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APPENDIX 1 - PREPROPOSAL INSTRUCTIONS

A. Preproposals should be submitted electronically via an **USAMRMC BAA PREPROPOSAL FORM** <http://extranet.tatrc.org/usamraa/99BAAPRE.html>. If you do not utilize the html form, you can submit your preproposal on an IBM formatted disk in a format readable by Microsoft Office or Adobe Acrobat.

1. Principal Investigator's Full Name, Address, City, State, Zip, E-mail, FAX and Daytime telephone number.
2. Organization's Full Name, Address, City, State, Zip, E-mail FAX and Daytime telephone number.
3. Preproposal Title (Limited to 120 characters).
4. Six - Eight Keywords
5. Problem to be Studied
6. Significance and/or Uniqueness of the Proposed Effort
7. The Potential Military Relevance
8. Proposed Duration of the Project in Years and Months
9. Names, Title, Roles and Percent of Effort of Participating Personnel.
10. Itemized List of Major Capital Equipment/Subcontracts > \$10K (If Known)
11. Brief Description of Animal and Human Use
12. Conclusions
13. Brief Curriculum Vitae (CV) for PI & Key Personnel

B. If sending on an IBM formatted disk, mail to the following address:

US Army Medical Research Acquisition Activity
ATTN: BAA 99-1
820 Chandler Street
Fort Detrick MD 21702-5014

Questions can be answered by calling 301/619-7631 or emailing to: Q&A.BAA@amedd.army.mil.

APPENDIX 2 - CONFERENCE OR SYMPOSIUM SUPPORT INSTRUCTIONS

A. Conference or Symposium Support requests should be submitted electronically via **USAMRMC BAA99 CONFERENCE OR SYMPOSIUM SUPPORT FORM** <http://extranet.tatrc.org/usamraa/99conf.html>. The conference or symposium support form information will be received by email. If you do not utilize the html form, you can submit your conference or symposium support request on an IBM formatted disk in a format readable by Microsoft Office or Adobe Acrobat.

1. Requestor's Full Name, Address, City, State, Zip, E-mail, FAX and Daytime telephone number.
 2. Recipient's Organization's Full Name, Address, City, State, Zip, E-mail, FAX and Daytime telephone number.
 3. Conference/Symposium Title (Limited to 120 characters)
 4. Start and End Dates of Conference/Symposium
 5. City, State and County Where Conference/Symposium will be held.
 6. Explanation of Conference and/or benefits/relevance to the mission of USAMRMC
 7. Amount of Funds Requested
 8. Explanation of funds:
 - (1) Travel expenses of US participants
 - (2) Printing costs (Proceedings, etc.)
- (Note: Funds cannot be provided to reimburse scientists from communist and terrorist countries.)**
9. Include an agenda/tentative program as well as a list of invitees/speakers and their organizations and countries
 10. Include Curriculum Vitae (CV) of Chairperson and Co-chairperson, if available

B. If sending on an IBM formatted disk, mail to the following address:

US Army Medical Research Acquisition Activity
ATTN: BAA 99-1
820 Chandler Street
Fort Detrick MD 21704-5014

Questions can be answered by calling 301/619-7631 or emailing to: Q&A.BAA@amedd.army.mil.

APPENDIX 3 - COVER PAGE

A completed Research Proposal Cover Page must be the first page of the proposal. The Cover Page must contain the information listed below. A suggested format is provided.

1. USAMRMC Log Number. If a preproposal has been submitted, enter the log number that was provided in response to the BAA. If a preproposal was not submitted, leave this blank.
2. Offeror's Name and Address: The full name and address of the organization or institution submitting the proposal should be supplied for this item.
3. Type of Organization: Mark appropriate boxes to indicate type of organization/business.
4. Data Universal Numbering System (DUNS): The code is required and can be obtained by registering with Duns and Bradstreet by calling 800/333-0505 or online at <http://www.dnb.com/english/aboutdnb/default.asp>.
5. Trading Partner Identification Number (TPIN): This number is required if you are receiving an award of a contract. You receive the number when registering as a trading partner in the [Central Contractor Registration \(CCR\)](#) database. The CCR registration replaces multiple site registrations and replaces the SF 129. **(NOT REQUIRED SEE AMENDMENT 0004)**
6. Standard Industrial Classifications (SIC): The federal government uses this code to identify specific industries. It can be obtained by calling 800/827-5722 or accessing the website <http://www.osha.gov/cgi-bin/sic/sicsr5>.
7. Federal Supply Classifications (FSC): The code tells the government what types of products or services your company provides. The code can be obtained by accessing the website <http://www.govcon.com>.
8. Commercial and Government Entity (CAGE): This code is a unique five-character number, which is issued by the Defense Logistics Services Center (DLSC) to identify DoD contractors. You can obtain the number by calling 616/961-4373, Fax 616/961-4388, or by sending an email to cagemail@dlsc.dla.mil.
9. Taxpayer Identification Number (TIN): The TIN is needed for all financial purposes (social security number/employee identification number). (This number can be obtained by calling the IRS at (800/829-1040).)
10. Federal Interagency Committee on Education (FICE) Number: This number is required for statistical reporting of federal support to universities, colleges, and selected nonprofit institutions.
11. Proposal Title: Insert title of research proposal not to exceed 120 characters.
12. Estimated Cost: Total cost to complete research effort (including direct and indirect costs).
13. Proposed Start Date: Earliest date principal investigator believes work could begin (at least six months from the submission date).
14. Proposed Duration: Number of years to complete research effort and complete final reports.
15. Proposal Valid Until: Allow a minimum of six months from the date of submission.
16. Principal Investigator's Information, name, address, email, phone and fax.
17. Administrative Representative's Information, name, address, email, phone and fax.
18. Authorized Representative's Information, name, address, email, phone and fax.

