Wake Forest Baptist Medical Center	INVESTIGATIONAL / FDA CONDITIONALLY APPROVED MEDICAL DEVICES PPB-MC-31	Type:	Tier 2
		Original Effective Date:	01/01/2004
		Current (Revised) Date:	08/01/2009; 11/12/2012; 05/12/2015
		Contact:	Chris O'Byrne
Approval Signature:		Date Approved:	05/12/2015
Typed Name and Title: Christopher O'Byrne Assistant Dean, Biomedical Research Services			

1) **General Policy Statement:**

It is the policy of Wake Forest Baptist Medical Center, to provide high quality patient care activities. Our status as a tertiary referral center may involve the use of investigational medical devices as part of research studies, humanitarian use devices, and the compassionate or treatment use of such devices.

WFBMC seeks to ensure patients and their families have the opportunity, within applicable laws and regulations, to make informed decisions regarding the use of these investigational/FDA conditionally approved medical devices. The patient should accept or refuse such treatments knowing, to the extent possible, the medical and financial implications of the decision.

a) **Scope:** All faculty and staff are responsible for complying with this policy.
b) **Responsible Department Parties:**
   i. **Policy Owner:** Assistant Dean, Biomedical Research Services
   ii. **Procedure:** Departments responsible for determining/defining procedures relative to implementation and administration of the policy include: the Audit & Compliance Department, Biomedical Research Services and Administration (BRSA), and the Legal Department.
   iii. **Supervision:** BRSA
   iv. **Implementation:** BRSA

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 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) For the purposes of this policy, the term "investigational/FDA conditionally approved medical device" shall mean any medical device that falls under the categories listed below:

- Not approved by the FDA (an unapproved device)
- Used under the provisions of an Investigational Device Exemption (IDE)
- Not marketed or not available for commercial use or distribution in the United States
- Used under the Humanitarian Device Exemption (HDE)

- Used in a research study, investigational study, investigational trial, experimental study, clinical trial, clinical study, clinical investigation or adjunct clinical trial designed to test the safety, efficacy, effectiveness or performance of the device, regardless of whether or not the device is FDA approved
- Used under the provisions for compassionate or treatment use
- The emergency use of any unapproved device

Any use, purchase and billing of investigational/FDA conditionally approved devices will be in compliance with federal and state regulations and laws, contracts and institutional policies and procedures.

The medical staff, in conjunction with the hospital, is committed to providing comprehensive health care services of the highest quality and to advancing clinical standards of patient care through participation in research and education programs. This policy reflects the organization's key values of innovation, through participation in IRB approved research and of compassion and integrity by giving the patients the opportunity to make informed decisions regarding the use of these investigational/FDA conditionally approved medical devices, in an attempt to meet their medical care needs.

d) Refer to Appendix I for additional definitions associated with investigational devices and their use.

3) Policy Guidelines:

a) General Requirements:

This policy applies to the use, purchase and billing of all investigational/FDA conditionally approved medical devices in humans.

The principal investigator (when the device is used in research) or the attending physician (when the device is used for treatment) is responsible for compliance with this and all other applicable institutional policies and procedures regarding investigational/FDA conditionally approved medical devices, and maintaining sufficient knowledge and understanding of federal and state laws and regulations to ensure appropriate use of the device.

No part of this policy limits or restricts a physician's ability to use an FDA approved device for its labeled indications for the treatment and care of an individual patient.

b) Approval Process:

Prior to the purchase or use of any investigational/FDA conditionally approved medical device, the following procedures must be completed:

1. All devices must be used in full accordance with all applicable federal and state laws and regulations, and institutional policies and procedures.

2. All devices must be approved in accordance with IRB and other Medical Center policies and procedures which shall be congruent with any applicable FDA guidelines or conditions.

3. The principal investigator/attending physician must follow the IRB approved protocol and comply with all IRB determinations.

