Clinical Research Coordinator

Name: _______________________________________________________

The Function Statement is specific to the duties and responsibilities of each member of the research team.

- This form will be completed only once for each staff member
- The primary supervisor authorizes the staff member to perform certain duties on a regular and ongoing basis under his/her supervision.
- This form must be amended if there are any changes in duties
- This form must be reviewed by the primary supervisor and the research applicant for accuracy and amended as needed.

Statement of Staff Duties and Responsibilities:

This form is to be used by research staff that do not require clinical privileging for conduct of their duties and do not perform any clinical activity that requires supervision by their Professional Standards board. Any research staff member who must exercise independent clinical judgment or perform procedures that would require clinical privileges as part of his/her research duties must have appropriate privileges granted by the medical center.

Routine Research Duties (Please indicate with a check mark the privileges requested)

☐ Initiate submission of regulatory documents to the IRB committee and sponsor
☐ Prepare study initiation documents and activities
☐ Develop recruitment methods to be utilized for the study
☐ Screen patients to determine study eligibility by reviewing patient medical information or interviewing subjects
☐ Access or use private medical information while maintaining patient confidentiality
☐ Participate in the informed consent process and obtain informed consent from research subjects
☐ Maintain completed case report forms and source documents including progress notes, test results, diaries/cards or other necessary information for the study
☐ Provide education to patients, relatives and Medical Center staff on study activities as necessary per protocol
☐ Provide education and instruction of study medication use, administration, storage, and side effects; report adverse drug effects
☐ Initiate and/or expedite requests for consultation, special tests, or studies following the Investigator's approval

Miscellaneous Duties (if applicable):

The Research Staff Member named above is authorized to perform the following miscellaneous duties not otherwise specified in this Function Statement:

1. __________________________________________________________
2. __________________________________________________________
3. __________________________________________________________
Acknowledgement of practitioner

I certify that I will perform only the duties listed and approved above while participating in Human Subjects Research. If I perform research duties that require me to exercise independent clinical judgment or perform procedures or other actions that require clinical privileges at Texas Health Harris Methodist Hospital Southlake, I will first obtain clinical privileges before I participate in any such activities.

Signed: ________________________________

Date: ________________________________

Credentials Committee Recommendations: _____ Recommend _____ Deny

I have reviewed the requested clinical privileges and supportive documentation for the above named applicant and recommend action on the privileges as noted above.

Signed: ________________________________

Date: ________________________________

Primary Supervisor’s Statement:

After reviewing ___________________________________________ qualifications, research practice involving human subjects, peer reviews, and individual skills, I certify that he/she possesses the skills to safely perform the aforementioned duties.

Both the research staff member and I are familiar will all duties granted or not granted in this Function Statement. We agree to abide by the parameters of this Function Statement, and all applicable hospital policies and regulations.

This Function Statement will be reviewed every two years and amended, as necessary, to reflect changes in the research staff member’s duties/responsibilities and/or Texas Health Harris Methodist Hospital Southlake hospital policies.

________________________________________
Signature of Supervising Physician Date

________________________________________
Printed Name of Supervising Physician Date