

Date:
Protocol Title:
Version # 1

PI: 1

Study number:

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PROTOCOL TITLE:

PROTOCOL NUMBER:

PRINCIPAL INVESTIGATOR:

Type name and sign

Date

ASSOCIATE INVESTIGATORS:

Type name and sign

Date

Type name and sign

Date

TASK AREA MANAGER: The Task Area Manager 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 Investigators' credentialing packet(s) has been reviewed and is current.

Regulatory Compliance and Quality

Date

Revised Jan 2008

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

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

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

[(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:** The protocol will be conducted in accordance with the protocol submitted to and approved by the Brooke Army Medical Center Institutional Review Board, (BAMC IRB) the Clinical Investigation Regulatory Office (CIRO) and will not be initiated until written notification of approval of the research project is issued by the BAMC IRB.
- 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:** All modifications must be submitted as a written amendment to the local IRB for review and approval before implementing the change.
- E. Deviations to the Protocol:** I am aware that any protocol deviations discovered by either the PI or auditing official that affect the safety or rights of the subject or the integrity of the study must be reported to the Chair, IRB as soon as the deviation is identified. Documentation is accomplished on a Protocol Deviation Report Form in accordance with USAISR Policy on Protocol Deviations and BAMC IRB SOP on 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 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, and undergo OPSEC review and be reviewed for release of actionable medical information, if applicable.
- I. Data Sharing Agreement:** I am aware that data obtained from any of the USAISR databases such as JTTR, Burn Registry, Trauma Vitals, etc. will only be released to me based upon an IRB approved protocol. Such information will not be shared with anyone not authorized by the IRB to receive the information. Disposition of the data will occur as specified in the approved protocol. Any changes that impact on the type of data requested or in the utilization or disposition of the data will not occur until an amendment to the protocol is approved by the IRB. Upon completion of the study, all new data gained as a result of the study will be made available to the issuing database.

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Print name and sign (Principal Investigator)

Date: _____

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1.0 PROTOCOL TITLE:

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

3.0 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. If you are affiliated with the University of Texas Health Science Center, please include that affiliation with the information requested.)*

3.1 PRINCIPAL INVESTIGATOR:

3.2 CO-INVESTIGATOR(S): *(If applicable)*

3.2.1. *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.*

3.2.2

3.2.3

3.3 ROLES AND RESPONSIBILITIES:

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

5.0 DURATION OF STUDY:

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

5.1. Expected Start Date:

5.2. Expected Completion Date:

6.0 RESEARCH PLAN:

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

6.2 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*

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179 *remission between groups treated with drug Y and placebo, or stated as a null hypothesis 3) there*
180 *are no differences in the rate remission between groups treated with drug Y and placebo.*

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182 **6.3 SPECIFIC AIMS/SIGNIFICANCE:** *State concisely the importance and health relevance of the*
183 *research described by relating the specific aims to the broad, long- term objectives. State the practical*
184 *application(s). Significance is often demonstrated using numbers affected, cost of care, impact on*
185 *quality of life, etc.*

186

187 **6.4 DESIGN:** *State in detail how the research will be designed to answer the hypotheses/research*
188 *questions. Define what measurements (operational definitions-independent and dependent variables)*
189 *the study will evaluate to answer the research questions. Show a clear course of action and a clear*
190 *definition of the end points.*

191

192 **6.5 MILITARY RELEVANCE:** *With regards to military needs and mission requirements, this*
193 *paragraph should provide a brief and succinct military justification for the research. If applicable state*
194 *the Science and Technology Objective (STO) that this work supports.*

195

196 **6.6 MEDICAL APPLICATION:** *Explain briefly the necessity to perform the study, procedure, or*
197 *demonstration or the medical importance and possible usefulness of the study.*

198

199 **6.7 BACKGROUND/REVIEW OF LITERATURE:** *Briefly describe the background leading to the*
200 *present study. Critically evaluate existing knowledge, and specifically identify the gaps that the project*
201 *is intended to fill.*

202

203 **6.7.1. Date of Search**

204 **6.7.2. Period Searched**

205 **6.7.3. Sources Searched**

206 **6.7.4. Key words of Search**

207 **6.7.5. Summary of Search**

208

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210 **7.0 HUMAN SUBJECT PROTECTION:**

