Application Instructions & General Information

Department of Defense (DOD) Congressionally Directed Medical Research Programs

Prostate Cancer Research Program (PCRP)

Clinical Trial Award

Funding Opportunity Number: W81XWH-08-PCRP-CTA

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These instructions apply only to this mechanism.

I. HELPFUL INFORMATION

A. Contacts

1. Program announcement, proposal format, or required documentation: To view all funding opportunities offered by the Congressionally Directed Medical Research Programs (CDMRP), perform a Grants.gov basic search using the CFDA Number 12.420. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079

Fax: 301-619-7792

Email: cdmrp.pa@amedd.army.mil

2. eReceipt system: Questions related to pre-application components through the CDMRP eReceipt system should be directed to the eReceipt help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time.

Phone: 301-682-5507

Website: https://cdmrp.org

Email: help@cdmrp.org

3. Grants.gov contacts: Questions related to submitting applications through the Grants.gov (http://www.grants.gov/) portal should be directed to Grants.gov help desk. Deadlines for proposal submission are 11:59 p.m. Eastern time on the deadline date. Therefore, there is an approximate 3-hour period during which the Grants.gov help desk will NOT be available. Please plan ahead accordingly, as the CDMRP help desk is not able to answer questions about Grants.gov submissions.

Phone: 800-518-4726, Monday through Friday, 7:00 a.m. to 9:00 p.m. Eastern time

Email: support@grants.gov

Grants.gov will notify Principal Investigators (PIs) of changes made to this Program Announcement and/or Application Package ONLY if the PI clicks on the "send me change notification emails" link and subscribes to the mailing list on the Opportunity Synopsis Page for this announcement. If the PI does not subscribe and the Application Package is updated or changed, the original version of the Application Package may not be accepted.

B. National Technical Information Service

The technical reference facilities of the National Technical Information Service (www.ntis.gov) are available for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering effort and the expenditure thereby represented. All other sources should also be consulted to the extent practical for the same purpose.

C. Commonly Made Mistakes

- Not obtaining or confirming the organization's DUNS number well before the proposal deadline.
- Not obtaining or confirming the organization's registration with the Central Contractor Registry well before the proposal submission deadline.
- Failing to request "send me change notification emails" from Grants.gov.
- Not contacting HELP DESKS until just before or after deadlines.
- Not completing the pre-application submission before the mandatory pre-application deadline (i.e., pre-application remains in draft status).
- Using an incorrect Grants.gov application package to submit a proposal through Grants.gov. Each Program Announcement/Funding Opportunity requires a specific application package.
- Uploading attachments into incorrect Grants.gov forms.
- Attaching files in the wrong location on Grants.gov forms.
- Submitting attachments that are not PDF documents, except for the R&R Subaward Budget Attachment(s) Form.
- Exceeding page limitations.
- Failing to submit a proposal 48-72 hours before the deadline so that Grants.gov can provide notification of errors and allow for resubmission of application package.
- Failing to submit proposal by submission deadline.

II. SUBMISSION PROCESS

Proposal submission is a two-step process consisting of (1) a pre-application submission through the CDMRP eReceipt system (https://cdmrp.org/) and (2) a proposal submission through Grants.gov (http://www.grants.gov/).

Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative proposals.

A. STEP 1 – Pre-Application Submission

Proposal submission will not be accepted unless the pre-application process is completed by the pre-application deadline. The PI and Organization identified in the proposal submitted through Grants.gov should be the same as those identified in the pre-application. If there is a change in PI or organization after submission of the pre-application, the PI must contact the eReceipt help desk at: help@cdmrp.org or 301-682-5507.

Pre-application Components and Submission

All pre-application components must be submitted electronically through the CDMRP eReceipt system by **5:00 p.m. Eastern time on the deadline identified in the specific Program Announcement/Funding Opportunity**. Material submitted after the pre-application submission deadline, unless specifically requested by the Government, will not be forwarded for processing. Failure to meet this deadline shall result in pre-application rejection and subsequent proposal rejection.

The pre-application consists of the components discussed below.

1. **Proposal Information:** Enter the Proposal Information as described in the CDMRP eReceipt system before continuing the pre-application.

2. **Proposal Contacts:** Enter contact information for the PI and Contract Representative (CR). The CR is the organization's business official responsible for sponsored program administration (or equivalent). This is the individual listed as the *person to be contacted on matters involving this application* in Block 5 of the Grants.gov SF-424 form.

3. **Collaborators and Conflicts of Interest (COI):** To avoid COI during the screening and review processes, list the names of all scientific participants in the proposed research project including collaborators, consultants, and subawardees. Add all individuals outside of the proposal who may have a COI in the review of this proposal and choose "COI" from the drop-down list. Inclusion of the Program's Fiscal Year 2008 (FY08) Integration Panel (IP) members in any capacity in the proposal, budget, or supporting documentation, with the exception of References Cited, is considered a COI and will result in administrative withdrawal of the proposal. A list of each of the Program's FY08 IP members may be found at http://cdmrp.army.mil/research

4. Letter of Intent (LOI) Narrative: One-page limit. The LOI Narrative page limit is inclusive of figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons. The narrative should be a brief description of the research to be conducted. LOI Narratives are used for program planning purposes and will not be reviewed during either peer or programmatic review.

5. Formatting Guidelines and Submission: All pre-application documents must be individual PDF files, in accordance with the formatting guidelines and uploaded under the "Required Files" tab of the CDMRP eReceipt system.

6. PI Responsibilities: The PI is responsible for completing the pre-application submission (by completing the "Submit Pre-application" tab) in the CDMRP eReceipt system, and for reviewing the submission to ensure compliance with the program announcement requirements.

7. CR/Authorized Organizational Representative (AOR) Responsibility: The pre-application does not require approval by either the CR or AOR of the organization before submission.

B. STEP 2 – Proposal Components and Submission

Proposal submission will not be accepted unless a pre-application was submitted by the pre-application deadline. Proposals must be submitted electronically by the AOR through Grants.gov (www.grants.gov). No paper copies will be accepted.

Submission of a proposal through Grants.gov has several institutional requirements, which may take several weeks to complete.

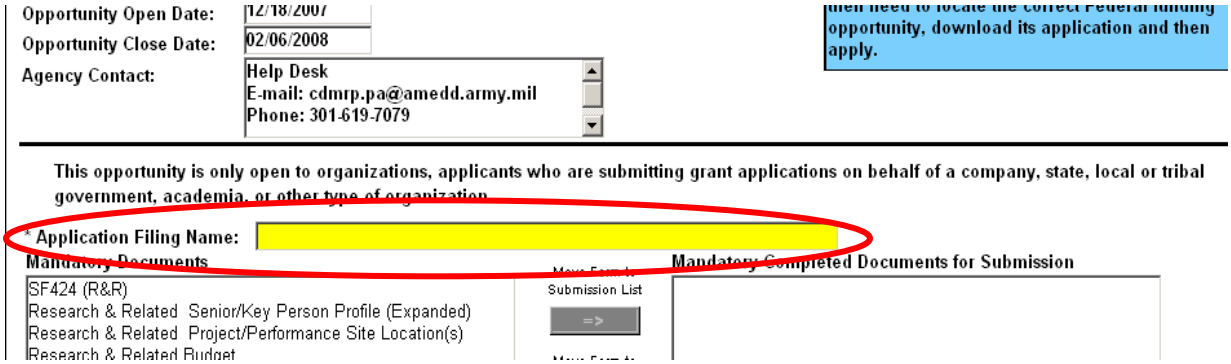
The PI and Organization identified in the proposal submitted through Grants.gov should be the same as those identified in the pre-application. If there is a change after submission of the pre-application, please contact the eReceipt help desk at help@cdmrp.org or 301-682-5507.

Please note that Grants.gov may take at least 48-72 hours to process proposal submissions and to notify the applicant institution of any errors. Submit applications as early as possible to allow sufficient time for error correction and resubmission as a "Changed/Corrected Application" prior to the deadline. Grants.gov may allow submission of proposals after the deadline and may send a message that the application is being processed. However, in this case, notification will be sent at a later date stating that the proposal was not submitted on time and will not be accepted by Grants.gov.

Proposal Components and Submission

Each proposal submission requires the completion of a Grants.gov application package of forms and attachments identified in Grants.gov (www.grants.gov) for the specific funding opportunity.

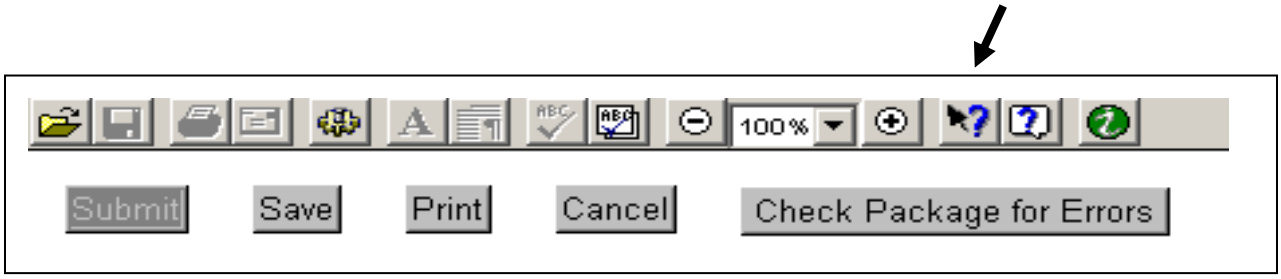
First, fill in the **Application Filing Name** on the first screen of the Grant Application Package using the **CDMRP log number** acquired during the pre-application process. *Do not fill in the Competition ID.*



The following table lists the forms required for this Grants.gov application package. Several documents must be attached to the application forms. Requirements for each attachment are described below and in the specific Program Announcement/Funding Opportunity.

