
	<b>Data Ownership Policy</b>	<b>Type:</b>	Tier 2
		<b>Original Effective Date:</b>	July 19, 2012
		<b>Current (Revised) Date:</b>	January 1, 2017
		<b>Contact:</b>	Office of Regulatory Affairs and Research Integrity
<b>Approval Signature:</b> 		<b>Date of Signature:</b>	January 20, 2017
<b>Typed Name and Title: Edward Abraham, M.D. Professor and Dean</b>			

**1) General Policy Statement:**

Individual researchers and Wake Forest Baptist Medical Center (WFBMC) have rights and responsibilities with respect to research data. This policy describes the basis of data ownership and the standards for the collection and retention of data, in addition to requirements for data access. This policy also provides guidance with respect to transfer of research data in the event a researcher leaves WFBMC.

- 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), and all on-site and off-site subsidiaries 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) **Research –** Means a systematic investigation designed to develop or contribute to knowledge and may include the stages of development, testing, and evaluation.
- d) **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.

**3) Policy Guidelines:**

- a) Ownership and Responsibilities
  - i. Unless superseded by specific terms of sponsorship and contractual agreement or university policy, WFBMC owns all research data developed or acquired by the faculty, fellows,

students and employees of WFBMC through research projects conducted at or under the auspices of WFBMC, regardless of funding source. Although WFBMC, as owner of the research data, must meet the requirements of sponsors for custodians of research data, Principal Investigators (PIs) and other researchers are stewards of research data, and shall retain the principal responsibility for custody of the data.

### **Access to Research Data**

Research data are to be accessible to members of the WFBMC community, external collaborators and others as appropriate (e.g., patent applications or journal submissions). The Principal Investigator has primary responsibility for oversight and access to the Research Data generated by the project. Any other faculty, staff, student or person involved in the creation of Research Data may have the right to review that portion of the Research Data that he or she created. WFBMC will have access to the Research Data as necessary for technology transfer, compliance and other purposes. The University also has the option to take custody of the Research Data as determined by the appropriate institutional official. Such option will not be invoked without cause and subsequent notification of the Principal Investigator. In some instances, a research sponsor has a legal right of access or access may be requested through the sponsoring agency under the federal Freedom of Information Act (FOIA). Requests for data access will be coordinated through the CTSI Office of Regulatory Affairs and Research Integrity.

In cases of multi-institutional studies, the institution of the primary study director shall be responsible for arranging appropriate access to, use of, and retention of Research Data unless otherwise specified in the terms of the particular study.

When necessary, to assure needed and appropriate access, (e.g. research misconduct investigations) WFBMC may take custody of research data in a manner specified by the Research Integrity Policy ([link](#)).

WFBMC's responsibilities with respect to research data include, but are not limited to:

- Complying with the terms of sponsored agreements;
- Ensuring the appropriate use of project resources (e.g. animals, human subjects, recombinant DNA, biological agents, radioactive materials, etc.);
- Protecting the rights of researchers, including but not limited to their rights to access to data from research in which they participated; and
- Maintaining confidentiality of research data, where appropriate and as may be required pursuant to the terms of an applicable sponsored agreement.

The PI's responsibilities with respect to research data include, but are not limited to:

- Ensuring proper management and retention of data in accordance with this policy;
- Establishing and maintaining appropriate procedures for the protection of research data and other essential records, particularly for long-term research projects;
- Ensuring compliance with sponsor program requirements;
- Maintaining confidentiality of research data, where appropriate and as may be required pursuant to the terms of an applicable sponsored agreement; and
- Complying with applicable state and federal laws and regulations.

### **3) Data Retention**

It is the responsibility of the PI to preserve, where feasible, all research data generated at WFBMC for a minimum period of five (5) years from the date of the last publication or the date of the final report issued upon completion of the project, whichever is later. In addition, any of the following circumstances may justify longer periods of retention:

- Research data must be kept for as long as may be necessary to protect any intellectual property resulting from the work;
- If litigation or other dispute resolution, claim, financial management review or audit related to the research project is started before the expiration of the five year period, or commenced after the five year period, the research data and other project records must be retained until all litigation/dispute resolution, claims, financial management review or audit findings involving the records have been resolved and final action taken;
- If any charges regarding the research arise, such as allegation of research misconduct, research data must be retained in a manner consistent with WFBMC's policy on Research Integrity, or as otherwise instructed by the CTSI's Office of Research Integrity or Office of General Counsel; and
- When research is funded by an award to or contract with WFBMC that includes specific provisions regarding ownership, retention of and access to technical data, the provisions of that agreement will supersede this Policy
- If a student or trainee is involved in research that research data must be retained at least until the degree is awarded to the student, the training is complete, or it is clear that the student has abandoned the work.

Beyond the period of retention specified here, the destruction or permanent de-identification of research data is at the discretion of the PI. Destruction of research data must follow applicable federal regulations, sponsor requirements and other applicable guidelines.

Research data will normally be retained by the unit/Department where they were produced, in accordance with WFBMC practices for the secure storage of information.

#### **Transfer in the event a researcher leaves WFBMC**

When a PI for a research project leaves the employment of WFBMC, and the research project will no longer be conducted at WFBMC, but instead moved to another institution, ownership of the original data may be transferred from WFBMC to the PI's new institution upon request from the PI. An agreement on the disposition of research data must be negotiated between the PI and his/her department chair, in consultation with the Office of Regulatory Affairs within the CTSI, concerning possession of research data, notebooks, and other data retention materials and unique resources to be transferred to the departing investigator. If the departing faculty member is the department chair, he or she will work directly with the Office of Regulatory Affairs and Research Integrity. To fulfill obligations to funding sources and others, such agreements may provide for WFBMC to retain copies of the research data, where feasible.

In the event that research data must remain at WFBMC, as mandated by WFBMC, by law, or as required by the funding agency or commercial sponsor or other applicable policies, the PI will have the right to access and, where practical, to copy such research data produced by him/her subject to any restrictions

set forth in a sponsored agreement.

Upon the death of a PI, the Department Chair shall appoint a researcher to assume stewardship of the research data.

When individuals other than the PI, such as collaborating investigators, fellows, students or other trainees, leave WFBMC, they may take copies of research data for projects on which they have worked or have the right to reasonable access to such data, subject to relevant confidentiality restrictions and/or restrictions set forth in a sponsored agreement.

### **Research Data Ownership Policy Oversight and Dispute Resolution**

The Office of Regulatory Affairs and Research Integrity within the CTSI, under the direction of the Vice President for Research Administration and Operations, has responsibility for oversight of, and resolution of, disputes resulting from this policy. In an investigator desires to contest the decision of the Vice President for Research Administration and Operations, the investigator may file a written appeal to be reviewed by a committee of researchers, appointed by the Office of Regulatory Affairs and Research Integrity.

- ii. **5) Related Policies**
  - Research Integrity Policy
  - Intellectual Property Policy
  - Authorship Policy

### **6) Governing Law or Regulations**

### **7) Attachments**

None

### **8) Revision Dates**

January 1, 2017