

MEMORANDUM FOR All research investigators assigned/attached to USAISR

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

1. **PURPOSE:** Certain categories of research involving human subjects are exempt from review by the Institutional Review Board (IRB) in accordance with Title 45 Code of Federal Regulations Part 46. This policy provides guidelines for exempt designation of a research protocol including retrospective chart reviews without subject identifiers.
2. **APPLICABILITY.** This regulation is applicable to USAISR personnel assigned/attached to USAISR including, but not limited to, contractors and grantees supporting research and related activities in which human subjects are involved. Compliance with this regulation will in no way render inapplicable pertinent federal, state, or local laws or regulations. **NOTE:** The exemptions at 45 CFR 46.101(b) in paragraph 5.1 below do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, Subparts B and C. The exemption at 45 CFR 46.101(b)(2) in paragraph 5.2 below, for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, Subpart D, except for research involving observations or public behavior when the investigator(s) do not participate in the activities being observed.
3. **DEFINITIONS:**
 - a. Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
 - 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.
 - c. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
 - d. Interaction includes communication or interpersonal contact between investigator and subject.
 - e. 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

This policy supersedes HUC Policy Memorandum 01-005 dated 27 September 2002 and HUC Policy Memorandum 02-11 dated 27 September 2002.

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 the obtaining of the information to constitute research involving human subjects.

4. REFERENCES:

Title 32, Code of Federal Regulations, Part 219.101.

Title 45, Code of Federal Regulations, Part 46.101.

AR 70-25, Use of Volunteers as Subjects of Research (Appendix F).

5. POLICY:

a. If an investigator believes that the research is exempt according Section 6 of this policy, Appendix F of AR 70-25, or 45 CFR 46.101, the protocol and all corresponding documents will be submitted through the Human Use Protocol Coordinator to the Chair, IRB for review to evaluate the claim of exemption. The activities listed in Section 6 should not be deemed to be "exempt" studies simply because they are included on the list. Inclusion on the list merely means the activity is eligible for review by the Chair, IRB to determine the eligibility for exempt status.

b. The investigator will prepare the protocol along with all the required elements such as a current literature search, bibliography, statistical analysis to be used, a sample data collection sheet, and the HIPAA Waiver indicating how the data will be recorded in electronic or paper study files without subject identifiers. (See Appendix A)

c. In order to proceed with the research, the investigator must receive exempt designation by the Chair, IRB. This designation will only be given to studies in which exempt status is specifically authorized by regulations.

d. Exempt research will still be subject to routine inspection by the USAISR Quality Assurance Unit and annual review by the Director of Research.

6. EXEMPTION CATEGORIES:

a. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

(1.) Research on regular and special education instructional strategies, or

(2.) Research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods. 46.101(b)(1)

b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(1) Information taken from these sources is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and

(2) Any disclosure of the human subject's responses outside the research could reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subject's financial standing, employability, or reputation. 46.101(b)(2)

(3) The research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol. AR 70-25

c. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph 2 above, if:

(1) The human subjects are elected or appointed public officials or candidates for public office, or

(2) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. 46.101(b)(3)

d. Research involving 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. 46.101(b)(4)**(This involves retrospective chart reviews)**

d. Research and demonstration projects that are conducted by or subject to the approval of Department or Agency heads, and that are designed to study, evaluate, or otherwise examine:

(1) public benefit or service programs,

(2) procedures for obtaining benefits or services under those programs,

(3) possible changes in or alternatives to those programs or procedures, or

(4) possible changes in methods or levels of payment for benefits or services under those programs.

f. Taste and food quality evaluation and consumer acceptance studies if:

(1) wholesome foods without additives are consumed, or

(2) a food is consumed that contains: (1) a food ingredient at or below the level, and for a use found to be safe, or (2) agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency, or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

g. Routine epidemiological surveys that are of no more than minimal risk as set forth in 45 CFR 46.110.

h. Individual or group training of military personnel such as combat readiness, effectiveness, proficiency, or fitness exercise (for example, Army Training and Evaluation Program (ARTEP), Skill Qualification Test (SQT)). Evaluation of the training's effect on the individual participants may or may not be exempt depending on how the evaluation is made (for example, drawing of blood is not exempt.) AR 70-25

i. Job related tasks of military or civilian personnel who are qualified to test by duty assignments that call specifically for such qualifications. AR 70-25

j. Inclusion of human subjects as the indirect object of research involving minimal risk or less in the development and testing of military weapon systems, vehicles, aircraft, and other material are exempt from the requirement for obtaining informed consent from the participants. The determination of whether a proposal is minimal risk or less is made by an IRB.

