**GUIDANCE NUMBER 16**

**HUMANITARIAN USE DEVICE**

Procedures for the Use of Humanitarian Device Exemption

The Humanitarian Device Exemption requires the following information to be submitted for IRB review:

1. An application form “Application for Approval of HUD Use Device for Patient Care” located in the following link: <https://sites.rowan.edu/officeofresearch/compliance/irb/policiesguidance/guidancelisting/humanitarianusedevices.html#p7EPMc1_13>.

B. A letter or document from the FDA describing that the device has been approved for humanitarian use and

C. A brochure or an information sheet describing the device and how the device is going to be used.

FDA guidelines for Humanitarian Device Exemption are posted at: <https://sites.rowan.edu/officeofresearch/compliance/docs/irbdocs/guidancedocs/Guidance_Humanitarian_Device_Exemption.pdf>.