| Wake Forest Baptist Medical Center | Institutional Oversight of Human Research<br><br>03-05-0003<br><br>RARI-P-03 | Type: | Tier 3 |
|---|---|---|---|
| | | Original Effective Date: | 5-31-2005 |
| | | Current (Revised) Date: | 10-11-2017 |
| | | Contact: | Office of Regulatory Affairs and Research Integrity |
| Approval Signature: | | Date of Signature: | 10/18/17 |
| Name and Title: Christopher O'Byrne, VP, Research Admin + Operations | | | |

1) **General Policy Statement:**
It is the policy of Wake Forest University Health Sciences (WFUHS) to ensure that the safety, rights, and welfare of individual research subjects, in the conduct of human research at WFUHS, are considered above any interest of science and society. To this end, WFUHS is guided by the ethical principles for the protection of human research participants as set forth in the Belmont Report and the Declaration of Helsinki. WFUHS assures that whenever it engages in human research conducted or support by any federal department or agency that has adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule, the Institution will comply with the terms set forth in the Code of Federal Regulations at 45 CFR 46 (including all applicable Subparts), unless the research is otherwise exempt from these requirements, or the department of agency conducting or supporting the research has determined that the research shall be covered by a separate assurance. For clinical investigations regulated by FDA under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U. S. 6. 355(i)), WFUHS will apply FDA regulations human subjects regulations. These regulations include, but are not limited to Protections of Human Subjects (21 CFR 50), Institutional Review Boards (21 CFR 56), Investigational Drugs (21 CFR 312), Investigational Devices (21 CFR 812), and Application for FDA Approval to Market a New Drug (21 CFR 314). For all other human research WFUHS applies the Code of Federal Regulations at 45 CFR 46 and the ICH Good Clinical Practice Consolidated Guidance (1996) when applicable.

   a) Scope: This policy applies to faculty, staff, students, and other individuals engaged in human research activities under the oversight of WFUHS regardless of funding source.
   b) Responsible Department/Party/Parties:
      i. Policy Owner: Clinical and Translational Science Institute (CTSI)
      ii. Procedure: Office of Regulatory Affairs and Research Integrity
      iii. Supervision: Office of Regulatory Affairs and Research Integrity
      iv. Implementation: Director of IACUC and Animal Welfare Program

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) **Policy:** As defined in the Policy on Creating and Amending Policy, a statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration, or management of care, treatment, services or other activities of WFBMC. A policy may help to ensure compliance with applicable laws and regulations, promote one or more of the missions of WFBMC, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors and others are expected to operate.
   c) **IO:** Institutional Official
   d) **OHRP:** The Office for Human Research Protections
   e) **IRB:** Institutional Review Board
   f) Other terms related to human subject research are defined as per current federal regulations in the

IRB Standard Operation Procedures (SOPs). Each federal agency governing human research may elect to use its own definitions and these are provided in the IRB SOPs so that they can be applied as appropriate to research overseen by these agencies. The IRB SOPs will be updated as necessary to ensure that the most current definitions are provided.

3) **Policy Guidelines:**

a) WFUHS designates one or more IRBs for review of human research under its FWA. A Human subject is defined as stated in the IRB SOPs. IRBs designated under the WFUHS FWA "shall review and have authority to approve, required modifications in (to secure approval), or disapprove all research activities" subject to the regulations [45 CFR 46.109(a)][21 CFR 56.109(a)]. Further, the designated IRBs "shall conduct continuing review of research" annually or more often when appropriate [45 CFR 46.109(e)] [21 CFR 56.109(f)]. The designated IRBs also have the authority "to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects" [45 CFR 46.113][21 CFR 56.113]. The IRB may make determinations regarding the appropriateness of measures to correct non-compliance and may require specific corrective measures in order for research to continue if non-compliance has been identified. The disposition of human research data, which has been collected without IRB approval or in a manner non-compliant with IRB SOPs, falls under the IRB's authority to protect the rights and welfare of human subjects. No change to an approved human research protocol can be implemented until approval of the change has been granted by the IRB. Operation of the IRB shall follow the IRB SOPs approved by the Institutional Official (an individual with the legal authority to represent the institution) or a designee.

b) The HRPP/IRB Director and staff are part of the Clinical Translational Science Institute and report to the Assistant Dean for Regulatory Affairs and Research Integrity.

c) The Director of the HRPP/IRB, in conjunction with staff who have appropriate expertise in research regulation and application, ensure that appropriate conduct of the review, approval and oversight of human research. WFUHS HRPP components which operate outside the CTSI are accountable to the Institutional Official for carrying out the human research-related duties according to the policies, procedures, and standards set forth by the Institutional Official. The HRPP/IRB is charged with overseeing the efforts of persons conducting human research, overseeing the research related activities of all HRPP components, and ensuring that all portions of the human research program at WFUHS are in compliance with the directives communicated by the Institutional Official.

d) In order to comply with federal regulations, state and local laws, and institutional policies, WFUHS investigators must follow the policies and procedures detailed in the IRB SOP document. The HRPP/IRB office provides education, guidance material, and study specific consultation in order to assist investigators. Investigators should consider consulting the HRPP/IRB prior to initiating or modifying human research activities.

4) **Review/Revision/Implementation**

a) Review Cycle: This policy shall be reviewed by Clinical and Translational Science Institute at least every 3 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) **Related Policies**

Policy on the Quality Conduct of Research
IRB Standard Operating Procedures

**6) Governing Law or Regulations**

(Followed as applicable)
Title 21 Code of Federal Regulations Part 50
Title 21 Code of Federal Regulations Part 56
Title 21 Code of Federal Regulations Part 312
Title 21 Code of Federal Regulations Part 812
Title 21 Code of Federal Regulations Part 8140
Title 28 Code of Federal Regulations Part 46
Title 32 Code of Federal Regulations Part 219
Title 34 Code of Federal Regulations Part 97
Title 38 Code of Federal Regulations Part 16
Title 34 Code of Federal Regulations Part 99
Title 40 Code of Federal Regulations Part 26
Title 45 Code of Federal Regulations Part 46
Title 45 Code of Federal Regulations Part 164
Title 45 Code of Federal Regulations Part 690
Title 49 Code of Federal Regulations Part 11
SECNAVINST 3900.39D
OPNAVINST 5300.8B
DoDD 3216.2
ICH-GCP
Dual Compensation Act, 24 U.S.C 3-1
57 FR 13250
Public Law 104-191
20 U.S.C. § 1232g
Article 6 of Chapter 35A of the North Carolina General Statutes
North Carolina Department of Corrections Research Policies and Procedures Manual
VHA Handbook 1200.05

**7) Attachments**

None

**8) Revision Dates**

5-31-2005
3-16-2012
10-11-2017