United
States
Army
Medical
Research and
Materiel
Command

DEPARTMENT OF DEFENSE

BROAD AGENCY ANNOUNCEMENT

GENERAL INFORMATION & PROPOSAL PREPARATION

BAA 10-1

October 2009

FORT DETRICK, MARYLAND

U.S. Army Medical Research and Materiel Command
BAA 10-1

PREFACE

The U.S. Army Medical Research and Materiel Command's (USAMRMC) mission is to provide solutions to medical problems of importance to the American warfighter at home and abroad. The scope of this effort and the priorities attached to specific projects are influenced by changes in military and civilian medical science and technology, operational requirements, military threat assessments, and national defense strategies. The extramural research and development program plays a vital role in the fulfillment of the objectives established by the Command. General information on USAMRMC can be obtained from the USAMRMC website (https://mrmc.detrick.army.mil/).

This Broad Agency Announcement (BAA) is intended to solicit research ideas, and is issued under the provisions of the Competition in Contracting Act of 1984 (Public Law 98-369), as implemented in Federal Acquisition Regulation 6.102(a)(2). This Announcement provides a general description of the Command's research programs, including specific areas of interest; general information; the evaluation and selection criteria; and proposal preparation instructions. **All Attachments that are required with the submission of a full proposal are located under the Full Announcement tab of the Funding Opportunity and are described in the Mandatory Proposal Forms section of the BAA 10-01 General Information and Proposal Preparation document**. **Research proposals are sought from educational institutions, nonprofit organizations, private industry, and domestic and foreign government agencies. This is a continuously open announcement; preproposals may be submitted and will be evaluated at any time throughout the year, unless otherwise noted or stated in a separate announcement.**

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is continuing the process of preparing this BAA for electronic commerce. The BAA will be revised as other electronic processes are developed. Amendments of this brochure will be advertised on the USAMRAA website (www.usamraa.army.mil), at Grants.gov (www.grants.gov), and in Fedbizopps (www.fedbizopps.gov). Many of the programs and areas of interest may not have funding readily available, but the status of funds will be part of the advice elicited from a proposal. From time to time separate announcements or calls for proposals may supplement this BAA. These supplements will be featured on our homepage and announced at www.grants.gov.

Questions concerning the preparation of preproposals or proposals can be emailed to (QA.BAA@amedd.army.mil) or faxed to 301-619-3002, ATTN: BAA 10-1 at USAMRAA or by calling Rebecca Tama at 301-619-2381.

Mail: U.S. Army Medical Research Acquisition Activity
ATTN: BAA 10-1
820 Chandler Street
Fort Detrick, MD 21702-5014

Issues in submitting applications through the Grants.gov portal should be directed to the Grants.gov help desk at 1-800-518-4726 or email support@grants.gov. The Contact Center hours of operation are Monday-Friday, 7 AM to 9 PM Eastern Standard Time.

U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND

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A request for research funding includes the completion and submission of a full proposal with appropriate Attachments.

Representations for Assistance Agreements & Certifications and Assurances for Assistance Agreements are available as Attachments 5 and 6 to BAA 10-1 at www.grants.gov.

Representations & Certifications for Contracts http://orca.bpn.gov

I. GRANTS.GOV

A. PUBLIC LAW 106-107

The Federal Financial Assistance Management Improvement Act of 1999, also known as Public Law 106-107 (P.L. 106-107), was enacted on November 1999. The purposes of the Act 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.

B. GRANTS.GOV

Grants.gov is an E-Government initiative to provide a simple, unified electronic storefront for interactions between grant applicants and the Federal agencies that manage grant funds. The grant community, including commercial firms, educational institutions, nonprofit organizations, and state, local and tribal governments 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, USAMRMC requires proposals submitted in response to the BAA to be submitted through Grants.gov APPLY. This requires that Organizations register in Grants.gov to submit proposals through the Grants.gov portal. Individual Principal Investigators (PI)/Project Directors (PD) DO NOT register; however, the Authorized Organizational Representative (AOR) is required to register. The registration process can take several weeks so please register as soon as possible.

Organizations that submit a preproposal and are subsequently invited to submit a full proposal under the BAA will be directed to submit through Grants.gov APPLY. Early planning with your organization will facilitate this process. Issues in submitting applications through the Grants.gov portal should be directed to the Grants.gov help desk at 1-800-518-4726 or email support@grants.gov.

The following actions are required as part of the registration process. If you do business with the federal government on a continuing basis, it is likely you have already completed some of the actions, 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-digit identification number provided by the commercial company Dun & Bradstreet (D&B) (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/displayHomePage.do). 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 annual expiration – please verify the status of your organization's CCR registration well in advance of the proposal submission deadline.***

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

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 www.dlis.dla.mil/Forms/Form_AC135.asp.

3. Authorized Organizational Representative (AOR) must be registered with Grants.gov

In order to safeguard the security of your electronic information, Grants.gov requires an organization representative to register for a username and password. Your **CCR registration must be complete** and active before you can obtain a username and password. General information, tutorials, and checklists on the registration process are available at the following website: http://www.grants.gov/applicants/get_registered.jsp. 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.

To complete a Grants.gov profile and obtain a username and password, an AOR must first register with the Grants.gov credential provider at the following web address - https://apply07.grants.gov/apply/OrcRegister. After you have created an account with Grants.gov, the E-Business Point of Contact listed on your organization's CCR registration will receive a notification stating that you have registered by email and requesting assignment of user privileges. The AOR will also receive a copy of this email. The E-Business Point of Contact will need to login to Grants.gov at https://apply07.grants.gov/apply/loginhome.jsp and confirm you as an Authorized Organization Representative (AOR). ***Please note: There can be more than one AOR for your organization. However, in some organizations, a person may serve as both an E-Business POC and an AOR.*** When an E-Business POC approves an AOR, Grants.gov will send the AOR a confirmation email.

You will NOT be able to submit applications until the E-Business Point of Contact has completed the authorization of your Grants.gov profile.

II. GENERAL INFORMATION

A. USAMRMC AWARDS

The USAMRMC executes its extramural research program through the award of contracts and assistance agreements (grants and cooperative agreements). **The type of instrument used to reflect the business relationship between the recipient and the Government will be a matter of negotiation prior to award.** USAMRMC's supporting contracting office, USAMRAA, will process proposals selected for funding.

