IRBMED
MEDICAL SCHOOL OFFICE OF RESEARCH

U-MIC TRANSCRIPT
Humanitarian Use Devices (HUDs)

The Food and Drug Administration defines a Humanitarian Use Device—or HUD—as "a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 8,000 individuals in the United States per year." Because the research has shown a HUD to have only "probable benefit," rather than "a reasonable assurance of effectiveness," every HUD requires IRB approval and oversight, via the eResearch application system, whether for use in clinical care or in research.

Physicians and researchers may

- use a HUD in clinical care, according to its approved indication
- use a HUD off-label in clinical care for an *emergency use* not currently indicated
- collect data regarding the safety and effectiveness of a HUD's approved indication
- study a HUD for a new indication

Using a HUD in clinical care—whether on- or off-label and whether collecting safety and effectiveness data or not—is covered under an FDA-issued *Humanitarian Device Exemption* (HDE). In most instances, the device's manufacturer holds the HDE. Occasionally, the physician is the HDE holder.

Since HUD use under and HDE is clinical care, IRB review does not involve a risk/benefit assessment as with review of research applications. Once the IRB has approved a HUD application, the physician may use the HUD according to its approved labeling without obtaining IRBMED approval for each individual use.

Studying a HUD for a new indication requires an *Investigational Device Exemption* (IDE). An IDE may be issued either by the IRB or by the FDA, depending on the risk of the proposed use.

Researchers who plan to study a HUD for a new indication should submit to the IRB a standard eResearch application. If the sponsor identifies the risk of the proposed use to be non-significant, the IRB may grant the IDE. If the proposed use of the device presents significant risk to study subjects, the FDA must grant the IDE. Generally, all off-label uses of a HUD are considered significant-risk uses.

Within fourteen days of an adverse event associated with use of a HUD in clinical care, the physician or HDE holder must submit a Medical Device Report to both the FDA and the IRB, informing them

- whether the HUD appears to have caused or contributed to death or serious injury
  and
- whether the HUD appears to have malfunctioned and is likely to cause or contribute to death or serious injury if the malfunction reoccurs

FDA defines a *serious injury* as one that:

- is life-threatening;
- results in permanent impairment of a body function;
- results in permanent damage to a body structure;
- necessitates medical or surgical intervention to preclude permanent impairment of a body function; or

- necessitates medical or surgical intervention to preclude permanent damage to a body structure.

When using a HUD in clinical care under an HDE, physicians should submit to the IRB copies of any reports to or from the FDA within seven days. Also within seven days, physicians should submit copies of any reports to or from the sponsor, manufacturer, or HDE holder, regarding urgent safety concerns or calling for changes in the use of a HUD. Routine reports to or from the sponsor or manufacturer that do not involve urgent safety concerns or call for changes in a HUD's use should be submitted to the IRB as part of scheduled continuing review applications.

Physicians using a HUD in clinical care should report any breach of confidentiality immediately to the UMHS Privacy Office and to the IRB within seven days of identifying the breach.

Contact the IRB for more information about humanitarian use devices.

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