Form	Attachment	Action
SF-424 (R&R) Application for Federal Assistance Form	None	Enter the appropriate information in data fields
Attachments Form	Clinical Protocol	Upload as Attachment 1 (Protocol.pdf)
	Supporting Documentation	Upload as Attachment 2 (Support.pdf)
	Technical and Public Abstracts	Upload as Attachment 3 (Abstracts.pdf)
	Statement of Work (SOW)	Upload as Attachment 4 (SOW.pdf)
	Impact Statement	Upload as Attachment 5 (Impact.pdf)
	Federal Agency Financial Plan (if applicable)	Upload as Attachment 6 (FedFin.pdf)
Research & Related Senior/Key Person Profile (Expanded)	PI Biographical Sketch	Attach to PI Biographical Sketch field (Biosketch_LastName.pdf)
	PI Current/Pending Support	Attach to PI Current & Pending Support field (Support_LastName.pdf)
	Key Personnel Biographical Sketches	Attach to Biographical Sketch field for each senior/key person (Biosketch_LastName.pdf)
	Key Personnel Current/Pending Support	Attach to Current & Pending Support field for each senior/key person (Support_LastName.pdf)
Research & Related Budget Form	Budget Justification for entire performance period	Attach to Section K in budget period one (Justification.pdf)
Research & Related Project/Performance Site Location(s) Form	None	Enter the appropriate information in data fields
R&R Subaward Budget Attachment(s) Form (if applicable)	Individual subaward budgets and justifications	Attach a separate budget with justification for each subaward (Justification_LastName.pdf)

Click on **"**Help Mode" in the Grants.gov PureEdge tool bar and scroll over the blocks for tips on navigating through the forms in the application package.



1. SF-424 (R&R), Application for Federal Assistance Form

This form is required for each application. All appropriate information must be entered into this form to allow for auto-population of all subsequent forms in this application package. The form is self-explanatory, with the following exceptions:

- **Applicant Identifier** box should be filled in with the submitting Institution's Control Number.
- **State Application Identifier** is not applicable.
- **Block 1 – Type of Submission.** For all submissions, the "Application" box should be chosen. For changes that must be made after the original submission, the complete application package must be resubmitted, with the "Changed/Corrected Application" box checked and the Grants.gov tracking number entered in Block 4 - Federal Identifier.
- **Block 3 – Date Received by State** is not applicable.
- **Block 4 – Federal Identifier Box.** Populated by Grants.gov for an original application. If "Changed/Corrected Application" is entered in Block 1, then manually enter the Grants.gov tracking number (i.e., the Federal Identifier Number assigned to the original application).
- **Block 5 – Applicant Information.** This is the information for the Applicant Organization, not an individual. The "Person to be contacted on matters involving this application" is the CR or Business Official. This is not the Project Director/Principal Investigator (PD/PI).
- **Block 6 – Employer Identification.** Enter the EIN (Employer Identification Number) or TIN (Tax Identification Number) as assigned by the Internal Revenue Service. If applying from a foreign institution, enter 44-4444444.
- **Block 7 – Type of Applicant.** This is for the Applicant Organization, not an individual. This is not the PD or PI.
- **Block 8 – Type of Application.** For all submissions, the "New" box must be chosen.
- **Block 9 – Name of Federal Agency.** Populated by Grants.gov.
- **Block 10 – Catalog of Federal Domestic Assistance Number.** Populated by Grants.gov.

- **Block 11 – Descriptive Title of Applicant's Project**. Enter a brief descriptive title of the project.
- **Block 12 – Areas Affected by Project**. List the largest political entities affected by the project (e.g., state, county, city). Enter N/A for not applicable.
- **Block 13 – Proposed Project.** The start date should be 9 months to a year from the deadline for proposal submission for this award mechanism.
- **Block 14 – Congressional Districts Of.** If applying from a foreign institution, enter "00-000" for both applicant and project.
- **Block 15 – Project Director/Principal Investigator Contact Information.** Enter information for the individual (PI) responsible for the overall scientific and technical direction of this application.
- **Block 16 – Estimated Project Funding**. Enter the total funds (direct + indirect costs) requested for the entire performance period of the project.
- **Block 17 – Is Application Subject to Review by State Executive Order 12372 Process?** Choose option "b. NO, program is not covered by E.O.12372."
- **Block 18 – Complete Certification.** Check "I agree" box to provide the required certifications and assurances**.**
- **Block 19 – Authorized Representative.** The AOR is the individual with the organizational authority to sign for an application. The "signature of AOR" is not an actual signature and is automatically completed upon submission of the electronic application package. **Paper copies of applications will not be accepted.**
- **Block 20 – Pre-application.** Do not attach any documents to this block.

Each attachment to the Grants.gov application forms must be a single PDF file in accordance with the formatting guidelines.

All proposals must comply with the compliance guidelines. Failure to meet compliance guidelines may result in proposal rejection.

2. Attachments Form

The following information must be included as attachments to this form:

Attachment 1: Clinical Protocol: Named "Protocol.pdf". The Clinical Protocol is the main body of the proposal. The Clinical Protocol must be submitted as a single PDF file. ***Refer to the Program Announcement/Funding Opportunity for specific information regarding page limits, peer review criteria and Appendix 8 for required content of the Clinical Protocol.***

Attachment 2: Supporting Documentation: Single PDF file named "Support.pdf". Submitting material that was not requested may be construed as an attempt to gain a competitive advantage and such material will be removed. Submitting such material may be grounds for administrative rejection of the proposal. ***The Supporting Documentation attachment is not intended for additional figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, cartoons, or other information needed to judge the proposal.***

a. References Cited: No page limit. List all relevant references using a standard reference format that includes the full citation (i.e., author(s), year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate). The inclusion of Internet URLs to references is encouraged.

b. Acronyms and Symbol Definitions: No page limit. Starting on a new page titled "Acronyms and Symbol Definitions," provide a glossary of acronyms and symbols.

c. Facilities & Other Resources: No page limit. Describe the facilities available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the USAMRMC. Indicate if Government-owned facility or equipment is proposed for use. Reference should be made to the original or present contract under which the facilities or equipment items are now accountable. There is no form for this information.

d. Description of Existing Equipment: No page limit. Include a description of existing equipment available to be used for the proposed research project.

e. Publications and/or Patent Abstracts: ***NEW FOR FY08:*** Include up to five relevant publication URLs and/or patent abstracts. If publications are not publicly available, documents must be scanned at the lowest resolution (100 to 150 DPI). Extra items will not be reviewed.

f. Letters of Institutional Support: Two-page limit per letter. Provide a letter(s) of institutional support, signed by the Department Chair or appropriate institutional official, that reflects the laboratory space, equipment, and other resources available for this project.

g. Letters of Collaboration (if applicable): Two-page limit per letter. Provide a signed letter from each collaborating individual or institution that will demonstrate that the PI has the resources necessary for the proposed work.

h. Intellectual and Material Property Plan (if applicable): No page limit. Provide a plan for resolving intellectual and material property issues among participating institutions.

Attachment 3: Technical and Public Abstracts: Single PDF file named "Abstracts.pdf". Abstracts of all funded proposals will be posted on the CDMRP website at http://cdmrp.army.mil. Proprietary or confidential information should ***not*** be included in either the technical or the public abstract.

Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed in either abstract.

Technical Abstract: One-page limit. Use the outline below.

- Background: Present the ideas and reasoning behind the proposed work.
- Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- Specific Aims: State the specific aims of the study.
- Study Design: Briefly describe the study design including appropriate controls.
- Impact: Summarize briefly how the proposed project will have an impact on prostate cancer research or patient care.

Public Abstract: One-page limit. Start on a new page. The public abstract is an important component of the proposal review process because it addresses issues of particular interest to the consumer advocate community.

- Clearly describe, in a manner readily understood by laypersons, the rationale and objective for the proposal.
  - Do not duplicate the technical abstract.
- Describe the ultimate applicability of the research.
  - What types of patients will it help and how will it help them?
  - What are the potential clinical applications, benefits, and risks?
  - What is the projected time it may take to achieve a patient-related outcome?
- What are the likely contributions of this study to advancing the field of research?

Attachment 4: Statement of Work (SOW): Two-page limit. Named "SOW.pdf". The SOW is a concise restatement of the research proposal that outlines, step by step, how each major goal or objective of the proposed research/services will be accomplished during the period for which the USAMRMC will provide financial support. When a proposal requesting funding as part of a larger study is submitted, the proposal's SOW must include aims to be funded by this proposal. The SOW should:

- Describe the work to be accomplished as tasks (tasks may relate to specific aims);
- Include the following information for each study site/subcontract site (collaborative site and consultant) that will be actively participating in the study:
  - Institution name

- Institution address
- Collaborator, consultant, and/or subawardee name
- Human studies at this site

- Identify the timeline and milestones for the work over the period of performance for the proposed effort;
  - Allow at least 6 months for regulatory review and approval processes for studies involving human subjects.
- Note the number of research subjects and/or anatomical samples required for each task;
- Identify methods; and
- Identify outcomes, products, and deliverables for each phase of the project.

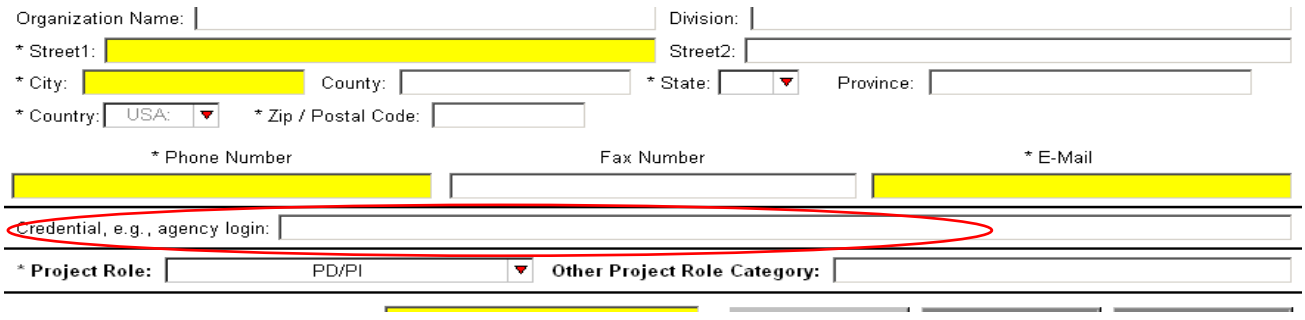
Attachment 5: Impact Statement: One-page limit. Named "Impact.pdf". Refer to the Program Announcement/Funding Opportunity for specific instructions regarding content of the Impact Statement. The Impact Statement will be available for both peer and programmatic review.