1. **Excluded Parties List**: To protect the public interest, the Federal Government ensures the integrity of Federal programs by only conducting business with responsible recipients. The 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 DODGAR 25.1125).

2. **Administrative Requirements**: A recipient organization should meet certain minimum standards pertaining to institutional support, financial resources, prior record of performance, integrity, organization, experience, operational controls, facilities and conformance with safety and environmental statutes and regulations (OMB Circulars at www.whitehouse.gov/omb).

Investigators are cautioned that awards are made to organizations, not individuals. A principal investigator (PI) must submit a proposal through, and be employed by an organization in order to receive support. (Federally Funded Research and Development Centers are not eligible for awards in accordance with FAR 35.017)**. Should the PI of a funded project leave the recipient institution, both the PI and institution must contact USAMRAA as soon as possible to discuss options for continued support of the research project. Every effort should be made to notify USAMRAA prior to the PI leaving the institution.**

By submitting a proposal and accepting an award, the recipient organization is certifying that the investigators' credentials have been examined and verifying that the investigators are qualified to conduct the proposed study and to use humans or animals as research subjects, if proposed.

3.. **J-1 VISA Waiver**: Organizations located outside of the U.S. may submit in response to the BAA, however, it is the organizations' responsibility 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. **In addition, the Government will not provide funds to support scientists from terrorist countries.** Additional information on J-1 VISA Waivers can be located at the following Department of State web site: travel.state.gov/visa/temp.

4. **Funding**: Funding may be provided incrementally during the life of the award. Under cost-reimbursement type awards, payments are made in response to monthly vouchers or invoices submitted by the awardee. Under grants and cooperative agreements, advance payments are normally made periodically, in accordance with the negotiated payment schedule included in the award document.

5. **Special Programs**: Evaluation and selection of proposals is based upon scientific merit, programmatic relevance, and Congressional intent for awarded funds. Military relevance, collaborative efforts with DOD and/or VA scientists and clinicians, or other

priorities may be evaluation criteria or requirements. Criteria and requirements for submission and evaluation of proposals may differ from those of other USAMRMC solicitation instruments, as well as other requirements stated in this BAA. Such differences will be noted in the specific BAA Supplement or solicitation instrument. For example, these special programs usually specify a submission closing date, and a specific submission process. Other areas where differences may apply are:

a. Submission of Pre-Proposals of one page or longer may be required;

b. Submission of Letters of Intent may be required;

c. Full Proposal submission requirements may be sent to applicant with invitation to submit full proposal;

d. Progress reporting requirements may differ and will be detailed in award document;

e. Points of contact for Principal Investigator (PI) inquiries may be identified;

f. Travel Cost guidelines may differ; and,

g. PI notification of proposal receipt may differ.

You will find detailed information on proposal evaluation and selection in the following section titled Evaluation and Selection.

6. **Titles to Inventions and Patents**: In accordance with the Bayh-Dole Act (Title 35, United States Code, Section 200 et seq.), title to inventions and patents resulting from 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. An investigator must follow the instructions in the assistance agreement or contract concerning license agreements and patents.

7. **Contracted Fundamental Research**: Any awards under this BAA to universities or industry and funded by Basic Research funds (6.1), or to universities for on-campus research and funded by Applied Research funds (6.2), meet the DoD definition of "Contracted Fundamental Research." The results of this research are to be unrestricted to the maximum extent possible. The research shall not be considered fundamental in those rare and exceptional circumstances where the 6.2-funded effort presents a high likelihood of disclosing performance characteristics of military systems or manufacturing technologies that are unique and critical to defense, and where agreement on restrictions have been recorded in the contract or grant.

B. CONFLICT OF INTEREST

There are certain post-employment restrictions on former federal officers and employees as defined in Section 207 of Title 18 United States Code and Federal Acquisition Regulation (FAR), Part 3.104-4(c). If a submitter believes a post-employment restriction or conflict of interest exists, the situation should be discussed with the USAMRMC legal staff (telephone 301-619-2065) prior to expending time and effort in preparation of a proposal.

C. DISCLOSURE OF INFORMATION OUTSIDE THE GOVERNMENT

Proposals will only be disclosed outside of the Government for the sole purpose of technical evaluation. The USAMRMC obtains a written agreement from the evaluators that information in the proposal will only be used for evaluation purposes and will not be further disclosed. Proposals for funded projects will be subject to public release under the Freedom of Information

Act to the extent that they are incorporated into an award document; proposals that are not selected for funding will not be subject to public release.

D. GOVERNMENT OBLIGATION

Only a warranted Contracting/Grants Officer may obligate the Government to the expenditure of funds for awards under this BAA. The Government does not fund preparation of proposals or support research that is inferred from discussions with technical project officers.

E. INFORMATION SERVICE

Submitters may use the technical reference facilities of the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 telephone: 703-605-6000 (www.ntis.gov) to acquire information of existing research to avoid duplication of scientific and engineering effort.

F. CONFERENCE OR SYMPOSIUM SUPPORT

The USAMRMC may provide financial support (if funds are available) for conferences or symposia that benefit the Command's research program. The BAA Instructions for submitting a conference or symposium proposal can be found at www.usamraa.army.mil under the BAA link. The BAA Conference or Symposium Support electronic form can be found at www.usamraa.army.mil/pages/BAA_Forms/User/login.cfm. All conference or symposium proposals will be assigned a proposal log number and an e-mail or postcard will acknowledge receipt of a proposal. Usually, the PI should receive a decision letter or e-mail regarding the proposal within 60 - 90 days of submission.