BAA 99-1 RESEARCH PROPOSAL COVER PAGE

1. USAMRMC Log No.:	USAMRMC PROPOSAL COVER PAGE		
2. Name and Address of Offeror:	3. Type of Organization: <input type="checkbox"/> EDUCATIONAL: <input type="checkbox"/> HBCU <input type="checkbox"/> MI <input type="checkbox"/> FDP <input type="checkbox"/> COMMERCIAL: <input type="checkbox"/> Large <input type="checkbox"/> Small <input type="checkbox"/> Woman-Owned <input type="checkbox"/> Disadvantaged Business <input type="checkbox"/> NON-PROFIT <input type="checkbox"/> FOREIGN <input type="checkbox"/> OTHER:		
4. Data Universal Numbering System (DUNS):	5. Trading Partner Identification No. (TPIN): Not Applicable		
6. Standard Industrial Classifications (SIC):	7. Federal Supply Classifications (FSC):		
7. Commercial and Gov't Entity (CAGE):	8. Taxpayer Identification No. (TIN):		
9. Federal Interagency Committee on Education (FICE) No.:			
11. Proposal Title:			
12. Estimated Cost: \$	13. Proposed Start Date:	14. Proposed Duration	15. Proposal Valid Until:
16. Principal Investigator's Name and Address:		17. Administrative Representative Name & Address:	
Email:	Email:		
Phone No.:	Phone No.:		
FAX No:	FAX No:		
Alternate's Name:	Alternate's Name:		
Alternate's Phone No:	Alternate's Phone No:		
18. Authorized Representative:			
Typed Name:	Signature:		
Title:	Date Signed:		

NOTHING ON THIS PAGE IS PROPRIETARY INFORMATION

APPENDIX 4 - ABSTRACT

A completed Abstract must be the second page of each copy of the proposal.

The Abstract must include the information listed below. A suggested format is also provided.

1. Proposal Title (120 characters maximum)
2. Keywords. 6-8 words.
3. Abstract. Approximately 200 words. If possible nothing on this page should be proprietary or subject to other restrictions on distribution for evaluation purposes.

BAA 99-1 PROPOSAL ABSTRACT

Proposal Title: *(120 Characters Maximum)*

Keywords: *(6-8 words)*

Abstract: *(Type within outline: approximately 200 words)*

NOTHING ON THIS PAGE IS PROPRIETARY INFORMATION

APPENDIX 5 - PROPOSAL TABLE OF CONTENTS

- A. Research Proposal Cover Page
- B. Abstract
- C. Table of Contents (with pagination)
- D. Statement of Work
- E. Body of Proposal
- F. Detailed Cost Estimate
- G. Addenda
 - 1. Acronym/Symbol Definition
 - 2. Biographical Sketch
 - 3. Personnel Curriculum Vitae
 - 4. Existing/Pending Support
 - 5. Letter Confirming Collaboration
 - 6. Facilities/Equipment Description
 - 7. Human Use
 - a. Optional Form 310, Protection of Human Subjects,
 - b. Human Use Documentation (32CFR 219 and 45 CFR 46)
 - c. Copy of all protocols and consent forms
 - d. Documentation of Local Institutional Review Board Review and Approval
 - 8. Animal Use
 - a. Justification for animal/species use
 - b. AAALAC approval or compliance with PHS and Federal
 - c. Current approval letter/minutes from local Institutional Animal Care and Use Committee
 - d. Assurance signed by the Principal Investigator
 - 9. Certificate of Environmental Compliance
 - 10. Other

NOTHING ON THIS PAGE IS PROPRIETARY INFORMATION

APPENDIX 6 – DETAILED COST ESTIMATE

PRINCIPAL INVESTIGATOR (last, first, middle):								
DETAILED BUDGET FOR YEAR *:		<input type="checkbox"/> 1 ST	<input type="checkbox"/> 2 ND	<input type="checkbox"/> 3 RD	<input type="checkbox"/> 4 TH	<input type="checkbox"/> 5 TH	FROM	THROUGH
PERSONNEL		TYPE APPT. (MONTHS)	ANNUAL BASE SALARY	EFFORT ON PROJECT	DOLLAR AMOUNT REQUESTED			
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTALS	
	PI			%				
				%				
				%				
				%				
				%				
				%				
				%				
SUBTOTALS								
CONSULTANT COSTS								
MAJOR EQUIPMENT (ITEMIZE)								
MATERIALS, SUPPLIES AND CONSUMABLES (ITEMIZE BY CATEGORY)								
TRAVEL COSTS								
RESEARCH-RELATED PATIENT COSTS								
OTHER EXPENSES (ITEMIZE BY CATEGORY)								
SUBTOTAL OF DIRECT COSTS FOR THIS BUDGET PERIOD								
CONSORTIUM COSTS	DIRECT COST							
	INDIRECT COST							
TOTAL DIRECT COST FOR THIS BUDGET PERIOD								
TOTAL INDIRECT COSTS FOR THIS BUDGET PERIOD								
TOTAL COSTS FOR THIS BUDGET PERIOD								

***USE SEPARATE FORM FOR EACH BUDGET YEAR.**

Principal Investigator (last, first, middle):

SUMMARY BUDGET FOR ENTIRE PROPOSED PERIOD OF SUPPORT

BUDGET CATEGORY TOTALS	INITIAL BUDGET PERIOD	ADDITIONAL YEARS OF SUPPORT REQUESTED				TOTAL
		2 ND	3 RD	4 TH	5 TH	
PERSONNEL						
FRINGE BENEFITS						
CONSULTANT COSTS						
MAJOR EQUIPMENT						
MATERIALS, SUPPLIES, AND CONSUMABLES						
TRAVEL COSTS						
RESEARCH-RELATED PATIENT COSTS						
OTHER EXPENSES						
SUBTOTAL DIRECT COSTS						
CONSORTIUM COSTS	DIRECT					
	INDIRECT					
TOTAL DIRECT COSTS						
TOTAL INDIRECT COSTS						
TOTAL COST FOR EACH YEAR						*

** This amount should agree with the amount entered in block 12 on the Research Proposal Cover Sheet.*

NOTE: Itemize all budget categories for each year on the *Justification* page, which follows. Follow Section E, Detailed Cost Estimate under Proposal Preparation in preparing your justification. Use continuation pages as needed.