Attachment 6: Federal Agency Financial Plan (if applicable). No page limit. Named "FedFin.pdf". Proposals from Federal agencies **must** provide a plan delineating how all funds will be obligated by September 30, 2009, and how funds will be available to cover research costs over the entire award period. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, such as through agreements with foundations, non-Federal institutions, and universities.

3. Research & Related Senior/Key Person Profile (Expanded)

Include the requested information for each person who will contribute significantly to the proposed project.

NEW FOR FY08: In the **"**PROFILE – Project Director/Principal Investigator" section of this form, enter the PI's User Name provided from the CDMRP eReceipt system into the data field labeled "Credential, e.g., agency login".



a. PI Biographical Sketch: Four-page limit. Suggested format is provided in Appendix 10. Name the PDF file as "Biosketch_LastName.pdf" where "LastName" is the name of the PI.

b. PI Current/Pending Support: No page limit. This file must be named "Support_LastName.pdf" where "LastName" is the last name of the PI.

Proposals submitted under this program announcement should not duplicate other funded research projects.

For all existing and pending research projects include:

- Title
- Time commitments
- Supporting agency
- Name and address of the Funding Agency's Procuring Contracting/Grants Officer
- Performance period
- Level of funding
- Brief description of the project's goals
- List of the specific aims

Provide justification for the requested support and identify where the projects overlap or parallel. If no current support exists, enter "None." Updated current and pending support will be required during award negotiations.

c. Key Personnel Biographical Sketches: Four-page limit per individual. Suggested format is provided in Appendix 10. Each biographical sketch must be saved as "Biosketch_LastName.pdf" where "LastName" is the last name of the appropriate individual.

d. Key Personnel Current/Pending Support: No page limit. Current/Pending Support for each individual must be submitted. Name each file as "Support_LastName.pdf" where "LastName" is the last name for the individual. Refer to content requirements under "PI Current/Pending Support" listed above.

4. Research & Related Budget Form

An estimate of the total research project cost, with a breakdown by category and year, must accompany each proposal. Refer to the Program Announcement/Funding Opportunity for limits on funding and period of performance.

The program does not allow for renewal of grants or supplementation of existing grants. Projects requiring lower levels of funding may also be submitted. The maximum funding amount may be requested for less than the maximum period of performance if addressed adequately in the Budget Justification.

All costs must be entered in US dollars. Recipients performing research outside of the United States should include the cost in local currency, the rate used for converting to US dollars, and justification/basis for the conversion rate used.

The following cost regulations and principles must be adhered to regarding budget calculations:

- **Subcontracting Indirect Costs:** When an applicant institution calculates its own indirect costs, it can only calculate indirect costs on the first $25,000 of each subaward.
- **Maximum Obligation:** The USAMRMC does not amend grants to provide additional funds for such purposes as reimbursement for unrecovered indirect costs resulting from the establishment of final negotiated rates or for increases in salaries, fringe benefits, and other costs.
- **Cost Regulations and Principles:** Costs proposed must conform to the regulations and principles:
  - **Commercial Firms:** Federal Acquisition Regulation (FAR) Part 31 and Defense FAR Supplement Part 31, Contract Cost Principles and Procedures (http://farsite.hill.af.mil).
  - **Educational Institutions:** 2 CFR Part 220, Cost Principles for Educational Institutions (http://www.gpoaccess.gov/cfr/index.html).
  - **Nonprofit Organizations:** 2 CFR Part 230, Cost Principles for Nonprofit Organizations (http://www.gpoaccess.gov/cfr/index.html). OMB Circular A-133, Audits of States, Local Governments, and Nonprofit Organizations (http://www.whitehouse.gov/OMB/circulars/index.html).
  - **State, Local, and Tribal Governments:** 2 CFR Part 225, Cost Principles for State, Local, and Indian Tribal Governments (http://www.gpoaccess.gov/cfr/index.html).
  - **Cost of Preparing Proposals:** The cost of preparing proposals in response to this Program Announcement/Funding Opportunity is not considered an allowable direct charge to any resultant contract, grant, or cooperative agreement. It is, however, an allowable expense to the bid and proposal indirect cost specified in FAR 31.205-18, and 2 CFR Parts 220 and 230.

Section A & B – Senior/Key Person and Other Personnel: The basis for labor costs should be predicated upon actual labor rates or salaries. Budget estimates may be adjusted upward to forecast salary or wage cost-of-living increases that will occur during the period of performance. The proposal should separately identify and explain the ratio applied to base salary/wage for cost-of-living adjustments and merit increases in the budget justification (Section K).

Qualifications of the PI and other professional personnel and the amount of time that they will devote to the research are important factors in selecting proposals for funding. For all personnel identified on the budget form, list the percentage of each appointment to be dedicated to this project.

Section C – Equipment Description: It is DOD policy that all commercial and nonprofit recipients provide the equipment needed to support proposed research. In those rare cases where specific additional equipment is approved for commercial and nonprofit organizations, such approved cost elements will be separately negotiated.

An itemized list of proposed permanent equipment is required, showing the cost for each item. Permanent equipment is any article of nonexpendable tangible property having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit. The justification for the cost of each item of equipment included in the budget must be disclosed in the budget justification (Section K) to include:

- Vendor Quote: Show name of vendor and number of quotes received and justification if intended award is to other than the lowest bidder.
- Historical Cost: Identify vendor, date of purchase, and whether or not cost represented the lowest bid. Include reason(s) for not soliciting current quotes.
- Estimate: Include rationale for estimate and reasons for not soliciting current quotes.
- Special test equipment to be fabricated by the contractor for specific research purposes and its cost.
- Standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs; list separately.
- Existing equipment to be modified to meet specific research requirements, including modification costs. Do not include as special test equipment those items of equipment that, if purchased by the contractor with contractor funds, would be capitalized for Federal income tax purposes.
- Title of equipment or other tangible property purchased with Government funds may be vested in institutions of higher education or with nonprofit organizations whose primary purpose is the conduct of scientific research. Normally, the title will vest in the recipient if vesting will facilitate scientific research performed by the institution or organization for the Government.
- Commercial organizations are expected to possess the necessary plant and equipment to conduct the proposed research. Equipment purchases for commercial organizations will be supported only in exceptional circumstances.

Section D – Travel

- Travel costs to attend one scientific/technical meeting. Costs should not exceed $3,600 total per year.
- **Travel costs associated with the execution of the proposed work.** If applicable, reasonable costs for travel between collaborating institutions should be included and are not subject to the yearly $3,600 limitation on travel to meetings. Justification for these travel costs should be provided. Travel outside the United States, including between foreign countries, requires prior approval from the US Army Medical Research Acquisition Activity 30 days before travel unless identified in the proposal that is part of the award.

- **Travel to CDMRP-required meetings** (if applicable). Costs should be reasonable.

Section E – Participant/Trainee Support Costs: This section is self-explanatory.

Section F – Other Direct Costs (as applicable)

Section F.1 – Materials and Supplies (Consumables): The justification (to be included in Section K) supporting material and supply (consumable) costs should include a general description of expendable equipment and supplies. If animals are to be purchased, state the species, strain (if applicable), and the number to be used. If human cell lines are to be purchased, state the source and the description.

Section F.2 – Publication Costs: This section is self-explanatory.

Section F.3 – Consultant Services: Regardless of whether funds are requested, the justification (to be included in Section K) should include the names and organizational affiliations of all consultants. State the daily consultant fee, travel expenses, nature of the consulting effort, and why consultants are required for the proposed research project.

Section F.4 – ADP/Computer Services: This section is self-explanatory.

Section F.5 – Subaward/Consortium/Contractual Costs: On the project's Research and Related Budget Form, enter the total funds requested for (1) all subaward/consortium organization(s) proposed for the project and (2) any other contractual costs proposed for the project.

Section F.6 – Equipment or Facility Rental/User Fees: This section is self-explanatory.

Section F.7 – Alterations and Renovations: Not allowable.

Sections F.8–F.10 – Additional Direct Costs (if applicable):

a. Research-Related Subject Costs: Include itemized costs of subject participation in the research study. These costs are strictly limited to expenses specifically associated with the proposed study. The USAMRMC will not provide funds for ongoing medical care costs that are not related to a subject's participation in the research study.

b. Miscellaneous costs: Include other anticipated direct costs that are not specified elsewhere in the budget. Unusual or expensive items should be fully explained and justified in Section K.

Section G – Direct Costs: This section is self-explanatory. All direct and indirect costs of any subaward must be included in the total direct costs of the primary award.

Section H – Indirect Costs (overhead, general and administrative, and other): The most recent rates, dates of negotiation, base(s), and periods to which the rates apply should be disclosed, along with a statement identifying whether the proposed rates are provisional or

fixed. When an applicant institution calculates its own indirect costs, it can only calculate indirect costs on the first $25,000 of each subaward.

If negotiated forecast rates do not exist, provide sufficient detail in the budget justification (Section K) regarding a determination that the costs included in the forecast rate are allocable according to applicable FAR/DFARS or CFR provisions. Commercial firms can also visit www.dcaa.mil for additional information on indirect rates. Disclosure should be sufficient to permit a full understanding of the content of the rate(s) and how it was established. As a minimum, justification for indirect costs should identify: (1) all individual cost elements included in each forecast rate; (2) the basis used to prorate indirect expenses to cost pools, if any; (3) how each rate was calculated; and (4) the distribution basis of each developed rate.

