

**DANA-FARBER / HARVARD CANCER CENTER
STANDARD OPERATING PROCEDURES FOR CLINICAL RESEARCH**

TITLE: At Home Study Medication Adherence	
SOP #: PM-406	Page: 1 of 2

Applicable Regulations & Guidelines:	21 CFR 312.61, 21 CFR 312.62 ICH GCP Guidelines Sections 4.6 and 5.14
Other References:	SOP # PM-404: Return of Unused Study Medications to Pharmacy
Responsible Personnel:	Principal Investigator, Research Nurse, Nurse Practitioner, Physician Assistant, Study Coordinator (CRC/CRA)
Policy Statement:	All DF/HCC protocols requiring research subjects to take study medications and/or protocol mandated medications at home must utilize a method to document the medication administration.
Definition:	<p><u>Study medication:</u> Investigational medications supplied by the research pharmacy. This does not include commercially available medications purchased at local pharmacies.</p> <p><u>Protocol mandated medications:</u> Medications required by the protocol which impact patient safety and or the scientific integrity of the study regardless of whether they are investigational or commercially available (e.g. G-CSF, prednisone, and dexamethasone).</p> <p><u>Source documentation:</u> Original documents, data and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).</p>
Procedure:	The study team must have a mechanism to document the administration of at home study medications and protocol mandated medications.

- 1) Study medication diary (if applicable): Study medication diaries must be approved by the IRB prior to use. Study medication diaries must have the DF/HCC protocol number and study identifier for the participant. Study medication diaries are considered source documentation. They should be initialed or signed and dated by the person completing the form. Participants are asked to bring study medication diaries to study visits.
- 2) Source documentation of medication adherence: A note must be entered into the source documentation clearly documenting study medication adherence. The phrase “as instructed” or “as per protocol” is not sufficient documentation of adherence. Study medication adherence must be entered into the source documentation at time points indicated in the protocol. Notes must include the dates and/or doses of study medication taken since the last dispense and must include any missed or vomited doses.
- 3) If required by the sponsor, documentation of the date the study medication was dispensed (available on the prescription label) and the amount of study medication returned (pill counts) may be required for overall study medication adherence.
- 4) If discrepancies between the drug diary and the amount of study medication returned are discovered during a clinic visit, the patient should change the study diary. If discrepancies are discovered after the clinic visit, this must be documented in a note to file.

Original Approval Date: CLINPOC 4/20/05
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Effective Date: