

MULTIPLE PROJECT ASSURANCE

DOD's Multiple Project Assurance (MPA) of Compliance for the Protection of Human Research Subjects

MULTI-NATIONAL CORPS, IRAQ

Multi-National Corps, Iraq, hereinafter known as the "Institution," hereby gives assurance that it will comply with the Department of Defense (DOD) regulations for the Protection of Human Subjects (32 CFR 219); Title 10, United States Code, Section 980, Limitation on use of humans as experimental subjects (hereinafter referred to as 10 USC 980); U.S. Army Regulation AR 70-25; DODD 3216.2; and, where applicable, 21 CFR Part 50, 21 CFR Part 56, and 45 CFR Part 46 (Subparts B and D) under the authority of the DOD.

Part 1

Ethical Principles and Institutional Policies Governing Research Involving Human Subjects

I. Applicability:

Except when research is exempt from the requirements of 32 CFR 219, or applicability of 32 CFR Sec. 219 is waived under 32 CFR Sec. 219.101, this Assurance applies to all research involving human subjects, and all other activities which involve such research even in part, regardless of whether the research is otherwise subject to federal regulation, if:

- A. the research is sponsored by this Institution, or
- B. the research is conducted by or under the direction of any employee or agent of this Institution in connection with Institutional responsibilities, or
- C. the research is conducted by or under the direction of any employee or agent of this Institution using any property or facility of this Institution, or
- D. the research involves the use of this Institution's nonpublic information to identify or contact human research subjects or prospective subjects.

II. Ethical Principles:

This Institution assures that all of its activities related to human subject research will be guided by the ethical principles set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report").

A. This Institution recognizes the principles of respect for persons, beneficence (including minimization of harms and maximization of benefits), and justice, as stated in the Belmont Report, and will apply these principles in all research covered by this Assurance.

B. This Institution acknowledges and accepts its responsibilities for protecting the rights and welfare of human research subjects.

III. Policies:

A. This Institution acknowledges that it and its investigators bear full responsibility for the performance of all research covered by this Assurance, including full responsibility for compliance with Federal, State, and local laws as they apply to such research.

B. This Institution assures that before human subjects are involved in research, proper consideration will be given to:

1. the risks to the subjects,
2. the anticipated benefits to the subjects and others,
3. the importance of the knowledge that may reasonably be expected to result,
4. the informed consent process to be employed,
5. the provisions to protect the privacy of subjects, and
6. the additional safeguards for vulnerable populations.

C. This Institution recognizes the need for appropriate additional safeguards in research involving subjects who are likely to be vulnerable to coercion or undue influence, such as children, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

D. This Institution encourages and promotes constructive communication among the Institutional officials, research administrators, department heads, research investigators, clinical care staff, human subjects, and all other relevant parties as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.

E. This Institution will exercise appropriate administrative overview, carried out at least annually, to ensure the effective application of its practices and procedures designed for the protection of the rights and welfare of human subjects.

F. Federal funds for research involving human subjects, to which this Assurance applies, may not be expended unless the requirements of this Assurance have been satisfied.

G. Certification of IRB review and approval shall precede accrual of human subjects in research involving human subjects to which this Assurance applies.

H. When research covered by this Assurance is conducted at or in cooperation with another institution, this Institution will insure that the other institution has obtained approval on appropriate Assurance of Compliance prior to accrual of human subjects in such research.

I. When research covered by this Assurance is conducted at or in cooperation with another entity, this Institution may accept, for purposes of meeting the IRB review requirements, the review by an IRB established under another DOD-MPA. Such acceptance must be: (1) in writing and (2) be approved by appropriate officials of both Institutions.

Part 2

Responsibilities:

I. The Institutional Responsibilities:

A. This Institution acknowledges that it bears full responsibility to comply with the requirements of 32 CFR 219; 10 USC 980; AR 70-25; DoDD 3216.2; and, where applicable, 21 CFR Part 50, 21 CFR Part 56, and 45 CFR Part 46 (Subparts B and D) under the authority of the DOD; and other Federal, State and local laws as they may relate to human subjects research.

B. In accordance with the compositional and quorum requirements of 32 CFR 219.107 and 219.108, the Institutional Review Boards (IRBs) designated in Part 3 and in the attached roster are responsible for the initial and continuing review of all projects covered by this Assurance.