Section I – Total Direct and Indirect Costs: This section is self-explanatory.

Section J – Fee: A profit or fixed fee is not allowable on grants or cooperative agreements.

Section K – Budget Justification: The Budget Justification for the entire performance period must be attached as a PDF file named "Justification.pdf" to the Research & Related Budget – Section K (under budget period one). Organizations must provide sufficient detail and justification so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research effort.

NOTE: While the budget justification must include information for all budget periods, this file must be uploaded for budget period one before access will be granted for subsequent budget periods.

5. Research & Related Project/Performance Site Location(s) Form

Indicate the primary site where the work will be performed. If a portion of the work will be performed at any other site(s), include the name and address for each collaborating location in the data fields provided. If more than eight performance site locations are proposed, provide the requested information in a separate file and attach to this form. Please note that each additional research site requesting funds will require a subcontract budget.

6. R&R Subaward Budget Attachment(s) Form (optional form; use if applicable)

Files attached to the R&R Subaward Budget Attachment(s) Form must be PureEdge documents. Extract an R&R Subaward Budget Attachment for each subaward, using the button provided on this form. Save each attachment to a computer and complete the form(s).

The Budget Justification for each subaward must be attached as a PDF file named "Justification_LastName.pdf" where "LastName" is the investigator of the subaward to the Research & Related Budget – Section K for that subaward. Each subaward budget justification must include information for all budget periods. This file must be uploaded for budget period one before access will be granted for subsequent budget periods for the subaward. Once all subaward budget files are completed, attach all subaward budget file(s) for this application to the R&R Subaward Budget Attachment(s) Form.

The DUNS number for each subaward site should be included on this form.

A description of services or materials that are to be awarded by subcontract or subgrant is required. Organizations must provide sufficient detail and justification so that the Government can determine the proposed costs to be allocable and reasonable for the proposed research effort. The following information must be provided on subawards totaling $10,000 or more:

- Identification of the type of award to be used (e.g., cost reimbursement, fixed price);
- Identification of the proposed subcontractor or subgrantee, if known, and an explanation of why and how the subcontractor or subgrantee was selected or will be selected;
- Whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition; and
- The proposed acquisition price.
- The applicant's cost or price analysis for the subgrant or subcontract proposed price (applicable only if the award exceeds $500,000).

If the resultant award is a contract that exceeds $550,000 and the applicant is a large business or an educational institution (other than a Historically Black College or University/Minority Institution), the applicant is required to submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.7 http://farsite.hill.af.mil. A mutually agreeable plan will be incorporated as part of the resultant contract.

APPENDIX 1

Eligibility Information

To protect the public interest, the Federal Government ensures the integrity of Federal programs by only conducting business with responsible recipients. The US Army Medical Research and Materiel Command (USAMRMC) uses the Excluded Parties List System (EPLS) to exclude recipients ineligible to receive Federal awards. The EPLS is online at http://epls.arnet.gov. (Reference Department of Defense Grant and Agreement Regulations [DODGAR] 25.110.)

Individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution and meet the specific Program Announcement/Funding Opportunity requirements.

Eligible Institutions: USAMRMC makes awards to institutions; eligible institutions include for-profit, nonprofit, public, and private organizations, such as universities, colleges, hospitals, laboratories, and companies.

Historically Black Colleges and Universities/Minority Institutions (HBCU/MI): A Department of Defense goal is to allocate funds for the Congressionally Directed Medical Research Programs (CDMRP) peer reviewed research to fund proposals from HBCU/MI. This provision is based on guidance from Executive Orders 12876, 12900, and 13021. Proposals are assigned HBCU/MI status when the submitting institution is so designated by the Department of Education on the date the program announcement is released. The most current Department of Education list is posted on the CDMRP website at http://cdmrp.army.mil/spp under "Minority Institutions."

Government Agencies: Local, state, and Federal Government agencies are eligible to the extent that proposals do not overlap with their fully funded intramural programs. Federal agencies are expected to explain how their proposals do not overlap with their intramural programs.

Duplicate Submissions: Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative proposals.

APPENDIX 2

Formatting Guidelines

The proposal must be clear and legible and conform to the formatting guidelines described below. The font size, spacing, page size, and margins may differ between the word processing, PDF, and printed versions. These guidelines apply to the document properties of the electronic version of the PDF file(s) as viewed on a computer screen.

- **Document Format:** All attachments must be in PDF.
- **Font Size:** 12 point or larger.
- **Font Type:** Times New Roman is strongly recommended.
- **Spacing:** No more than six lines of type within a vertical inch (2.54 cm).
- **Page Size:** No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
- **Margins:** Must be at least 0.5 inch (1.27 cm) in all directions.
- **Print Area:** 7.5 inches x 10.0 inches (19.05 cm x 25.40 cm).
- **Color, High-Resolution, and Multimedia Objects:** Project narratives may include color, high-resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these objects must not exceed 15 seconds in length and a size of 10 MB. Since some reviewers work from black and white printed copies, PIs may wish to include text directing the reviewer to the electronic file for parts of the proposal that may be difficult to interpret when printed in black and white. Photographs and illustrations must be submitted in JPEG format; bit map or TIFF formats are not allowed.
- **Scanning Resolution:** 100 to 150 dots per inch.
- **Internet URLs:** URLs directing reviewers to websites containing additional information about the proposed research are not allowed in the proposal or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. Links to publications referenced in the proposal are encouraged.
- **Language:** English.
- **Headers and Footers:** Should not be used.
- **Page Numbering:** Should not be used.
- **Recommended Attachment Size:** Each attachment should not exceed 20 MB.

All attachments that require signatures must be filled out, printed, signed, scanned, and then uploaded as a PDF file.

APPENDIX 3

Compliance Guidelines

Compliance guidelines have been designed to ensure the presentation of all pre-applications and proposals in an organized and easy-to-follow manner. Peer reviewers expect to see a consistent, prescribed format. Failure to adhere to formatting guidelines makes documents difficult to read, may be perceived as an attempt to gain an unfair competitive advantage, and may result in preapplication or proposal rejection. **Pre-applications or proposals missing required components as specified in the Program Announcement/Funding Opportunity may be administratively rejected.**

The following will result in administrative rejection of the entire proposal:

- Clinical Protocol is missing.
- Margins are less than specified in the formatting guidelines.
- Print area exceeds that specified in the formatting guidelines.
- Spacing is less than specified in the formatting guidelines.
- Budget and/or budget justification are missing.
- Fiscal Year 2008 (FY08) Integration Panel (IP) members are included in any capacity in the pre-application process, the proposal, budgets, and any supporting document. A list of the FY08 IP members may be found at http://cdmrp.army.mil/research

For any other sections of the pre-application or proposal with a defined page limit, pages exceeding the specified limit will be removed and not forwarded for peer review.

Material submitted after the submission deadline, unless specifically requested by the Government, will not be forwarded for peer review.

Proposals that appear to include plagiarized information will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to perform the investigation and provide those findings to the Grants Officer for a determination of the final disposition of the application.

APPENDIX 4

Grants.gov Instructions

A. Public Law 106-107

Proposals requesting funding from the Congressionally Directed Medical Research Programs (CDMRP) will be submitted through the Federal Government's single entry portal, Grants.gov, in compliance with Public Law 106-107 (P.L. 106-107). The Federal Financial Assistance Management Improvement Act of 1999, also known as P.L. 106-107, was enacted in November 1999. The purposes of the P.L. 106-107 are to (1) improve the effectiveness and performance of Federal financial assistance programs, (2) simplify Federal financial assistance application and reporting requirements, (3) improve the delivery of services to the public, and (4) facilitate greater coordination among those responsible for delivering services.

Individual program announcements and required forms can also be found on this website. As in previous years, award mechanisms requiring pre-applications including Letter of Intent Narratives, preproposals, nominations, and/or confidential letters will be submitted through the CDMRP eReceipt system at https://cdmrp.org.

B. Grants.gov

Grants.gov is an E-Government initiative to provide a simple, unified electronic storefront for interactions between Principal Investigators (PIs) and the Federal agencies that manage grant funds. The grant community, including state, local, and tribal governments, academia and research institutions, commercial firms and not-for-profits, can access the annual grant funds available across the Federal Government through one website, Grants.gov. In addition to simplifying the grant application process, Grants.gov also creates avenues for consolidation and best practices within each grant-making agency.

In compliance with P.L. 106-107, the US Army Medical Research and Materiel Command requires proposals submitted in response to the program announcements to be submitted through Grants.gov. This requires that organizations register in Grants.gov to submit proposals through the Grants.gov portal. Individual PIs DO NOT register; however, the Authorized Organizational Representative (AOR) is required to register.

The following actions are required as part of the registration process. **The registration process can take several weeks, so please register as soon as possible.** If the PI's organization conducts business with the Federal Government on a continuing basis, it is likely that some of the actions have already been completed, e.g., obtaining a DUNS number or registration in CCR. Detailed information, automated tools, and checklists are available at http://www.grants.gov/applicants/get_registered.jsp

1. Applicant Organization Must Have a Data Universal Number System (DUNS) Number

An organization will need a DUNS number. A DUNS number is a unique nine-character identification number provided by the commercial company Dun & Bradstreet (http://fedgov.dnb.com/webform/displayHomePage.do). If an organization does not have a DUNS number, an authorized official of the organization can request one by calling 866-705-5711 or online via web registration (http://fedgov.dnb.com/webform/index.jsp). Organizations located outside of the United States can request and register for a DUNS number online via web registration.