G. PREPROPOSALS

Organizations are strongly encouraged to explore USAMRMC interest by submitting a preliminary research proposal (preproposal). Preproposals may be submitted at any time describing a specific idea or project that pertains to any of the research areas of interest outlined in the BAA. Brochures or other descriptions of general organizational or individual capabilities will not be accepted as a preproposal. The Preproposal electronic form is located at www.usamraa.army.mil/pages/BAA_Forms/User/login.cfm. All preproposals will be assigned a proposal log number and an e-mail or postcard will acknowledge receipt of a preproposal. Usually, the PI should receive a decision letter or e-mail regarding the preproposal within 60 - 90 days of submission. **PLEASE NOTE: Individuals requesting to speak to USAMRMC personnel about whether there is interest in a specific research idea will be directed to submit a preproposal.**

H. FULL PROPOSALS

Full Proposals should be submitted within 90 days after being requested. Receipt of full proposals will be acknowledged by e-mail or postcard. The proposal log number for the full proposal will be the same number used for the preproposal (if one was submitted).
The forms identified in www.grants.gov for the USAMRMC BAA Funding Opportunity must be completed and included as part of the submission for a full proposal. Full proposals may be submitted without protocols for human and animal use. However, protocols with required institutional approvals must be submitted not later than 60 days after award to demonstrate continued progress and ensure continuation of payment. The contracting office may make exceptions in situations where human and/or animal use are not expected to begin until after the first year of the research project. In such cases, a time frame for submission of the appropriate protocols should be established during discussions/negotiations, prior to award

PIs and partnering organizations may not use, employ, or subcontract for the use of any human participants, including the use of human anatomical substances and/or human data, or laboratory animals until applicable regulatory documents are requested, reviewed, and approved by USAMRMC to ensure that DoD regulations are met.

There are no specified funding limitations identified for the proposals submitted under the USAMRMC BAA. The budget should be commensurate with the nature and complexity of the proposed research. Generally, research proposals are awarded for three years, and in no case should the period of performance exceed five years. An award decision should be forwarded by the Government within 180 days after submission.

III. EVALUATION AND SELECTION

A. EVALUATION FACTORS

The USAMRMC scientists or outside experts will evaluate preproposals for scientific merit and programmatic/military relevance. PIs whose preproposals meet preliminary qualifications may be invited to submit full proposals. Full proposals will be evaluated using a two-tier review process.

USAMRMC scientists and/or outside experts will conduct the first tier, peer review. Peer reviewers evaluate proposals and assign scores based on the following factors (in descending order of importance):

1. Military and Program Relevance: Military-relevant research must be responsive to the health care needs of the Armed Forces, family members of the Armed Forces, and the U.S. Veteran population. Proposals must address a military-relevant health problem responsive to one of the areas of interest outlined in the BAA.

2. Research Objectives: The stated objectives must be clear, valid, and logical. Research projects that demonstrate an innovative approach are desired.

3. Scientific Excellence: The proposed plans, methods, techniques and procedures must be feasible, clear, valid, adequately referenced, and state-of-the-art. Literature searches are recommended for documenting the strengths of the proposed project.

4. Impact/Outcomes: Explain how the results of this research are expected to impact the intended beneficiaries. Expound upon the dual (military and commercial) purpose for the research, as appropriate.

5. PI and Key Personnel Qualifications: Document the qualifications, capabilities, and experience of the proposed PI and other key personnel in sufficient details to demonstrate that the proposed staff has the knowledge and skills to achieve the proposed objectives as well as the time available for the percentage of effort indicated for the project.

6. Facilities: Describe the proposed facilities and equipment, or unique combinations of these, in detail to demonstrate that the organization has the necessary facilities required for the accomplishing the proposed objectives.

7. Budget: The budget must reflect the actual needs of the proposed work and be fully justified so that the Government can evaluate and determine the cost to be fair and reasonable and commensurate with the complexity and nature of the research proposed.

8. Commercialization Strategy: Describe the commercialization plan. Commercialization plan must include: Intellectual Property, Market Size, Financial Analysis, Strengths and Weaknesses, Barriers to Market, Competitors and Management Team.

The second tier of the review, the programmatic review, may be conducted by USAMRMC scientists, other Federal Agency Representatives, outside scientists with diverse expertise, clinicians, consumers, or combinations thereof. The programmatic review is primarily concerned with three criteria: peer review recommendations, programmatic priorities, and portfolio balance. Other programmatic priorities that may be considered include:

1. Congressional guidance
2. Military mission, relevance, health, medicine, beneficiaries
3. DoD Priorities
4. VA Priorities
5. Collaborations with federal researchers

B. SELECTION

After the two-tiered evaluation, proposals recommended for funding may be prioritized. A prioritized listing of alternates may also be prepared when warranted. Subsequent awards depend upon the availability of funds and fulfillment of requirements and priorities determined to exist at the time of award. In some cases, funding priorities may change as certain scientific tasks are addressed and new mission assignments arise. Award is also dependent upon demonstration by the applicant that they have adequately addressed the following requirements:

1. Research involving Human Subjects/Anatomical Substances (if proposed),
2. Research involving Animals (if proposed),
3. Facility Safety Plan (FSP),
4. Certificate of Environmental Compliance, and
5. Representations for Assistance Agreements & Certifications and Assurances for Assistance Agreements or Representations & Certification for a Contract, as appropriate.

IV. AWARD ADMINISTRATION

A. INFORMATION RELEASE

Award recipients are required to agree to the release of information pertaining to the research and development supported by the USAMRMC. Statement 1 shall be included in all such releases; Statements 2-5 shall be included if relevant to the research being conducted:

1. "This work was supported by the US Army Medical Research and Materiel Command under Award No. _____. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army."

2. In conducting research using humans and/or human anatomical substances, the investigator is required to include approvals, documents and information specified on the Human Research Protection Office (HRPO) website:
https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo

3. "In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture." Include required assurances, approvals, documents and information specified on the Animal Care and Use Review Office (ACURO) website
https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.acuro_AnimalAppendix.

4. "In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving recombinant DNA molecules." (www.nih.gov)

5. "In the conduct of research involving hazardous organisms or toxins, the investigator adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories." (www.cdc.gov/od/ohs/biosfty/biosfty.htm)

6. "Information" includes but is not limited to news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association meetings, and symposia.

Failure to include Statement 1 on all information releases and Statements 2-5 when required can result in loss of funding.