7. A HIPAA Waiver of Authorization must be submitted with all protocols being reviewed for EXEMPT approval.

8. Point of contact for this policy is the Regulatory Compliance and Quality Coordinator at 210-916-2250.

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Attachment:
Exempt Protocol Template

(FOR USE WITH **EXEMPT** STUDIES)

*(This form is used for research involving the collection or study of existing data, documents, records and pathological or diagnostic specimens if these sources are publicly available or if the information is recorded in such a way that **subjects cannot be directly identify or through identifiers linked to the subject.** Refer to 45 CFR 46. 10, and AR 70-25, Appendix F.)*

PROTOCOL TITLE:

PROTOCOL NUMBER:

PRINCIPAL INVESTIGATOR:

Type name and sign

Date

ASSOCIATE INVESTIGATORS:

Type name and sign

Date

Type name and sign

Date

SUPERVISOR: The Supervisor has reviewed the protocol and has insured coordination for support as required by the protocol. (If Applicable)

Type name and sign

Date

REGULATORY COMPLIANCE AND QUALITY: The Principal Investigator's credentialing packet has been reviewed and is current.

Regulatory Compliance and Quality

Date

Revised Dec 2003

DIRECTOR OF RESEACH: I have reviewed this protocol and agree it contains scientific merit.

(Director of Research) Print name and sign

DATE

USAISR, COMMANDER: I have reviewed this protocol and approve it for forwarding to the IRB for EXEMPT consideration.

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, MD
COL, MC
Commanding

DATE

This protocol was reviewed and Approved/Disapproved by the Institutional Review Board on _____ . See IRB Minutes Dated _____ .

ASSURANCES:

As the Primary Investigator on this protocol I acknowledge my responsibilities and provide assurances for the following:

- A. **General Assurance:** I agree to conduct the study as outlined herein. I certify that all procedures involving human subjects have been described in full.
- B. **Training:** I verify that the personnel performing these procedures described in this protocol are technically competent, have been properly trained, and are appropriately qualified.
- C. **Compensation:** I am aware that we are not authorized to accept any form of personal compensation for our efforts in conducting this research.
- D. **Modifications:** Any modifications to the protocol must be approved by the IRB before implementation.
- E. **Deviations to the Protocol:** Any protocol deviations discovered by either the PI or auditing official will be immediately reported to the Chair, IRB and documented with a Protocol Deviation Report Form in accordance with USAISR Human Use Policy 02-010, Protocol Deviations. All corrective actions will be documented and become a part of the master study file, along with the report.
- F. **Duplication of Effort:** I have made a reasonable good faith effort to ensure that this protocol is not an unnecessary duplication of previous experiments.
- G. **Statistical Assurance:** I assure that I have consulted with an individual who is qualified to evaluate a statistical design or strategy of this proposal and that the minimum number of subjects needed for scientific validity are used.

Print name and sign (Principal Investigator)

Date: _____

I. PROTOCOL TITLE:

II. PROTOCOL NUMBER:

III. PERSONNEL INVOLVED: *(List the names, positions, department, and telephone and pager numbers of all persons directly involved in the project work)*

A. PRINCIPAL INVESTIGATOR:

B. CO-INVESTIGATOR(S): *(If applicable)*

1. *List any individuals who will be involved in the acquisition, analysis or review of the data (paper or electronic) or research results prior to public dissemination.*

2.

3.

IV. LOCATION OF STUDY: *Cite facility, room number, etc.*

V. DURATION OF STUDY:

State the month and year of expected start and completion times.

A. Expected Start Date:

B. Expected Completion Date:

VI. RESEARCH PLAN:

A. PURPOSE: *Enumerate the objectives and nature of the measured end-points.*

B. HYPOTHESES/RESEARCH QUESTIONS: *State the specific hypotheses or research questions you wish to test. (For example you could use the following research question: 1) Are there differences in the rate of remission of disease X between groups treated with drug Y and a placebo. This could be stated as a hypothesis: 2) There are statistically significant differences in the rate of remission between groups treated with drug Y and placebo, or stated as a null hypothesis 3) there are no differences in the rate remission between groups treated with drug Y and placebo.*

