Wake Forest Baptist Medical Center	Policy on Quality Conduct of Clinical Research 03-05-0003 RARI-P-03	Type:	Tier 3
		Original Effective Date:	October 20, 2017
		Current (Revised) Date:	
		Contact:	Office of Regulatory Affairs and Research Integrity
Approval Signature:		Date:	10/20/17
Name and Title: Christopher O'Byrne VP, Research Admin + Operations			

1. **General Policy Statement:**

It is the policy of Wake Forest Baptist Medical Center (WFBMC) to ensure there is appropriate review of research, sufficient/appropriate monitoring (internal and external) and a quality assurance plan to conduct research in accordance with all internal and external policies, procedures, and regulations governing research. This Policy is guided by the ethical principles set forth in the Belmont Report and Declaration of Helsinki, regulations found in 45 Code of Federal Regulations Part 46, the regulatory requirements of the Food and Drug Administration, policies of the National Institutes of Health, and other applicable laws, regulations, local standards, and ordinances that pertain to human subjects research in which WFBMC is engaged. The purpose of this policy is to set forth the requirements and processes to ensure clinical research is conducted in a quality and compliant manner.

a) **Scope:** This policy applies to faculty, staff, students, and other individuals engaged in research activities conducted at WFBMC or its affiliates.

b) **Responsible Department/Party/Parties:**

i. Policy 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 Policy, 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) **Human Research Protection Program:** The unit within the Clinical and Translational Science Institute which serves participants in human research by coordinating the safety, ethics, and regulatory reviews of research projects in compliance with approved protocols, federal regulation, state and local laws, and institutional policy.

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.

3. Policy Guidelines:

The Office of Regulatory Affairs and Research Integrity within the Clinical and Translational Science Institute (CTSI) is responsible for setting forth and maintaining requirements, policies, and procedures to foster a consistent approach to the human subjects research, yielding conduct and results of the highest quality and integrity.

Principle Investigators are responsible for ensuring all study personnel are appropriately trained to conduct the research, that there is a clear monitoring plan in place, and that a process for ensuring data integrity is followed. The following standard operating procedures are implemented to provide guidance to investigators and study staff on proper procedure at Wake Forest Baptist Medical Center.

4. Standard Operating Procedures

a) Data Retention and Destruction of Human Subjects Data/Records
b) External Audits of Human Subjects Research
c) Internal Post-approval Monitoring of Human Subjects Research
d) Sponsor Monitoring of Human Subjects Research
e) Training of Human Subjects Research Coordinators
f) Investigational Medical Devices used in Human Subjects Research

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4. Review/Revision/Implementation

a) Review Cycle: This policy 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 policy in a policy database and shall be the office of record for this policy.

5. Other Related Policies and SOPs

Policy on Research Integrity

Authorship Policy
Data Ownership Policy
Institutional Oversight of Human Research Policy
Human Research Protection Program 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. Revision Dates

July 25, 2017