4. Upon approval by the IRB, the Clinical Trials Office and the Compliance Office, will be notified electronically by the IRB that an investigational/conditionally approved device has received IRB approval.

5. The Clinical Trials Office (CTO), in collaboration with the Compliance Office, as appropriate, will review the IRB File. The CTO will be responsible for completing and submitting the required Medicare request for approval or notification of use for an Investigational Device (IDE). Each Investigational Use Device requires a single Medicare submission for approval or notification unless there is a change in/modification to the device and/or a change in the protocol which requires a new request for approval.

    a. CMS revised the IDE regulations (42 CFR 405 Subpart B), effective January 1, 2015. CMS added criteria for coverage of IDE studies and changed from local Medicare Administrative Contractor (MAC) review and approval of IDE studies to a **centralized review and approval of IDE studies**.

    b. An approval for a Category A (Experimental) IDE study will allow coverage of routine care items and services furnished in the study, but not of the Category A device, which is statutorily excluded from coverage.

    c. An approval for a Category B (Non-experimental/investigational) IDE study will allow coverage of the Category B device and the routine care items and services in the trial.

    d. Palmetto GBA Medicare (North Carolina MAC) still requires notification of use for IDEs approved through the central review process. The same packet of information submitted for approval requests is required to be submitted for notification of use.

    e. IDE studies approved by MACs prior to January 1, 2015 will continue to be administered by the MAC. Study sponsors do not have to submit the protocol to CMS if the participating study investigator sites have already received approval from their MAC. Study sponsors should continue to follow the approval process established by the MAC for any site additions or protocol changes.

6. *If the device is a Humanitarian Use Device (HUD) and conditionally approved under the Humanitarian Device Exemption (HDE):*

    a) **Medicare requires pre-approval for each patient**, based on medical necessity. If the patient is a Medicare beneficiary, then the Clinical Trials Office, working collaboratively with the Compliance Office, will complete and submit pre-approval for the HDE. In addition to information submitted to the IRB, the submission to Medicare (and generally other insurers/payors) will require a letter/statement of medical necessity detailing the clinical condition of the patient, previous treatment methods which have been tried and failed, and/or alternative treatments/devices available.

    b) **Note Medicare Post Procedure Notification: In the event that a HUD is placed on an emergent basis and a patient specific pre-approval has not been obtained (e.g., coronary stent placement), then the investigator or his/her designee must still submit this information to the Clinical Trials Office so that the information can be submitted to Medicare, post procedure.**

    c) If the patient is not a Medicare beneficiary, but is covered by another type of insurance/payor, then pre-approval based on medical necessity should be obtained/verified with the specific insurer. This process will be managed through the Corporate Revenue Cycle, Office of Pre-Registration/Financial Clearance. The principle investigator or designee will be notified, of approval and of any restrictions or specific instructions.

7. If Medicare approval is required, patients may not be enrolled in a device study nor can the investigational device (IDE) or FDA conditionally approved medical device (HDE) be used or purchased until the principal investigator/attending physician receives written approval from the Clinical Trials Office, working in conjunction with the Compliance Office, except for emergency use. (Sec Section E regarding emergency use.) **Medicare approval for use of a device typically takes a minimum of 30 days.**

c) **Charge Description Master and Patient Scheduling:**

1. Once the Clinical Trials Office has reviewed and received approval for the use and/or billing of the IDE/HDE and associated services, and the principle investigator or designee has been notified, **the principle investigator/physician or designee must notify the hospital and/or physician department, where the device is to be used, to advise them of the approval.**

2. Hospital departments will notify Financial Services/Controller's Office to establish the hospital charge for the device, if appropriate. The hospital department should submit to Financial Services/Controller's Office both the Charge Description Master Form and a copy of the approval. Once charges have been established, patients can be scheduled for services.