B. FREEDOM OF INFORMATION ACT REQUESTS

The Freedom of Information Act (FOIA) (5 USC 552) provides a statutory basis for public access to official Government records. "Records" are defined to include documentation received by the government in connection with the transaction of public business. Records must be made available to any person requesting them unless the records fall under one of nine exceptions to the Act. (www.usdoj.gov/oip/index.html)

When a FOIA request asks for information contained in a successful proposal that has been incorporated into an award document, the submitter will be contacted and given an opportunity to object to the release of all or part of the information that was incorporated. A valid legal basis must accompany each objection to release. Each objection will be evaluated by USAMRMC in making its final determination concerning which information is or is not releasable. If information requested is releasable, the submitter will be given notice of USAMRMC's intent to release and will be provided a reasonable opportunity to assert available action.

C. SITE VISITS

During the term of the award, the PI is encouraged to visit USAMRMC laboratories and institutes to discuss related work with USAMRMC scientists. All such visits must have prior funding and should be coordinated through the USAMRAA Contracting/Grants Officer. Funding for visits may be made available through the award instrument. The USAMRMC laboratory personnel, as well as other DoD personnel, are also encouraged to visit the PI during their award efforts. The visits must all be coordinated with the Contracting/Grants Officer and are intended for technical discussion and monitoring of progress of the funded project.

D. REPORTS

Reports are necessary for continuation of the research efforts and funding. Each award instrument will state the necessary reports that are due to the government. Reporting requirements may include the following:

1. Periodic reports that outline the accomplishments and progress for that period.

2. Quarterly Standard Form Report, SF425, Federal Financial Report, used for grants and cooperative agreements that track the expenditure of funds on the project.

3. 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.

4. Annual reports that consist of detailed summaries of scientific issues, accomplishments and animal research usage during the project.

5. Final report that details the findings and issues of the completed project.

6. Copies of all scientific publications as a result of funding.

7. Abstracts that are suitable for publication in relation to planned meetings.

8. Oral Presentations that detail the status of a project to a panel of subject matter experts.

9. Programmatic Meetings that include discussions regarding findings, accomplishments and direction for the program.

V. FULL PROPOSAL PREPARATION

A. FORMATTING GUIDELINES

Full Proposals should be submitted within 90 days after being requested and an award decision should be rendered by the Government within 180 days after submission. Forms and information supporting the submission of a full proposal are located at www.grants.gov.

The proposal must be clear and legible. Attachments must conform to the following guidelines:

1. Type Font: 12 point, 10 pitch (Times New Roman is strongly recommended).

2. Type Density: No more than 15 characters per inch (including spaces). (For proportional spacing, the average for any representative section of text should not exceed either 15 characters per inch or 114 characters per line.)

3. Spacing: Single-spaced between lines of text, no more than five lines of type within a vertical inch

4. Margins: Minimum of 0.5 on all sides.

5. Color, Resolution and Multimedia Objects: Proposals 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 megabytes (MB). Since some reviewers work from black and white printed copies, applicants may wish to include text in the proposal 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, etc. must be submitted in JPEG format only (no bitmaps or TIFF).

6. Acronyms: Spell out all acronyms the first time they are used. One page following the proposal body is allocated to spell out acronyms, abbreviations and symbols.

7. Language: English

8. Print Area: 7.5 x 10.0 inches (approximately 19.05 cm x 25.4 cm)

B. MANDATORY PROPOSAL FORMS.

Each submission must include the completed package of forms identified in www.grants.gov for the USAMRMC BAA. The Package includes: SF 424 (R&R) Application for Federal Assistance; Research & Related Budget; Research & Related Project/Performance Site Location(s); Research & Related Senior/Key Person Profile and Research & Related Other Project Information. The R&R Subaward Budget Attachment(s) Form is optional (to be used as needed). **NOTE: Attachments are located under the Full Announcement tab of the funding opportunity. All Attachments that require signatures must be filled out electronically, printed, signed, scanned and then uploaded as an Attachment to the proposal as a .PDF file.**

1. The SF 424 (R&R), Application for Federal Assistance 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, if applicable. The Institution's Office of Sponsored Research should be contacted to determine whether the organization has an Institution Control Number. If there is no Institution Control Number, this field should be left blank.
- **State Application Identifier** is not applicable.
- **Block 1 – Type of Submission.** For all submissions the "Application" box should be chosen. For substantial changes that must be made after the original submission, the complete application package must be resubmitted. In these cases, the "Changed/Corrected Application" box must be checked and the Grants.gov tracking number must be entered in Block 4 - Federal Identifier.
- **Block 3 – Date Received by State** is not applicable
- **Block 4 – Federal Identifier Box.** This box will be populated by Grants.gov for an original application, but the Grants.gov tracking number (i.e., the Federal Identifier Number assigned to the original application) must be manually entered for changed or corrected applications.
- **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 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 19 – Authorized Representative.** The "signature of AOR" is not an actual signature and is automatically completed upon submission of the electronic application package. ***Hard copies of applications will not be accepted.***
- **Block 20 – Pre-application** box and attachment should be used to attach the pre-proposal file associated with this proposal. **Preproposal File name should be the eight digit log number assigned to the preproposal so the number will automatically populate to the pre-application box.**

2. Research & Related Budget – An estimate of the total research project cost, with a breakdown by category and year, must accompany each full proposal. All costs must be entered in U.S. dollars. Recipients performing outside of the U.S. should include the cost in local currency, the rate used for converting to U.S dollars and justification/basis for the conversion rate used. Multiple year proposals are encouraged to cover the total estimated duration of the project. Incremental funds may be provided by USAMRMC for effort performed during each Federal fiscal year. Costs proposed must conform to the following regulations and principles:

Commercial Firms: Federal Acquisition Regulations (FAR) Part 31 and Defense FAR Supplement Part 31, (http://farsite.hill.af.mil) Contract Cost Principles and Procedures.

Educational Institutions: CFR, Title 2, Part 220, "Cost Principles for Educational Institutions." This was previously in OMB Circular A-21.

Nonprofit Organizations: CFR, Title 2, Part 230, "Cost Principles for Nonprofit Organizations." This was previously in OMB Circular A-122.

State, Local and Tribal Governments: CFR, Title 2, Part 225, "Cost Principles for State, Local and Indian Tribal Governments." This was previously in OMB Circular A-87.

The cost of preparing proposals in response to this BAA 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 OMB Circulars A-21 and A-122.

