Guideline for Developing Pharmacy Procedures for Clinical Trials –RPG-010

Guideline

Purpose
This guideline provides a resource for the development and implementation of research pharmacy procedures for clinical research studies conducted at Boston Children’s Hospital (BCH), ensuring compliance with clinical research best practices for the overall management of study drugs and other therapeutic agents for clinical research conducted at BCH.

Definitions
Drug or therapeutic agent
In the context of this Guideline, the term “drugs or other therapeutic agents” includes all investigational and commercially available drugs or medications (including, but not limited to, prescription, over-the-counter, or alternative therapies) used in a clinical research study.

Procedure

General guidelines
- The ultimate responsibility for overall study drug accountability at a study site rests with the investigator. The investigator may delegate this responsibility to a qualified individual after documenting the delegation of this task (FDA and ICH GCP). At BCH, the clinical research pharmacist is most often the individual to whom the task of management of study drug is delegated.
- At least 1 month prior to submission of the protocol to the Children’s IRB and/or to an external funding agency, the investigator should meet with the clinical research pharmacist or designee to review the feasibility of the proposed protocol. The study protocol, as well as all requirements for study drug preparation, shipping, packaging, and distribution should be reviewed. See a checklist of topics that should be discussed with the clinical research pharmacist at this meeting.
- For a blinded clinical trial, the investigator must identify the blinded study personnel and review the labeling requirements for blinded medication with the pharmacist.
Procedures to follow in the event of an intentional or inadvertent unblinding of a blinded study staff member must be determined and documented a priori. For investigator initiated, placebo controlled blinded studies, it is especially important to involve the research pharmacy in placebo selection, packaging and labeling to ensure blinding is maintained.

- For Randomized, Investigator initiated trials, the investigator should contact the Clinical Research Center (CRC) for a randomization schemata and a master randomization list that will be provided to the research pharmacist. Refer to CRC Research Practice Guideline RPG-03-Guideline For Developing Randomization Procedures.

- Prior to study initiation, all pharmacy procedures and pharmacy budget must be documented and approved by the research pharmacist and the study investigator.

Storage of Study Drug
- All drugs or therapeutic agents used as part of a clinical investigation at BCH MUST be shipped to and stored at the hospital pharmacy.

- The investigator and the clinical research pharmacist must discuss and document procedures for receipt of study drug, storage requirements, as well as distribution and destruction of unused and expired study drug. These procedures must be agreed upon before the study drug is shipped to the hospital pharmacy.

- Upon receipt, the study drug should be stored in the research pharmacy under appropriate temperature/humidity conditions as specified in the protocol or by the manufacturer. The amount of study drug shipped to and stored in the pharmacy should be compatible with the expected rate of enrollment into the study, as well as the space available in the pharmacy. The shipping schedule must be agreed upon prior to initiation of the study.

- The investigator and research pharmacist must develop procedures to control access to the storage site and permit access for a limited number of authorized personnel only.

Distribution of Study Drug
- The letter of final IRB approval of the study protocol must be provided to the research pharmacy prior to the start of drug distribution.

- The procedures for distribution of study drug must be documented prior to study initiation.

- The appropriate personnel authorized (licensed) to prescribe the drug must be identified. All study drug prescription templates must be developed and approved by Research Pharmacy.

- The research pharmacy must receive a copy of each participant’s signed informed consent form, as well as a completed medication order or prescription form signed by the investigator or designee prior to distribution of study drug.
After receipt of the informed consent and medication order, the research pharmacist prepares and distributes the drug as per the protocol. The drug is then given to the authorized personnel (usually the study coordinator) to be dispensed to the participant.

It is the investigator’s responsibility to inform each participant about the correct use of the drug. In the case of a study where the drug is administered to a participant on site or as an inpatient by nursing staff, it is important to develop nursing procedures at the outset to ensure correct dispensing of the drug in accordance with the protocol. Proper coordination between the PI, study coordinator, and nursing staff will ensure participant safety and prevent protocol deviations.

**Drug Accountability and Destruction**

- It is essential to track the chain of custody of the medication: from sponsor or supplier to research pharmacy to sponsor or supplier. The research pharmacy must maintain a drug accountability log to track drug received and drug dispensed to meet regulatory and sponsor or supplier requirements.

- It is the investigator’s responsibility to monitor participants’ adherence to the study drug regimen. If the study drug is self-administered by the participant/guardian at home, the investigator should inform the participant/guardian to return all unused medication (including empty bottles) to the study staff at the next study visit.

- Procedures to evaluate participants’ adherence to the study drug regimen must be established prior to study initiation. This might include maintenance of a drug diary by the participant, pill counts at each study visit, and/or blood tests to measure blood level of the drug.