2. Applicant Organization Must Be Registered with the Central Contractor Registry (CCR)

An organization must be registered with CCR before submitting a grant application through Grants.gov or receiving an award from the Federal Government. CCR validates institution information and electronically shares the secure and encrypted data with Federal agencies' finance offices to facilitate paperless payments through electronic funds transfer. **CCR registrations have an expiration – PIs should verify their organization's CCR registration well in advance of the proposal submission deadline.**

Register by calling the CCR Assistance Center at 888-227-2423 or register online at http://www.ccr.gov. Collecting the information (Employer Identification Number [EIN] or Tax Identification Number [TIN]) can take 1-3 days. With the necessary information in place, online registration will take about 30 minutes to complete, depending upon the size and complexity of the organization. Allow a minimum of 5 business days to complete the entire CCR registration. If the organization does not have either an EIN or TIN, allow at least 2 weeks to obtain the information from the Internal Revenue Service.

Foreign organizations must obtain a CAGE code prior to registering with the CCR. A CAGE code can be obtained by calling 269-961-7766 or online at http://www.dlis.dla.mil/Forms/Form_AC135.asp.

3. Authorized Organizational Representative (AOR) Must Be Registered with Grants.gov

Before submitting a proposal, an organization representative needs to register to submit on behalf of the organization at Grants.gov - https://apply.grants.gov/OrcRegister. An organization's E-Business point of contact (POC), identified during CCR registration, must authorize someone to become an AOR. This safeguards the organization from individuals who may attempt to submit proposals without permission. The AOR's username and password serve as "electronic signatures" when an application is submitted on Grants.gov. **Note: In some organizations, a person may serve as both an E-Business POC and an AOR.**

An AOR must first register with the Grants.gov credential provider at https://apply.grants.gov/OrcRegister to obtain a username and password. The AOR must then register with Grants.gov for an account at https://apply.grants.gov/GrantsgovRegister. Once an AOR has completed the Grants.gov process, Grants.gov will notify the E-Business POC for assignment of user privileges. When an E-Business POC approves an AOR, Grants.gov will send the AOR a confirmation email.

APPENDIX 5

Administrative Information

A. Administrative Requirements

Awards are made to organizations, not individuals. Thus, a Principal Investigator (PI) must submit a proposal through, and be employed by, an organization to receive support. An organization must meet certain minimum standards pertaining to institutional support, financial resources, record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations (2 CFR Part 215 and Department of Defense [DOD] Grant and Agreement Regulations) to be eligible for an award.

Unless restricted by the specific Program Announcement/Funding Opportunity, a change in institutional affiliation will require the PI to resubmit the entire proposal packet through his or her new institution to include any regulatory documentation that may require protocols, etc., to be approved for the new institution. The PI's original institution must agree to relinquish the award. Any delay in the submission of the new information will result in a delay in contracting and regulatory review and a subsequent delay in resuming work on the project. Unless restricted, changes in PI will be made at the discretion of the Grants Officer, provided that the intent of the award mechanism is met.

B. Disclosure of Proprietary Information Included in a Proposal

Proprietary information submitted in a proposal may be disclosed outside the Government for the sole purpose of technical evaluation. The US Army Medical Research and Materiel Command (USAMRMC) will obtain a written agreement from the evaluator that proprietary information in the proposal will only be used for evaluation purposes and will not be further disclosed or used. Funded proposals may be subject to public release under the Freedom of Information Act; proposals that are not selected for funding are not subject to public release.

C. Award Notices

Each PI will receive notification of the award status of his or her proposal. A copy of the peer review summary statement, if applicable, will be posted to the Congressionally Directed Medical Research Programs (CDMRP) eReceipt system. PIs can expect to receive this notification approximately 4 weeks after programmatic review.

D. Inquiry Review Panel

PIs may submit a letter of inquiry to the US Army Medical Research Acquisition Activity (USAMRAA) in response to funding decisions. Members of the CDMRP staff, the USAMRMC Judge Advocate General staff, and USAMRAA Grants Officers constitute an Inquiry Review Panel. They review each inquiry to determine whether factual or procedural errors in either peer or programmatic review have occurred, and if so, what action should be taken.

E. Award Negotiation

Prior to award negotiations, the Certificate of Environmental Compliance, Principal Investigator Safety Program Assurance, regulatory documents related to human and animal studies, and other documents, Appendix 6, will be requested from the PI. Also at that time, the negotiated indirect rate agreement, Certifications and Assurances for Assistance Agreements, and Representations for Assistance Agreements will be requested from the Contracting Representative or AOR at the organization.

Award negotiation consists of discussions, reviews, and justifications of critical issues involving the USAMRAA. A Contract Specialist and/or representative from the USAMRAA will contact the Contract Representative authorized to negotiate contracts and grants at the PI's institution. Additional documentation and justifications related to the budget may also be required.

Only an appointed Contracting/Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government to fund preparation of a proposal or to support research should be inferred from discussions with a technical project officer. PIs who, or organizations that, make financial or other commitments for a research effort in the absence of an actual legal obligation signed by the USAMRAA Contracting/Grants Officer do so at their own risk.

The USAMRMC implements its extramural research program predominantly through the award of grants and cooperative agreements. Awards will be made approximately 4 to 6 months after receiving the funding notification letter, but no later than September 30, 2009. The award start date will be determined during the negotiation process.

The Government requires reports, Appendix 7, to be submitted by each PI for continuation of the research and funding.

F. Clinical Trial Registry

PIs are required to register clinical trials individually on www.clinicaltrials.gov using a Secondary Protocol ID number designation of: CDMRP-CDMRP Log Number. If several protocols exist under the same proposal, the Secondary Protocol ID number must be: CDMRP-CDMRP Log Number-A, B, C, etc. Clinical trials must be registered prior to enrollment of the first patient. All trials that meet the definition on the National Institutes of Health database (see http://prsinfo.clinicaltrials.gov/, click on "Data Element Definitions") are required to register. Failure to do so may result in a civil monetary penalty and/or the withholding or recovery of grant funds as per the US Public Law 110-85.

G. Title to Inventions and Patents

In accordance with the Bayh-Dole Act (Title 35, United States Code, Sections 200 et seq.), title to inventions and patents resulting from such Federally funded research may be held by the grantee or its collaborator, but the US Government shall, at a minimum, retain nonexclusive rights for the use of such inventions. Instructions in the assistance agreement concerning license agreements and patents must be followed.

H. J-1 Visa Waiver

It is the responsibility of the organization to ensure that the research staff is able to complete the work without intercession by the DOD for a J-1 Visa Waiver on behalf of a foreign national in the United States under a J-1 Visa.

APPENDIX 6

Instructions for Regulatory Requirements

Principal Investigators (PIs) may not use, employ, or subcontract for the use of any human subjects, including the use of human anatomical substances and/or human data, or laboratory animals until applicable regulatory documents are requested, reviewed, and approved by the US Army Medical Research and Materiel Command (USAMRMC) to ensure that Department of Defense (DOD) regulations are met.

Concurrent with the US Army Medical Research Acquisition Activity (USAMRAA) negotiation, the Office of Surety, Safety and Environment will review the Certificate of Environmental Compliance and the Principal Investigator Safety Program Assurance form to be submitted upon request.

A. Certificate of Environmental Compliance

The Certificate of Environmental Compliance will be requested prior to award negotiations. If multiple research sites/institutions are funded in the proposal, then a Certificate of Environmental Compliance for each site will also be requested.

B. Safety Program Documents

The Principal Investigator Safety Program Assurance form will be requested prior to award negotiations.

A Facility Safety Plan from each PI's Institution is required; it will be requested at award negotiations. A Facility Safety Plan from the PI's institution may have been received previously and approved by the USAMRMC. A list of institutions that have approved Facility Safety Plans can be found on the USAMRMC website at https://mrmc.amedd.army.mil/docs/rcq/sohd/Facility_Safety_Plan_Approved_Institutions.pdf . If the PI's institution is not listed on the website, contact the institution's Facility Safety Director/Manager to initiate completion of the institution-based Facility Safety Plan. Specific requirements for the Facility Safety Plan can be found at https://mrmc.amedd.army.mil/docs/rcq/FY02FSPAppendix.pdf.

If multiple research sites/institutions are funded in the proposal, a Facility Safety Plan for each site/institution not listed in the aforementioned website will be requested at a later date.

C. Research Involving Animal Use

Specific documents relating to the use of animals in the proposed research will be requested by the Congressionally Directed Medical Research Programs (CDMRP) if the proposal is selected for funding (these documents should not be submitted with the proposal). The Animal Care and Use Review Office (ACURO), a component of the USAMRMC Office of Research Protections (formerly Regulatory Compliance and Quality), must review and approve all animal use prior to the start of working with animals. PIs must complete and submit the animal use appendix titled

"ACURO Animal Use Appendix for Research Involving Animals," which can be found on the ACURO website https://mrmc.amedd.army.mil/docs/rcq/ACUROAnimalAppendix.doc). Allow 2 to 4 months for regulatory review and approval processes for animal studies.

Specific requirements for research involving animals can be found at https://mrmc.amedd.army.mil/rodorpaurd.asp.

D. Research Involving Human Subjects or Biological Substances Including the Use of Human Anatomical Substances and/or Human Data

For all other studies, documents related to the use of human subjects, anatomical substances, and/or data will be requested by the CDMRP if the proposal is selected for funding (these documents should not be submitted with the proposal).

During the regulatory review process for research involving human subjects, the recommendations of the second tier Human Research Protection Office (HRPO) must be considered by the local institutional review board (IRB). It is strongly recommended that PIs carefully read the "Guidelines for Investigators" found at https://mrmc.amedd.army.mil/docs/rcq/GuidelinesforInvestigators.pdf (specifically pages 28-47 for protocol and consent guidance) as well as consulting Appendix 8 of this Application Instructions document. The time to approval depends greatly on adherence to these guidelines in a **clear** and **comprehensive** manner. If the protocol has not been submitted to the local IRB at the time of award negotiation, these guidelines should be considered before submission. An initial review by the HRPO before local IRB approval will be considered on a case-by-case basis.

