

MEMORANDUM FOR All research investigators assigned/attached to USAISR

SUBJECT: USAISR Human Use Policy Memorandum 01-004\*, Guidelines for Use of Expedited Review.

1. **PURPOSE:** This policy provides guidance, prescribes procedures, and delineates responsibilities for activities that may be reviewed by the Brooke Army Medical Center Institutional Review Board (IRB) using an expedited review process.
2. **APPLICABILITY.** This regulation is applicable to USAISR personnel assigned/attached to USAISR including, but not limited to, contracts and grants 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. This policy also applies to retrospective chart reviews.

3. **REFERENCES:** □

Title 21, Code of Federal Regulations, Part 56.110.

Title 32, Code of Federal Regulations, Part 219.110.

Title 45, Code of Federal Regulations, Part 46.110.

AR 70-25, Use of Volunteers as Subjects of Research.

63 FR 60364-60367, 9 Nov 98, Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure

4. **POLICY:**

a. Research activities at the U. S. Army Institute of Surgical Research that involve no more than minimal risk and appear in one or more of the categories on the attached "Explanation for Expedited Review of Research Protocol" may qualify for Institutional Review Board (IRB) review using an expedited review process. **NOTE:** The activities listed on the explanation attachment should not be deemed to be "minimal risk" studies simply because they are included on the list. Inclusion on the list merely means the activity is eligible for review through the minimal risk review process when specific circumstances of the proposed research involves no more than minimal risk to the human subjects. Evaluation of risk is a formulation that considers both the research procedures and the subjects on whom the procedure will be done.

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\*This memorandum supersedes HUC Policy 01-004 dated 27 September 2002 and HUC Policy 02-012 dated 27 September 2002.

b. A protocol submitted for expedited review may still have to be presented at the USAISR Scientific Seminar. The Director of Research will make the final determination.

c. The expedited review procedure may also be used for continuing review of research previously approved by the Institutional Review Board as follows:

(1.) Where the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; or

(2) Where no subjects have been enrolled and no additional risks have been identified; or

(3.) Where the remaining research activities are limited to data analysis.

d. The expedited review procedure may be used for continuing review of research, not conducted under an investigational new drug application or investigational device exemption and if the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

e. The expedited review may be used for approval of an addendum to a greater than minimal risk protocol when the addendum does not change the overall risk to the subject and may even decrease the risk.

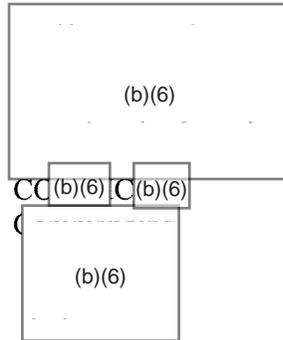
f. The expedited review may also be used to review addenda which involves minor changes in already approved protocols which do not affect the treatment, comfort or degree of risk to the subject such as change in Principal or Associate Investigator, or changes in telephone numbers.

g. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

h. The expedited review procedure may not be used for classified research involving human subjects.

5. The protocol and all corresponding documents will be submitted through the USAISR Human Use Protocol Coordinator to the Chair, IRB for expedited review and approval.

6. The point of contact for this memorandum is the Regulatory Compliance and Quality Coordinator at 916-2250.



Attachments:  
Application for Expedited Review of Research Protocol  
Expedited Review Protocol Template

U. S. ARMY INSTITUTE OF SURGICAL RESEARCH HUMAN USE

EXPLANATION FOR EXPEDITED REVIEW OF RESEARCH PROTOCOL

1. This is a form of administrative review that will be conducted by the Chair, IRB. Only those research activities expressly encompassed in one of the enumerated categories below are eligible for expedited review.

2. Expedited review may not be used when the proposed research poses greater than minimal risk. An exception would be an addendum to an already approved greater than minimal risk study, which does not change the overall risk to the subject and may even decrease it.

a. Minimal risk is defined as “the risk of harm anticipated in the proposed research that is not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

3. Informed Consent: An Informed Consent document may be required for submission with the protocol for Expedited Review. If you wish to request a waiver of the requirement for Informed Consent, please address each one of the following in the context of your proposed research:

a. The waiver or alteration will not adversely affect the rights and welfare of the subjects:

b. The research could not practicably be carried out without the waiver or alteration:

c. Whenever appropriate, the subjects will be provided with additional pertinent information after participation:

4. A HIPAA Authorization or Waiver must be submitted as part of the protocol.

5. Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Process<sup>1</sup>

a. Clinical studies of drugs and medical devices only when condition (1) or (2) is met.

(1.) Research involving drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review).