C. This Institution has reviewed and approved the composition of the IRBs.

D. This Institution has established written procedures for:

1. verifying whether proposed activities qualify for exemption from, or waiver of, IRB review,

2. conducting IRB initial and continuing review (not less than once per year), approving research, and reporting IRB findings to the investigator and the Institution,

3. determining which projects require review more often than annually, and which projects need verification from sources other than the investigator that no material changes have occurred,

4. ensuring that changes in approved research are reported promptly and are not initiated without IRB approval, except when necessary to eliminate apparent immediate hazards to the subject, and

5. ensuring prompt reporting to the IRB, Institutional officials, the relevant Department or Agency Head, and any applicable regulatory body, of any:
(a) unanticipated problems involving risks to subjects or others in any covered research;
(b) serious or continuing noncompliance with Federal, Institutional, or IRB requirements;
and (c) suspension or termination of IRB approval for the DOD-supported research.

E. The Institutional Signatory Official will complete the appropriate relevant human subjects protection and assurance training approved by the DOD approving authority prior to submitting this Assurance. Research investigators must complete appropriate

Institutional training before conducting human subject research.

F. The Institution has established education and oversight mechanisms (appropriate to the nature and volume of its research) to verify that research investigators, and other relevant personnel maintain continuing knowledge of, and comply with, relevant Federal regulations, other applicable guidance, State and local law, and Institutional policies for the protection of human subjects. The Institution will require documentation of such training from research investigators as a condition for conducting DOD-supported human subject research.

G. The designation of the IRB(s) from the Brooke Army Medical Center, which is not administered by the Institution, has been documented by a written agreement between the Institution and the Surgeon General of the United States Army. Any designation of any other IRB(s) not administered by the Institution must be documented by a written agreement between the Institution and the IRB organization outlining their relationship and including a commitment that the designated IRB will adhere to the requirements of this Assurance.

H. This Institution is responsible for ensuring that all Institutions and investigators collaborating in its DOD-supported human subject research operate under an appropriate Assurance of Protection for Human Subjects. All Institutions engaged in such research, including subcontractors and sub-grantees, must hold their own Assurance.

I. This Institution will update information provided under this Assurance every **36 months**, even if no changes have occurred, in order to maintain an active Assurance. Failure to update this information may result in restriction, suspension, or termination of the Institution's Assurance of Protection for Human Subjects.

II. The Institutional Review Board's (IRB's) Responsibilities:

A. The IRBs shall review and must approve all research activity conducted under this Assurance, and any proposed changes to such research activity, before human subjects may be involved.

B. The IRBs have the authority to require modification to, or disapprove research activity conducted under, this Assurance.

C. The IRBs will determine, in accordance with the criteria found at 32 CFR 219.111, and, where applicable, 45 CFR 46 Subparts B and D, that protections for human research subjects are adequate.

D. The IRBs have the authority to suspend or terminate approval of research activity in accordance with 32 CFR 219.113 because of: (1) noncompliance with 32 CFR 219, this Assurance document, or the IRB's requirements; or (2) unexpected serious harm to

subjects.

E. The IRBs will determine that legally effective informed consent will be obtained for all research in a manner and method which meets the requirements of 32 CFR 219.116 and 219.117.

F. The IRBs shall conduct continuing reviews of all research at intervals appropriate to the degree of risk, but not less than once per year (32 CFR 219.109(e)). The IRB may be called into an interim review session by the Chairperson at the request of any IRB member or Institutional Official to consider any matter concerned with the rights and welfare of any subject.

G. The IRBs shall prepare and maintain adequate documentation of its activities in accordance with 32 CFR 219.115.

H. The IRBs shall report promptly to Institutional Officials:

1. any serious or continuing noncompliance by investigators with the requirements of the IRB,
2. any suspension or termination of IRB approval, and
3. any unanticipated problems or injuries involving risks to subjects or others.

I. Where appropriate the IRBs will determine that adequate additional protections are ensured for fetuses, pregnant women, prisoners, and children as required under 45 CFR 46, Subparts B, C, and D, and, if applicable, 10 USC 980. The IRB will notify the ORP promptly and update the Assurance file when IRB membership is modified to satisfy the requirements in 45 CFR 46.304 and when the IRB fulfills its duties under 45 CFR 46.305(c).

J. The IRBs will comply fully with the requirements of applicable Federal polices and guidelines, including those concerning notification of sero-positivity, counseling, and confidentiality of subjects.

K. The IRBs will comply fully with 10 USC 980, which states that if an individual cannot give his/her own consent (for example, minors), and there is no intent to benefit the individual, he/she cannot be entered into a study funded by the DOD.