3. When scheduling the patient, the physician office will be responsible for informing the hospital department that a patient is involved in a clinical trial study or will be receiving treatment using an investigational/FDA conditionally approved device. The name of the specific type of device (IDE or HDE) and description/use must be provided to the person scheduling the patient.

4. The Corporate Revenue Cycle, Office of Pre-Registration/Financial Clearance will be responsible for making a notation in WakeOne notes screen on the Hospital Account Record (HAR) indicating the name and type of medical device. Physician Office/Clinic staff will be responsible for documenting this in the outpatient/office medical record.

d) **Financial Eligibility:**

Corporate Revenue Cycle (CRC) will be responsible for reviewing notes in Wake One and ensuring that appropriate insurance verification, patient financial counseling, and regulatory and hospital billing guidelines have been followed. This must be done **prior to the patient's scheduled date of service**.

1. The Pre-Registration Department will work with the physician, the hospital department director, and the patient to determine what part of the treatment is covered by the patient's insurer and what part will be patient responsibility.

2. When an investigational/FDA conditionally approved medical device has been deemed non-covered by a third party payor, the appropriate Financial Responsibility Forms must be obtained. **This is an additional and separate requirement from the Patient Informed Consent Document explained later.**

   a. Medicare requires that patients sign an Advanced Beneficiary Notice of Noncoverage (ABN) that provides an estimate of non-covered costs and states that the patient is aware that an investigational/FDA conditionally approved medical device is being rendered for the sake of research and treatment, and that he/she will be responsible for the bill if the service is performed. A **Medicare patient cannot be held financially responsible without having this ABN form on file.**

   b. For other third party payors including Medicaid, a Waiver of Liability Form must to be signed for all non-covered uses of these investigational/FDA conditionally approved medical devices.

3. Where the only available course of treatment involves placement/use of an investigational/FDA conditionally approved medical device for which there is no funding, and cannot be managed through the charity care policy, the treatment **must be approved by the AVP of the Corporate Revenue Cycle (or Vice Chief Financial Officer).**

e) **Informed Consents:**

1. The patient must give written informed consent for research procedures as required by the IRB, as well as for any clinical services/procedures as required by WFBMC policy (see WFBMC-189).

2. When informed consent is required by the IRB, a signed and dated copy of the research informed consent must be maintained as part of the On-Base (Media) portion of the patient's electronic medical record in accordance with the IRB SOPs. When a research sponsor is involved, the Informed Consent Form should appropriately inform study participants of the related activities or materials paid for by the sponsor.

3. As required by Informed Consent policy WFBMC-189, non-research informed consent for surgeries and procedures must be maintained as part of the patient's medical record. ***The Informed Consent Document does not replace the need for an Advanced Beneficiary Notice/ABN (for Medicare Patients) or a Statement of Financial Responsibility (for other payors), if the patient is to be held financially responsible for costs associated with the IDE/HDE.***

f) **Emergency Use:**

1. The emergency use of a device that is not approved by the FDA may be justified when:

   a. The patient is in a life-threatening condition that needs immediate treatment

   b. No generally acceptable alternative for treating the patient is available

   c. Because of the immediate need to use the devices there is no time to use existing procedures to get FDA or other required governmental approval or for approval through this policy.

2. In the event that a device is to be used in circumstances meeting the above criteria the principal investigator/attending physician will:

   a. Arrange for the device to be immediately obtained.

   b. Comply with all federal and state laws and regulations regarding emergency use of unapproved devices.

   c. Comply with IRB policies and procedures regarding emergency use of unapproved devices.

   d. Notify the appropriate Coding/Billing Compliance Department (NCBH Patient Financial Services Compliance Manager and/or WFUHS Director of Coding & Regulatory Compliance) in writing within 5 days of the emergency use of a device.

3. Compassionate or treatment use (use of an investigational/FDA conditionally approved medical device when a serious, but not life-threatening condition exists, where no alternative device is available) does not constitute emergency use. Compassionate or treatment use of an investigational/FDA conditionally approved medical device must be in accordance with this policy, all applicable federal

and state regulations, and institutional policies and procedures.

