TITLE: Protocol Mandated Drug Taken at Home		
POLICY #: INV-103	**Page:** 1 of 3	**Effective Date:** 1/31/18

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:

Accountability of all protocol mandated drug must be maintained. 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. Subinvestigator
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.

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.

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

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

5.2.2. Drug diaries are considered source documentation.

5.2.3. Each returned drug diary must be initialed or signed and dated by the person completing the diary, preferably by the study participant. Assigned electronic pin numbers or other electronic signature equivalent are also acceptable.

5.2.4. Subjects will be instructed to bring their drug diaries and pill containers to each visit or, at a minimum, at the end of each cycle, unless otherwise required by 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.

5.5. 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

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