Allow at least 6 months for regulatory review and approval processes for studies involving human subjects.

The following are reporting requirements and resposibilities of the PI to the USAMRMC's Office of Research Protections, HRPO and should be reflected in the protocol:

1. Requirements: Personnel involved in human subjects research must have appropriate training in the protection of human subjects. Documentation confirming that this training has been completed will be required during the regulatory review process.

Additional information pertaining to the human subjects regulatory review process, guidelines for developing protocols, and suggested language for specific issues can be found at: https://mrmc.amedd.army.mil/rodorphrpo.asp.

2. Informed Consent Form: Elements to include in the informed consent form can be found at https://mrmc.amedd.army.mil/docs/rcq/GuidelinesForInvestigators.doc#p41SecF and an informed consent form template is located at https://mrmc.amedd.army.mil/docs/rcq/consentform_template.pdf.

3. Intent to Benefit: PIs must consider the requirements of Title 10 United States Code Section 980 (10 USC 980; http://www.dtic.mil/biosys/downloads/title10.pdf) applicable to DOD-sponsored research before writing a research protocol. 10 USC 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."

Furthermore and consistent with the Common Federal Policy for the Protection of Human Subjects, if an individual cannot give his or her own consent to participate in a research study, consent of the individual's legally authorized representative must be obtained before the individual's participation in the research. Moreover, an individual not legally competent to consent (e.g., incapacitated individuals, incompetents, minors) may not be enrolled in a DOD-supported experiment unless the research is intended to benefit each subject enrolled in the study. For example, a subject may benefit directly from medical treatment or surveillance beyond the standard of care. PIs should be aware that this law makes placebo-controlled clinical trials problematic because of the "intent to benefit" requirement whenever participation is sought of subjects from whom consent must be obtained by the legally authorized representative.

4. Conditions Regarding DOD Funding of Research on Human Embryonic Stem Cells: Research involving the derivation and use of human embryonic germ cells from fetal tissue may be conducted with DOD support ***only*** when the research is in compliance with 45 CFR 46, Subpart B (Title 45 of the Code of Federal Regulations, Section 46, Subpart B); 42 USC 289g through 289g 2; US Food and Drug Administration regulations; and any other applicable Federal, state, and local laws and regulations.

Research on existing human embryonic stem (hES) cell lines may be conducted with Federal support through the DOD ***only*** if the cell lines meet the current US Federal criteria as listed on the following National Institutes of Health (NIH) website (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html). A list of the currently approved cell lines can be obtained from the NIH Human Embryonic Stem Cell Registry (http://stemcells.nih.gov/research/registry). The NIH code should be used to identify the cell lines in the proposal.

Research involving the derivation of new stem cells from human embryos or the use of hES cells that are not listed on the NIH Human Embryonic Stem Cell Registry may not be conducted with Federal support through the DOD.

This restriction applies to hES cells derived from blastocysts remaining after infertility treatments and donated for research, blastocysts produced from donated gametes (oocytes and sperm) for research purposes, and the products of nuclear transfer. The research is subject to all applicable local, state, and Federal regulatory requirements.

APPENDIX 7

Instructions for Reports

The Government requires reports to be submitted by each Principal Investigator (PI) for continuation of the research and funding. The specific reports due to the Government will be described in each assistance agreement. Report requirements can be found at https://mrmc-www.army.mil, under "Links and Resources". **Failure to submit required reports by the required date may result in a delay in or termination of award funding.**

Report requirements include the following:

1. Research Progress Reports. Reporting requirements consist of an annual report (for each year of research except the final year) that presents a detailed summary of scientific issues and accomplishments and a final report (submitted in the last year of the award period) that details the findings and issues for the entire project. Additional reports may be required as stipulated during award negotiations. Copies of all scientific publications and patent applications resulting from Congressionally Directed Medical Research Programs funding should be included in the progress report. The Government reserves the right to request additional reports.

2. Fiscal Reports. Quarterly fiscal report requirements may include the Standard Form Report, SF 272, Federal Cash Transaction, used for grants and cooperative agreements to track the expenditure of funds on the research project.

3. Non-Exempt Human Studies Reports. For non-exempt human subjects research, documentation of local Institutional Review Board (IRB) continuing review (in the intervals specified by the local IRB, but at least annually) and approval for continuation must be submitted directly to the Office of Research Protections – Human Research Protection Office.

4. Animal Use Reports. PIs are required to submit annual animal use information for a report to Congress, verification of annual protocol review, and notification of protocol suspension or revocation. Institutions are required to provide updated US Department of Agriculture reports and notification of changes to accreditation status as verified by the Association for Assessment and Accreditation of Laboratory Animals and Office of Laboratory Animal Welfare.

APPENDIX 8

Clinical Protocol and Supporting Clinical Documentation

A. Required Elements of the Protocol

Please note that the protocol should address the following elements:

- Trial design
- Intervention, drug or device to be tested
- Feasibility of the study
- Statistical plan
- Personnel involved in the study
- Ethics and/or regulatory issues

Protocol elements:

1. **Protocol Title.**

2. **Phase.** Designate the phase of the trial (i.e., Phase 0, I, II, or III).

3. **Principal Investigator (PI)/Study Staff.** List the complete name, address, telephone and fax number, and email address of the PI. List the names of all key study personnel who will have significant involvement in the study; include their professional credentials (e.g., M.D. or R.N.), highest degree(s), job title, and employing institution.

4. **Study Location(s).** List all centers, clinics, or laboratories where the study is to be conducted. Provide the Federal-wide or Department of Defense (DOD) Assurance number for each institution engaged in study. Include the name, degree(s), title, employing institution, and complete address of the PI(s) for each study site.

5. **Time Required to Complete the Study.** State the month and year of the expected start and completion times.

6. **Background. Suggested Limit: 10 pages.** Include a literature review that describes in detail the rationale for conduct of the study. Include descriptions of any preliminary studies and findings that led to the development of the protocol. The background section should clearly support the choice of study variables and explain the basis for the study questions and/or study hypotheses. This section establishes the relevance of the study and explains the applicability of its findings.

Note: If the protocol was initiated using other funding prior to obtaining the DOD funding, explain the history and evolution of the protocol and declare the source of prior funding. Specifically identify the portions of the study that will be supported with DOD funds. For ongoing protocols, Human Research Protections Office (HRPO) approval is

required prior to initiation of any human subjects research activities supported by the US Army Medical Research and Materiel Command (USAMRMC).

7. Objectives/Specific Aims/Study Questions. Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/hypotheses.

8. Study Design. Describe the type of study to be performed (e.g., prospective, retrospective, randomized, controlled, etc.) and outline the proposed methodology in sufficient detail to show a clear course of action.

- Define the study variables and describe how they will be measured.
- Describe the methods that will be used to obtain a sample of volunteers from the accessible population (i.e., convenience, simple random, stratified random).
- If applicable, describe the subject to group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures).
- Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
- Describe the reliability and validity of psychometric measures, if applicable.

9. Study Population. Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site (population from which the sample will be recruited/drawn). Further, discuss past efforts in recruiting volunteers from the target population for previous clinical trials (if applicable), any potential barriers to accrual, such as a change in the target population demographics, a change in medical practices, or competing clinical trials; and plans for addressing unanticipated delays (e.g., slow accrual). Volunteer selection should be equitable. The protocol should include justification of any age, race, ethnicity, or sex limitations provided.

10. Inclusion/Exclusion Criteria. List the inclusion and exclusion criteria in the protocol. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted. Ensure that exclusions are justified. Clearly state the exclusion criteria for volunteers with disease, taking medications, or from certain groups.

Inclusion of Women and Minorities in Study. Consistent with the Belmont Report and recent congressional legislation, special attention is given to inclusion of women and minorities in studies funded or supported 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 from the protocol, an appropriate justification must be included.

11. Description of the Recruitment Process. Explain methods for identification of potential volunteers (e.g., medical record review, obtaining sampling lists, health care provider identification, etc.).

Describe the recruitment process ***in detail***. Address who will identify potential volunteers, who will recruit them, and what methods will be used to recruit them.

If volunteers will be compensated for participation in the study, a detailed description of the compensation plan should be included in the protocol. Ensure that the compensation plan is fair and does not provide undue inducement. If the study requires multiple visits, a plan for pro-rating payments in the event of volunteer withdrawal should be considered.

Provide copies of all recruitment and advertisement materials for review as part of the submission. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study. An ombudsman should be considered for use with particularly vulnerable populations.

12. Sample Size Justification. A complete power analysis must be included in the protocol to ensure that the sample size is appropriate to meet the objectives of the study. The protocol should specify the approximate number of volunteers that will be enrolled. If the protocol involves multiple sites, the number enrolled at each site should be stated in the master protocol.

13. Description of the Informed Consent Process. Specifically describe the plan for obtaining informed consent from volunteers.

- Identify who is responsible for explaining the study, answering questions, and obtaining informed consent.
- Include information regarding the timing and location of the consent process.
- If applicable, address issues relevant to the mental capacity of the potential volunteer (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or volunteer age).
- Address how privacy and time for decision making will be provided and whether or not the potential volunteer will be allowed to discuss the study with anyone before making a decision.
- As consent is an ongoing process, consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.
- If volunteers will be included in the study that cannot give their own consent to participate, there must be a plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the volunteer's participation in the study. State law defines who may act as the LAR. The institutional review board (IRB) of record should be consulted for guidance regarding who can serve as LAR for research at the study site.
- If illiterate volunteers are anticipated, the consent process to be followed for illiterate volunteers should be outlined in the protocol. The consent form should be verbally read/explained to the volunteer in the presence of a witness. The volunteers must sign or make a mark (such as a thumbprint) to indicate agreement to participate, and

the witness must sign to attest that the content of the written consent form was accurately conveyed to the volunteer.