4. Humanitarian Use Devices (HUD) can be used in emergency and compassionate/treatment use cases. HUDs require IRB approval on a case by case basis.

g) Medical Coding and Documentation Requirements:

1. It is imperative that the physician note in the medical record the description of any investigational/FDA conditionally approved medical device along with the medical rationale for the use of the device. This will ensure appropriate medical coding of these devices.

2. It will be the responsibility of the physician and hospital departments to retain any data that is not typically housed in the hospital medical record related to these devices.

3. The following is data that is required by Medicare and many other third party payors when submitting medical records for medical review:

   a. The trial name & device name
   b. Sponsor
   c. Sponsor-assigned protocol number
   d. Patient's signed informed consent
   e. Medical documentation justifying the medical necessity of use of the investigational/FDA conditionally approved medical device

4) Review/Revisions/Implementation:

a) **Review Cycle:** Annually
b) **Office of Record:** Legal Department

5) Related Policies:

WFBMC Policy-189; Intranet, Office of Research, IRB, Policies

6) Governing Law or Regulations:

42 CFR Parts 405 and 411; 34 CFR Part 97.116; 45 CFR Parts 46; CMS-Pub. 14-3 §3044.24; 21 CFR 812; 21 CFR 814

7) Attachments:

Appendix I – Terms & Definitions Related to Medical Devices

Appendix I

Terms and Definitions Related to Medical Devices

➢ **Device:**
The term device means an instrument, apparatus, implement, machine, contrivance, implant in vitro reagent, or other similar or related article, including any component, part, or accessory, which is -

- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. [21 USC 321]

For the purpose of this policy, device (investigational/FDA conditionally approved medical device) means any article meeting the above criteria that is:

- Not approved by the FDA
- Used under the provisions of an Investigational Device Exemption (IDE)
- Not marketed or not available for commercial use in the United States
- Used under the Humanitarian Use Device (HUD) provisions (Humanitarian Device Exemption - HDE)
- Used in a research study, investigational study, investigational trial, experimental study, clinical trial, clinical study, clinical investigation or adjunct clinical trial designed to test the safety, efficacy, effectiveness or performance of the device, regardless of whether or not the device is FDA approved
- Used under the provision for treatment or compassionate use
- The emergency use of any unapproved device

➢ **Device Classes:**
The class distinction is made primarily on the level of risk to users/patients and, therefore, the level of FDA oversight needed to ensure that the device is safe and effective as labeled. Generally, but not always, this corresponds to logical risk evaluations. The higher the class, the greater the risk and degree of regulation. [21 CFR 860.3]

Class	Controls	Example Products
Class I	General controls such as registration of the producer and distributor, listing, and compliance with good manufacturing practices and labeling requirements	Crutches, band aids
Class II	Special controls such as special labeling requirements, mandatory performance standards and post-market surveillance	Wheelchairs, tampons, infusion pumps
Class III	Pre-market approval	Heart valves, coronary angioplasty catheters

➢ **Device Categories:**
For the purpose of consideration for reimbursement under the Medicare program, the FDA categorizes devices available through investigational device exemptions (IDEs) as either Category A or Category B.

- A **Category A** (experimental) device refers to an innovative device believed to be in Class III for which absolute risk of the device type has not been established (i.e., initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.

  Category A devices are not eligible for Medicare payment, although, Medicare may pay for the routine costs of clinical trials involving a Category A IDE. If the device is used for a Medicare beneficiary, an Advanced Beneficiary Notice would need to be signed by the patient explaining that the device and some non-routine services may not be covered. **The Medicare beneficiary would then be billed for charges associated with the use of the device unless such charges are covered by research funds.**

- A **Category B** device (non-experimental/investigational) device refers to a device believed to be in Class I or Class II, or a device believed to be in Class III for which the incremental risk is the primary risk in question (i.e.. underlying questions of safety and effectiveness of the device have been resolved) or it is known that the device type can be safe and effective (e.g., other manufacturers have obtained FDA approval of that device type).