NOTE: Itemize all budget categories for each year on the *Justification* page, which follows. Follow Section E, Detailed Cost Estimate under Proposal Preparation in preparing your justification. Use continuation pages as needed.

APPENDIX 7 – BIOGRAPHICAL SKETCH

Provide the following information for the key personnel listed on the budget page.			
NAME	POSITION TITLE		
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include post-doctoral training).			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY
<p>RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List in chronological order, the titles, all authors, and complete references to all publications during the past 3 years and to representative earlier publication pertinent to this application. If the list of publications in the last 3 years exceeds 2 pages, select the most pertinent publications. PAGE LIMITATIONS APPLY. DO NOT EXCEED 3 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INVESTIGATOR.</p>			

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED). PAGE LIMITATIONS APPLY.
DO NOT EXCEED 3 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INVESTIGATOR.

APPENDIX 8 - CERTIFICATE OF ENVIRONMENTAL COMPLIANCE

The offeror currently IS IS NOT (check appropriate category) in compliance with applicable national, state, and local environmental laws and regulations. (If not in compliance, attach details and evidence of approved mitigation measures.)

The offeror has examined the activities encompassed within the proposed action entitled

(Enter title and/or Solicitation number and Principal Investigator's name),

for compliance with environmental laws and regulations. The offeror states that the conduct of the proposed action:

- A. WILL NOT violate any applicable national, state, or local environmental law or regulation, and
- B. WILL NOT have a significant impact on the environment.

The offeror agrees that if the work required under the proposed action at any time results in a significant impact on the environment or a violation of any applicable environmental law or regulation, the offeror will immediately take appropriate action, to include notifying and/or coordinating with the appropriate regulatory agencies as required by law and notifying the Contracting/Grants Officer.

Name of Official Responsible for Environmental Compliance

Signature

Title

Date

Name of Organization

APPENDIX 9 - RESEARCH INVOLVING HUMAN SUBJECTS AND/OR ANATOMICAL SUBSTANCES

Guidelines for Submitting Proposals for the Conduct of Research Involving Human Subjects <http://mrmc-www.army.mil> (including human organs, tissues, cells, body fluids from human subjects as well as graphic, written, or recorded information derived from human subjects).

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Research Involving Human Subjects and/or Anatomical Substances

1. Introduction

In 1991, the DOD, along with 15 other federal agencies, adopted regulations that are known collectively as the Common Federal Rule. These regulations embody the ethical principles of the Belmont Report. Title 32, Code of Federal Regulations Part 219 (32 CFR 219), “Protection of Human Subjects” applies to all research involving human subjects conducted or supported by the DOD. The Department of Health and Human Services (DHHS) National Institutes of Health (NIH) corollary is 45 CFR 46. Research conducted or funded by the USAMRMC is also governed by Army Regulation (AR) 70-25, January 1990 and Office of The Army Surgeon General (OTSG) Regulation 15-2, January 1989. The USAMRMC also adheres to the Food and Drug Administration’s (FDA’s) regulation, Title 21, Code of Federal Regulations for research involving investigational drugs or devices.

The OTSG maintains the overall responsibility for protecting human research subjects for the Department of the Army (DA).

2. Definitions

2-a. Research

32 CFR 219, The Common Federal Rule, defines “research” as a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

21 CFR 312 (FDA) defines “clinical investigation” as “any experiment that involves a test article and one or more human subjects...”

2-b. Human Subjects

32 CFR 219 defines “human subject” as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.” **The regulations extend to the use of human organs, tissues, cells, body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects.**

21 CFR 312 (FDA) defines “human subject” as “an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient.”

3. Human Subjects Research Review Process

3-a. Review Levels

In addition to first level of review and approval by the local Institutional Review Board (IRB), the OTSG requires a second level of review and approval by its Human Subjects Research Review Board (HSRRB) of all research involving human subjects. See Section 2-a of this appendix for the definition of a human subject. Approval must be obtained **prior** to initiation of the research protocol.

The HSRRB is functionally similar to a civilian IRB. The HSRRB is supported administratively by the USAMRMC, Office of the Deputy Chief of Staff for Regulatory Compliance and Quality, Human Subjects Protection Division (HSPD).

If your research proposal is recommended for funding and the research involves human subjects, the HSPD, in accordance with 32 CFR 219, will determine that the research:

1. is exempt from HSRRB review,
2. is eligible for expedited review,
3. is no greater than minimal risk and, therefore, can be administratively reviewed and approved by the HSPD, or
4. is greater than minimal risk and, therefore, requires full HSRRB committee review.

3-b. Timelines and Outcomes

In general, research protocols that pose greater than minimal risk to subjects are submitted through the HSPD to the HSRRB for full committee review and approval prior to implementation of the study. Review and approval by the HSRRB is usually accomplished within 45-90 days after submission of the protocol to the HSRRB. Any revisions to the protocol, consent form, advertisements, questionnaires, and other related study documentation recommended by the HSRRB must be reviewed and approved by the HSPD **prior to implementation of the study**.