- If it is anticipated that volunteers that do not speak the primary language of the host country will be enrolled in a trial, all documentation provided to volunteers (consent form, information sheets, etc.) should be translated with a copy provided to the HRPO for review at a later date. A plan for ensuring that volunteers' questions will be addressed during the consent process and throughout the trial should be included.

  NOTE: When consent will be obtained in a language other than English, documentation that the foreign language version of the consent form is an accurate translation of the English version of the consent form must be provided to the HRPO at a later date. Documentation from a qualified translator certifying the translation must be provided along with the English and foreign language version of the consent forms. The documentation of translation should include the following statement: "I certify that this is an accurate and true translation." The signature, name, address, phone number, and, if available, fax number of the translator should also be included.

- If a waiver of all or parts of the consent process is being sought, or a waiver of documentation of consent is desired, justification of why the waiver should be considered to include how the protocol meets the criteria set forth in 32 CFR 219 (Title 32 of the Code of Federal Register, Section 219) should be included in the protocol. If consent to use existing samples or data in a future study was provided as part of another study protocol, this should be clearly explained. If the institution is a covered entity, justification for Health Insurance Portability and Accountability Act (HIPAA) waiver requests should also be provided.

Assent. When minors are included in a study, a plan to obtain assent (agreement) from those with capacity to provide it or a justification for a waiver of assent should be provided. Age-appropriate assent forms should be developed for use with minors when assent is obtained. Capacity to provide assent should also be considered for other populations that cannot provide informed consent, and assent should be obtained whenever possible.

14. Volunteer Screening Procedures. List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. Please note that some screening procedures may require a separate consent or a two-stage consent process. Informed consent must be obtained prior to initiation of any procedures for the purpose of determining eligibility.

15. Study Procedures/Study Interventions. Describe the study intervention or activity that the volunteer will experience. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the volunteer will experience and when it will occur. Provide a schedule of study evaluations and follow-up procedures. Provide all case report forms, data collection forms, questionnaires, rating scales, and interview guides, etc., that will be used in the study.

16. Description of Protocol Drugs or Devices. If the protocol uses a drug, biologic, device, or dietary supplement, provide the following information:

- For medical products regulated by the Food, Drug, and Cosmetic Act, designate the protocol as Phase 0, I, II, or III research.
- If the study is in support of an application to the Food and Drug Administration (FDA), provide the Investigational New Drug/Investigational Device Exemption (IND/IDE) number and name of the sponsor.
- Provide complete names and composition of all medications, devices, or placebos.
- Identify the source of medications, devices, or placebos.
- Describe the location of storage for study medications.
- Describe the dose range, schedule, and administration route of test articles.
- Describe the washout period, if used, in detail.
- Describe the duration of drug or device treatment.
- Declare concomitant medications allowed.
- Identify any antidotes and treatments available for potential side-effects.
- Describe the plan for disposition of unused drug.
- For FDA-regulated studies, describe the procedure by which the IND sponsor will monitor the protocol in accordance with 21 CFR 312.

17. Laboratory Evaluations.

- **Specimens to be collected, schedule, and amount.** All specimens that will be collected for study purposes must be clearly stated in the protocol. The collection schedule and amount of material collected must also be clearly described. This may be represented using a table or schematic for more involved protocols.
- **Evaluations to be made.** All evaluations that will be made for study purposes should be stated in the protocol. Copies of all data collection forms must be provided. The protocol should explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of volunteers).
- **Storage.** Specimen storage must be described in the protocol, to include where, how long, any special conditions required, labeling, and disposition. If there is a plan to store specimens for future use (either by the PI or through an established repository) this should be outlined in the protocol. If samples will be collected for future use in other study (and if this is not the sole purpose of the protocol), volunteers should be given the chance to opt out. Potential future uses of samples should be addressed to the degree possible. If volunteers are given a menu of options regarding sample donation for future research, procedures should be in place to ensure that volunteers' wishes for use of the samples are honored. Procedures for withdrawal of samples at the request of the volunteer should be described if samples will remain coded or identified.

- **Labs performing evaluations and special precautions.** The laboratory performing each evaluation should be clearly identified in the protocol, as well as any special precautions that should be taken in handling the samples. Special precautions that should be taken by the volunteer before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, provisions for ensuring proper storage during transport should be included in the protocol.

18. Data Analysis. Describe the data analysis plan. The data analysis plan should be consistent with the study objectives.

19. Data Management.

- **Methods used for data collection.** All methods used for data collection should be described in the protocol. Copies of data collection forms and any test instruments administered should be provided. Data collection forms should be adequate and accurate according to the data collection plan described in the protocol. Whenever possible, identifiers should be removed from data collection forms. Critical measurements used as endpoints should be identified.
- **Volunteer identification.** If unique identifiers or a specific code system will be used to identify volunteers, this process should be described in the protocol.
- **Confidentiality.**
    - The protocol should explain measures taken to protect the privacy of study volunteers and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed. PIs collecting particularly sensitive information should consider obtaining a Certificate of Confidentiality.
    - The protocol should address who will have access to study records, data, and specimens. The protocol should acknowledge that representatives of USAMRMC are eligible to review study records.
    - Requirements for reporting sensitive information to state or local authorities should be addressed in the protocol. Examples of sensitive information that may require reporting include positive HIV (human immunodeficiency virus), hepatitis, or tuberculosis test results, illegal residency, child or spouse abuse, or participation in other illegal activities. These requirements will vary from state to state. PIs should consult his or her IRB for assistance with state requirements.
- **Disposition of data.** Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, and the length of time data will be stored. Note that records of IND studies must be kept until 2 years after a New Drug Application is approved/issued or for 2 years after the IND is withdrawn. Records required for IDE studies should be retained for 2 years following the date that the investigation is terminated or completed or the date that the records are no longer required for support of the pre-market approval application, whichever is sooner.

- **Sharing study results.** In cases where the volunteer could possibly benefit medically or otherwise from the information, the protocol should explain whether or not the results of screening and/or study participation will be shared with volunteers or their primary care provider, to include results from any screening or diagnostic tests performed as part of the study. The potential benefits of providing volunteers with the information should be weighed against the potential risks. It is generally not advisable to use experimental assays or techniques to guide clinical care.

20. Risks/Benefits Assessment.

- **Foreseeable risks.** The protocol should clearly identify all study risks. Study risks include any risks that the volunteer is subjected to as a result of participation in the protocol. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated in the protocol. If applicable, any potential risk to the study personnel should be identified.
- **Risk management and emergency response.**
    - The protocol should clearly list all measures to be taken to minimize and/or eliminate risks to volunteers and study personnel or to manage unpreventable risks. All safety measures in place to mitigate risk (e.g., core temperature monitoring, electrocardiogram monitoring, observation periods, special procedures to avoid disclosure of potentially damaging information) should be described.
    - Planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values, and other safeguards should be detailed in the protocol.
    - If there is a chance a volunteer may require emergency care or treatment for an adverse event, the protocol should discuss the overall plan for provision of care for study-related injuries, to include who will be responsible for the cost of such care. For example, if a study sponsor or institution has committed to providing care for study-related injury at no cost to volunteers, this provision should be explained in the protocol. The clinical site must have adequate personnel and equipment to respond to expected adverse events, and the nearest medical treatment facility should be identified in the emergency response plan.
    - Any special precautions to be taken by the volunteers before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention, etc.) must be addressed. If pregnant volunteers will be excluded from participation in the study, the method used to determine pregnancy status in women of childbearing potential must be specified. Also, the time that will elapse between the pregnancy test and exposure to study procedures or medical products must be stated, as well as how long the non-pregnant volunteer should use effective contraceptive practices after participating in the study. Please note that contraceptive practices may be necessary for male volunteers participating in certain types of studies. For IND studies, pregnancy testing is recommended within 48-72 hours before the start of the study. Consideration should be given to repeating testing prior to administration of test articles.

- Any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for volunteers enrolled in the study must be described in the protocol.

- **Potential benefits.** Describe real and potential benefits of the study to the volunteer, a specific community, or society. Ensure that the benefits are not overstated.

  NOTE: Payment and/or other compensation for participation are not considered to be benefits and must be addressed in a separate section.

- **Intent to benefit.** If volunteers cannot give their own consent to participate in an experimental study, and Title 10 United States Code Section 980 (10 USC 980) (http://www.dtic.mil/biosys/downloads/title10.pdf) applies, a clear intent to benefit each volunteer must be described in the protocol.

21. Study Personnel.

- **Roles and responsibilities of key study personnel.** Briefly describe the duties of key study personnel. Describe their roles in the study effort. A study coordinator is required at an appropriate level of effort whose duties may include the following: recruit and consent volunteers, maintain study records, administer study drug, take and record vital signs, enter data into computer database. A key person must be identified who will be responsible for guiding the protocol through the IRB, HRPO and other regulatory approval processes, coordinating activities from all sites participating in the trial and coordinating participant accrual.

- **Conflicts of interest.** PIs and key study staff must disclose any real or apparent conflicts of interest (financial or other). This information may be provided in the protocol or by submission of a conflict of interest declaration form. (Many institutions have a form for this purpose, as does the FDA. A Financial Disclosure Form for PIs is also available on the HRPO website at https://mrmc-www.army.mil/rodorphrpo.asp that will meet this requirement). Measures taken to mitigate the impact of conflicts of interest must be provided. Information regarding conflicts of interest should be disclosed to volunteers in the consent form. All protocols that support development of a drug, device, or other intellectual property require completion of a conflict of interest declaration by all investigators on the protocol. Other protocols may require conflict of interest statements on a case by case basis.

22. Roles and Responsibilities of Medical Monitor. The DOD requires that a medical monitor be assigned to greater than minimal risk protocols. The specific roles the medical monitor will fulfill should be outlined in the protocol.

