



REPLY TO  
ATTENTION OF

DEPARTMENT OF THE ARMY  
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND  
504 SCOTT STREET  
FORT DETRICK, MD 21702-5012

rec. 10/11/2006  
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OCT 10 2006

Office of the Commander

Division of Dockets Management (HFA-205)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, Maryland 20852

A Presentation to Public Hearing regarding Guidelines on Emergency Research  
Conducted without Informed Consent under FDA's Emergency Research Rule.  
Docket No. 2006D-0331

On behalf of the U.S. Army Medical Research and Materiel Command, I welcome  
• the guidance proposed by the Agency to further explain the procedures to be followed  
when an exception from the informed consent requirement for emergency research is  
requested.

As an organization committed to developing products to provide America's military  
Forces with the best emergency and intensive care possible, I recognize that the  
research community at large is in need of clear, practical guidance in order to protect all  
potential participants in research.

Furthermore, I understand that the burden of morbidity and mortality from trauma  
on the American population is great with trauma as a leading cause of death responsible  
for over 160,000 deaths in the U.S. annually. These sobering statistics underscore the  
reality that the products currently available do not adequately address the Nation's  
trauma treatment needs. New technologies **must** be evaluated using scientifically  
sound methods in relevant patient populations.

With this clear guidance, sponsors and researchers can prepare meaningful  
research protocols that appropriately address the critical priorities of informing the  
community and protecting potential research participants. Additionally, Institutional  
Review Boards will better understand their responsibilities in reviewing protocols seeking  
exemptions from informed consent regulatory requirements.

Sincerely,

Eric B. Schoomaker, M.D., Ph.D.  
Major General, US Army  
Commanding General

2006D-0331

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