Section A & B – Senior/Key Person: 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)

The qualifications of the PI and the percentage of time that they and other professional personnel will devote to the research are important factors in selecting research proposals for funding. For each key staff member identified on the budget form, list the percentage of each appointment to be spent on this project.

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

An itemized list of 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 two years 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 to include:

(1) Vendor Quote: Show name of vendor and number of quotes received and justification if intended award is to other than the lowest bidder.

(2) Historical Cost: Identify vendor, date of purchase and whether or not cost represented the lowest bid. Include release(s) for not soliciting current quotes.

(3) Estimate: Include rationale for estimate and reasons for not soliciting current quotes.

(4) Special test equipment to be fabricated by the contractor for specific research purposes and its cost.

(5) Standard equipment to be acquired and modified to meet specific requirements, including acquisition and modification costs, listing separately.

(6) 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.

(7) 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.

(8) 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: The justification supporting travel costs should list the number of trips, number of people per trip, the destinations and the purpose for all proposed travel annually. Estimate round trip fare and per diem costs for each trip. Travel to scientific meetings requires identification of the specific meeting and purpose. The number of trips funded for scientific meeting is limited. **Travel outside the United States, including between foreign countries, requires prior approval from USAMRAA at least 90 days before travel.**

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

Section F - Other Direct Costs

Section F.1. – Materials and Supplies (Consumables): The justification supporting materials and supplies (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 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: The cost justification must include a description of services or materials that are to be awarded by subcontract or sub grant. The following information must be provided on sub awards totaling $10,000 or more:

a. Identification of the type of award to be used (e.g., cost reimbursement, fixed price);

b. Identification of the proposed subcontractor or sub grantee, if known, and an explanation of why and how the subcontractor or sub grantee was selected or will be selected;

c. Whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition; and

d. The proposed acquisition price.

e. The offeror’s cost or price analysis for the sub grant or subcontract proposed price (applicable only if the award exceeds $650,000).

USAMRMC is committed to supporting small businesses. Small business, veteran-owned small business, service-disabled veteran-owned small business, HUBZone small business, small disadvantaged business, and woman-owned small business concerns must be given the maximum practical opportunity to participate through subawards on research proposals submitted through the BAA.

If the resultant award is a contract that exceeds $550,000 and the offeror is a large business or an educational institution (other than Historically Black Colleges and Universities/Minority Institutions HBCU/MI), the contractor is required to submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.7. A mutually agreeable plan will be incorporated as part of the resultant contract.

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

Section F.7. – Alterations and Renovations: This section is self-explanatory.

Section F.(8 – 10) – Research-Related Subject Costs: Include Itemize 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.

Section F.(8 – 10) – Other Direct Cost (if applicable): Include other anticipated direct costs that are not specified elsewhere in the budget. Unusual or expensive items should be fully explained and justified.

Section G – Direct Costs: This section is self-explanatory.

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. If negotiated forecast rates do not exist, provide sufficient detail regarding a determination that the costs included in the forecast rate are allocable according to applicable FAR/DFARS or OMB Circular provisions (see above). 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. When an applicant institution calculates its own indirect costs, it can only calculate indirect costs on the first $25,000 of each subaward.

As a minimum, justification for indirect costs should identify:

a. All individual cost elements included in the forecast rate(s);
b. The basis used to prorate indirect expenses to cost pools, if any;
c. How the rate(s) was calculated; and
d. The distribution basis of the developed rate(s).

Payment of indirect costs for contracts, grants, cooperative agreements (or similar arrangements) using Basic Research (6.1) funds made available by the 2008 or later DoD Appropriations Acts will be limited to no more than 35% of the total costs negotiated.

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. If a contract will be awarded, a profit/fee will be negotiated. Any fixed fee applied to the research project must be listed and any claimed Facilities Capital Cost of Money must be supported by **DD Form 1861** and submitted with the full proposal. The website for the form is: (www.dtic.mil/whs/directives/infomgt/forms/forminfo/forminfopage2192.html)

Section K. – Budget Justification: The Budget Justification must be included as an attachment at Research & Related Budget – Section K for each research period. 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. Attach one file that addresses each of the cost elements proposed.

The budget justification must include information for all budget periods. This file must be uploaded for budget period one before you will be allowed to access subsequent budget periods.

Federal Financial Plan (if applicable) must be attached as part of the budget justification if the proposal is submitted by a Federal agency. (No page limit.)
Proposals from Federal agencies must provide a plan delineating how all funds will be obligated before their expiration for obligation, 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. It should be noted, however, that it is contrary to policy to allow for any Recipient to send funds back to a U.S. Government entity except under very limited circumstances provided for in USAMRAA policy, such as:

(1) The Recipient can show that such funds will not originate from the USAMRMC award, or
(2) There is separate statutory authority, aside from Cooperative Research and Development Agreement (CRADA) authority, that would allow for it, or
(3) The Recipient can show that exceptional or extraordinary circumstances exist that merit a waiver of this policy.

Such waiver must receive approval from the USAMRMC Resource Management Office and the Staff Judge Advocate before approval by USAMRAA. Examples of exceptional circumstances that could merit approval would be (i) if the research protocol involved numerous radiological studies, such as computer tomography scans, which needed to be performed and analyzed at a U.S. Government medical treatment facility (MTF) facility after the normal expiration of the Appropriation from which the award was made, and which studies would otherwise not be performed as part of the standard of medical care, and/or (ii) if the research calls for the purchase and use of chemical or biological materials that cannot legally be purchased and/or used by the Recipient but can legally be purchased by the Government lab or MTF, then a CRADA can be employed for the Recipient to provide those funds to the lab or MTF to make such purchases.

Recipients under a cooperative agreement are allowed to provide non-fund resources to a Government lab or MTF, such as supplies, equipment, or personnel. This should be specifically provided for under the assistance document.

3. Research & Related Project/Performance Site Location(s) – Include the names and addresses for each location where research will be performed for the proposal. 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.

4. Research & Related Senior/Key Person Profile: Include the requested information for each senior/key person proposed on the project and attach 1) a current biographical sketch (**Attachment 1,** located at www.grants.gov) and 2) current & pending support on which this person is working or proposed. The list of Current/Pending Support should be attached in MS Word format and should include the title, time commitments, supporting agency and level of funding for all existing and pending research projects involving the PI and key personnel. Provide justification for USAMRMC support and interest where the projects overlap or parallel.