The HSRRB will make 1 of 4 recommendations to The Surgeon General (TSG):

1. approval without changes,
2. conditional approval contingent upon changes and/or clarification,
3. deferred (Note: Protocols are deferred when the HSRRB has substantive concerns about the conduct of the protocol or the safety of the subjects. The PI will receive written comments from the HSRRB and the investigator's responses will go to full committee for further deliberation.), or
4. disapproved (Note: The PI will be notified in writing. The PI must then notify the HSPD of his or her intention to re-submit the protocol or to terminate consideration of the protocol.)

4. Claim of Exempt Research

4-a. Approval of Exempt Research Involving Human Subjects or Anatomical Substances

Certain categories of research may be exempt from review by the HSRRB. Those categories are specific and follow Federal Guidelines. Your research must fit into one or more of the categories in order to file the Claim of Exemption Form.

4-b. Exempt Categories

The following list details the exemption categories.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
 - a. research on regular and special education instructional strategies, or
 - b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:
 - a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - b. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. 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 of this section, if:
 - a. the human subjects are elected or appointed public officials or candidates for public office; or
 - b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, or pathological 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.
5. 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:
 - a. Public benefit or service programs
 - b. procedures for obtaining benefits or services under those programs
 - c. possible changes in or alternatives to those programs or procedures or
 - d. possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies,
 - a. if wholesome foods without additives are consumed, or
 - b. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

4-c. Claiming Exemption

Complete the form in Section 9 of this appendix to claim exemption for research involving human subjects or anatomical substances.

4-d. Final Judgement

The HSPD retains final judgment as to whether a particular activity is covered by this policy.

5. Guidelines for Writing Research Protocols Involving Human Subjects

5-a. The Basic Protocol

A detailed research protocol is required for the HSRRB review of your research. All submissions should include the following information:

1. **Project Title.** The consent form title should match that of the project.
2. **Phase.** For Food, Drug, and Cosmetic Act-regulated medical products, designate as a Phase I, II, III, or IV protocol.
3. **Principal Investigator.** The complete name, address, and phone number of the PI should be listed.
4. **Location of Study.** List all centers, clinics, or laboratories where the study is to be carried out. The complete addresses and site investigator(s) should be listed.
5. **Time Required to Complete.** The month and year of expected start and completion dates should be listed.
6. **Objectives.** State briefly, but specifically the objectives of the project.
7. **Study Population.** Detail source, number, age range, and sex of subjects along with inclusion/exclusion criteria.
8. **Protocol Design.** Outline the proposed methodology in enough detail to show a clear course of action. Technological reliability and validity of procedures should be indicated. Minimum guidance for the plan includes:
 - a. Subject identification (Describe code system to be used.)
 - b. Subject assignment
 - c. Evaluations prior to entry
 - d. Evaluations to be made during the conduct of the study (i.e., laboratory evaluations, specimens to be collected, schedule and amounts, storage to include where and whether special conditions are required, labeling and disposition)
 - e. Clinical Assessments (i.e., schedule of clinical evaluations and follow-up procedures, and adverse events)

9. **Risks/Benefits Assessment.** (Detail benefits of the research to the subject, precautions to be taken to minimize and/or eliminate risks, and specific medical or nursing care that will be needed.)
10. **Reporting of Serious and Unexpected Adverse Events.** (See HSPD Clause 001.02.- Section 5-b.i.)
11. **Description of Protocol Drug(s) or Device(s).** If the protocol uses an investigational drug or device, provide the following information:
- a. Investigational New Drug (IND)/Investigational Device Exemption (IDE) number and sponsor.
 - b. Complete names and composition of all medication(s), device(s), or placebo(s).
 - c. Source of medication(s), device(s), placebo(s).
 - d. Place where study medication(s) will be stored.
 - e. Dose range, schedule, and administration.
 - f. Washout period (The washout or pre-drug period must be noted carefully.)
 - g. Duration of drug or device treatment.
 - h. Concomitant medications.
 - i. Antidotes and treatments available.
 - j. Disposition of unused drug.
- 12 **Disposition of Data.** Where will the data be stored and for how long? **Note:** Records for IND studies must be kept until 2 years after a New Drug Application (NDA)/license for the investigational drug is approved/issued, or for 2 years after the IND is withdrawn. Records required for IDE studies should be retained for 2 years after the latter of the following dates: the date that investigation is terminated or completed; or the date that records are no longer required for support of a premarket approval application.
13. **Modification of the Protocol.** Describe the procedure to be followed if the protocol is modified.
14. **Roles and Responsibilities of Study Personnel.** Briefly describe the duties of study personnel.
15. **Signature of Principal Investigator.** Type the following statement, "I have read the foregoing protocol and agree to conduct the study as outlined herein." The PI should sign and date following this statement.

5-b. Requirements Unique to DOD/MRMC-Funded Research

5-b.i. Reporting of Serious and Unexpected Adverse Events

HSPD Clause 001.02

Serious and unexpected adverse experiences will be immediately reported by telephone to the USAMRMC Deputy Chief of Staff for Regulatory Compliance and Quality 301/619-2165, during non-duty hours call 301/619-2165 **and** send information by Fax to 301/619-7803. A written report will follow the initial telephone call within three working days. Address the written report to the U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RCQ-HR, 504 Scott Street, Fort Detrick, MD 21702-5012.

