

MEMORANDUM OF UNDERSTANDING  
BETWEEN  
THE UNITED STATES ARMY SURGEON GENERAL  
AND  
COMMANDER, MULTI-NATIONAL CORPS-IRAQ

SUBJECT: The Conduct of Human Subjects Research in Army Medical Treatment Facilities (MTFs) in the Multi-National Corps-Iraq (MNC-I) Area of Operations

1. References:

- a. 10 USC 980, Limitation on Use of Humans as Experimental Subjects.
- b. 32 Code of Federal Regulations (CFR) 219, Protection of Human Subjects (This is the DOD version of the "Common Rule" 45 CFR 46, part a)
- c. 45 CFR 46, Parts b, c, and d.
- c. DOD Directive 3216.2, Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research, 25 March 2002.
- d. AR 70-25, Use of Volunteers as Subjects of Research, 25 January 1990.
- e. AR 40-38, Clinical Investigation Program, 1 September 1989
- f. AR 40-68, Clinical Quality Management, 26 February 2004.

2. Purpose: This memorandum establishes policies and procedures for the conduct of human subjects research in Army MTFs in the MNC-I Area of Operations. It establishes the procedures and responsibilities for scientific review and human subjects protections review, approval and compliance oversight for all research conducted in Army MTFs in the MNC-I Area of Operations.

3. Scope: These policies and procedures apply to all human subjects research conducted in Army MTFs in the MNC-I Area of Operations.

4. Definitions:

a. Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy,

whether or not they are conducted or supported under a program which is considered research for other purposes.

b. Human Subject means a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

*Intervention* includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

*Interaction* includes communication or interpersonal contact between investigator and subject.

*Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

c. Institutional Review Board (IRB) means the group or committee with institutional authority to review that institution's research projects involving human subjects. The primary purpose of the IRB review is to assure the protection of the safety, rights and welfare of the human subjects.

#### 5. General:

a. Research in the deployed setting is a time-honored tradition of deployed medical personnel. Traditionally, great advances in medicine accompany the cauldron of combat casualty care. The deployed medical professional personnel in Operation Iraqi Freedom (OIF) desire to perform the highest quality research possible and conform to the current guidelines and policies on human research.

b. The conduct of human subjects research is subject to Federal, DOD and Army regulations governing human subjects protection. Many categories of human subjects research are subject to the requirement for an IRB review.

c. A research activity is considered exempt from the requirement of IRB review if it involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. If identifiers are present or linkage to a code exists then the study is NOT exempt but may be considered eligible for an expedited IRB review if the study is determined to pose minimal risk to study

participants.

d. The use of a systematic investigation and the potential generalizability of results are not the sole considerations in the classification of an activity as *research*. To accurately classify projects as either research or nonresearch, the critical factor is the primary intent (design) of the activity. Health services operational data collection and analyses conducted for the primary purpose of health care delivery improvement are NOT research activities subject to the requirement for IRB review IAW 32 CFR 219 and AR 40-38 and AR 70-25. These activities include the collection and analyses of health services operational data, e.g. health care utilization statistics, event surveillance data, infection control and/or quality assurance/performance improvement data. These systematic analyses routinely involve retrospective record reviews and do not require patient consent. Data sources include medical records, trauma registries, tumor boards, hospital infection control records, performance improvement databases, and utilization review reports. Although reports of these analyses may eventually be published in professional journals, professional publication is not the *primary intent* of these activities.

e. Human subjects research studies conducted in the deployed setting are largely limited to systematic retrospective reviews of patient medical records to provide information that can not only inform medical care planning and improve future patient care in theatre, but also generate generalizable knowledge about healthcare outcomes. Each human subjects research protocol must undergo a scientific review and an assessment to determine if the protocol meets the criteria for exemption from human subjects protection regulatory review requirements or requires review by an IRB.

## 6. Policy and Procedures:

a. Health services data analyses conducted for the primary purpose of healthcare delivery improvement are EXEMPT from the requirement for IRB review and approval IAW 32 CFR 219, AR 40-38 and AR 70-25.

b. In order to conduct NON-EXEMPT human subject research in the DOD, the institution in which the research is conducted must meet the following minimal requirements:

1. The institution must operate under an approved DOD Assurance of Compliance with Protection of Human Research Subjects signed by an accountable institutional official (IO). A DOD Multiple Project Assurance may be approved by the Deputy, Office of Research Protections, U.S. Army Medical Research and Materiel Command (USAMRMC).

2. The IO will assure that all human subjects research, not exempt from Federal, DOD, or Army human subjects protection regulations, is reviewed and approved by a duly constituted IRB.