- Study coordinators must maintain regular communication with pharmacy to ensure their accountability records match with those of the pharmacy and that adequate supply of study drug is maintained for participants on study.

- All returned study drug bottles, whether empty or containing unused study drug, must be returned to the research pharmacy.

- The research pharmacist updates the drug accountability log and then destroys or returns the study drug to the sponsor or supplier (depending on the protocol and the sponsor’s requirements).

- Unused study drug returned by participants must never be re-dispensed to another participant. Similarly, expired drug must never be dispensed to participants.

- At the end of the study, all unopened bottles of study drug must be returned to the sponsor or supplier or destroyed as per the sponsor’s/supplier’s requirements.

- All documentation pertaining to the management of study drug for a clinical trial must be maintained by the research pharmacy.
Pharmacy Monitoring Visits

- During the course of a clinical trial, a sponsor or monitor may conduct site visits including visits to the BCH research pharmacy to monitor the clinical trial. Advance notice must be given to the research pharmacy prior to the visit.

Related Content

Procedure development checklist

Items to be discussed and included in the written pharmacy procedures:

- Is this an investigator-initiated study?
- Who is the study sponsor?
- Is it a single or multi-site trial?
- What are the study sites involved (if a multi-site trial)?
- Is the medication in compliance to Compendia Standards?
- What are the applicable pharmacy fees?
- What are the storage requirements of the ingredients and final products?
- What are the pharmacy space considerations for study drug storage?
- Describe the drug procurement procedures
- What are the documentation requirements for the receipt, distribution, and destruction of study drug?
- What are the packaging requirements for dispensing study drug final product to subject?
- Describe the coordination of drug dispensing with scheduled study visits
- What are the requirements for informed consent verification?
- Describe drug administration considerations
  - Identification of location(s) of drug administration
  - Identification of personnel that will administer drug
- Prepare (with the research pharmacist) customized prescription or physician order form template
- Identify individuals authorized to write medication orders or prescriptions
- Provide drug product stability information
- What is the content of any drug information counseling material for research subjects?
- Provide dosing information
- Describe regulatory agency and sponsor requirements for compounding and dispensing
- Provide drug delivery equipment requirements
- Provide ancillary medication dispensing requirements
For blinded randomized clinical trials, the investigator must also …

- Develop written randomization procedures. Investigator-initiated studies should contact the CRC for a randomization assignment schemata.
- Identify blinded study personnel.
- Describe pharmacy product labeling requirements for blinded medication.
- Identify the randomized treatment arm for each subject.
- Identify the source for placebo supply if applicable.
- Describe the procedures for pre-study completion withdrawal or exclusion.
- Describe procedures to follow in the event of intentional or inadvertent unblinding of blinded study staff.
I. Pharmacy Review of Industry-Sponsored Protocol Flowsheet

PI or designee arranges meeting with sponsor and Clinical Research Pharmacist

Sponsor or designee meets with the Clinical Research Pharmacist

Sponsor or designee inspects Pharmacy Facility. Sponsor determines if the Pharmacy meets criteria to qualify as study site.

Clinical Research Pharmacist determines if the Pharmacy can accommodate the Sponsor’s requirements within regulatory guidelines and departmental limitations.

Role assignments (order writing, pick-up, delivery, subject medication counseling etc.) reviewed with PI/designee and Pharmacist.

Study binder containing records for specific protocol is prepared by the Clinical Research Pharmacist or the sponsor’s binder is amended and applied.

Study drug preparation and dispensing begins only after IRB approval and all groups involved in the drug administration are in agreement. Informed consent must be verified before drug can be dispensed.
II. Pharmacy Review of Non-Industry-Sponsored Protocols

PI or designee arranges meeting with Clinical Research Pharmacist

PI or designee meets with the Clinical Research Pharmacist to determine study feasibility, availability of resources (material and staff). Clinical Research Pharmacist determines if the Pharmacy can accommodate the PI’s requirements within regulatory guidelines and departmental limitations.

Commitments from CTSU, CRC, and other services are negotiated by the PI.

Task assignments (order writing, pick-up, delivery, subject medication counseling, etc.) are reviewed with PI/designee and Pharmacist.