HSPD Clause 007.01

An adverse event temporally related to participation in the study should be documented whether considered to be related to the test article. This definition includes intercurrent illnesses and injuries, and exacerbations of pre-existing conditions. Include the following in all IND safety reports: Subject identification number and initials; associate investigator's name and name of hospital or medical treatment facility; subject's date of birth, gender, and ethnicity; test article and dates of administration; signs/symptoms and severity; date of onset; date of resolution or death; relationship to the study drug; action taken; concomitant medication(s) including dose, route and duration of treatment, and date of last dose.

5-b.ii. Volunteer Registry Data Base

HSPD Clause 002.01

It is the policy of USAMRMC that data sheets are to be completed on all volunteers participating in research for entry into this Command's Volunteer Registry Database. The information to be entered into this confidential database includes name, address, social security number, study name, and dates. The intent of the data base is two-fold: first, to readily answer questions concerning an individual's participation in research sponsored by USAMRMC; and second, to ensure that the USAMRMC can exercise its obligation to ensure research volunteers are adequately warned (duty to warn) of risks and to provide new information as it becomes available. The information will be stored at USAMRMC for a minimum of 75 years.

5-c.iii. Sample Donation

HSPD Clause 004.01

If the samples donated in this study will be used in other studies, the statement "I understand that there is a possibility that the blood, tissue, body fluid, product, or sample(s) (specify type) which I am providing under this study may also be used in other research studies and could potentially have some commercial applicability" should be included in the consent form. In addition, a donation form must be prepared for signature by the volunteer and a witness that states "I voluntarily and freely donate any and all blood, tissues, body fluid, product, or sample(s) (specify type) to the study sponsor (insert institution name) and hereby relinquish all right, title, and interest to said items." The title of the study should be inserted at the top of this donation form. The samples that will be stored should contain no personal identifiers.

5-b.iv. Title 10 United States Code, Section 980

HSPD Clause 006.01

10 United States Code 980 requires that "Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless— (1) the informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject."

5-b.v. Medical Monitor

HSPD Clause 008.01

A medical monitor must be assigned to any study involving greater than minimal risk to subjects. The name and curriculum vitae of the medical monitor must be provided. This individual should be a qualified physician, other than the Principal Investigator, not associated with this particular protocol, able to provide medical care to research subjects for conditions that may arise during the conduct of the study, and who will monitor the subjects during the conduct of the study.

5-b.vi. Serum Pregnancy Testing

If pregnant subjects will be excluded from participation in the study, the **method of determining pregnancy** status in women of childbearing potential must be specified. Also, the time that will elapse between the pregnancy test and exposure to research procedures or medical products must be documented. Serum pregnancy tests are required for all clinical medical product studies. For IND studies, serum pregnancy testing is required within 48 hours prior to the start of the study.

5-c. Advertisements, Posters, Flyers, or Press Releases to Recruit Subjects

If subjects will be recruited through an advertisement, newspaper article, or similar process, a copy of the local IRB-approved advertisement must be provided. For studies involving investigational drugs or devices, local IRB review of advertisements is necessary to ensure the information is not misleading to the subjects participating in IND studies. The FDA has established guidelines on advertisements for subjects. General guidance includes: name and address of PI, summary of research purpose, brief eligibility criteria, truthful list of benefits, and the person to contact for further information.

5-d. Surveys, Questionnaires, or Other Instruments

If the research involves surveys, questionnaires, or other instruments, include copies of the instruments in the Human Use Appendix.

5-e. Investigational Drugs or Devices

For research that involves an investigational drug or device:

1. Submit a copy of the Investigator's Drug Brochure and/or device manual and associated case report/data collection forms.
2. For IND products, specify the IND number, name of the sponsor, and the procedure by which the IND sponsor will monitor the protocol in accordance with 21 CFR 312.
3. For Investigational Devices, include your local IRB's assessment of the risk of the investigational device you plan to use in your study. If the device poses significant risk to research subjects, specify the IDE number obtained from the FDA, the name of the sponsor, and the procedure by which the IND sponsor will monitor the protocol in accordance with 21 CFR 812.
4. Contact your local IRB and/or the FDA if you have questions regarding IND or IDE submission requirements.

6. Informed Consent Requirements

The information that is given to the subject, or his or her representative shall be in language understandable to the subject or the representative. No informed consent may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

6-a. Elements of Informed Consent

The following information is essential for informed consent documents:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the subject.
3. A description of any benefits to the subject or to others that may reasonably be expected from the research.
4. Disclosures of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
6. For research involving more than minimal risk, include the following explanation of medical care available for research-related injury, (HSPD Clause 003.01):

Should you be injured as a direct result of participating in this research project, you will be provided medical care, at no cost to you, for that injury. You will not receive any injury compensation, only medical care. You should also understand that this is not a waiver or release of your legal rights. You should discuss this issue thoroughly with the principal investigator before you enroll in this study.

Four possible mechanisms are available to offset the costs of this requirement:

- a. The proposed recipient may absorb such costs into the institution's operating budget.
 - b. The proposed recipient's liability insurance, if available, may be sufficient to cover any medical care costs. The proposed recipient's business office and/or legal advisor must ensure that there is adequate coverage under this liability insurance.
 - c. The proposed recipient could negotiate an additional amount of funds, if available, into the award that will cover such medical care cost (such as liability insurance).
 - d. Third-party payers may be billed for such medical expenses. If this method is used, the subject must be informed, in the consent document, that his/her insurance company will be billed.
7. A contact for answers to questions about the research and research subjects' rights, and a contact in the event of a research-related injury to the subject.
 8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

6-b. Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
3. Any additional costs to the subject that may result from participation in the research.
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
5. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.
6. The approximate number of subjects involved in the study.

