| **TITLE:** Protocol Mandated Drug Taken at Home | | |
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## 1. POLICY STATEMENT:

Research requiring subjects to take protocol mandated drug(s) at home must utilize a method to document the administration and assessment of drug adherence.

## 2. BACKGROUND:

All protocol mandated drug must be accounted for. Returned and/or unused drug must be counted and compared with the amount of drug expected to have been used since the previous research visit.

## 3. RESPONSIBLE PERSONNEL:

3.1. Principal Investigator (PI)
3.2. Sub-investigator
3.3. Research Nurse
3.4. Study Coordinator

## 4. DEFINITIONS:

4.1. **Protocol Mandated Drug**: A drug under an Investigational New Drug Application (IND) or commercially available drug taken on a particular dose schedule and/or as defined in the protocol.

4.1.1. Note that standard of care treatment and ancillary medications given free of charge by the sponsor to the patient that do not contribute to the primary research outcome will not be considered protocol mandated drugs if agreed upon by the sponsor.

## 5. POLICY:

5.1. The research team must have a mechanism to document the administration and assessment of at home protocol mandated drugs, regardless of their IND status. Approved documentation tools may include paper drug diaries and electronic drug diaries.

5.2. If drug diaries will be used, they must be submitted to the Office for Human Research Studies (OHRS) for nursing and IRB sign-off prior to use

5.2.1. Drug diaries must display the protocol number and identifier for the subject.

5.2.1.1. Pertinent information to include:

5.2.1.1.1. Drug name
5.2.1.1.2. Drug Strength
5.2.1.1.3. Route of administration
5.2.1.1.4. Schedule of administration
5.2.1.1.5. Special instructions (i.e., fasting, vomited, missed dosing)
5.2.1.1.6. Prohibited concomitant meds if applicable related to dosing

5.2.2. Drug diaries are considered source documentation.

5.2.3. Returned drug diary/diaries will be initialed or signed and dated by the person completing the diary, preferably the study participant. Assigned electronic pin numbers or other electronic signatures equivalent are also acceptable.

5.2.3.1. Subjects will be instructed to bring their drug diaries and pill containers to visits according to study protocol.

5.2.3.2. Electronic drug diaries will be reviewed at clinic visits according to the study protocol

5.3. Source documentation for drug adherence:

5.3.1. A note must be placed in the medical record or research chart clearly documenting the amount of drug taken by the subject. The phrase "as instructed" or "as per protocol" is not sufficient documentation.

5.3.2. At a minimum, drug adherence must be documented in the medical record or research chart at the end of a cycle or at the time of next dispense (whichever occurs first) and again at the end of treatment.

5.3.3. Notes describing drug adherence must include: the dates and/or doses of drug taken since the last dispense; and held, missed, or vomited doses; and any dosing errors.

5.4. For drugs dispensed by a research pharmacy: Documentation of the date the drug was dispensed (often available on the label) and the amount of drug returned (pill counts) are required for overall drug adherence.

5.4.1. Exception: standard of care ancillary medications given free of charge by the sponsor to the patient that do not contribute to the primary research

outcome will not be considered protocol mandated drugs if agreed upon by the sponsor.

5.5. For drugs dispensed by a commercial pharmacy: Documentation of the date and amount of drug dispensed should be recorded in the research chart.

5.6. If discrepancies between the drug diary and the amount of drug returned are discovered during a research visit, the subject will be asked to correct the drug diary and explain the discrepancy. If discrepancies are discovered after the research visit, resolution will be sought by a member of the research team and the outcome will be documented in the subject's medical record or research chart and reported to the sponsor and the IRB as applicable.

## 5 APPLICABLE REGULATIONS & GUIDELINES:

21 CFR 50 – Protection of Human Research Subjects
21 CFR 54 – Financial Disclosure by Clinical Investigators
21 CFR 56 – Institutional Review Boards
21 CFR 312 - Investigational New Drugs – Drugs for Human Use
45 CFR 46 – Protection of Human Subjects
FDA Industry Guidelines and Information Sheets
FDA Compliance Policy Guidance Programs: 7348.809, 7348.810, and 7348.811
DFHCC: Deviation/Violation/Exception and Other Event Reporting to DFCI IRB

## 6. RELATED REFERENCES:

International Conference on Harmonisation – E6

## 7. RELATED FORMS & TOOLS:

DF/HCC Guidance on Creating a Drug Diary
Drug Diary Template – Multiple Drugs
Drug Diary Template – One Drug