NOTE: The HRPO requires that the medical monitor review all unanticipated problems involving risk to volunteers or others, serious adverse events, and all volunteer deaths associated with the protocol and provide an unbiased written report of the event within 10 calendar days. At a minimum, the medical monitor should comment on the outcomes of the adverse event and relationship of the event to the protocol or test article. The medical monitor should also indicate whether he/she concurs with the details of the report provided

by the PI. Reports for events determined by either the PI or medical monitor to be possibly or definitely related to participation and reports of events resulting in death should be promptly forwarded to the HRPO.

23. Study Organization and Management Plan. Provide an organizational chart and a timetable for completion for the clinical trial and publication. Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). Provide a plan for real-time communication among collaborating institutions (if applicable).

24. Withdrawal from the Protocol. Volunteers may discontinue participation in the study at any time without penalty or loss of benefits to which the volunteer is otherwise entitled. If appropriate, the protocol should describe the procedure in place to support an orderly end of the volunteer's participation (e.g., exit exam or follow-up safety visits outside of the context of the research study, information regarding prorated payment for partial participation, etc.) and the consequences of a volunteer's decision to withdraw from the study. The anticipated circumstances under which the volunteer's participation may be terminated by the PI or others should also be addressed (e.g., noncompliance, safety issues, loss of funding, etc.).

25. Modifications to the Protocol. Describe the procedures to be followed if the protocol is to be modified, amended, or terminated before completion. Note that any modification to the protocol, consent form, and/or questionnaires, including a change to the PI, must be submitted to the local IRB for review and approval. Major modifications to the study protocol and any modifications that could increase risk to volunteers must be submitted to the HRPO for approval ***prior to implementation***. Some examples of major modifications include a change in PI, addition of a study site, changes in study design, and addition or widening of a study population. All other amendments will be submitted with the continuing review report to the HRPO for acceptance. Address the procedure for submitting amendments even if modifications to the protocol are not anticipated.

Protocol Deviations. Describe procedures and notifications to be made in the event of deviations from the approved protocol to include both the local IRB and the HRPO.

Note: Any deviation to the protocol that may have an effect on the safety or rights of the volunteer or the integrity of the study must be promptly reported to the HRPO.

26. Reporting of Serious Adverse Events and Unanticipated Problems.

- Reporting procedures will differ from institution to institution, so it is important for PIs to identify the reporting requirements for all entities involved in review of the protocol and to clearly define this procedure within the protocol.
- Serious adverse events and unanticipated problems can occur in any and all types of studies, not just experimental interventions or clinical trials.
- Include a definition of what constitutes an adverse event in the study. For IND or IDE studies include definitions as described in 21 CFR 312.32 and the ICH (International Conference on Harmonization) E2A Guidelines (http://www.ich.org/cache/compo/475-272-1.html).

- Describe agencies or offices to be notified with point of contact information in the event of an unanticipated problem or serious adverse event.
- All protocols should contain the following language regarding the HRPO reporting requirements for adverse events and unanticipated problems:

  "Unanticipated problems involving risk to volunteers or others, serious adverse events related to participation in the study, and all volunteer deaths related to participation in the study should be promptly reported by phone (301-619-2165), by email (hsrrb@amedd.army.mil), or by facsimile (301-619-7803) to the US Army Medical Research and Materiel Command's Office of Research Protections, Human Research Protections Office. A complete written report should follow the initial notification. In addition to the methods above, the complete report can be sent to the US Army Medical Research and Materiel Command, ATTN: MCMR-ZB-P, 504 Scott Street, Fort Detrick, Maryland 21702-5012."

For protocols that have a medical monitor assigned, the following language should also be included.

"The medical monitor is required to review all unanticipated problems involving risk to volunteers or others, serious adverse events, and all volunteer deaths associated with the protocol and provide an unbiased written report of the event to the USAMRMC Office of Research Protections (ORP) Human Research Protections Office (HRPO). At a minimum, the medical monitor should comment on the outcomes of the event or problem and in the case of a serious adverse event or death comment on the relationship to participation in the study. The medical monitor should also indicate whether he/she concurs with the details of the report provided by the PI. Reports for events determined by either the PI or medical monitor to be possibly or definitely related to participation and reports of events resulting in death should be promptly forwarded to the HRPO."

27. Continuing Review and Final Report. The protocol should acknowledge that a copy of the approved continuing review report and the local IRB approval notification will be submitted to the HRPO as soon as these documents become available. A copy of the approved final study report and local IRB approval notification will be submitted to the HRPO as soon as these documents become available.

B. Surveys, Questionnaires, and Other Data Collection Instruments

If the study involves surveys, questionnaires, case report forms, data collection forms, rating scales, interview guides, or other instruments, include a copy of the most recent version of each of these documents with the protocol submission.

For each instrument that is used, the following information at a minimum should be addressed.

1. Information collected with study instrument must be related to the objectives of the study. Procedures for use of study instruments should be clear in the protocol. Study instruments should be coded to protect confidentiality whenever possible.

2. For study instruments provided to and/or completed by volunteers, the study instrument should be legible and presented at a reading level appropriate to the population. Copies of instruments submitted for review must also be legible.

C. Advertisements, Posters, and Press Releases to Recruit Volunteers

If volunteers will be recruited through an advertisement, newspaper article, or similar process, a copy of the advertisement must be provided for review and approval by the HRPO. Any "Dear Doctor" letters that will be used to aid in recruitment must also be provided for review. For studies involving investigational drugs or devices, the FDA has established guidelines on advertisements for volunteers. General guidance includes name and address of PI, summary of study purpose, brief eligibility criteria, accurate list of benefits, and the person to contact for further information.

Some important considerations for recruitment materials include:

1. Recruitment materials should not promise a cure or benefit beyond what is mentioned in the protocol or consent form.

2. If the volunteers will be paid, the amount of payment should not be presented in bold type, larger than other text, or otherwise overemphasized.

3. Recruitment materials should not promise "free medical treatment" when treatment is not the true intent of the study.

D. Additional Protocol Language Requirements

The following are reporting requirements and responsibilities of the Principal Investigator to the United States Army Medical Research and Materiel Command's (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO) and should be reflected in the protocol:

1. The protocol will be conducted in accordance with the protocol submitted to and approved by the USAMRMC ORP HRPO and will not be initiated until written notification of approval of the research project is issued by the USAMRMC ORP HRPO.

2. Accurate and complete study records will be maintained and made available to representatives of the U.S. Army Medical Research and Materiel Command as a part of their responsibility to protect human subjects in research. Research records will be stored in a confidential manner so as to protect the confidentiality of subject information.

3. The knowledge of any pending compliance inspection/visit by the FDA, OHRP, or other government agency concerning clinical investigation or research, the issuance of Inspection Reports, FDA Form 483, warning letters or actions taken by any Regulatory Agencies including legal or medical actions and any instances of serious or continuing noncompliance with the regulations or requirements will be reported immediately to USAMRMC ORP HRPO.

APPENDIX 9

Acronym List

ACURO .....Animal Care and Use Office
ADP .....Automated Data Processing
AOR .....Authorized Organizational Representative
ARP .....Autism Research Program
AVI .....Audio Video Interleave
BCRP .....Breast Cancer Research Program
CCR .....Central Contractor Registration
CDMRP .....Congressionally Directed Medical Research Programs
CFDA .....Catalog of Federal Domestic Assistance
CFR .....Code of Federal Regulations
cGMP .....Current Good Manufacturing Practices
CAGE .....Commercial and Government Entity
COI .....Conflicts of Interest
CR .....Contract Representative
DFARS .....Department of Defense Federal Acquisition Regulation Supplement
DOD .....Department of Defense
DODGAR .....Department of Defense Grant and Agreement Regulations
DPI .....Dots per inch
DUNS .....Data Universal Number System
EIN .....Employer Identification Number
EPLS .....Excluded Parties List System
FAR .....Federal Acquisition Regulation
FDA .....Food and Drug Administration
FY .....Fiscal Year
GCP .....Good Clinical Practice
GLP .....Good Laboratory Practice
GWVIRP .....Gulf War Veterans' Illnesses Research Program
HBCU/MI .....Historically Black Colleges and Universities/Minority Institutions
HIPAA .....Health Insurance Portability and Accountability Act
hES .....Human Embryonic Stem
HRPO .....Human Research Protection Office
HSRRB .....Human Subjects Research Review Board
IDE .....Investigational Device Exemption
IND .....Investigational New Drug
IP .....Integration Panel
IRB .....Institutional Review Board
JPEG .....Joint Photographic Experts Group
LAR .....Legally Authorized Representative
LOI .....Letter of Intent
M .....Million
MB .....Megabyte
MPEG .....Moving Picture Experts Group

NIH .....National Institutes of Health
NFRP .....Neurofibromatosis Research Program
OCRP .....Ovarian Cancer Research Program
OMB .....Office of Management and Budget
ORP .....Office of Research Protections
PCRP .....Prostate Cancer Research Program
PD .....Project Director
PDF .....Portable Document Format
PI .....Principal Investigator
P.L. .....Public Law
POC .....Point of Contact
PRMRP .....Peer Reviewed Medical Research Program
PTSD .....Post-Traumatic Stress Disorder
R&R OPI .....Research & Related Other Project Information
SOW .....Statement of Work
SPORE .....Specialized Programs of Research Excellence
TBI .....Traumatic Brain Injury
TIFF .....Tagged Image File Format
TIN .....Tax Identification Number
TRL .....Technology Readiness Level
TSCRP .....Tuberous Sclerosis Complex Research Program
URL .....Uniform Resource Locator
USAMRAA .....US Army Medical Research Acquisition Activity
USAMRMC .....US Army Medical Research and Materiel Command
USC .....United States Code
WAV .....Waveform Audio

APPENDIX 10

FORMS

Biographical Sketch

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded).			
NAME	POSITION TITLE		
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY

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 also to representative earlier publications 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 4 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED). PAGE LIMITATIONS APPLY. DO NOT EXCEED 4 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.