6-c. Requirements Unique to DOD/MRMC-Funded Research

6-c.i. Certification of Translation

HSPD Clause 005.01

Provide documentation that the foreign language version of the consent form is an accurate translation. Documentation should include the following statement, "I certify that this is an accurate and true translation" as well as the signature, name, address, phone number and, if available, Fax number of the translator.

6-c.ii. Payment for Study Participation: Active Duty Military Personnel

Under 24 CFR 30, payment for participation is limited to blood donation and may not exceed \$50 per blood draw. Active duty research subjects may not receive any other payment for participation in a research study.

6-c.iii. Confidentiality: Military Personnel

The following statement is **MANDATORY** for studies utilizing military personnel:

All data and medical information obtained about you, as an individual will be considered privileged and held in confidence; you will not be identified in any presentation of the results. Complete confidentiality cannot be promised, particularly to subjects who are military personnel, because information bearing on your health may be required to be reported to appropriate medical or command authorities.

6-c.iv. Pregnant Women

If pregnant women will be excluded, the following statement, HSPD Clause 009.01 (or equivalent) must be included:

I should avoid becoming pregnant for at least (time period in days, weeks, or months) after participation in the study. To avoid becoming pregnant, I should either abstain from sexual relations or practice a method of birth control. Except for surgical removal of the uterus, birth control methods such as the use of condoms, a diaphragm or cervical cap, birth control pills, IUD, or sperm-killing products are not totally effective in preventing pregnancy.

6-c.v. Volunteer Registry Data Base

For all studies involving greater than minimal risk, HSPD Clause 002.01, Volunteer Registry Database, must be included in the consent form. See Section 5-b.ii. of this appendix.

7. Assurances

If an institution has filed a Multiple Project Assurance (MPA) with the DHHS Office for Protection from Research Risks (OPRR), that assurance number should be documented on the Optional Form 310 (OF 310, Protection of Human Subjects Assurance/Certification/Declaration, page A-53), which replaced DHHS Form 596.

If the institution has not filed a MPA with OPRR, a written Assurance of Compliance should be filed with the USAMRMC Office of the Deputy Chief of Staff for Regulatory Compliance and Quality, Human Subjects Protection Division. A DOD Assurance number will be issued for the research project. There are three different assurance applications: (1) for institutions that have an IRB but no MPA; (2) for overseas institutions; and (3) for institutions using another institution's IRB. Sample assurance documents and the OF 310 can be downloaded from the USAMRMC Congressionally Directed Medical Research Programs website (<http://cdmrp.army.mil/>).

The OF 310 should be completed and signed by the Chairperson of the IRB. If another agent signs this document, verification of authority should be included in the remarks column (individual's signature authority). The OF 310 **must** include the level of risk that the project poses to the subject. These risk levels are: exempt, minimal risk, and greater than minimal risk. The HSPD reserves the right to determine whether the assigned risk level is in compliance with all applicable regulations.

8. Inclusion of Women and Minorities in Research

Consistent with the Belmont Report and recent congressional legislation, special attention is given to inclusion of women and minorities in research funded by the USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects' research. If women and/or minorities will be excluded, a justification must be included.

9. Where to Go for Help and Information

If your research involves human subjects, you should first contact your local IRB for institutional requirements.

If you have questions regarding the USAMRMC protocol and consent form requirements or the review and approval process, contact the Office of the Deputy Chief of Staff for Regulatory Compliance and Quality, Human Subjects Protection Division at the address or phone number listed on the following page.

Phone: (301/619-2166

Mail: Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-RCQ-HR
504 Scott Street
Fort Detrick MD 21702-5012

References:

- Title 32 Code of Federal Regulation, Part 219, Protection of Human Subjects
- Title 21 Code of Federal Regulation, Part 50, Protection of Human Subjects
- Title 21 Code of Federal Regulation, Part 56, Institutional Review Boards
- Title 21 Code of Federal Regulation, Part 312, Investigational New Drug Application
- Title 21 Code of Federal Regulation, Part 812, Investigational Devices
- Title 45 Code of Federal Regulation, Part 46 (45 CFR 46), Subparts B,C, and D, Protection of Human Subjects
- Code of Federal Regulations is online at <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>.
- Army Regulation 70-25, Use of Volunteers as Research Subjects
- Army Regulation 40-7, Use of Investigational Drugs and Devices in Humans and the Use of Schedule I Controlled Drug Substances
- Army Regulations can be located at <http://www-usappc.hoffman.army.mil/gils/epabs.html>
- Office of The Surgeon General Regulation 15-2, Human Subjects Research Review Board
- Title 10 United States Code, Section 980
- Department of Defense Directive 3216.2 (when using organs or tissues obtained at autopsy)
- Department of Defense Directive 6465.2

Copies of the preceding references can be obtained from either the U.S. Government Printing Office or the National Technical Information Service at:

Phone: 202/512-1800

Mail: U.S. Government Printing Office
North Capital & G Street, NW
Washington DC 20401

Phone: 703/487-4650 or 4684

Mail: National Technical Information Service
5285 Port Royal Road
Springfield VA 22161

10. Claim of Exemption from Review by the Human Subjects Research Review Board

United States Army Research and Materiel Command
Office of the Deputy Chief of Staff for Regulatory Compliance and Quality
Human Subjects Protection Division

PROTOCOL TITLE:
PI'S NAME:
INSTITUTION:

EXEMPT CATEGORY CLAIMED (Please refer to Exempt Categories - Section 4-b.)