Study binder containing records for specific protocol is prepared by the Clinical Research Pharmacist

Study drug preparation and dispensing begins only after IRB approval and all groups involved in the drug administration are in agreement. Informed consent must be verified before drug can be dispensed.
### Investigational Drug Accountability Record

**Children's Hospital Boston Pharmacy**  
**Investigational Drug Service**  
**300 Longwood Avenue Boston, MA 02115**

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<td>Package Size:</td>
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Sample Product Labels

Medication/placebo study drug 2mL vial
One spray to the right nostril each morning on even days
One spray to the left nostril each morning on odd days
Name:____________________Date:____________

Exp:____________________________MD

Medication/placebo study drug 2mL vial
One spray to the right nostril each morning on even days
One spray to the left nostril each morning on odd days
Name:____________________Date:____________

Exp:____________________________MD

Medication/placebo study drug 2mL vial
One spray to the right nostril each morning on even days
One spray to the left nostril each morning on odd days
Name:____________________Date:____________

Exp:____________________________MD

Medication/placebo study drug 2mL vial
One spray to the right nostril each morning on even days
One spray to the left nostril each morning on odd days
Name:____________________Date:____________

Exp:____________________________MD

Medication/placebo study drug 2mL vial
One spray to the right nostril each morning on even days
One spray to the left nostril each morning on odd days
Name:____________________Date:____________

Exp:____________________________MD
Sample Pharmacy Subject-Specific Record

(This Record is Study Specific and Optional)

Sample Pharmacy Record

<table>
<thead>
<tr>
<th>Protocol Number: xx-yy-zzz</th>
<th>PI: Doc Sample M.D.</th>
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</table>

Protocol Title: USE OF INTRANASALLY ADMINISTERED MEDICINE IN THE TREATMENT OF CONDITIONS IN CHILDREN, ADOLESCENTS AND YOUNG ADULTS WITH OTHER CONDITIONS: A PILOT STUDY

Name: __________________________________ Randomization # : _______________

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<thead>
<tr>
<th>β Medication/placebo study drug 2mL vial</th>
<th>β Active</th>
<th>β Placebo</th>
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<td>MO-9 Date: ___ QTY dispensed: ___ Lot Number: ___ Checked By: ___</td>
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<td>MO-12 Date: ___ QTY dispensed: ___ Lot Number: ___ Checked By: ___</td>
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<tr>
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<tr>
<th>Vitamin D β 400 unit tablet bottle of 130</th>
<th>β 200 unit per drop bottle 60 mL</th>
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<tr>
<th>Calcium Carbonate β Tums 500mg 150tab</th>
<th>β Tums-EX 750mg 96tab</th>
<th>β Suspension 250mg/mL 500 mL</th>
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<td>MO-15 Date: ___ QTY dispensed: ___ Lot Number: ___ Checked By: ___</td>
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Note: If subject is randomized to active (Medication®) reserve 42 vials of the same lot number for this subject.

Note: If Vitamin D or Calcium Carbonate dose form is changed check new form and document the remaining months here: New Form used: Vitamin D β 400 unit tablet bottle of 130 β 200 unit per drop bottle 60 mL

Calcium Carbonate β Tums 500mg 150tab β Tums-EX 750mg 96tab β Suspension 250mg/mL 500 mL

MO# ___ Date: ___ QTY dispensed: ___ Lot Number: ___ Checked By: ___
MO# ___ Date: ___ QTY dispensed: ___ Lot Number: ___ Checked By: ___
MO# ___ Date: ___ QTY dispensed: ___ Lot Number: ___ Checked By: ___
MO# ___ Date: ___ QTY dispensed: ___ Lot Number: ___ Checked By: ___
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MO# ___ Date: ___ QTY dispensed: ___ Lot Number: ___ Checked By: ___
MO# ___ Date: ___ QTY dispensed: ___ Lot Number: ___ Checked By: ___
Sample Investigational Drug Study Prescription-Example 1

<table>
<thead>
<tr>
<th>Protocol Number: xx-yy-zzz</th>
<th>PI: Doc Sample M.D.</th>
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<tbody>
<tr>
<td>Protocol Title: USE OF INTRANASALLY ADMINISTERED MEDICINE IN THE TREATMENT OF CONDITIONS IN CHILDREN, ADOLESCENTS AND YOUNG ADULTS WITH OTHER CONDITIONS: A PILOT STUDY</td>
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<table>
<thead>
<tr>
<th>Initial</th>
<th>Study ID #__________________</th>
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<tbody>
<tr>
<td>Name: ___________________</td>
<td>Date: _______________</td>
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Stratification Info: β M : β F β Pre-pub : β Pub : β Post-pub Appointment Date: _____________

Medication/placebo study drug 2mL vial Dispense 7 vials (3 month supply)
Sig: One spray to the right nostril each morning on even numbered days of the month.
One spray to the left nostril each morning on odd numbered days of the month.