3. The IO will ensure investigators are trained in the basic tenets of human subject protection.

c. Procedures for Human Subjects Protection Review, Approval and Oversight of USCENTCOM Human Subjects Research Protocols:

1. The current Senior Medical Unit Commander for the MNC-I Area of Operations (MEDCOM, Medical Brigade, Combat Support Hospital) may serve as the MNC-I institutional signatory of the DOD Assurance of Compliance with Human Subjects Protection for the Protection of Human Research Subjects.

2. A local (in-theatre) principal investigator (PI) assigned to an Army MTF (e.g. Army Combat Support Hospital) in the MNC-I Area of Operations will develop a research question, and with approval of both a MTF-level research committee (appointed by the MTF Commander) and the MTF Commander, the PI will write a research protocol. Due to the complicated issues involved in obtaining informed consent from trauma patients, these protocols must be limited to retrospective studies and will use as a guide the US Army Institute of Surgical Research (USAISR) outline for retrospective chart reviews. (Enclosure A to this MOU).

3. The MTF Commander-approved protocol will then be sent through the Senior Medical Unit Commander for the MNC-I Area of Operations to the MNC-I Surgeon's Office for approval.

4. The PI will forward the theatre-approved protocol to the Commander of the USAISR who will insure that each submission is reviewed for scientific merit.

5. After the scientific review is complete and documented, each protocol will be sent for an initial human subjects protection review to Chief, Clinical Investigation Regulatory Office (CIRO), Army Medical Department Center and School (AMEDD C&S). The protocol will be evaluated for applicability of Federal, DOD, and Army Human Subjects Protection regulations, to include the Common Rule (32 CFR 219, 45 CFR 46, parts b,c,d), DODD 3216.2 and AR 70-25. If a research protocol is determined to be exempt from the requirement for IRB review, the Chief, CIRO and Commander, USAISR will notify the PI, via e-mail, who may then initiate the protocol.

6. If a proposed protocol is determined not to be exempt, the Chief, CIRO will send the protocol to the Chair, IRB, Brooke Army Medical Center (BAMC), who will facilitate the appropriate level (expedited or full board) of review by the BAMC IRB. Informed consent of subjects will be required by the IRB if and as needed under applicable regulations.

7. When the study is approved by the BAMC IRB, the Chair, IRB will notify the Commander, USAISR, the Chief, CIRO and the PI, and the Senior Medical Unit Commander for the MNC-I Area of Operations in writing. This entire process (steps 1-7) should be accomplished within 60 days of submission. The IRB determines the

period of approval. Protocols that require IRB review can be approved for a maximum of one year. A continuing review report must be submitted prior to the conclusion of the approval period to allow for the IRB to review and approve the study to continue.

d. Procedure for Human Subjects Protection Training of Principal Investigators

1. All investigators conducting human subjects research must complete Human Subject Protection Training. Completion of one of the following options listed below fulfills this requirement:

a. Completion of the on-line Collaborative IRB Training Initiative (CITI) Course in the Protection of Human Research Subjects course via attached instructions. Investigators should register as BAMC investigators, complete BAMC-specific module for Group 2. (Enclosure B)

b. Previous completion of the CITI Course in the Protection of Human Research Subjects within the two years prior to the current deployment. The PI must provide the original IRB affiliation and the approximate date of course completion to the BAMC IRB.

c. Completion of the hard copy version of the CITI course (BAMC Module Group 2) and quizzes in theatre with follow-on submission to the BAMC IRB.

2. Documentation of education

a. The MTF Commander will provide the Chair, BAMC IRB, a Memorandum for Record that documents the PI name, unit affiliation, and date and location of previous CITI course -or- date of on-line completion of CITI course while in theatre -or- date of in-theatre completion of hard copy CITI course.

b. The MTF Commander will retain a list of those staff members who have completed CITI training and the date completed.

7. The point of contact for questions regarding this memorandum is COL (b)(6)  
(b)(6) Office of Research Protections, U.S. Army Medical Research and Materiel  
Command, Fort Detrick, Maryland, DSN (b)(2) CML (b)(2)  
(b)(6)

  
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JOHN R. VINES  
Lieutenant General  
18th Corps Commander  
*19 Mar 05*  
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Date

  
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KEVIN C. KILEY  
Lieutenant General  
The Surgeon General  
*16 Mar 2005*  
\_\_\_\_\_  
Date

5 Encl

Enclosure A:

USAISR Human Use Policy Memorandum 01-004, Guidelines for use of expedited review

USAISR Expedited Protocol Explanation

USAISR Human Use Policy Memorandum 01-005, Approval of Exempt Status for Research Involving Human Subjects, Anatomical Substances or Retrospective Chart Reviews

USAISR Exempt Protocol Explanation

Enclosure B:

Guidance for on-line CITI training

CF

USACENTCOM CJOA

USAMRMC – ORP

USAISR

BAMC DCI

CIRO