(2.) Research involving medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(1.) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 450 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(2.) From other adults and children,<sup>2</sup> considering the age, weight and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

c. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

(1.) hair and nail clippings obtained in a nondisfiguring manner;

(2.) deciduous teeth at time of exfoliation, or if routine patient care indicates a need for extraction;

(3.) permanent teeth if routine patient care indicates a need for extraction;

(4.) excreta and external secretions (including sweat);

(5.) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;

(6.) placenta removed at delivery;

(7.) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

(8.) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

(9.) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

(10.) sputum collected after saline mist nebulization.

d. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications). Examples:

(1.) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;

(2.) weighing or testing sensory acuity;

(3.) magnetic resonance imaging, without use of a contrast agent;

(4.) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography;

(5.) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

e. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt).

f. Collection of data from voice, video, digital, or image recordings made for research purposes.

g. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt).

<sup>1</sup>An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

<sup>2</sup>Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."  
CFR 46.402(a).

(Source: <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/63fr60364.html>)

h. An addendum, even to a greater than minimal risk study, that does not increase the overall risk to the subject.

i. A protocol involving a retrospective review of charts may be submitted for expedited review and approval.

(FOR USE WITH EXPEDITED REVIEW)

**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. ( Include this signature block , 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

**DIRECTOR OF RESEARCH:** 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.

\_\_\_\_\_  
(b)(6) 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 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. SPECIFIC AIMS/SIGNIFICANCE:** *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) with subject identifiers that permit the potential association of recorded data elements with identifiable individuals, and the nature of the identifiers.*
- 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. RECORDING OF EXTRACTED DATA WITH IDENTIFIERS:** *Describe the direct identifiers used, if any (e.g., name, medical record number, social security number). Describe the indirect identifiers used (e.g., unique study identifier, encrypted/coded identifier).*
- C. 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.*
- D. TRANSMISSION OF EXTRACTED DATA FOR COLLABORATIVE RESEARCH:** *If you are going to transmit extracted data electronically to collaborators, describe the necessity for the inclusion of identifiers and the general security measures, such as encryption of data, you intend to employ.*
- E. LINKAGE OF EXTRACTED DATA TO OTHER DATABASES:** *Provide details concerning these databases and the mechanism of linkage.*

**F. 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. Examples: deletion of data set, removal of identifiers.*

**G. BENEFITS:** *Describe any benefits that may be reasonably expected from the research.*

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

**XII. WAIVER OF INFORMED CONSENT:** *Please address each one of the following issues as it is pertinent to your research proposal.*

**A. The research involves no more than minimal risk to the subjects.** *(In medical records research, risk is primarily psychosocial in nature, attendant on breaches of privacy and confidentiality.)*

**B. The waiver will not adversely affect the rights and welfare of the subjects.** *Explain how or why the waiver will not adversely affect the rights and welfare of the subjects, e.g. the subjects are no longer living.*

**C. The research could not practicably be carried out without the waiver.** *Explain why the research could not be carried out without the waiver of informed consent. E.g. it is impossible to contact the subjects, some of the subjects may no longer be alive.*

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

**XIV. BIBLIOGRAPHY:**

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

**XVI. IMPACT:**

**XVII. FUNDING:**

**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"> <li>• <i>Names</i></li> <li>• <i>Address</i></li> <li>• <i>Dates except year</i></li> <li>• <i>Ages over 89 (can be grouped as age 90 or older)</i></li> <li>• <i>Phone numbers</i></li> <li>• <i>Fax numbers</i></li> <li>• <i>E-mail addresses</i></li> <li>• <i>Social security numbers</i></li> <li>• <i>Medical record numbers</i></li> <li>• <i>Account numbers</i></li> <li>• <i>Certificate/license numbers</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>Health plan beneficiary numbers</i></li> <li>• <i>Vehicle identifiers and serial numbers, or license plate numbers</i></li> <li>• <i>Device identifiers and serial numbers</i></li> <li>• <i>Web Universal Resource Locators (URLs)</i></li> <li>• <i>Internet Protocol (IP) address numbers</i></li> <li>• <i>Biometric Identifiers, including finger and voice prints</i></li> <li>• <i>Full face photographic images and any comparable images</i></li> <li>• <i>Any other unique identifying number, characteristic, or code</i></li> </ul>
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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)

1. The research could not practicably be conducted without the waiver because: (explain below).  
*You may use the same justification as for the waiver of informed consent.*

2. The research could not practicably be conducted without access to and use of the PHI  
because: (explain below)  
*You may use the same justification as for the waiver of informed consent.*

3. 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) .....  
LTC, MC  
Chair, BAMC Privacy Board

\_\_\_\_\_  
Date