



Medication Management Policy/Procedure

TITLE: Amendments to Clinical Research Trials	NUMBER: 15.04
Sponsor: Manager of Pharmacy	Page: 1 of 4
Approved by: Director of Pharmacy	Approval Date: Sept 2017 Effective Date: Sept 2017
Applies To: Pharmacy Department, Research Services, Oncology Service	

POLICY

Notice of amendments, revisions, memos or other correspondence related to an open, approved clinical oncology research trial at the IWK Health Centre will be reviewed by relevant Research Support Pharmacy (RSP) or other appropriate pharmacy team member. Applicable changes to procedure will be acknowledged, documented and incorporated into practice.

PROCEDURE/SOP

Children's Oncology Group (COG) Trials:

- A Drug Accountability Binder is compiled when pharmacy is notified of patient enrollment (or likelihood of enrollment) on a clinical trial protocol using an investigational agent (IA) that is either a non-marketed drug in Canada or is supplied by NCI or other research study sponsor.
- A designated individual in the COG office at the IWK will forward a copy of all amendments, revisions, memos and/or correspondence related to the use of IAs in an open clinical COG research study to the research support pharmacist and oncology clinical pharmacists.
- The RSP or COG pharmacist will review the amendments, revisions, etc. to determine the impact on any pharmacy related processes. The amendment number, revision or memo date will be recorded on the *Revision History Form* (Appendix 1) in the Drug Accountability Binder along with the action taken, if any.
- If the RSP pharmacist is unavailable, an oncology clinical pharmacist will assume this responsibility.

This is a CONTROLLED document for internal use only. Any documents appearing in paper form are not controlled and should be checked against the electronic file version prior to use.

Industry Sponsored Oncology Research Trials:

- A Drug Accountability Binder is compiled when pharmacy is notified of patient enrollment (or likelihood of enrollment) on an approved Industry Sponsored clinical trial protocol using an investigational agent that is supplied by the sponsor.
- The sponsor assumes responsibility to notify the RSP team of any amendments or changes to the protocol.
- The RSP or COG pharmacist (for industry sponsored or collaborative COG trials) will review the amendments, etc. to determine the impact on any pharmacy related processes. The amendment number, revision or memo date will be recorded on the *Revision History Form* (Appendix B) in the Drug Accountability Binder along with action taken, if any.
- If the RSP or COG pharmacist is unavailable, an oncology clinical pharmacist will assume this responsibility.

RELATED DOCUMENTS:

Appendix A: Definition

Appendix B: Clinical Trial Revision History

Appendix A

DEFINITION

A **clinical trial** means an investigation in respect of a drug or natural product for use in humans that involves human subjects and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the drug, identify any adverse events in respect of the drug, study the absorption, distribution, metabolism and excretion of the drug, or ascertain the safety or efficacy of the drug.

Appendix B

Clinical Trial Revision History

Protocol Number and Title:

Start Date of Pharmacy Review*: _____

Amendment number	Amendment Date	Reviewed by	Therapy change	Summary of changes

* A Drug Accountability Binder is compiled when pharmacy is notified of patient enrollment (or likelihood of enrollment) on a protocol using an investigational agent that is either a non-marketed drug in Canada or is supplied by NCI or supplied by the sponsor (if an industry sponsored trial). Following on from that, protocol amendments will be reviewed by pharmacy and the information that appears in the binder and/or Drug Dispensing Summary Sheets will be updated as needed (see Pharmacy Policy 7.45).

IWK Policies Being Replaced

(Please List)

Version History

Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)
	April 2012, May 2015, March 2017, September 2017