Wake Forest Baptist Medical Center	**Sponsor Monitoring of Human Subjects Research** RARI-S-03-04	**Dept:**	**CTSI**
		SOP Number:	04
		Effective Date:	10/19/2017
		Current (Revised) Date:	
		Contact:	**Office of Regulatory Affairs and Research Integrity - CTSI**
Approval Signature:		**Date:**	10/19/17
Name and Title: Christopher O'Byrne VP, Research Admin + operations			

1) **General Procedure Statement:**
It is the standard operating procedure (SOP) of Wake Forest Baptist Medical Center to support appropriate monitoring plans for studies as approved by the IRB of record and required by the contract or agreement with the sponsor. Sponsors may utilize auditors /monitors from the study sponsor, a CRO, or an independent monitoring organization.

   a) Scope: All WFBMC employees, faculty and staff are responsible for complying with this SOP

   b) Responsible Department/Party/Parties:
      i. Procedure Owner: Clinical Translational Science Institute (CTSI)
      ii. Procedure: Office of Regulatory Affairs and Research Integrity
      iii. Supervision: Office of Regulatory Affairs and Research Integrity
      iv. Implementation: Office of Regulatory Affairs and Research Integrity

2) **Definitions:** For purposes of this SOP, the following terms and definitions apply:

   a) **WFBMC:** Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), all on-site subsidiaries as well as those off-site governed by WFBMC policies and procedures.
   b) **Research:** Means a systematic investigation designed to develop or contribute to knowledge and may include the stages of development, testing, and evaluation.
   c) **Research Data:** Means all information in whatever form (e.g. both physical and electronic). For the purposes of this policy, Research Data are further defined as including any records that would be used for the reconstruction and evaluation of reported or otherwise published results. Research Data also includes materials such as unmodified biological specimens and environmental samples. Research Data differ among disciplines. Examples of Research Data and Materials include laboratory and other notebooks, notes of any type, photographs, films, digital images, original biological and environmental samples, protocols, numbers, graphs, charts, numerical raw experimental results, instrumental outputs from which Research Data can be derived, case report forms, patient charts, and other source documentation for human research studies.
   d) **Clinical Trial** – The NIH defines a clinical trial as a prospective biomedical or behavioral research study of human subjects that is designed to determine the safety, efficacy, and effectiveness of biomedical (drugs, nutritional supplements, surgical intervention, or devices) or behavioral (diet, physical activity, cognitive therapy, etc.) interventions.

e) **Research Records**: Information recorded for the purpose of a research study, regardless of form or the media on which it may be recorded. Research records include the Case Report Form, Regulatory Binder, Consent Form and Source Data.
f) **Case Report Form (CRF)** – Document (printed or electronic) designed to record all of the protocol required information to be reported to the sponsor on each trial subject. (ICH GCP 1.11)
g) **Informed Consent Forms (ICF)** – Documents that provide a description of the study and are signed by both the study participant and a member of the study team.
h) **Adverse Event (AE)** – Any untoward or unfavorable medical occurrence in a clinical research study participant, including any abnormal sign (e.g. abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participants' involvement in the research, whether or not considered related to participation in the research.
i) **Enrolled Subject**- The WFUHS IRB considers any subject who signs a consent form to be an enrolled subject, even if they are subsequently found not to qualify for the study.
j) **Regulatory Binder (or Files)** – Place where all study-specific information and regulatory documentation, including IRB approved protocols, amendments, informed consent, case report forms, FDA 1571 and 1572 (if applicable) and recruitment materials, is maintained. The regulatory binder provides a thorough history of the research study from protocol development to study completion.
k) **Source Data** – Information contained within source documents that represent the original documentation of findings and observations of subjects participating in clinical research studies (ICH GCP 1.51).
l) **Source Documents** – Original documents, data and records such as medical records, laboratory results, x-rays, pharmacy records and subject diaries. (ICH GCP 1.52)

3) Procedure Guidelines:

Sponsor monitoring of human research may occur via on-site visit, medical monitor review of data, review by a Data Safety Monitoring Board, or other methods as agreed to in the funding agreement and approved by the IRB as part of the study protocol. The following provides the process study teams must follow regarding sponsor monitoring.

a) On-site Monitoring

When the monitoring plan calls for on-site review of records, the study team must complete the Wakehealthlink Research Study Monitor Access Request Form available for download on the IRB website. The form must be emailed to the individuals within the IRB (listed in the instructions at the top of the form) for verification that access to WakeOne for external monitoring by the sponsor is an approved part of the protocol. The IRB then signs off on the request and submits it to Health Information Management for monitor account creation.

