PURPOSE: The purpose of this SOP is to establish procedures for the research team to perform required visit specific study evaluations for research studies conducted at the CRC.

SCOPE: This SOP applies to research staff members who conduct study visits at the CRC.

RESPONSIBILITIES: The investigator and research staff will coordinate and perform the required evaluations for assigned research protocols in accordance with the protocol guidelines, regulatory authorities, sponsor, and institutional review board guidelines and regulations.

DEFINITIONS:

Case Report Form (CRF): A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor or entered into the research database for each clinical trial participant.

Concomitant Medications: Any prescribed or over-the-counter medications, folk and herbal treatments, vitamin supplements, and drugs or agents used on the street to alter body or mind function.

Documentation: All records, in any form (including but not limited to written, electronic, magnetic and optical records; and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a clinical trial, the factors affecting a clinical trial, and the actions taken.

Source Data: All information in original records or certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies), and serve to verify the research record.

Source Documents: Original documents, data, and records, including: hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or questionnaires, 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, laboratories, and at medico-technical departments involved in the conducting the clinical trial.

Subject Identification Code: A unique identifier assigned by the investigator to each trial subject to protect the subject's identity and used in lieu of the subject's name when the investigator reports adverse events and/or other trial related data.

PROCEDURES:

1. The investigator, clinical research coordinator or designee will implement screening and study visit procedures as directed by the assigned protocol.

2. **Informed Consent:** Verify the completion of the informed consent document including correct date and signatures PRIOR to performing any screening procedures. Refer to Informed Consent Process SOP # 402 for details.

3. **Clinical Evaluations:** Perform the required clinical evaluations for the assigned protocol to include, but not limited to the following:
   - physical assessment
   - medical history
   - review of signs and symptoms
   - new diagnoses
   - hospitalizations
   - medication changes
   - adherence to study medications, tolerability, and side effects
   - laboratory tests and/or procedures.

   3.1. **Medical History**:
   - Obtain a medication history as directed by the protocol and for inclusion/exclusion eligibility for all potential study participants.
   - Medications may be documented on the visit specific source document if provided or on a subject specific medication log.
   - If a medication log is used, original entries and changes should be reviewed, signed, and dated by the Principal Investigator.
   - If the protocol requires documentation of concomitant medications, the drug start dates, dosage, route and frequency must be documented.
   - The Principal Investigator and research team will verify that no study exclusionary medications are being used by the research subject. If the subject is on an exclusionary medication, the research team will query the participant's provider of the medication and research team to inquire whether an allowable non-exclusionary substitution exists.

   3.2. **Research Procedures and Laboratory Analysis:**
   - Obtain all research procedures and laboratory as outlined in the protocol AFTER the subject has provided written informed consent. No research procedures may be obtained prior written consent.
   - Coordinate with the receiving laboratories to assure that the correct procedures and specimens are labeled, collected, and that laboratory staff are available to receive and process research specimens.

PROCEDURE (cont.):

- All research test results and procedures will be reviewed, signed and dated by the Principal Investigator.
- Abnormal results will be graded and if clinically significant must be documented, including action taken.
- The research team will verify protocol required actions, and assure compliance.

4. **Eligibility checklist:**
   - Use to verify that all inclusion criteria are met and that no exclusion criteria exist.
   - Supportive documentation of all inclusion/exclusion criteria must be contained within the research record.
   - The clinical research coordinator and Principal Investigator will confirm each subject's eligibility prior to the research subject's randomization and study entry.

5. **Source Documentation:** Complete a protocol-specific flow sheet or other source documentation for the appropriate study visit and submit it to the Principal Investigator for review and signature.
   - All signed source documentation must be filed in the study patient binder.
   - Hard copy laboratory or procedure results may be filed in the subject's medical record chart or the subject research binder but should be consistent throughout the study. If filed in the subject research binder, only code identifiers should be used.

6. **Case Report Forms (CRF):** Complete CRFs as required by the assigned protocol (Refer to SOP 501: Case Report Form Completion).

7. **Data Management:** Collaborate with data management to schedule a new randomization/entry visit.

8 **Pharmacy:** Verify communication with the pharmacist when a randomization is scheduled for protocols that include study medications.

9. **Return Visits:**
   - Schedule a return study visit for each subject as outlined in the protocol.
   - Verify that visits occur within the protocol specified time frame (window).
   - Notify the study subject and research team, including, data management, receiving laboratories, and research pharmacy (if applicable) of the anticipated entry date.

- Maintain a schedule of anticipated study visits.
- Document and follow-up on missed study visits

PROCEDURE (cont.):

10. **Missed Study Visits:**
    - Anticipated study visits that are missed or out of the protocol specified time-frame (window) must be documented as missed study visits.
    - The clinical research coordinator (or designee), together with research team will attempt to contact/locate the study participant and bring the study subject back into care.
    - If the study participant wishes to discontinue study prematurely, then it will be documented appropriately and filed as source documentation.
    - All attempts and action to locate and bring the study participant back into care or for study discontinuation must be documented and filed as source documentation.

11. **Study Discontinuation**:
    - Subjects should not be discontinued as lost to follow-up until all efforts to locate and bring the subject back into care have been exhausted.
    - If the study subject chooses to discontinue prematurely, the study team, including data management and pharmacy, and the sponsor must be notified of the premature discontinuation visit.
    - If the study participant has missed consecutive study visits and all attempts to locate the study subject are unsuccessful, the study participant may be prematurely discontinued as lost to follow-up. Refer to protocol for specifics on premature discontinuation.
    - For protocols that are using an investigational product (IP), the clinical research coordinator must record the return of all study medications in the source document flow sheet, clinic/study visit note, or appropriate medication log at the discontinuation visit. Documentation must include: agent, route, dose and frequency, stop date, return of all study medication/product, and if the research subject is transitioned to commercial drug supply. The Principal Investigator will review, sign and date any new entries or changes.
    - If the study participant does not return all previously dispensed study product, the clinical research coordinator (or designee) must attempt to determine if the participant has any study product in his/her possession or if this was discarded, and document these findings.
    - For research subjects who admit to having additional study product(s), the clinical research coordinator (or designee) must counsel and document attempts to have that remaining study product returned.

- The research coordinator (or designee) will notify the research pharmacy of study product disposition.

Approval Date **01/01/2015**	**Effective Date** **01/01/2015**	**Review/Revision Date**	
REFERENCES:	21 CFR 312.59 Disposition of Unused Supply of Investigational Drug 21 CFR 312.60 General Responsibilities of Investigators 21 CFR 312.62 Investigator Recordkeeping and Record Retention May 1997 International Conference on Harmonization (ICH) Good Clinical Practices		
	SOP 113: Responsibilities of the Research Team		
RELATED POLICIES:	SOP 204: Adverse Event Reporting SOP 305: Investigational Product Accountability SOP 307: Venipuncture SOP 308: Specimen Collection and Management SOP 402: Informed Consent Process SOP 403: Eligibility and Enrollment SOP 404: Protecting Confidential Information SOP 501: Case Report Form Completion SOP 502: Source Documentation		
APPENDICES:			
REVISION HISTORY: Keep a running history of all revision dates.			