5. Research & Related Other Project Information: This form is self-explanatory. The following information must be included as attachments to this form:

Blocks 1 - 5: This section is self-explanatory in addressing the use of human subjects, the use of animals, proprietary information and environmental impact of the research.

Block 6 – Project Summary/Abstract (Attachment 2, located at www.grants.gov**):** The abstract is vitally important to both the peer and programmatic review process. The programmatic review includes an evaluation of the abstract as part of the peer review summary statement; therefore, it is paramount that the investigator submits an abstract that fully describes the proposed work. The abstract must contain the title of the proposal and the name of the PI. Do not include figures or tables in the abstract. Spell out all Greek or other non-English letters. Abstracts of all funded proposals may be posted; therefore, proprietary or confidential information should not be included in the abstract.

The structured technical abstract should provide a clear and concise overview of the proposed work, including the background, objective, or hypothesis and its supporting rationale, significance of the proposed work to the program's goals, specific aims of the study and the study design.

An outline is provided below for preparing the structured technical abstract.

a. Background: Provide a brief statement of the ideas and reasoning behind the proposed work.

b. Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.

c. Specific Aims: State concisely the specific aims of the study.

d. Study Design: Briefly describe the study design.

e. Relevance: Provide a brief statement explaining the potential relevance of the proposed work to the specific topic area being addressed and its impact on health outcomes.

A sample technical abstract can be found at www.usamraa.army.mil/pages/pdf/2001_BAA_sample_technical_abstract.pdf.

Block 7 – Project Narrative (limit 21 pages) **–** The Project Narrative includes the statement of work and the body of the proposal – in that order. There is no form for this information. The attachments should be in MS Word, in accordance with the formatting guidelines specified for full proposal preparation.

The Statement of Work (SOW) is the section of a research award that outlines and establishes the PI and an organization's performance expectations for which USAMRMC may provide funding. Unlike the general objectives which are agreed to in a grant or cooperative agreement, the contract SOW sets rather specific goals and conditions for each year of the contracted project. The PI and contractor are expected to meet the provisions and milestones of the SOW. (The SOW may be incorporated into the award document and, as such, is subject to release under FOIA.)

A series of relatively short statements should be included which comprise the approach to each of the major goals or objectives of the proposed research. The statements should outline the specific tasks, systems and materials that are reasonable estimates for testing the proposed hypotheses of the study. An outline should be included which shows the work statements to be accomplished in each year of the award. The SOW for a three-year research effort should **not exceed one page** of single-spaced typing.

BODY OF PROPOSAL - A detailed description of the research to be undertaken should be submitted. This will include background, hypothesis, objectives, approach, methods, and their relationship to the state of knowledge in the field and to comparable work in progress elsewhere. This information **should not exceed 20 pages**. Evaluation of the proposed research will be influenced by the adequacy of this information. Literature references and curriculum vitae will be shown in separate addenda entries. The following general outline should be followed:

1. **Background**. Provide a brief statement of ideas and reasoning behind the proposed study. Describe previous experience most pertinent to this proposal. Cite relevant literature references;

2. **Hypothesis**. State the hypothesis to be tested and the expected results;

3. **Technical Objectives.** State concisely the question to be answered by each research objective;

4. **Project Milestones**: Identify time-lines for critical events that must be accomplished in order for the project to be successful in terms of cost, schedule and performance.

5. **Military Significance.** State precisely the estimates as to the immediate and/or long-range usefulness of this study to the Armed Forces, as distinguished from general advancement of knowledge in medicine.

6. **Public Purpose**. If appropriate, provide a concise, detailed description of how this research project will benefit the general public.

7. **Methods.** Give details about the experimental design and methodology. If the methodology is new or unusual, describe in sufficient detail for evaluation. For synthetic chemistry proposals include a clear statement of the rationale for the proposed syntheses. Outline and document the routes to the syntheses.

Block 8 – Bibliography & References Cited. List the references in the order they appear in the proposal narrative. Use a reference format, which gives the title of the citation. Do not send or attach copies of articles in print. There is no form for this information. The attachments should be in MS Word, in accordance with the formatting guidelines specified for full proposal preparation.

Block 9 – Facilities & Other Resources. Describe the facilities available for performance of the proposed request and any additional facilities or equipment proposed for acquisition at no cost to 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. The attachments should be in MS Word, in accordance with the formatting guidelines outlined for full proposal preparation.

Block 10 – Equipment: Include a description of existing equipment to be used for the proposed research project. There is no form for this information. The attachments should be in MS Word, in accordance with the formatting guidelines outlined for full proposal preparation.

Block 11 – Other Attachments. Include in this section all items listed below as well as any other documentation not specified elsewhere, that supports the research proposed and could influence the evaluation and selection process.

- ACRONYMS AND SYMBOL DEFINITION - . Provide a glossary of acronyms and symbols, which might not be familiar to reviewers who are not current in the proposal, and research area.

- COLLABORATION AND JOINT SPONSORSHIP - Provide letter(s) supporting stated collaborative efforts, which are provided at no cost, and are necessary for the project's success. Describe present or prospective joint sponsorship of any portion of the program outlined in the proposal. In the absence of agreements among sponsors for joint support, the proposal should be structured so that the research can be carried out without the resources of any other sponsor. If, however, it is desirable to request partial support from another agency, the proposed plan should be stated and the reasons documented. If the plan cannot be formulated at the time the proposal is submitted, information should be sent later as an addendum to the proposal. Prior approval from both agencies must be secured for research to be undertaken under joint sponsorship.

- CERTIFICATE OF ENVIRONMENTAL COMPLIANCE - Information regarding environmental compliance must be provided with the full proposal (**Attachment 3**, located at www.grants.gov**).**

- RESEARCH INVOLVING THE USE OF ANIMALS, HUMAN SUBJECTS, OR HUMAN ANATOMICAL SUBSTANCES/HUMAN DATA

PIs and partnering organizations may not use, employ, or subcontract for the use of any human participants, including the use of human anatomical substances and/or human data, or laboratory animals until applicable regulatory documents are requested, reviewed, and approved by USAMRMC to ensure that DoD regulations are met.

