

**UNIVERSITY MEDICAL CENTER**

**NOTICE OF CLINICAL TRIAL AND/OR USE OF INVESTIGATIONAL AND/OR HUMANITARIAN USE DEVICE**

**Department:**

**Description of the Clinical Trial and/or Investigational and/or Humanitarian Use Device:**

- Sponsor Assigned Protocol Number:
- Clinical Trial and/or IDE Number for the Investigational Device (if applicable):

**Name of the Principal Investigator(s):**

**Contact Name and Phone Number:**

**Please Copy and Attach the Following Information Related to the Clinical Trial and/or Investigational and/or Humanitarian Use Device:**

- A copy of the FDA approval letter provided to the sponsor or manufacturer of the device
- The name of the device including trade, common or unusual, and classification name
- Action taken to conform to any applicable FDA special controls
- A narrative description of the device that is sufficient to make a payment determination
- A statement indicating how the device is similar to and/or different from other comparable products
- The provider's protocol for obtaining informed consent for patients participating in the clinical trial

**OR**

- A copy of the IRB approval for the use of a device for humanitarian purposes

***Please copy and forward this form as follows:***

- ◆ Director, UMC Business Office (including attachments)
- ◆ Director, Health Information Management, UMC (including attachments)
- ◆ Director, Transition Management UMC (including attachments)

***It is recommended that the provider also forward a copy of the attached information to their professional billing services agent as well.***