	<b>Policy on Creating and Amending Policy</b> LAB Admin 1	<b>Type:</b>	Tier 2
		<b>Effective Date:</b>	Nov. 10, 2011
		<b>Revised Date:</b>	June 24, 2016
		<b>Contact:</b>	WFBMC Legal Dept.

**1) General Policy Statement (Entities Affected / Responsible Party for Implementation)**

It is the policy of Wake Forest Baptist Medical Center to establish and maintain up-to-date policies, procedures and guidelines, consistent with institutional and regulatory standards and requirements. This policy shall establish a clear operationally sound control in which such policies are proposed, reviewed, and approved throughout the organization.

- a) Scope: All WFBMC employees, faculty and staff, are responsible for complying with this policy for the development, revision, approval, implementation and warehousing of all WFBMC policies, procedures, and guidelines.
- b) Responsible Department/Party/Parties:
  - i. Policy Owner: Legal Department
  - ii. Procedure: Legal Department
  - iii. Supervision: Legal Department
  - iv. Implementation: All Cabinet Members and Executive Management

**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: 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 WFUBMC. 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) Guideline: A recommended process or method for accomplishing a specific task or objective. All guidelines must comply with applicable WFBMC policies and procedures.
- d) Procedure / Protocol: A required process or method for implementing a WFBMC policy.
- e) Scope: The subunits within the organization to which a policy applies.
- f) Responsible Department: The owner of the policy.
- g) Champion: The executive level advocate of the Policy who manages its revision, review and implementation.

**3) Policy Guidelines:**

- a) General Requirements:
  - i. All policies must be in writing and approved as outlined in the Tier System established

herein.

- ii. Policies in Tiers 1 and 2 must be reviewed and approved within a minimum of three (3) years from the Effective Date or more frequently as required by governing laws, regulations or needs of WFBMC.
- iii. Application of the policy will be clearly stated in a Scope section.
- iv. The Legal Department shall be the office of record for all approved policies in Tiers 1, 2 and 3 issued by WFBMC.
- v. All Policies shall fall within the Tier System outlined on Exhibit A hereto.

- vi. All Policies shall be categorized into one of the following categories with appropriate Champion:

Category 1:	Health System Administrative/ Operational/General	Champion:	President and Chief Operating Officer or General Counsel
Category 2:	Financial Management	Champion:	Chief Financial Officer
Category 3:	Human Resources	Champion:	Chief Human Resources Officer
Category 4:	Patient Care	Champion:	Chief Medical Officer or President and Chief Operating Officer
Category 5:	Research	Champion:	Dean, School of Medicine
Category 6:	Education/Faculty Services	Champion:	Dean, School of Medicine
Category 7:	Information Services	Champion:	Chief Information Officer

- vii. Prior to approval, all policies that are impacted by regulatory standards, including without limitation The Joint Commission, Center for Medicare and Medicaid Services, and other governing authority must be reviewed by Corporate Compliance. This compliance review process shall be initiated by the Champion of the specific policy. If regulatory standards apply, the Champion will engage Corporate Compliance and/or the Chief Audit and Compliance Officer for appropriate management and review.
- viii. Departments may issue operational guidance, procedures, forms and other general informational documentation so long as these do not contradict conflict with or negate the Policy. Such implementing procedures, guidance and forms shall be retained by the responsible department stated in the Policy.
- ix. Tier 2 policies, procedures and guidelines are subordinate to and should not conflict with Tier 1 policies. Tier 3 policies, procedures and guidelines are subordinate to and should not conflict with Tier 1 and Tier 2 policies.
- x. All policies in Tiers 1, 2, and 3, once finalized, shall be provided to the Legal

Department to be housed in the policy database.