Vitamin D (select appropriate dose form)
β 400 unit tablet bottle of 130 sig: 1 tablet orally daily (3 month supply)
β 200 unit per drop bottle 60 mL sig: 2 drops orally daily (3 month supply)

Calcium Carbonate
β Tums 500mg (200mg elemental calcium/tablet) sig: 2 tablets orally twice daily or as directed. (3 X 150tab/3month supply < 11 y.o.)
β Tums-EX 750mg (300mg elemental calcium/tablet) sig: 2 tablets orally twice daily or as directed. (4 X 96tab/3month supply 11y.o and > )
β Suspension 250mg/mL ( 100mg / mL elemental calcium) Bottle 500 mL
β < 11 y.o. dispense 2 bottles/3month supply sig: 4mL orally twice daily or as directed.
β 11 y.o. and > dispense 3 bottles/3 month supply. sig: 6mL orally twice daily or as directed.

Authorized Signature: _______ DOC A  M.D./PNP
X DOC A MD β DOC B MD β DOC C MD β DOC D MD β DOC E PNP β DOC F MD
β DOC G MD β DOC H MD β DOC I MD β DOC J MD β DOC K MD

For Pharmacy Use Only

Date: _______ Lot Number: _________ Qty dispensed: ________Checked By: _______
Sample Investigational Drug Study Prescription - Example 2

Children's Hospital  Department of Pharmacy
300 Longwood Avenue, Boston, MA 02115
Investigational Drug Study Prescription

Protocol Number: xx-yy-zzz
PI: Doc Sample M.D.

Protocol Title: USE OF INTRANASALLY ADMINISTERED MEDICINE IN THE TREATMENT OF CONDITIONS IN CHILDREN, ADOLESCENTS AND YOUNG ADULTS WITH OTHER CONDITIONS: A PILOT STUDY

Name: ___________________________ Date:_______________ Age: ___________
Study ID # : _______________ Appointment Date:_______________ Wgt: ___________

β Medication/placebo study drug 2mL vial  Dispense 7 vials (3 month supply)
Sig: One spray to the right nostril each morning on even numbered days of the month.
One spray to the left nostril each morning on odd numbered days of the month.

Vitamin D (select appropriate dose form)
β 400 unit tablet bottle of 130  sig: 1 tablet orally daily (3 month supply)
β 200 unit per drop bottle 60 mL  sig: 2 drops orally daily (3 month supply)

Calcium Carbonate:  β Usual dose  β Increased ____%  β Decreased ____%

β Tums 500mg (200mg elemental calcium/tablet) Dispense: ____ bottles of 150 tablets
sig: ___ tablets orally qAM and ___ tablets orally qPM. or as otherwise directed.
Usual: < 11 y.o 800mg/day: 2 tablets qAM and qPM or as directed. (3 X 150tab/3month.)

β Tums-EX 750mg (300mg elemental calcium/tablet) Dispense: ____ bottles of 96 tablets
sig: ___ tablets orally qAM and ___ tablets orally qPM. or as otherwise directed.
Usual: 11y.o and > 1200mg/day: 2 tablets qAM and qPM or as directed. (4 X 96tab/3month)

β Suspension 250mg/mL (100mg / mL elemental calcium) Dispense: ____ bottles of 500 mL
sig: ___ mL orally qAM and ___ mL orally qPM. or as otherwise directed.
Usual: < 11 y.o. dispense 2 bottles/3month  sig: 4mL orally qAM and qPM or as directed
11 y.o. and > 3 bottles/3 month  sig: 6mL orally qAM and qPM or as directed

Authorized Signature: ____ DOC A ___________ M.D./PNP
X DOC A MD  β DOC B MD  β DOC C MD  β DOC D MD  β DOC E PNP  β DOC F

For Pharmacy Use Only
Date: _______ Lot Number: _________ Qty dispensed: ________Checked By: _______
References


Clinical Research Center: Research Practice Guideline: RPG-03-Guideline For Developing Randomization Procedures

Acknowledgement

The following CHB staff made substantive contributions to the development of this Guideline: Jui Haker, Rocco Anzaldi, Sarah Krathwohl, Rajna Filip-Dhima

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<th>Title</th>
<th>Guideline for Development of Pharmacy Procedures for Clinical Trials- RPG10</th>
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<tbody>
<tr>
<td>Author</td>
<td>Sarah Steltz</td>
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</table>
| Reviewed/Revised by | Adam Simmons, MPH  
Hana Gragg, MPH |
| Date of Origin | Dates  
Reviewed/Revised 3/31/2011; 6/18/2013 |
| Copyright | ©Boston Children’s Hospital, 2013  
Last Modified 08/28/2013 |
| Approved | SIGNATURE ON FILE  
Stavroula Osganian, MD, ScD, MPH  
Co-Chief, Clinical Research Center  
SIGNATURE ON FILE  
Ellis Neufeld, MD, PhD  
Associate Chief, Division of Hematology/Oncology |

Disclaimer: Should Hospital and CRC policies conflict, Hospital policy will supersede CRC policy in all cases.