file and follow the trial specific procedures on disposal/destruction of clinical trial medication.
3.1.2 Collate together all clinical trial medication requiring disposal/destruction which may include returned clinical trial medication from participants, expired stock and/or unused stock to be disposed of at the end of a trial.
3.1.3 Confirm that sponsor has provided written authorisation to proceed with the disposal/destruction of clinical trial medication indicated in step 3.1.2 (unless approval is not required as specified in the trial specific pharmacy instructions).
3.1.4 Locate the relevant accountability log(s) from the pharmacy site file. This may include participant specific accountability log and/or product specific cumulative accountability log and/or inventory log. Where required, complete the relevant sections relating to disposal/destruction.
3.1.5 Perform a two/three way stock level check (actual vs. log vs. computer). If incorrect, refer to the clinical trial pharmacist / technician.
3.1.6 Evidence of clinical trial medication disposal/destruction must be documented. Complete any documentation necessary as requested by the sponsor. If unavailable, use an in house *Disposal/destruction of clinical trial medication form* (Form 04). Where required, obtain a signature from the sponsor's representative or another member of the pharmacy team to verify that the information is correct.
3.1.7 File the completed log(s)/form(s) in the appropriate section of the pharmacy site file.
3.1.8 Remove any patient/subject identifiers (as appropriate) from the clinical trial medication and dispose of these as confidential waste.

3.1.9 Proceed to section 3.2 for local disposal/destruction procedures, and section 3.3 for returning to sponsor procedures.

3.2 Local disposal/destruction

3.2.1 Print off a 'Record of Disposal of Clinical Trial Supplies' form (Form 04) or use specific forms / documentation from sponsor
3.2.2 Fill in the Trial details
3.2.3 Place all clinical trial medication for disposal/destruction into a clinical waste bin appropriate for the nature of that clinical trial medication as per local hospital waste policy
3.2.4 Put on gloves if there is contamination of the package or leakage
3.2.5 Outer packaging should be disposed of in a confidential waste bin

3.3 Returning to the sponsor

3.3.1 Packaging of clinical trial medication for returning to the sponsor is usually carried out by the sponsor's representative during monitoring visit.
3.3.2 Where pharmacy is responsible for packaging of clinical trial medication for returning to the sponsor, follow the steps as specified in the trial specific pharmacy instructions.
3.3.3 Where required, liaise with the sponsor designated courier for the collection of the clinical trial medication.
3.3.4 Obtain a copy of the courier receipt when the courier collects the package.
3.3.5 File the copy of the courier receipt in the appropriate section of the pharmacy site file.

	Responsibility	Undertaken by	Activity
1	Sponsor	Study monitor or Clinical Research Associate	The sponsor of the trial is responsible for the disposal of returned and unused IMP. The study monitor or CRA will act on behalf of the sponsor.
2	Clinical Trials Pharmacist	Research nurse and pharmacy staff	Assisting study monitor or Clinical Research Associate to complete paperwork and return to sponsor for disposal.
3	Clinical Trials Pharmacist	Research nurse and pharmacy staff	Complete paperwork and prepare IMP for disposal at site.

4. SUPPORTING MATERIAL and ATTACHMENTS

- Disposal/destruction of clinical trial medication form (Form 04)
- CP R&D_018: Processing of returned clinical trial medication SOP

5. TRAINING

Knowledge of the Clinical Trial Protocol is essential as specific instructions regarding the destruction of the drugs may be detailed in the Protocol and may vary between trials.

6. REFERENCES