- xi. Policies shall be uniformly numbered using the following numbering convention:  
xx.yyy.zzzz
- where xx represents the Tier (eg. Tier I would be represented as 01);
  - yyy represents the category (eg, a Category 1 policy would be represented as 001);  
and
  - zzzz represents a consecutive number issued by the responsible department.

b) All policies shall be developed using the following format:

- i. General Purpose
  - Scope
  - Responsible Department/Party/Parties
    - Policy Owner
    - Procedure
    - Supervision:
    - Implementation
- ii. Definitions as deemed necessary
- iii. Policy Guidelines (the heart of the policy)
- iv. Review/Revision/Implementation
  - Review Cycle
  - Office of Record
- v. Related Policies (list of related policies, procedures or guidelines)
- vi. Governing Laws or Regulations (Must reference applicable laws, regulations, governing authority)
- vii. Attachments

#### 4) Review/Revision/Implementation

- a) Review Cycle: This policy shall be reviewed the Legal Department at least every three (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

NONE

#### 6) Governing Law of Regulations

NONE

#### 7) Attachments

Exhibit A: Tier System

**EXHIBIT A**  
**TIER STRUCTURE FOR POLICY APPROVAL**

WFBMC utilizes a three tier policy system. In the event of conflicts or clarifications between and among tiers, the higher level tier policy has precedence over a lower level tier policy.

**Tier 1**

Policies pertaining to the Institutional Governance of WFBMC shall be designated as Tier 1 or WFBMC Institutional Governance Policies.

- Tier 1 policies, including any amendments thereto, require approval of the WFBMC Board of Directors prior to implementation.
- Tier 1 policies may apply to all employees of WFBMC, although some Tier 1 policies may have more limited application. In addition, Tier 1 policies may also apply to students, visitors and/or others.
  - Prior to being presented to the WFBMC Board of Directors for approval, all Tier 1 policies, including any amendments thereto, must also first be approved by the Chief Executive Officer of WFBMC.
  - In some instances, approval of the Wake Forest University Board of Trustees may also be required.

**Tier 2**


Policies designated as Tier 2 are Executive Level Governance Policies. These policies govern patient care and medical operations of WFBMC.

- Tier 2 policies, including amendments, require executive level approval of the appropriate Champion.
- Tier 2 policies may apply to all employees of WFBMC, although some Tier 2 policies may have more limited application. In addition, Tier 2 policies may also apply to students, visitors and/or others.
- Prior to being presented to the executive for approval, all Tier 2 policies, including amendments thereto, must have been first reviewed and approved by an authorized manager designated by the appropriate executive as listed above to ensure all impacted stakeholders have been included in policy development

**Tier 3**

Policies designated as Tier 3 pertain to the administration or management of WFBMC.

- Tier 3 policies, procedures and guidelines, including any amendments thereto, require approval, indicated by signature, of the relevant vice president of the department charged with ownership of the policy prior to implementation.
- Tier 3 policies, procedures and guidelines may apply to all employees of WFUBMC, although some Tier 3 policies, procedures and guidelines may have more limited application. In addition, Tier 3 policies, procedures and guidelines may also apply to students, visitors and/or others.
- Prior to being signed and approved by the responsible vice president, all Tier 3 policies, including amendments, must have been first reviewed and approved by an authorized manager designated by the appropriate vice president as listed above to ensure all impacted stakeholders have been included in policy development.

	<b>(INSERT NAME OF POLICY)</b>	<b>Type:</b>	<b>Tier * (tiers are defined in the Policy on Policies)</b>
		<b>Original Effective Date:</b>	
		<b>Current (Revised) Date:</b>	<b>Complete this section if this document is a revision of an already published policy</b>
		<b>Contact:</b>	<b>Department that is policy owner as listed in responsible department below</b>
<b>Approval Signature:</b>		<b>Date of Signature:</b>	
<b>Name and Title:</b>			

**1) General Policy Statement:**

{Insert Brief Narrative to begin with “It is the policy of Wake Forest Baptist Medical Center to .....”}