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

215

216 **7.1 NATURE AND LOCATION OF DATABASE(S):** *Identify the database of interest and*
217 *source, type of study, and type of subject population to be observed. Please attach a printed copy of*
218 *the datasheet you are going to use to record the extracted data.*

219

220 **7.2 RECORDING OF EXTRACTED DATA WITH IDENTIFIERS:** *Describe the direct*
221 *identifiers used, if any (e.g., name, medical record number, social security number). Describe the*
222 *indirect identifiers used (e.g., unique study identifier, encrypted/coded identifier).*

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224 **7.3 LOCATION OF EXTRACTED AND RECORDED DATA:** Describe where the medium
225 containing the recorded data used for analysis/evaluation is going to be kept, and enumerate the
226 measures utilized to secure it from unauthorized access. Examples: locked file for paper records,
227 password-protected PC and electronic files, encrypted electronic files, firewall for network
228 computers.

229 **7.4 TRANSMISSION OF EXTRACTED DATA FOR COLLABORATIVE RESEARCH:** If
230 you are going to transmit extracted data electronically to collaborators, describe the necessity for
231 the inclusion of identifiers and the general security measures, such as encryption of data, you intend
232 to employ.

233
234 **7.5 LINKAGE OF EXTRACTED DATA TO OTHER DATABASES:** Provide details
235 concerning these databases and the mechanism of linkage.

236
237 **7.6 STATUS OF THE EXTRACTED DATA AFTER COMPLETION OF THE RESEARCH**
238 **STUDY:** Describe what you are going to do with the extracted data after completion of the project.
239 Examples: deletion of data set, removal of identifiers.

240
241 **7.7 BENEFITS:** Describe any benefits that may be reasonably expected from the research.

242
243 **7.8 RISKS:** Describe any potential risks in the collection of this data.

244
245 **7.9 WAIVER OF INFORMED CONSENT:** Please address each one of the following issues as it
246 is pertinent to your research proposal.

247
248 **7.9.1 The research involves no more than minimal risk to the subjects.** (In medical records
249 research, risk is primarily psychosocial in nature, attendant on breaches of privacy and
250 confidentiality.)

251
252 **7.9.2 The waiver will not adversely affect the rights and welfare of the subjects.** Explain how or
253 why the waiver will not adversely affect the rights and welfare of the subjects, e.g. the subjects
254 are no longer living.

255
256 **7.9.3 The research could not practicably be carried out without the waiver.** Explain why the
257 research could not be carried out without the waiver of informed consent. E.g. it is impossible
258 to contact the subjects, some of the subjects may no longer be alive.

259
260 **7.9.4 Whenever appropriate, participants will be provided with additional pertinent**
261 **information after their participation.**

262
263
264 **8.0 DATA ANALYSIS:** Describe what data (outcome measures) will be compared for each
265 research question, and by what method (statistic or methodology as appropriate).

266
267
268 **9.0 BIBLIOGRAPHY:**

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270 **10.0 FUNDING/BUDGET**

271

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273 **11.0 IMPACT**

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275 Yes No -Pharmacy

276 Yes No -Nursing

277 Yes No -Laboratory

278 Yes No -Information Management

279 Yes No -Radiology

280 Yes No -Operating Room

281 Yes No -Anesthesiology

282 Yes No -ISR Outpatient Clinic

283 Yes No -Respiratory

284 Yes No -Other _____

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287 **12.0 CASE REPORTING FORM/DATA COLLECTION SHEET: *Include a sample of the data***
288 *collection sheet for this study.*

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IMPACT STATEMENT:

PROTOCOL TITLE:

PRINICPAL INVESTIGATOR:

LOCATION OF STUDY:

ASSISTANCE REQUESTED:

NUMBER OF SUBJECTS/PATIENTS TO BE STUDIED

LENGTH OF STUDY:

NUMBER OF SAMPLES/ACTIVITIES PER MONTH:

FUNDING REQUIREMENT:

Approved, no comment

Approved with comment

Disapproved, cannot support activity

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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.
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).

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365 OR

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

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

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

373

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

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

377

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

382

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384

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

392

393

394 _____
Principal Investigator's Typed Name

PI Signature

395

396

397

398 _____
Date

399

400

401 Approved:

Disapproved:

402

Comment: _____

403

404

405

406

(b)(6)

Date

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408 Chairman, Privacy Board