WAYNE STATE UNIVERSITY

HIC Policy/Procedure

Wayne State University Human Investigation Committee	
SUBJECT	Humanitarian Use Device (HUD)
Section	
Form Date	
Approvals	6/21/06 Steering Committee, Administrative Approval 7/20/07

Background

A Humanitarian Use Device (HUD) is a medical device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 4,000 individuals in the United States. A HUD is considered somewhere between research and ordinary clinical practice. These devices do not undergo the same stringent requirements that investigational devices do, yet they may be recognized as the "approved" standard, and in some cases, preferred medical device.

To use a HUD, a Humanitarian Device Exemption (HDE), must be obtained from the Food and Drug Administration (FDA). Because of the expected small market, there is little hope to be able to obtain efficacy data required by ordinary pre-market approval (PMA). FDA regulations (21 CFR 814.124) provide for the submission of an HDE in which the manufacturer is not required to provide the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose prior to marketing. This regulation was developed to provide an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting less than 4,000 persons a year. The application must provide sufficient information in order for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury to the patient and that the probable benefits to health outweigh the risk of injury or illness from its use. Additionally, the application should ensure that no comparable devices are available to treat or diagnose the disease or condition. It must be clear that without the HDE the manufacturer could not otherwise bring the device to market.

After the HDE has been approved, the labeling for the HUD must state that the device is a HUD and that, although the FDA authorizes the device, effectiveness of the device for the specific indication has not been demonstrated.

An approved HDE authorizes marketing of the HUD. However, an HUD may only be used in facilities that have an established local institutional review board (IRB). The use of a HUD does not constitute a research protocol. This is the only situation where federal regulations require the IRB to approve and monitor an activity that is clearly not research (21 CFR 814.124).

HIC Policy

The Principal Investigator's (PI) Responsibility

The physician/investigator is responsible for obtaining IRB approval before the HUD is administered to or implanted in a patient. EXCEPTION: Refer to the HIC Policy/Procedure "Emergency Single Time Use of a Test Article".

All initial HUD submissions must be reviewed by a full-convened IRB. The following items must be included in the original submission:

- Humanitarian Use Device Form
- Humanitarian Device Exemption Letter from the FDA
- Informed Consent using the HUD template
- Copy of patient brochures or education materials
- Any other documentation received from the sponsor

Annual Review via a Medical Behavioral Continuation Form must be approved prior to the expiration date given at the time of approval. Generally this is 364 days after protocol submission. If the IRB approval lapses, the device cannot be used until approval is received. Continuations may be reviewed under an expedited review, if indicated in original approval letter.

The PI must only use the device within the scope of its labeling. All devices must be kept secure and only used by physician's approved by the IRB.

The PI must report any adverse reactions or unexpected events to the IRB for prompt review.

IRB Responsibilities

When a submission is received, it is assigned an HIC Protocol number. The Chair of the IRB or his/her designee then assigns the protocol for review. As this protocol is not research, it is appropriate to use a primary reviewer only.

A full convened IRB must review all initial HUD submissions. As part of the approval process, the committee shall determine what interval for approval is appropriate based on the degree of risk, but not more than annually. In addition, the IRB may elect to use the expedited review process for continuing review (21 CRF 56.110).

All Adverse Reactions and Unexpected Events will be reviewed according to the HIC Policy/Procedure: "Adverse Reactions and Unexpected Events".

Off-Label Use of a HUD in Emergency or Compassionate Situations

It is recognized that there may be circumstances in which "off-label" use of a HUD may be necessary to save the life or protect the well-being of a patient. When this situation arises, the physician-investigator should determine if the situation meets the requirements for emergency use of the device, see HIC Policy/ Procedure: "Single Time Emergency Use of a Test Article". If circumstances do not qualify for the single time emergency use, a new study must be submitted for review.