

Date:
Protocol Title:
Version # 1

PI: 1

Study number:

(EXPLANATION SHEET FOR USE WITH EXEMPT REVIEW)

PROTOCOL TITLE:

PROTOCOL NUMBER:

PRINCIPAL INVESTIGATOR:

Type name and sign

Date

ASSOCIATE INVESTIGATORS:

Type name and sign

Date

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

TASK AREA MANGER: I approve of this protocol being submitted for review.

Typed name of TAM

Date

Revised May 2005

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

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

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[(b)(6)], PhD DATE: _____

[(b)(6)], MD DATE _____
COL, MC
Commanding

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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. Minor Protocol Deviations will be documented on the Protocol Deviation Table and become a part of the master study file.
- 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/charts needed for scientific validity is used.
- H. Publications:** I am aware that any presentation or publications resulting from this research must be cleared by the appropriate Public Affairs Office, undergo OPSEC review and be reviewed for release of actionable medical information.

Print name and sign (Principal Investigator)

Date:_____

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PROTOCOL TITLE:

PROTOCOL NUMBER *(ISR protocol coordinator will assign a study number)*

PERSONNEL INVOLVED: *(List the names, positions, department, and telephone and pager numbers of all persons directly involved in the project work, include rank and corps for all military personnel)*

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.

LOCATION OF STUDY: *List facility, room number, etc.*

DURATION OF STUDY:

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

A. Expected Start Date:

B. Expected Completion Date:

RESEARCH PLAN:

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

B. HYPOTHESES/RESEARCHQUESTIONS: *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.*

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168 **SPECIFIC AIMS/SIGNIFICANCE:** *State concisely the importance and health relevance of the*
169 *research described by relating the specific aims to the broad, long- term objectives. State the*
170 *practical application(s). Significance is often demonstrated using numbers affected, cost of care,*
171 *impact on quality of life, etc.*

172

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174 **DESIGN:** *State in detail how the research will be designed to answer the hypotheses/research*
175 *questions. Define what measurements (operational definitions-independent and dependent variables)*
176 *the study will evaluate to answer the research questions. Show a clear course of action and a clear*
177 *definition of the end points.*

178

179 **MILITARY RELEVANCE:** *With regards to military needs and mission requirements, this paragraph*
180 *should provide a brief and succinct military justification for the research. If applicable state the*
181 *Science and Technology Objective (STO) that this work supports.*

182

183

184 **BACKGROUND/REVIEW OF LITERATURE:** *Briefly describe the background leading to the*
185 *present study. Critically evaluate existing knowledge, and specifically identify the gaps that the*
186 *project is intended to fill.*

187

188 **A. Date of Search**

189 **B. Period Searched**

190 **C. Sources Searched**

191 **D. Key words of Search**

192 **E. Summary of Search**

193

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195 **HUMAN SUBJECT PROTECTION:**

196 *Describe the nature and location of the database(s) to be used in the research, the method of*
197 *extraction of data from the database(s), whether the extracted data are recorded (on paper or*
198 *electronic medium) with subject identifiers that permit the potential association of recorded data*
199 *elements with identifiable individuals, and the nature of the identifiers.*

200

201 **A. NATURE AND LOCATION OF DATABASE(S):** *Identify the database of interest and*
202 *source, type of study, and type of subject population to be observed. Please attach a printed copy of*
203 *the datasheet you are going to use to record the extracted data.*

204

205 **B. RECORDING OF EXTRACTED DATA WITH IDENTIFIERS:** *Describe the direct*
206 *identifiers used, if any (e.g., name, medical record number, social security number). Describe the*
207 *indirect identifiers used (e.g., unique study identifier, encrypted/coded identifier).*

208

209 **C. LOCATION OF EXTRACTED AND RECORDED DATA:** *Describe where the medium*
210 *containing the recorded data used for analysis/evaluation is going to be kept, and enumerate the*
211 *measures utilized to secure it from unauthorized access. Examples: locked file for paper records,*
212 *password-protected PC and electronic files, encrypted electronic files, firewall for network*

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213 *computers.*

214 **D. TRANSMISSION OF EXTRACTED DATA FOR COLLABORATIVE RESEARCH:** *If*
215 *you are going to transmit extracted data electronically to collaborators, describe the necessity for*
216 *the inclusion of identifiers and the general security measures, such as encryption of data, you intend*
217 *to employ.*

218
219 **E. LINKAGE OF EXTRACTED DATA TO OTHER DATABASES:** *Provide details*
220 *concerning these databases and the mechanism of linkage.*

221
222 **F. STATUS OF THE EXTRACTED DATA AFTER COMPLETION OF THE RESEARCH**
223 **STUDY:** *Describe what you are going to do with the extracted data after completion of the project.*
224 *Examples: deletion of data set, removal of identifiers.*

225
226 **G. BENEFITS:** *Describe any benefits that may be reasonably expected from the research.*

227
228 **H. RISKS:** *Describe any potential risks in the collection of this data.*

229
230 **WAIVER OF INFORMED CONSENT:** *Please address each one of the following issues as it is*
231 *pertinent to your research proposal.*

232
233 **A. The research involves no more than minimal risk to the subjects.** *(In medical records*
234 *research, risk is primarily psychosocial in nature, attendant on breaches of privacy and*
235 *confidentiality.)*

236
237 **B. The waiver will not adversely affect the rights and welfare of the subjects.** *Explain how or*
238 *why the waiver will not adversely affect the rights and welfare of the subjects, e.g. the subjects*
239 *are no longer living.*

240
241 **C. The research could not practicably be carried out without the waiver.** *Explain why the*
242 *research could not be carried out without the waiver of informed consent. E.g. it is impossible*
243 *to contact the subjects, some of the subjects may no longer be alive.*

244
245
246 **DATA ANALYSIS:** *Describe what data (outcome measures) will be compared for each research*
247 *question, and by what method (statistic or methodology as appropriate).*

248
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250 **BIBLIOGRAPHY:**

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

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257 **IMPACT**

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FUNDING/BUDGET

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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.

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296 3. All identifiers collected during the study will be destroyed at the earliest opportunity consistent
297 with the conduct of research, which is: (explain below).

298 Please describe the procedure used to destroy all the data collected during the study
299 (electronically, paper, audio/video, photography, other).

300

301 OR

302

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

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306

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

308 You may use the same justification as for the waiver of informed consent.

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

315 You may use the same justification as for the waiver of informed consent.

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

323

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

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335 _____
Principal Investigator's Typed Name

PI Signature

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340 _____
Date

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Approved:

Disapproved:

Comment: _____

(b)(6)

Date

COL, MC
Chairman, Privacy Board