

**UNIVERSITY MEDICAL CENTER
Tucson, Arizona**

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

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 complete this form 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 electronically including all attachments to each of the following:

Director, UMC Business Office

dfearing@umcaz.edu

Director, UMC Health Information Management

eoviedo@umcaz.edu

Director, UMC Transition Management

msisson@umcaz.edu

It is recommended that the provider also forward a copy of the attached information to his/her respective professional billing services agent as well.