	YES	NO
1. Will existing or archived data, documents, records, or biological specimens be used?	<input type="checkbox"/>	<input type="checkbox"/>
a. Will any data or biological specimens be collected from subjects?	<input type="checkbox"/>	<input type="checkbox"/>
b. What is the source(s) of existing or archived data/biological specimens? (Check all that apply)		
<input type="checkbox"/> Existing data publicly available?	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Archived data publicly available?	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> Biological specimens publicly available?	<input type="checkbox"/>	<input type="checkbox"/>
c. Will the information be recorded in such a manner that subjects cannot be identified, directly or indirectly through links?	<input type="checkbox"/>	<input type="checkbox"/>
2. Will data be recorded?	<input type="checkbox"/>	<input type="checkbox"/>
a. By audiotape?	<input type="checkbox"/>	<input type="checkbox"/>
b. By videotape?	<input type="checkbox"/>	<input type="checkbox"/>
3. If survey instruments are used, will sensitive or private topics be explored?	<input type="checkbox"/>	<input type="checkbox"/>
4. Will the subjects be identifiable either by name or through demographic data? If yes, describe on a separate sheet how the confidentiality of a subject's identity will be maintained and plans for maintaining or destroying identifying links to subjects after the study is completed.	<input type="checkbox"/>	<input type="checkbox"/>

PI's Signature

APPENDIX 10 - RESEARCH INVOLVING ANIMALS

Table of Contents

1. Introduction
2. Alternatives to Painful Procedures
3. Rationale for Using Animals
4. Species Identification and Rationale
5. Rationale for the Number of Animals Required
6. Experimental Design
7. Anesthesia/Analgesia/Tranquilization
8. Study Endpoint
9. Euthanasia or Final Disposition
10. Institutional Animal Care and Use Committee(s) (IACUC) Approval
11. U.S. Department of Agriculture (USDA) Inspection Report
12. Qualifications
13. Accreditation
14. Assurances /Statements

Research Involving Animals

1. Introduction

If using animals, provide all information required by this appendix. All subcontractors using animals must also provide the same information.

DOD definition of **animal: Any live nonhuman vertebrate.**

The DOD Directive 3216.1, dated April 17, 1995, provides policy and requirements for the use of animals in DOD-funded research. **These requirements may differ from those of other funding agencies.** Each of the following items **must be** addressed in Appendix 10, RESEARCH INVOLVING ANIMALS. Questions concerning animal use should be directed to:

Phone: 301/619-2144

Fax: 301/619-4165

Mail: U.S. Army Medical Research and Materiel Command
ATTN: MCMR-RCQ-AR
504 Scott Street
Fort Detrick MD 21702-5012

2. Alternatives to Painful Procedures

A painful procedure is defined as any procedure that would reasonably be expected to cause more than slight or momentary pain and/or distress in an animal to which that procedure is applied. A written narrative description of the methods and sources used to search for alternatives to painful procedures, including alleviated pain, **must** be provided. The minimal written narrative must include: the databases searched or other sources consulted, the date of the search and the years covered by the search, and the key words and/or search strategy used by the

Principal Investigator when considering alternatives or descriptions of other methods and sources used to determine that no alternatives were available to the painful or distressful procedure. Where Federal law requires specific testing available to the painful or distressful procedures, the CFR references or other legal guidelines requiring then should be noted. (The USAMRMC reserves the right to request evidence that a literature search for alternatives to painful procedures was performed.)

3. Rationale for Using Animals

Provide a rationale for using animals in the proposed research. Explain what alternatives to animal use were considered, such as computer modeling or cell cultures, and explain why these alternatives cannot be used to obtain the research objectives. **It is USAMRMC policy that alternatives to the use of animals be thoroughly investigated prior to submission of any proposal involving animals.**

4. Species Identification and Rationale

Identify the species of animals to be used and provide a rationale for their use. Explain this particular animal model(s) was chosen over other animal models.

5. Rationale for the Number of Animals Required

Provide the **number of each species of animals** to be used by experimental design. Justify these numbers either **scientifically or mathematically**. **Show how these numbers were determined to be the minimum** required to obtain valid results.

6. Experimental Design

Provide a complete description of the proposed use of the animals by experimental design. Include surgical procedures biosamples (frequency, volume, harvest site, and method of tissue collection), adjuvants, and other injections (agent, dosage, route, and other injections (agent, dosage, route, and anatomical site of administration).

7. Anesthesia/Analgesia/Tranquilization

Describe what anesthetics, tranquilizers, and analgesics will be used by agent, dosage, route, and anatomical site of administration. If none are to be used, provide an explanation.

8. Study Endpoint

Describe the projected endpoint or termination of the study for the animals.

9. Euthanasia or Final Disposition

Describe the method of euthanasia by agent, dosage, route, and anatomical site of administration. If animals are not euthanized, state final disposition of the animals.

10. Institutional Animal Care and Use Committee(s) (IACUC) Approval

Provide evidence that the protocol was approved by the IACUC of the institution where animal research will be performed, including any subcontracting facility. If it was not possible to have the protocol reviewed by the Committee prior to submission of the proposal, then so state. Evidence of committee review can follow proposal submission, but must be provided prior to award. **RESEARCH WILL NOT BE FUNDED WITHOUT EVIDENCE OF APPROVAL FROM THE IACUC(s).**

11. U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service Animal Care Inspection Report

Include a copy of the most recent USDA Inspection Report for any and all facilities where animal research will be performed, including any subcontracting facility.

12. Qualifications

Provide information on the qualifications and training of personnel performing the animal procedures. It must specifically address the training and experience these personnel possess in using and manipulating the species of animals detailed in the proposal.

13. Accreditation

One of the following must be provided for each facility where the animal research will be conducted:

1. Evidence that the facility is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).
2. A copy of the Institutional Letter of Assurance of Compliance with the "Public Health Service Policy on Humane Care and Use of Laboratory Animals," revised September 1986.
3. A statement signed by the Institutional Official that the care and use of animals will be performed according to the National Research Council 1996 "Guide for the Care and Use of Laboratory Animals" and applicable Federal regulations.