Additionally, ***studies involving animals and studies that meet the definition of non-exempt human subjects research (to include direct intervention/interaction, obtaining individually identifiable information, and obtaining individually identifiable anatomical substances)***, must be approved through a regulatory review process by the PI's local IACUC and/or IRB **and** by the Office of Research Protections (ORP) at USAMRMC. For animal research, the ORP office responsible is the Animal Care and Use Review Office (ACURO), and for all research involving human subjects the Director, ORP will designate either ORP Clinical Investigations Regulatory Office (CIRO) or ORP Human Research Protection Office (HRPO) as the responsible office

Exempt human subjects research needs a determination from the PI's local IRB **as well as** the ORP at USAMRMC. Protocols and required approvals must be submitted no later than 60 days after award to ensure continuation of payments. The contracting office may grant exceptions in situations where human use is not expected to occur until after the first year of the research project. In such cases a timeframe for submission of the appropriate protocols should be established during discussion/negotiation.

1. Research involving Animal Use

Specific documents relating to the use of animals in the proposed research will be requested 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 (ORP;), 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 "Research Involving Animals", which can be found on the ACURO website (https://mrmc-www.army.mil/rodorpaurd.asp). 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.detrick.army.mil/AnimalAppendix.asp.

2. Research Involving Human Subjects, Human Subjects Data, or Human Anatomical Substances

All DOD-funded research involving human subjects and human biological substances must receive a headquarters-level administrative review (HLAR) and be approved by the USAMRMC Office of Research Protections (ORP) in addition to local Institutional Review Boards (IRBs). The ORP is mandated to ensure that all research complies with specific laws and directives governing research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed, and may require information in addition to that supplied to the local IRB.

During the regulatory review process for research involving human subjects, the recommendations of HLAR must be addressed and approved by the local Institutional Review Board (IRB). It is strongly recommended that investigators 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). 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.

Documents related to the use of human subjects or human anatomical substances will be requested if the proposal is selected for funding. ***Allow at least 6 months for regulatory review and approval processes for studies involving human subjects.***

Requirements: Specific requirements for research involving human subjects or human anatomical substances can be found at https://mrmc.amedd.army.mil/rodorptoolkit.asp.

Assurance of Compliance. Each institution engaged in non-exempt human subjects research must have a current Health and Human Services Office for Human Research Protection (OHRP) Federalwide Assurance (FWA) or DOD Assurance. All awardees (institution listed on proposal,

contract, assistance agreement) receiving funds that will support non-exempt human subjects research are considered to be "engaged" in the research and responsible for oversight, even if the research is sub-contracted to other institutions.

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

Informed Consent Form: An informed consent form template is located at https://mrmc.detrick.army.mil/docs/rcq/Proconsent/ConsentFormGuidelines.doc.

The following must appear in the consent form:

1. A statement that the DOD or a DOD organization is funding the study.

2. A statement that representatives of the U. S. Army Medical Research and Materiel Command (or the DOD) are authorized to review research records.

3. In the event that a separate HIPAA (Health Insurance Portability and Accountability Act) authorization is required, representatives of the USAMRMC must be listed as one of the parties to whom private health information may be disclosed.

For Greater than minimal risk research, the following paragraph must be included in the consent form after the institutional provisions for medical care for research related injury are described:

> *"If you are hurt or get sick because of this research study, you can receive medical care at an Army hospital or clinic free of charge. You will only be treated for injuries that are directly caused by the research study. The Army will not pay for your transportation to and from the hospital or clinic. If you have questions about this medical care, talk to the principal investigator for this study, (name and telephone number of principal investigator). If you pay out-of-pocket for medical care elsewhere for injuries caused by this research study, contact the principal investigator. If the issue cannot be resolved, contact the U.S. Army Medical Research and Materiel Command (USAMRMC) office of the staff judge advocate (legal office) at 301- 619 - 7663/2221."*

Note: This language may not be necessary for intramural protocols, protocols conducted within a military medical treatment facility, VA protocols, and protocols in which the institution or sponsor is providing free medical care.

Intent to Benefit: Investigators 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, cognitively impaired, 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 phase I and 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.

Note: This statute is only applicable to certain intervention studies. 10 USC 980 does not apply to retrospective studies, observational studies, blood draws and tissue collections. Contact HRPO for further clarifications regarding applicability of 10 USC 980 to your project.

Medical Monitor Requirement. An independent medical monitor must be identified in the protocol for all greater than minimal risk protocols. A CV or biosketch and human subjects protection training is provided. The medical monitor must have no apparent conflict of interest. The medical monitor must not be under the supervision of the principal investigator or other investigators or research staff. It is acceptable to provide appropriate compensation to the medical monitor for his or her services.

The role of the medical monitor must be described in the protocol and be consistent with DOD guidance. Medical monitors should be physicians, dentists, psychologists, nurses, or other healthcare providers capable of overseeing the progress of research protocols, especially issues of individual volunteer management and safety. Medical monitors must be independent of the investigative team and possess sufficient educational and professional experience to serve as the volunteer advocate. Depending on the nature of the study, the medical monitor may be assigned to assess one or more of the following phases of research project: volunteer recruitment, volunteer enrollment, data collection, or data storage and analysis. The medical monitor provides an independent evaluation of serious adverse events and unanticipated problems involving risk to subjects or others to the IRB and the ORP. The medical monitor may be assigned to discuss research progress with the principal investigator, interview volunteers, consult on individual cases, or evaluate adverse event reports. Medical monitors must promptly report discrepancies or problems to the IRB and the ORP. They shall have the authority to stop a research study in progress, remove individual volunteers from a study, and take whatever steps are necessary to protect the safety and well-being of research volunteers until the IRB can assess the medical monitors report

Recruitment of Military Personnel. Civilian investigators attempting to access military volunteer pools are advised to seek collaboration with a military investigator who will be familiar with service-specific requirements.

A letter of support from the Commander of military facilities or units in which recruitment will occur or the study will be conducted will be requested. Some sites may also require that each volunteer seek written permission from their supervisor prior to participation in research studies.