Monitors are expected to perform research reviews on site. The IRB must be made aware of any requests by a sponsor or monitor to access WakeOne or other records containing Protected Health Information (PHI) remotely. These requests will be considered by the IRB on a case-by-case basis.

Reports received by the study team after completion of a research study monitor visit must be submitted to the IRB within 30 calendar days of receipt by the investigator or study team. These reports are initially reviewed by the Human Research Oversight and Outreach (O & O) who may thereafter request additional review by the IRB Executive Chair, the IRB Director, IRB members

or non-IRB members with special expertise related to the event.

b) Medical Monitor

In some cases, a medical monitor may be selected to review study data to ensure that the study is safe to continue and if so, to determine whether changes are needed. Use of a medical monitor must be approved by the IRB as a part of the monitoring plan detailed in the protocol.

Reports from a medical monitor must be submitted to the IRB within 30 calendar days of receipt by the investigator or study team. These reports are initially reviewed by the Human Research Oversight and Outreach (O & O) who may thereafter request additional review by the IRB Executive Chair, the IRB Director, IRB members or non-IRB members with special expertise related to the event.

c) Data and Safety Monitoring Board Reports

Other safety reports, such as Data and Safety Monitoring Board (DSMB)/Data Safety Monitoring Committee (DMC) reports or information received from the sponsor that impact the conduct of the study must be submitted to the IRB within 30 calendar days of receipt by the investigator or study team. These reports are initially reviewed by the Human Research Oversight and Outreach (O & O) who may thereafter request additional review by the IRB Executive Chair, the IRB Director, IRB members or non-IRB members with special expertise related to the event.

O & O Review of Monitoring Reports:

The O & O may request more detailed information from the investigator(s), the sponsor, the study coordinating center, external monitoring entity. The O & O makes an initial assessment of whether: Any proposed response is appropriate to ensure the safety, rights and welfare of subjects; Risks to subjects are minimized (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subject for diagnostic or treatment purposes.

The O & O then places the reports and any clarifying or supporting documentation on the agenda for review by the full IRB. If the IRB determines the report represents unanticipated problems involving risks to subjects or others the IRB will then determine whether: The proposed response is appropriate to ensure the safety, rights and welfare of subjects; Risks to subjects are minimized (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subject for diagnostic or treatment purposes Risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects, and the importance of the knowledge that may reasonably be expected to result

If DSMB reports are expected but not received prior to the annual continuing review of a study, the convened IRB should not vote to approve the study without the appropriate updates and information provided by the DSMB. Audit/Monitoring Reports All reports received from

external auditors/monitoring visits should be reported to the IRB within 30 days of receipt. The O & O will review each audit report to ensure that the safety, rights, and welfare of subjects are protected. External reports will be assessed and processed in the same manner as DSMB reports.

4) Review/Revision/Implementation

a) Review Cycle: This SOP shall be reviewed by the Office of Regulatory Affairs and Research Integrity at least every three years from the effective date.

b) Office of Record: After authorization, the Legal Department shall house this SOP in a policy database and shall be the office of record for this SOP.

4) Related Policies and SOPs

Policy on the Quality Conduct of Research
HRPP Standard Operating Procedures

6) Governing Law or Regulations

Title 45 Code of Federal Regulations Part 46
Title 21 Code of Federal Regulations Part 50
Title 21 Code of Federal Regulations Part 312
Title 45 Code of Federal Regulations Part 164

7) Attachments

None

8) Revision Dates

July 25, 2017