

University of Arizona Medical Center - University Campus

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

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