1 PURPOSE

To describe the management plan for research conducted at satellites sites under the umbrella of Memorial Healthcare System.

2 GENERAL INSTRUCTIONS AND RESPONSIBILITIES

The Memorial Cancer Institute (MCI) is a single entity of the South Broward Hospital District and offers services at four locations:

- Memorial Cancer Institute at Memorial Regional Hospital
- Memorial Cancer Institute at Memorial Hospital West
- Breast Cancer Center at Memorial Regional Hospital
- Breast Cancer Center at Memorial Hospital West

The Principal Investigator (PI)'s location will be named as the primary site, and any additional sites where patients may be seen and treated will be named as "satellite sites". The PI will provide oversight of the trial at satellite sites through the Communication Plan outlined below.

3 SPECIFIC PROCEDURES

The PI will lead the protocol discussion at monthly MD/research team meetings and where appropriate:

a. Conduct required training (Reference SOP 104 Study Team Training) to properly execute the protocol, review accruals of research subjects (Reference SOP 602 Subject Recruitment Practices), adverse events (Reference SOP 605 Adverse Event Recognition and Reporting), protocol changes and/or amendments (Reference SOP 302 Clinical Protocol Amendments).
Investigator Standard Operating Procedures

new information, and the need for re-consenting (where applicable) (Reference SOP 601.1 Obtaining and Documenting Informed Consent/Assent).

b. Ensure that research related correspondence is distributed to study staff and physicians within same or following week of receipt.

c. Reporting of all safety letters received, as required, to the IRB.

d. Discuss trials’ progress at monthly meetings, including a review of screening and enrollment logs (Reference SOP 603 Subject Screening and Enrollment).

e. Participate, along with research staff, in meetings or conferences held to report and review study progress.

f. Ensure site is compliant with all monitoring reports and recommendations (Reference SOP 504 Routine Monitoring Visits).

g. Review status of trial CRF’s accuracy and submission through meeting and/or phone conferences with monitors, through query resolution and overall data accuracy percentages (Reference SOP 701 Case Report Forms).

h. Direct communication with research staff to review protocol specifics at each defined research visit to ensure protocol compliance.

i. Train any additional staff who were unable to attend the Site Initiation Visit (SIV), or delegate appropriate staff to do the training per SOP 103 and 104.

Monthly Meetings
The PI will ensure adequate oversight of the study at each of the satellite locations by appointing Sub-Investigators. Monthly physician meetings will serve to disseminate any new information or safety updates regarding clinical trials to Sub-Investigators. Weekly research meetings will also be held at the Office of Human Research (OHR), where all new information is reviewed and discussed with relevant staff, including study coordinators, regulatory staff, pharmacists (when necessary), etc. New information received via paper or electronic transmission is disseminated to all appropriate personnel and sites via inter-site couriers or via email. Urgent information is made available as soon as it is received via conference call and/or email followed by discussion in staff meetings.

Training
New and satellite staff will be trained by Study Coordinators Research Nurse/Research Specialist and/or the Principal Investigator.

Research Records
The Regulatory Coordinator for each study will maintain the regulatory and training documents, and the corresponding Study Coordinator will maintain patient-related study binders at the satellite site where the patient will be seen and treated.

A restricted access folder on a shared drive will contain all current study related documents, such as Protocols, Investigator Brochure, IRB approved Informed Consents, Patient Information, etc. Another folder will contain all relevant Regulatory documents, including physicians’ CVs, medical
Regulatory documents will be maintained within the regulatory binder at the Office of Human Research, located at 4411 Sheridan Street, Hollywood, FL 33021, where the Regulatory Coordinators are situated.

After completion of study, the study documents will be maintained for about 6 months to complete outstanding issues, and will then be archived at Recall, Miami (11800 NW 100 Rd. Suite #2, Medley, FL 33178) (Reference SOP 503 Documentation and Records Retention).

4 REFERENCES TO OTHER APPLICABLE SOPS

- 103 Investigator Responsibility and Delegation of Authority Log
- 104 Study Team Training
- 302 Clinical Protocol Amendments
- 503 Documentation and Records Retention
- 504 Routine Monitoring Visits
- 601.1 Obtaining and Documenting Informed Consent/Assent
- 602 Subject Recruitment Practices
- 603 Subject Screening and Enrollment
- 605 Adverse Event Recognition and Reporting
- 701 Case Report Forms

5 ATTACHMENTS

None

6 APPLICABLE REGULATIONS AND GUIDELINES

- General Responsibilities of Investigators (21 CFR 312.60 and 21 CFR 812.100)
- Investigator’s Qualifications and Agreement (ICH E6, section 4.1)
- Recordkeeping and Record Retention (21 CFR 312.57)
- Monitoring Investigations (21 CFR 812.46)