III. Research Investigator's Responsibilities:

A. Investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of this Assurance including 32 CFR 219; 10 USC 980; AR 70-25; DoDD 3216.2; where applicable 21 CFR 50, 21 CFR 56, and 45 CFR 46 (Subparts B and D) under the authority of the DOD; and other Federal, State and local laws as they may relate to proposed human subjects research.

B. An investigator who intends to involve human subjects in research will not make the final determination of exemption from applicable Federal regulations or provisions of this Assurance.

C. Investigators are responsible for providing a copy of the IRB approved and signed informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement.

D. Research investigators shall report promptly to the appropriate IRB any proposed changes to research activity. The changes shall not be initiated without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects. Any change in the investigator or change to the protocol shall be reported to the ORP.

E. Research investigators shall report promptly to the IRB any unanticipated problems involving risks to subjects and others. Any serious and unexpected adverse event(s) shall be reported to the ORP.

Part 3

Institutional Endorsement

The officials signing below assure that all research activities at this Institution will be conducted in accordance with the requirements of 32 CFR 219; 10 USC 980; U.S. Army Regulation 70-25; DODD 3216.2; and where applicable 21 CFR 50, 21 CFR 56, and 41 CFR 46 (Subparts B and D) under the authority of the DOD; and this Assurance document. A roster listing the current membership of each designated IRB is attached at the end of this document.

Authorized Official of the Institution Providing This Assurance

The Signatory Official must be a senior Institutional Official who has the authority to commit the entire Institution named in the Assurance application, as well as all of the institutional components to a legally binding agreement. Entities that the Signatory Official is not legally authorized to represent may not be covered under the Assurance. This individual must also have the authority to assure compliance of the Institution and all of its components to the terms of the Assurance. The IRB Chair and IRB members are not appropriate personnel to serve as the Signatory Official.

Signature: G. Granger Date: 29 June 05

BLAINE GRANGER, MD
Brigadier General, USA
Commanding
FM 44 Medical Command
Multi-National Corps - Iraq
Phone number: (b)(2)
Email address: (b)(3),(b)(6)

Primary Contact

Signature: (b)(3), (b)(6) Date: 29 June 2005

(b)(3), (b)(6)
Director of Clinical Research
FM 44th Medical Command
Phone number: DSN: (b)(2)
Email address: (b)(3), (b)(6)

III. Authorized Official of the Institution with the IRB
(Include only if different from the Institution above)

This institution authorizes the designation of its IRB for review of the projects conducted or supported by the institution named on this Assurance.

Signature: (b)(6) Date: 8 July 2005

(b)(6) MD

COL, MC
Commander, Brooke Army Medical Center
3851 Roger Brooke Drive
Fort Sam Houston, TX 78234-6200

Phone number: (b)(6); Fax number: (b)(2)

Email address: (b)(6)

IV. IRB Co-Chairperson

Signature: (b)(6) Date: 5 July 2005

(b)(6) MD

COL, MC
Chief, Department of Clinical Investigation
IRB Co-Chair, Brooke Army Medical Center
3400 Rawley E. Chambers Ave., Ste A
Fort Sam Houston, TX 78234-6200

Phone number: (b)(2) Fax number: (b)(2)

Email address: (b)(6)

V. IRB Co-Chairperson

Signature: (b)(6) Date: 8 July 05

(b)(6) MD

MAJ, MC
Chief, Research Consultation Service
IRB Co-Chair, Brooke Army Medical Center
3400 Rawley E. Chambers Ave., Ste A
Fort Sam Houston, TX 78234-6200

Phone number: (b)(2) Fax number: (b)(2)

Email address: (b)(6)

DEPARTMENT OF DEFENSE

*Multiple Project Assurance (MPA) Number: DOD A20146

MULTI-NATIONAL CORPS, IRAQ

All parts of this Assurance are in compliance with requirements of Title 32 Code of Federal Regulations Part 219 (32 CFR 219); 10 U.S. Code 980; AR 70-25; DODD 3216.2; and where applicable 21 CFR 50, 21 CFR 56 and 45 CFR 46 (Subparts B, C, and D) under the authority of the Department of Defense (DOD).

