



Product Accountability Package

Clinical Research Stage:

- Development*
- Pre-Initiation*
- Active Study*
- Close-out*

ACRC Partner Organizations

Alberta Health Services

Alberta Innovates

College of Physicians & Surgeons

Covenant Health

University of Alberta

University of Calgary

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What are ‘Investigational Product Accountability Logs’?

Investigational Product Accountability Logs are tracking logs used to document all handling of investigational products (IP). Investigational products are defined as: “A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.” IP include drugs, devices and natural health products.¹ “The responsibility for investigational product accountability at the trial site rests with the investigator/institution.”²

This package includes several samples of common types of investigational product logs and examples of IP labels that meet Health Canada requirements:

- **Investigational Product Accountability Log:** Used to record the receipt, dispersal, return or disposal of the investigational product.
- **Participant Drug Accountability Log:** Used to record the investigational product dispensation, return, and destruction for *each participant*. **Note: One log is to be completed per participant.**
- **Device Accountability Log:** This log is for recording the dispensation, use, return and destruction of each device at the site level. This log contains information for multiple participants.
- **Investigational Product Labels:** A sample of the labels to be attached to the product should be retained in the files of the sponsor before the trial is initiated² and include any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package³.
- **Temperature Log:** Storage at the wrong temperatures can alter a drug’s potency, shelf life or physical composition. It is important to store all IP at the temperature range outlined by the study protocol and to document this storage for the required interval.⁴

Acknowledgements:

These templates were made possible through the ACRC partner organizations and the ACRC Strategic Priority #3 Working Group Members: Monica Adam (UofA); Mary-Ann Clarkes (Covenant Health); Ronda Danchak (AI); Marilyn David (AHS); Rose Farrell (UofC); Troy Hamilton (The Bailey Clinic); Scott Jamieson (UofA); Trina Johnson (AI); Nicky Kopac (AI); Tammy Mah-Fraser (AI), and Loralee Robertson (AHS). This project was funded by Alberta Innovates.

Thank you to the Clinical Research Pharmacists at Tom Baker Cancer Centre and Cross Cancer Institute for their review.

Reasonable efforts have been made to ensure accuracy of information and compliance with the regulations however, the ACRC and partner organizations are not responsible for any omissions or errors.

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**Best Practice:****Receipt, inventory and return of IP:**

- Upon receipt of shipment take immediate inventory ensuring quantities and lot numbers match shipping documentation.
- Check expiration dates to ensure appropriate usage.
- All information related to the shipping of IP should be retained (i.e. waybills/courier receipts).
- When returning unused IP to the sponsor, do so according to study protocol, keep file copies of all packing slips/shipment records and document returns/disposal accordingly (on appropriate log).

Dispensing (to study participants):

- At the time of product dispensing, record on logs to ensure completeness and accuracy.
- Documentation for dispensing should include date/time, participant ID, lot, amount, and initials of staff.
- Documentation for returned drug or device should include date/time, amount, participant ID, and initials of staff.
- Document any discrepancies between the amount of IP used by the participant and the amount returned.

Storage:

- All IP should be stored in a secure environment with limited access (I.E. behind a locked door *and* within a locked cabinet)
- IP should be stored within a temperature range in accordance with the study protocol which should be logged daily.

References:

¹ACRC Glossary version 2.2 <http://www.aihealthsolutions.ca/news-and-events/publications/acrc-glossary-common-terminology-version-2-2/>

²ICH Guidance E6: Good Clinical Practice: Consolidated Guideline, adopted by Health Canada, 1997 (English) <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php>

³Health Canada Food and Drugs Act and Regulations (C.05.011); the Natural Health Product Regulations Part 4, section 74; Medical Device Regulations, section 86

⁴Guidelines for Temperature Control of Drug Products during Storage and Transportation (GUI-0069) <http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/gui-0069-eng.php>