STANDARD OPERATING PROCEDURE

Destruction of Clinical Trial Materials

1 Scope

This procedure documents the requirements for the activities associated with destruction of clinical trial materials (CTM) in the Royal Children's Hospital (RCH) pharmacy department. This procedure applies to all CTM that have passed their use-by, expiry or retest date, unused CTM at the conclusion of a protocol and CTM returns from participants.

The destruction of CTM must comply with Good Clinical Practice (GCP) principles, protocol specific requirements and the RCH waste management procedure.

2 Responsibilities

2.1 Pharmacist/Pharmacy Technician

(i) Ensure that staff involved in processes associated with the destruction of CTM have completed Good Clinical Practice training meeting Minimum Criteria v.2.0 for ICH E6 (R2) GCP Investigator Site Personnel Training identified by TransCelerate BioPharma, Inc., as necessary to enable mutual recognition of GCP training among trial sponsors.

(ii) Ensure that all equipment and consumables required are assembled prior to destroying CTM.

(iii) Complete all necessary records associated with the destruction of CTM according to Institutional, Study Protocol and Regulatory requirements.

3 Procedure

3.1 CTM are not destroyed without the permission of the sponsor or clinical trial monitor in writing. For investigator initiated protocols, do not destroy any CTM until the study is fully completed and analysed unless prior written permission has been provided by the investigator.

3.2 Complete details of destruction on Record of Destruction of Clinical Trial Materials forms or form(s) supplied by the study sponsor or for investigator initiated trials the RCH form may be used if required: Destruction record for Clinical Trial Drugs.

3.3 Destruction records will be filed in the pharmacy site file which is stored in the RCH clinical trials pharmacy until archiving. The filed destruction record may be the wet ink original, a copy or a print out from online systems as required by the sponsor or investigator of individual trials.

3.4 CTM for destruction is placed in a Cleanaway Daniels™ pharmaceutical waste bin.

3.5 Cytotoxic CTM for destruction is placed in a Cleanaway Daniels™ cytotoxic waste bin

3.6 Schedule 8 (S8) CTM are subject to additional destruction procedures as per the Drugs, Poisons and Controlled Substances legislation:

3.6.1 Destruction must be witnessed by two authorised persons, at the RCH this will be 2 pharmacists. The destruction will be documented with: name of CTM, strength, quantity and form of CTM, date and method of destruction. Signatures from both pharmacists performing and witnessing the destruction will be in wet ink to acknowledge the destruction is completed.

3.6.2 Destruction must be performed to render the drug irretrievable using the following method:

Tablets, capsules, granules, lozenges, liquid and injectable S8 CTM are disposed of in pharmaceutical waste tubs that have a denaturing "bluey" sachet in the base of the tub. Water is added activating the denaturing agent sachet. The tub is sealed with a tamper evident lid and shaken for complete denaturation of the contents within the tub. The tamper evident sealed tubs will placed in a secondary larger tamper proof Cleanaway Daniels™ pharmaceutical waste bin which is sealed and collected for high temperature incineration.

S8 CTM Patches should be folded in half, cut with scissors then further disposed of in a tamper proof Cleanaway Daniels™ pharmaceutical waste bin which is sealed and collected for high temperature incineration.

3.7 Cleanaway Daniels™ Pharmaceutical and Cytotoxic Waste bins are destroyed as per the RCH Waste Management Plan.

3.8 Cleanaway Daniels™ Pharmaceutical and Cytotoxic Waste bins are collected by Spotless Group, the on-site RCH facility management company, from the RCH pharmacy department daily, Monday to Friday. Spotless group manage the waste collection service provided by Cleanaway Daniels™ who destroy pharmaceutical and cytotoxic waste by high temperature incineration. A certificate of destruction is not provided.

3.9 All clinical trial destruction records are retained in the pharmacy file for 15 years or until the youngest participant turns 25 years old, whichever is longer.

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