- VII. SIGNIFICANCE/SPECIFIC AIMS:** *State concisely the importance and health relevance of the research described by relating the specific aims to the broad, long-term objectives. State the practical application(s). Significance is often demonstrated using numbers affected, cost of care, impact on quality of life, etc.*
- VIII. DESIGN:** *State in detail how the research will be designed to answer the hypotheses/research questions. Define what measurements (operational definitions-independent and dependent variables) the study will evaluate to answer the research questions. Show a clear course of action and a clear definition of the end points.*
- IX. MILITARY RELEVANCE:** *With regards to military needs and mission requirements, this paragraph should provide a brief and succinct military justification for the research. If applicable state the Science and Technology Objective (STO) that this work supports.*
- X. BACKGROUND/REVIEW OF LITERATURE:** *Briefly describe the background leading to the present study. Critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill.*
- XI. HUMAN SUBJECT PROTECTION:**
Describe the nature and location of the database(s) to be used in the research, the method of extraction of data from the database(s), whether the extracted data are recorded (on paper or electronic medium. Please note that the collected data must be recorded without identifiers unless it involves one of the exempt categories listed in 45 CFR 46.101 or AR 70-25, Appendix F.
- A. NATURE AND LOCATION OF DATABASE(S):** *Identify the database of interest and source, type of study, and type of subject population to be observed. Please attach a printed copy of the data sheet you are going to use to record the extracted data.*
- B. LOCATION OF EXTRACTED AND RECORDED DATA:** *Describe where the medium containing the recorded data used for analysis/evaluation is going to be kept, and enumerate the measures utilized to secure it from unauthorized access. Examples: locked file for paper records, password-protected PC and electronic files, encrypted electronic files, firewall for network computers. Please note that the collected data must be recorded without identifiers*
- C. LINKAGE OF EXTRACTED DATA TO OTHER DATABASES:** *Provide details concerning these databases and the mechanism of linkage.*
- D. STATUS OF THE EXTRACTED DATA AFTER COMPLETION OF THE RESEARCH STUDY:** *Describe what you are going to do with the extracted data after completion of the project.*
- E. BENEFITS:** *Describe any benefits that may be reasonably expected from the research.*

F. **RISKS:** Describe any potential risks in the collection of this data.

XII. **DATA ANALYSIS:** Describe what data (outcome measures) will be compared for each research question, and by what method (statistic or methodology as appropriate).

XIII. **BIBLIOGRAPHY:**

XIV. **CASE REPORTING FORM/DATA COLLECTION SHEET:** Include a sample of the data collection sheet for this study.

BROOKE ARMY MEDICAL CENTER/WILFORD HALL MEDICAL CENTER
Application for Waiver of Authorization
 (AWA Template Version 1, Apr 03)

(TITLE OF PROTOCOL) _____

Principal Investigator: _____

Protected Health Information Definition:

"Any identifiable information (including demographic information) collected from an individual, that is created or received by a health care provider, health plan, employer or health care clearing house, and relates to (a) the past, present, or future physical or mental health or condition of an individual; (b) the provision of health care to the individual and identifies the individual or there is a reasonable basis to believe can be used to identify the individual."

Identifiers:

<ul style="list-style-type: none"> • <i>Names</i> • <i>Address</i> • <i>Dates except year</i> • <i>Ages over 89 (can be grouped as age 90 or older)</i> • <i>Phone numbers</i> • <i>Fax numbers</i> • <i>E-mail addresses</i> • <i>Social security numbers</i> • <i>Medical record numbers</i> • <i>Account numbers</i> • <i>Certificate/license numbers</i> 	<ul style="list-style-type: none"> • <i>Health plan beneficiary numbers</i> • <i>Vehicle identifiers and serial numbers, or license plate numbers</i> • <i>Device identifiers and serial numbers</i> • <i>Web Universal Resource Locators (URLs)</i> • <i>Internet Protocol (IP) address numbers</i> • <i>Biometric Identifiers, including finger and voice prints</i> • <i>Full face photographic images and any comparable images</i> • <i>Any other unique identifying number, characteristic, or code</i>
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1. The use or disclosure of Protected Health Information (PHI) involves no more than a minimal risk to the privacy of individuals. Explain why? Include a detailed list of the PHI to be collected (see definition above) and a list of the source(s) of the PHI.

2. Describe the plan to protect identifiers (see list above) and indicate where PHI will be stored and who will have access.

3. All identifiers collected during the study will be destroyed at the earliest opportunity consistent with the conduct of research, which is: (explain below).
Please describe the procedure used to destroy all the data collected during the study (electronically, paper, audio/video, photography, other).

OR

Alternatively, the identifiers collected during the study will **not** be destroyed because: (explain below)

4. The research could not practicably be conducted without the waiver because: (explain below).

5. The research could not practicably be conducted without access to and use of the PHI because: (explain below)

6. The HIPAA regulation requires reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure or request. Explain why PHI obtained for this study is/are the minimum information needed to meet the research objectives.

The information listed in the waiver application is accurate and all research staff (ALL study personnel including PI that are involved in the research) will comply with the HIPAA regulations and the waiver criteria. All research staff will complete HIPAA Research Training. I assure that the information I obtain as part of this research (including protected health information) will not be reused or disclosed to any other person or entity except as permitted by law. If at any time, I want to reuse this information for other purposes or disclose the information to other individuals or entity I will seek approval by the Privacy Board.

Principal Investigator's Typed Name

PI Signature

Date

Approved:

Disapproved:

Comment: _____

(b)(6)

Date

LTC, MC

Chair, BAMC Privacy Board

Date:
Protocol Title:
Version # 1

PI: 13

Study number:

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