Comparing Emergency Use Authorization to Investigational New Drug & Investigational Device Exemption Protocols

Fact Sheet

Overview

The Federal Food, Drug, and Cosmetic Act (FD&C Act) creates mechanisms to permit the use of medical products before they have been approved under the FD&C Act or for unapproved uses under the act:

- **Emergency Use Authorization (EUA)** for the use of unapproved medical products (drugs, biologics [e.g., vaccines], and devices [e.g., diagnostics]) or the use of approved medical products in unapproved ways to diagnose, treat, or prevent serious diseases or conditions caused by chemical, biological, radiological, or nuclear (CBRN) agents.
- **Investigational New Drug (IND)** for the use of unapproved drugs or biologics.
- **Investigational Device Exemption (IDE)** for the use of unapproved medical devices.

During an emergency, these mechanisms make it possible for public health officials to use unapproved medical products as part of their response efforts. However, the EUA and IND/IDE protocols are different mechanisms, each with its own distinct statutory and regulatory requirements that vary with specific circumstances such as the nature of the medical product or the size of the population to be treated. The chart below compares EUA and IND/IDE mechanisms on key points.[1] Public health officials interested in using any of these mechanisms should refer to relevant laws, regulations, and Food and Drug Administration (FDA) guidance before deciding which mechanism to use and to understand the requirements of each one.[2]

Requirement	Investigational Protocols (IND and IDE)	Emergency Use Authorization (EUA)
Description	The objective of the IND/IDE is to assess the safety and efficacy of an investigational drug/biologic/device (hereafter "investigational product") while ensuring that human subjects are protected during the research study of the investigational product. Investigational protocols specify requirements to ensure participant protection and the validity of the data collected during the clinical trial.	Congress created the EUA in the Project BioShield Act of 2004 to give the public health system access to a greater range of medical products during a declared emergency. The EUA mechanism provides appropriate participant protections based on the circumstances of the emergency. EUAs are intended to allow for faster use of a product than under an IND/IDE.
FDA Approval	FDA review and agreement that the study may proceed.	FDA is required to review and approve the request for EUA.
Institutional Review Board (IRB)	Requires IRB review and approval.	Does not require IRB review and approval.
Informed Consent	Requires written, signed, and witnessed informed consent.	Written, signed and witnessed informed consent is not automatically required but may be required at the discretion of the FDA commissioner. Distribution of information (e.g., fact sheets) for healthcare professionals and recipients that contains information on product safety, available alternative products, and the right to refuse administration of the EUA product is required.

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Requirement	Investigational Protocols (IND and IDE)	Emergency Use Authorization (EUA)
Protocol Training	All investigators must be trained on the investigational protocol and informed consent and reporting requirements.	No specific investigator training requirements, but these may be added as a condition of authorization for the EUA by the FDA commissioner.
Adverse Event Monitoring & Reporting	Requires monitoring and reporting of adverse events.	Adverse event monitoring and reporting is required at the discretion of the FDA commissioner. The FDA will require MEDWATCH and VAERS reporting for all EUA products.
Recordkeeping & Access	Requires recordkeeping and access to distribution and administration records.	Recordkeeping and access to product distribution and administration records required at the discretion of the FDA commissioner.
Duration of Approval	Length of the clinical trial.	Up to one year from the date of the declaration of emergency or for as long as the §564 emergency declaration is in effect, whichever is shorter.

[1] *Table adapted from:* U.S. Food and Drug Administration and the U.S. Centers for Disease Control and Prevention. "Emergency Use Authorization" online course. Available at www.bt.cdc.gov/training/eua/index.html. Accessed January 31, 2012.
[2] As of March 2012, Congress is in the process of reauthorizing the Pandemic and All-Hazards Preparedness Act (PAHPA), which reauthorization may impact provisions relevant to emergency use of medical products.

This document was compiled in August 2011-March 2012 and reflects the laws and programs current at the time. It reflects only selected portions of the laws relevant to public health emergencies; it is not intended to be exhaustive of all relevant legal authority. This resource is for informational purposes only and is not intended as a substitute for professional legal or other advice. The document was funded by CDC Award No. 1U38HM000454 to the Association of State and Territorial Health Officials; Subcontractor PI Elliott, Logan Circle Policy Group LLC.