- a) **Scope:** {Insert to whom the policy applies, for example. All WFBMC employees, faculty and staff are responsible for complying with this policy}
- b) **Responsible Department/Party/Parties:**
  - i. **Policy Owner:** {Champion, based on tier, who is charged with review and updating the policy on behalf of WFBMC}
  - ii. **Procedure:** {Department(s) which are charged with determining and defining the procedures relative to implementation and administration of the policy; this may include stakeholders who may own certain obligations to operationalize the policy}
  - iii. **Supervision:** {Department or Champion charged with managing compliance with regulations and operations to which this policy applies}
  - iv. **Implementation:** {Department or specific job title of an individual who makes the policy happen on a day-to-day basis}

**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) {Utilize any of the above and add other definitions as deemed necessary for a clear understanding of your terms or abbreviations }

**3) Policy Guidelines:**

- a) **General Requirements** {this is the ‘heart’ or body of the policy. Please use outline format}:
  - i. {Insert Narrative}
  - ii. {Insert Narrative}
  - iii. {Insert Narrative}
  - iv. {Insert Narrative}
  - v. {Insert Narrative}



- b) Critical Point
- c) Critical Point

**4) Review/Revision/Implementation**

- a) **Review Cycle:** {This policy shall be reviewed by (DEPARTMENT OR CHAMPION) at least every \_\_\_\_\_ years from the effective date. REMEMBER: Unless otherwise stated by regulation, the default is three years}
- b) **Office of Record:** {After authorization, the \_\_\_\_\_ Department shall house this policy in a policy database and shall be the office of record for this policy. REMEMBER: typically this is the Legal Department.}

**5) Related Policies**

{Insert Policy Names, if applicable}

**6) Governing Law or Regulations**

{Insert Citation to statute law or regulation and names of governing agencies/authorities. For example: Department of Labor/OSHA 29 CFR 1910.1030 Bloodborne Pathogens, or a requirement of a national professional organization}


**7) Attachments**

{Insert Exhibit Title and Number, if applicable and remember to provide these as attachments to the policy}

**8) Revision Dates**





	<b>Operational Guideline Name</b>	<b>Dept:</b>	
		<b>Effective Date:</b>	
		<b>Revised Date:</b>	
		<b>Contact:</b>	
		<b>Date:</b>	
<b>Name &amp; Title:</b>			
<b>Signature:</b>			

- 1) **General Procedure/Guideline Statement: (Entities Affected/Responsible Party for Implementation – Usually what is currently included in a policy statement or purpose statement)**
  - a. **Scope: Who will follow this procedure/guideline/protocol?**
  - b. **Responsible Department/Party/Parties:**
    - i. **Procedure owner: Who owns this procedure/guideline/protocol – may be same as contact**
    - ii. **Procedure: Who is responsible for carrying out the activities of the procedure/guidelines/protocol or who is educating the staff on how to perform**
    - iii. **Supervision: Who supervises the persons performing per the procedure/guidelines/protocol**
    - iv. **Implementation: Who is responsible for making the procedure/guidelines/protocol happen**
  
- 2) **Definitions:**
  - a. **Guideline: A process or method for accomplishing a specific task or objective. All guidelines must comply with applicable WFBMC policies and procedures.**
  
- 3) **Procedure/Guidelines: Basically the body of the procedure/guidelines**
  
- 4) **Review/Revision/Implementation:**
  - a. **Review Cycle: {This policy shall be reviewed by (DEPARTMENT OR CHAMPION) at least every \_\_\_\_\_ years from the effective date. REMEMBER: Unless otherwise stated by regulation, the default is three years}**
  - b. **Office of Record: {After authorization, the \_\_\_\_\_ Department shall house this policy in a policy database and shall be the office of record for this policy. REMEMBER: typically this is the Dept. that will follow the procedure/guidelines}**
  
- 5) **Related Governing Policies: If any**
- 6) **References, National Professional Organizations, etc.:**
- 7) **Attachments: If any needed they are titled Exhibit 1, etc.**
- 8) **Revision Dates: Please list all from effective date when available**

