Background

Humanitarian Use Device (HUD): A device intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year.

Humanitarian Device Exemptions (HDE): Issued by the FDA; an approved HDE authorizes marketing of the HUD.

Humanitarian Use Devices are regulated under 21 CFR 814 (Subpart H).

Applying for an Humanitarian Device Exemption (HDE)

To obtain approval for an HUD, an HDE application is submitted to FDA. The HDE application:

- *Must contain* sufficient information for FDA to determine that:
  - The device does not pose an unreasonable or significant risk of illness or injury, and
  - The probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.
- *Is not required to contain* the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose.

Criteria for HUD Use

All HUD use requires prospective IRB review and approval (except Emergency Use).

Clinical (non-research) use:

- The HUD may only be used after IRB approval has been obtained for the use of the device for the FDA approved indication.
- HUD use is subject to continuing review and approval by the IRB; if applicable, the expedited procedure may be used at continuing review.
- An IRB-approved consent form is not required.
- Medical device reports must be submitted to the FDA and to the IRB in accordance with 21 CFR 803.30 when:
  - the HUD may have caused or contributed to death or serious injury; or
  - the HUD has malfunctioned and likely cause or contribute to death or serious injury in the future if the malfunction recurs.
- To use a HUD for a new indication, a new designation of HUD status must be obtained (i.e., a new HDE submitted to the FDA); see 21 CFR 814.110.

Research use:

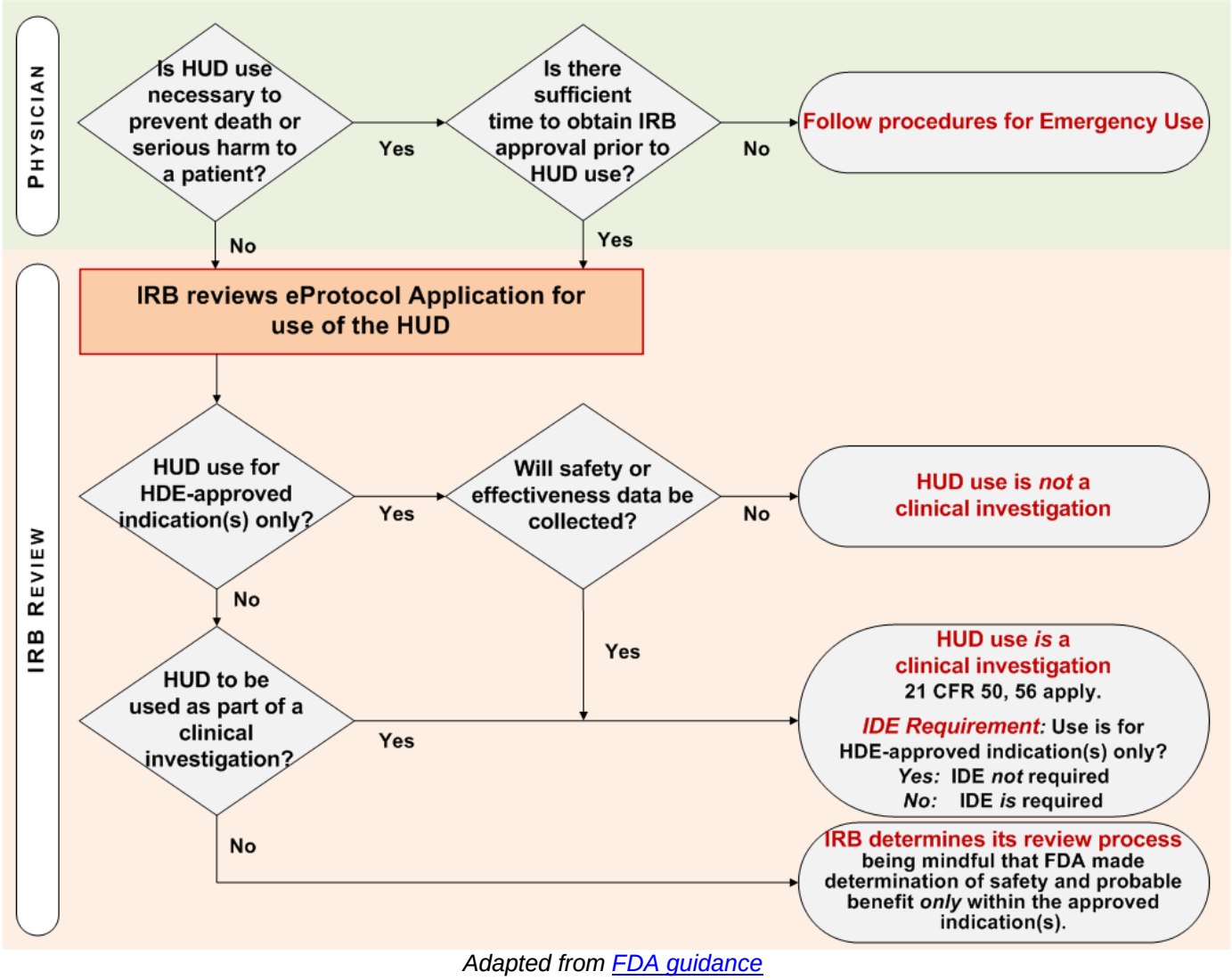
Prior IRB approval of a HUD is required before use. For research under a HDE, the scope of the IRB approval is to confirm the planned use is consistent with the FDA-approved indication for the HDE.

Researchers who want to study a HUD for a new indication must submit an IDE application to FDA if the device is a significant risk device. The investigational use of a HUD under these circumstances is a clinical investigation and must be conducted in accordance 21 CFR Parts 812, 50, 54, and 56.

IRB Review

New HUD use applications are submitted via eProtocol for regular review by the convened IRB.

Decision Tree for IRB when Reviewing Applications for HUD Use



Adapted from FDA guidance

Resources: Regulations and Guidance	
FDA	• 21 CFR 814 (Subpart H) Humanitarian Use Devices • Humanitarian Device Exemption • HDE Approvals • Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and FDA Staff - Humanitarian Device Exemption (HDE) Regulation: Q & A • 21 CFR 803 Medical Device Reporting

Resources: Other References	
Stanford HRPP	• Chapter 5.10 - Orphan Products: Humanitarian Use Device (HUD); Orphan Drugs • Emergency Use of a Test Article [GUI-6]