

Our Mission

. . . . is to develop and manage medical materiel to protect and sustain the Warfighter on point for the Nation.



Our Vision

. . . . is to integrate with USAMRMC, Federal agencies, and the DoD, as part of the joint biomedical research and materiel community, to focus on delivering the best medical solutions for today and tomorrow.

Our products are an integral part of the DoD Force Health Protection Program, to include vaccines, drugs, and medical devices, to prevent, diagnose, and treat infectious diseases, combat-related casualties, and CBRNE threats.

Our products enhance far-forward medical care across the full spectrum of health care missions worldwide.

How to help . . .

1. Call FHP/USAMMDA at 301-619-1104 or USAMRIID at 888-USA-RIID – can send Product Manager to your site to assist in protocol management.
 - Assist in securing product
 - Assist primary investigator (PI)/Support staff in fulfillment of regulatory requirements
 - Monitor regulatory files & provide guidance on maintenance of regulatory files
 - Coordinate availability/communication with subject matter experts (SME)
2. SMART IND team – (2)
 - 4 members assigned
 - Focus of training: protocol implementation
 - Will deploy in the event of an outbreak

SMART IND/EUA Team . . .



- Team Leader
- Physician
- Nurse
- Product Manager
- Subject Matter Expert

- Logistics Non-commissioned Officer (NCO)
 - Communications NCO
 - Home Liaison
- Will deploy to site



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USAMRMC



**U.S. Army
Medical Research
Materiel Command**

Force Health Protection Branch



*Investigational New Drugs/
Emergency Use Authorization*

USAMMDA

**U.S. Army Medical Materiel
Development Activity**

*Developing Quality Medical Products
for U.S. Forces*

Protect the Warrior; Sustain the Force.

Updated: Sep. 2008

Force Health Protection . . .

The Force Health Protection (FHP) branch is an organized program of healthcare preventive treatment, therapeutic treatment, or preparations for such treatment designed to meet the actual, anticipated, or potential needs of a group of military personnel in relation to military missions.

It is the DoD's policy that personnel carrying out military operations shall be provided the best possible force health protection, including safe and effective medical countermeasures to chemical, biological or radiological warfare, and in-theater disease threats. The FHP program provides and manages Investigational New Drugs (IND) as medical support for military personnel exposed to Chemical Biological Radiological Nuclear Explosive (CBRNE) events and diseases endemic to the area of operation.

The FHP Branch at USAMMDA serves as the executive agency for the management of the DoD's FHP IND program and the Special Medical Augmentation Response Investigational New Drug/Emergency Use Authorizations (SMART IND/EUA) teams. The mission of the FHP Branch is to plan, implement, and sustain DoD-directed FHP IND protocols. The FHP investigational staff are trained in the execution of the protocols according to FDA regulatory guidelines and Good Clinical Practices.

Vision . . .

Current medical countermeasures administered as IND's by FHP/USAMMDA include vaccines, drugs, and immunoglobulins to prevent and/or treat diseases caused by Category A Biothreat agents, such as Anthrax, Botulism and Smallpox. Our mission has expanded to include countermeasures for endemic disease threats such as Leishmaniasis and the hemorrhagic fevers.

A new regulatory tool arising out of the Bioshield Act of 2004 is the "Emergency Use Authorization" (EUA). In the event that an emergency is declared by the appropriate Cabinet level secretary (i.e., SEC DEF) selected medical countermeasures could be rapidly delivered to affected individuals at the incident site via the EUA mechanism.

FHP/USAMMDA now fields a SMART IND/EUA team. This team is designed to deploy to biological mass casualty incidents to facilitate the administration of IND/EUAs to military personnel in harm's way.

Legal Authority . . .

Executive Order 13139: Improving Health Protection of Military Personnel Participating in Particular Military Operations (Sep. 1999).

- Policy is to provide safe & effective vaccines, antidotes, treatments and countermeasures to negate or minimize health threats
- Preferential use of products approved by the FDA
- When FDA products are unavailable, an unapproved product may be used under strict controls (IND protocols)
- Protocols approved by The Surgeon General (TSG) Human Subject Research Review Board (HSRRB) (also serves as IRB of record)
- Requires prior consent of Servicemembers (waived in certain circumstances)
- Ongoing training on IND requirements required DoDI 6200.02 from Feb. 2008, Sec Army as Executive agent (Aug 2000) "Use of Investigational New Drugs for FHP"
- Designates The Secretary of the Army as the DoD Executive Agent for the use of IND's for FHP
- 2 Memos establish policy & assigns responsibility for INDs to TSG, USAMRMC, USAMMDA (Feb. 2003 & Oct. 2004)

Investigational New Drugs . . .

A drug or biological product subject to FDA regulations at 21 CFR 312 to include:

- A drug not approved by the FDA
- A biological not licensed by the FDA
- A drug unapproved for its applied use

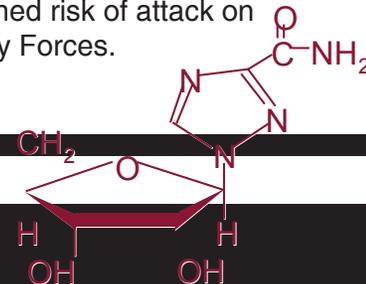
Protocols . . .

10 protocols:

- 3 smallpox
- 2 botulism
- 1 anthrax
- 2 hemorrhagic fever (HF)
- 1 crimean - Congo HF Lassa Fever
- 1 leishmaniasis

Emergency Use Authorization . . .

Emergency Use Authorization (EUA) is a special authority under U.S. federal law. The FDA issues an EUA to allow the use of an unapproved medical product or an unapproved use of an approved medical product during a declared emergency involving a heightened risk of attack on the public or military Forces.



For additional information, contact:

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