14. Principal Investigator Signed Assurances

The Principal Investigator must provide the following signed assurances (this page may be photocopied and signed):

1. I assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals.
2. I assure that the animals authorized for use in this protocol will be used only in the activities, manner, and quantities described herein, unless a deviation is specifically approved by my IACUC and the USAMRMC Animal Use Review Division.
3. I accept full responsibility for the proper care and use of the animals during the conduct of research outlined in the proposal.
4. I verify that I have made a reasonably good faith effort to ensure that this protocol is not an unnecessary duplication of previous experiments.
5. I verify that the personnel performing the animal procedures/manipulations described in this protocol are technically competent in those procedures and have received training on the use of animals in research as required by the Animal Welfare Act of 1985.
6. I assure that I have consulted with an individual who is qualified to evaluate the statistical design or strategy of this proposal and that the minimum number of animals needed for scientific validity will be used.

Principal Investigator's Signature

NOTE: For proposals that require the use of nonhuman primates, companion animals, marine mammals, or for research deemed sensitive by the USAMRMC, a site visit shall be conducted as necessary by the USAMRMC Animal Use Review Officer or designees.

APPENDIX 11 - SAFETY PROGRAM PLAN

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1. Affirmation of Safety
2. Research Operations/Standard Operating Procedures (SOPs)
3. Facility Equipment and Description
4. Hazard Analysis
5. Radioactive Materials
6. Recombinant DNA
7. Biological Defense Program Requirements

Safety Program Plan

Each of the applicable items below must be addressed in Appendix 11, SAFETY PROGRAM PLAN and must be prepared specifically for the proposal. Each section should be operation/research specific and addressed in order.

Institutional safety manuals may be referenced; however, **do not send copies of Facility Safety Plan (FSP) or Standard Operating Procedures (SOPs)**. A list of program contents with a brief description of each item (maximum 3 pages) is acceptable. If not applicable, so state. Provide a **website address**, if available, for additional safety and occupational health information.

Those items that do not apply to the proposed research will be labeled as “not applicable” or “N/A.”

1. Affirmation of Safety

The PI (**recipient**) shall sign and submit the following paragraph as affirmation that a safety program is in place and in accordance with all applicable regulations.

(Recipient name) affirms that there is an existing safety program that is in accordance with appropriate Federal, State, and Local regulations, as required by the Occupational Safety and Health Act; that hazards have been identified, eliminated, and/or controlled; and that research may be performed safely under laboratory conditions. (Recipient name) shall be held responsible and liable for inaccuracies of the information provided, failure to implement an effective safety and occupational health program, and/or adverse conditions that may result from the failure of the recipient to identify hazard information.

Signature of Recipient and Date

2. Research Operations/Standard Operating Procedures (SOPs)

Safety procedures relating to the research operation. These should include but are not limited to the following: description of safety procedures for performing the protocol; description of any special skills, training, and SOPs to assure safe research operations (Safety Committee, HAZCOM, Bloodborne Pathogen, and Chemical Hygiene, etc.); and description of medical surveillance and support.

3. Facility Equipment and Description

This should include a description of any biological safety cabinets, ventilation system employed and personal protective equipment.

4. Hazard Analysis

Include a description of each hazard identified, hazard analysis based on maximum credible event, and plan to minimize or eliminate hazards (infection, toxic substance, and biological hazards).

5. Radioactive Materials

If radioactive materials are used, the materials and the disposal method should be identified. A copy of the Nuclear Regulatory Committee (NRC)-approved license shall be submitted. If no such material is to be used, it should be so stated.

6. Recombinant DNA

Research involving recombinant DNA must meet or exceed NIH Guidelines for Research Involving Recombinant DNA Molecules, January 1997 edition. Include a written approval letter from the organization's Institutional Biosafety Committee (IBC). The IBC reviews all applications to perform protocols involving recombinant DNA (biohazardous material). If not applicable, it should be so stated.

Copies of the above NIH Guidelines are available at:

Fax: 301/496-9839

Phone: 301/496-9838

E-mail: www.nih.gov/od/orca

Mail: Office of Recombinant DNA Activities
National Institutes of Health, MSC 7010
6000 Executive Boulevard, Suite 302
Bethesda MD 20892-7010

7. Biological Defense Program Requirements

- Contractors performing work with **Biosafety Level-3 and 4** material must prepare a safety plan in accordance with 32 CFR 626.18.
- Local emergency support agencies, such as law enforcement, fire departments, health departments, and governments will be informed of Biological Defense Program (BDP) activities and the appropriate support necessary, to include any equipment and training to provide effective emergency response. Agreements with external agencies must be formalized. (For the purpose of this requirement, the term "local emergency support agencies" refers to any agency that could reasonably be expected to have some capability to provide timely and effective support in the management or resolution of a biological mishap arising from BDP operations.) **A copy of this agreement must be submitted with the proposal.**

(Sample)

Local Emergency Support

(Police, Fire, Health Department), is fully aware of the research program entitled _____ in the Department of _____ at _____, which is supported by the U.S. Army Medical Research and Materiel Command (Contract Number _____). In the event that a situation requires our response, we are equipped and prepared to handle those emergencies as appropriate for this project.

Acknowledged:

Name Title (e.g., Fire Chief) Date

- The PI is directly responsible and liable for all aspects of research project safety and ensures that all Facility Safety Plan requirements are in compliance with 32 CFR 626 and 627 (Biological Defense Safety Program and Biological Defense Safety Program, Technical Safety Requirements).