  Category B devices may be eligible for Medicare payment. In order to bill for these devices, they must be used within the context of an FDA approved clinical trial or Humanitarian Device Exemption.

- **Emergency Use:**
  The emergency use means the use of a device that is not approved by the FDA when:

  - The patient is in a life-threatening condition that needs immediate treatment
  - No generally acceptable alternative for treating the patient is available
  - Because of the immediate need to use the device there is no time to use existing procedures to get FDA or other required governmental approval.

  The emergency use of a device governed by the IDE regulations [21 CFR 812 35] and the FDA Guidance for the Emergency Use of Unapproved Medical Devices [50 FR 42866]. Such use must comply with all federal and state laws and regulations and IRB policies and procedures.

  Devices used under emergency use provisions may not be eligible for Medicare payment.

- **Compassionate Use:**
  Compassionate Use (also known as Single Patient/Small Group Access) is the use of a device when a serious, but not life-threatening, condition exists where no alternative device is available. Compassionate use does not constitute emergency use. Compassionate use is governed by the IDE regulations [21 CFR 812.35(a)]. Such use must comply with all federal and state laws and regulations and IRB policies and procedures.

  Devices used under compassionate use provisions are eligible for Medicare payment, but only if they are Category B devices.

- **FDA:**
  The United States Food and Drug Administration

- **FDA Approved Device:**
  A device approved for marketing and distribution in the United States by the FDA under the applicable provisions of the Food, Drug and Cosmetic Act and other federal law.

- **Humanitarian Use Device:**
  Humanitarian Use Device (HUD) means a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affects fewer than 4,000 individuals per year in the United States. Such devices are made available through a Humanitarian Device Exemption (HDE). Although, such devices have demonstrated safety, they are exempted from the effectiveness requirements necessary for an FDA pre-market approval (PMA). **A humanitarian use device may only be used for its labeled indication and must be IRB approved.** Humanitarian use devices are governed by the regulations for Pre-market Approval of Medical Devices [21 CFR 814]. Such use must comply with all federal and state laws and regulations and IRB policies and procedures.

  Humanitarian Use Devices are eligible for Medicare payment only if they are Category B devices.

- **Human Subject:**
  Human Subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

  (1) Data through intervention or interaction with the individual, or

  (2) Identifiable private information.

  Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. [45 CFR 46.102]

- **IRB:**
  IRB means an Institutional Review Board established in accordance with Wake Forest University Health Sciences policy and procedures, and federal regulations [45 CFR 46 and 21 CFR 56].

- **Investigational Device Exemption (IDE):**
  An investigational Device Exemption (IDE) allows a device that has not been approved by the FDA and is, therefore, considered investigational to be used in a research study in order to collect safety and effectiveness data required to support a Pre-Market Approval (PMA) application or a Pre-Market Notification [510(k)] submission to the FDA. [21 CFR 812].

- **Research:**
  Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. [45 CFR 46.102]

- **Research study, Investigational study, Investigational trial, Experimental study, Clinical trial, Clinical study, Clinical investigation or Adjunct clinical trial.**
  Terms used interchangeable to refer to any systematic study of human subjects undertaken to verify the safety, efficacy, effectiveness and performance of a specific medical device.

- **Treatment Use:**
  Treatment Use is the use of a device when a serious, but not life-threatening condition exists where no alternative device is available. Treatment use does not constitute emergency use. Treatment use is governed by the IDE regulations [21 CFR 812.36 and 62 FR 48490]. Such use must comply with all federal and state laws and regulations and IRB policies and procedures.

  Investigational/conditionally approved medical devices used under treatment use provisions are eligible for Medicare payment only if they are Category B devices.