DOD Approving Official

(b)(6)

(b)(6)

Colonel, MC
Assistant Surgeon General
for Force Projection

Date: (b)(6) 20 July 05

Mailing Address for Communications Regarding this Assurance:

Commanding General
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-ZB-P
504 Scott Street
Fort Detrick, MD 21702-5012

Telephone:
Facsimile:

(b)(2)

*Expiration Date: 19 July 2008

*This assurance expires **three years** from the date of its approval. It must be updated regularly subsequent to a change of the signatory official, the IRB Chair, the IRB membership, or of the policies and procedures to maintain this MPA file current. A revised and dated IRB membership roster must be submitted if there is a change in the IRB membership. For its uninterrupted continuation, this Assurance must be renegotiated with the Office of the U.S. Army Surgeon General via the Deputy, Office of Research Protections, U.S. Army Medical Research and Materiel Command prior to its expiration.

**DOD MULTIPLE PROJECT ASSURANCE
BAMC INSTITUTIONAL REVIEW BOARD (IRB) MEMBERSHIP**

NAME OF INSTITUTION OF THIS IRB: **BROOKE ARMY MEDICAL CENTER** [FWA NO: FWA00004092 OHRP's IRB Registration No.: IRB00002021] DATE: **15 April 2005**

MEMBER NAME First M.I. Last	HIGHEST DEGREES EARNED	PRIMARY SCIENTIFIC OR NONSCIENTIFIC SPECIALTY	AFFILIATION WITH INSTITUTION(S) ABOVE (YES/NO; IF YES, WHICH ONE)	ADDRESS AND PHONE NUMBER FOR CHAIRPERSON ONLY
(b)(6)	M.D.	Preventive Medicine	Yes	
(b)(6)	M.D.	Infect Dis	Yes	Commander
(b)(6)	PhD	Lab Dir	Yes	Brook Army Medical Center
(b)(6)	M.D.	Infect Dis	Yes	ATTN MCHC-CI
(b)(6)	M.D.	Pulm Dis	Yes	3851 Roger Brooke Drive
(b)(6)	M.D.	Infect Dis	Yes	Fort Sam Houston, TX 78234-6200
(b)(6)	M.D.	Hem-Onc	Yes	(b)(6)
(b)(6)	M.D.	Ophthal	Yes	(b)(6)
(b)(6)	M.D.	Ortho	Yes	IRB Chair
(b)(6)	M.D.	Anes	Yes	SIGNATURE:
(b)(6)	M.D.	OB/GYN	Yes	
(b)(6)	M.D.	OB/GYN	Yes	
(b)(6)	J.D.	Lawyer	Yes	
(b)(6)	J.D.	Lawyer	Yes	
(b)(6)	M. Div	Chaplain	Yes	
(b)(6)	M. Div	Chaplain	Yes	
(b)(6)	M.S.	Lab Tech	Yes	
(b)(6)	B.S.	Pharmacy	Yes	
(b)(6)	PharmD	Pharmacy	Yes	
(b)(6)	RPh	Pharmacy	Yes	
(b)(6)	M.D.	Anes	Yes	
(b)(6)	PhD	PharmD	Yes	
(b)(6)	PhD	Comp Science	Yes	
(b)(6)	J.D.	Lawyer, Ethicist	No (AMEDD C&S)	
(b)(6)	M.D. Div	Chaplain	No (AMEDD C&S)	
(b)(6)	PhD	Nutrition	No (AMEDD C&S)	
(b)(6)	M.D.	Internal Med	Yes	
(b)(6)	M.D.	Hem-Onc	Yes	
(b)(6)	M.D.	Inf Dis	Yes	
(b)(6)	R.N., PhD	Nurse	No (WHMC)	
(b)(6)	P.A.	Physician Asst	No (WHMC)	
(b)(6)	PhD	Microbiology/Immunology	No (WHMC)	
(b)(6)	R.N., PhD	Nurse	Yes	
(b)(6)	M.D.	Peds	Yes	
(b)(6)	M.D.	Radiology	Yes	
(b)(6)	PhD	Radiol Physicist	Yes	

Each IRB shall have at least five members. Every nondiscriminatory effort shall be made to ensure that this IRB does not consist entirely of men or entirely of women. No IRB may consist entirely of members of one profession. No IRB may have a member participate in review of any project in which the member has a conflicting interest. Each IRB shall include at least one member with scientific expertise in the area of research being reviewed and one member with nonscientific background. Under Affiliated, please indicate (Yes or No) whether an individual is affiliated with the Institution or not. At least one member must not be affiliated with the institution (32 CFR 219.107).