Special consideration must be given to the recruitment process for military personnel. The Chain of Command should not be involved in the recruitment of military personnel and should not encourage or order service members to participate in a research study. Per DOD Directive

3216.02, an ombudsman should be employed when conducting group briefings with Active Duty personnel to ensure that volunteers understand that participation is voluntary and may be recommended in other situations as well, especially when young enlisted service members are recruited who are trained to follow orders. Service members are trained to act as a unit, so peer pressure should also be considered and minimized if possible.

Payment to Military Personnel. Under 24 USC 30, payment to Active Duty military personnel for participation in research is limited to blood donation and may not exceed $50 per blood draw. Active Duty research volunteers may not receive any other payment for participation in a research study unless they are off duty or on leave during the time they are participating in the protocol.

Confidentiality for Military Personnel. Confidentiality risk assessment for military personnel requires serious consideration of the potential to affect the military career. Medical and psychological diagnoses can lead to limitation of duties or discharge. Information regarding alcohol or drug abuse, drunk driving, sexual or spousal abuse and sexual orientation can lead to actions under the Uniform Code of Military Justice including incarceration and dishonorable discharge. For aviators, loosing flight status due to a physical or psychological concern is an issue.

Please Note: The USAMRMC ORP HRPO conducts random site visits as part of its responsibility for compliance oversight. Accurate and complete study records must be maintained and made available to representatives of the USAMRMC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.
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.detrick.army.mil/rodorphrpo.asp.

The ORP accepts protocol submissions in the format required by the local IRB. To avoid delays in the approval process, PIs should take the ORP guidelines into account when developing protocols for submission to the local IRB.

- FACILITY SAFETY PLAN - The facility safety plan is outlined in **Attachment 4** (located at https://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.safety) and must be completed and included in the full proposal.

- REPRESENTATIONS AND CERTIFICATIONS - The form for contracts, located at http://orca.bpn.gov. ORCA is an e-Government initiative that was designed by the Integrated Acquisition Environment (IAE) to replace the paper based Representations and Certifications process. The form for Representations for Assistance Agreements (Grants & Cooperative Agreements) is identified as **Attachment 5**, located at www.grants.gov.

- CERTIFICATIONS AND ASSURANCES FOR ASSISTANCE AGREEMENTS - The required Assurances are outlined in **Attachment 6**, located at www.grants.gov. By signing and submitting a proposal or accepting an award, the recipient is concurring with the specified assurances and certifications, in compliance with the DoD 3210.6-R, Department of Defense Grants and Agreements Regulations, Part 22, Appendices A and B.

- MULTIMEDIA OBJECTS, PHOTOGRAPHS, ILLUSTRATIONS, GRAPHS, ETC. - Proposals 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 megabytes (MB). Since some reviewers work from black and white printed copies, applicants may wish to include text in the proposal 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, graphs etc. must be submitted in Microsoft Office or JPEG format only (no bitmaps or TIFF). **If photographs of identifiable patients are provided, release forms must also be submitted with the photographs.**

6. R&R Subaward Budget Attachment(s) Form

(Optional form: You may use this form if applicable OR attach subcontractor budgets in Word/and Excel formats as part of Budget Justification on tab K of Research and Related Budget forms. Regardless of the format used, the DUNS number for each subaward site should be included on this form.)

Please note that the files to be attached to the R&R Subaward Budget Attachment(s) Form must be PDF documents. Extract an R&R Subaward Budget Attachment for each subaward, using the button provided on this form. Save each attachment to your 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 you will be allowed to access 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.

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 $650,000).

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. A mutually agreeable plan will be incorporated as part of the resultant contract.

C. **COMMON PROBLEMS AND PROPOSAL SUBMISSION GUIDE**

- Failure to sign up for updates on any modification made to the initial Announcement.
- Attachments are uploaded into the incorrect form on Grants.gov forms. (Chart below)
- Files are attached in the wrong location on Grants.gov forms.
- Failure to contact the Grants.gov helpdesk.
- Failure to send attachments.
- Inability to locate Attachments. (Perform a Basic Search at www.grants.gov for Funding Opportunity number W81XWH-BAA10-1. When you reach the main screen for the funding opportunity, attachments are located under the middle tab entitled "Full Announcement".)

The chart on the following page details the forms that should be submitted and their accompanying attachments:

Form	Attachment	Action
SF-424 (R&R) Application for Federal Assistance Form		Enter the appropriate information in data fields
Research & Related Budget Form	Budget Justification for entire performance period	Attach to Section K in budget period one
Research & Related Project/Performance Site Location(s) Form		Enter the appropriate information in data fields
Research & Related Senior/Key Person Profile Form	Attachment 1 PI Biographical Sketch	Attach to Biographical Sketch field
	PI Current/Pending Support In MS Word format	Attach to Current & Pending Support field
	Attachment 1 Key Personnel Biographical Sketches	Attach to Biographical Sketch field for each senior/key person
	Key Personnel Current/Pending Support	Attach to Current & Pending Support field for each senior/key person
Research & Related Other Project Information	Attachment 2 Proposal Abstract	Attach to Block 6 Project Summary/Abstract
	Project Narrative and Body of Proposal in MS Word format	Attach to Block 7 Project Narrative
	Attachment 3 Certificate of Environmental Compliance	Attach to Block 11 Other Attachments
	Attachment 4 All applicable Facility Safety Plan documents	Attach to Block 11 Other Attachments
	Attachment 5 Representations for Assistance Agreements	Attach to Block 11 Other Attachments
	Attachment 6 Certifications and Assurances for Assistance Agreements	Attach to Block 11 Other Attachments
R&R Subaward Budget Attachment(s) Form (if applicable)	Individual subaward budgets	Attach a separate budget with justification for each subaward

(**LOCATION OF ATTACHMENTS 1-6: Perform a Basic Search at www.grants.gov for Funding Opportunity number W81XWH-BAA10-1. When you reach the main screen for the funding opportunity,** a**ttachments are located under the middle tab entitled "Full Announcement".)**

D. REGULATIONS AND FORMS

1. Copies of the Federal Acquisition Regulation (FAR) and Defense FAR Supplement referenced in this BAA may be purchased from the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 or located at website http://farsite.hill.af.mil.

2. Office of Management and Budget Circulars referenced in this BAA may be obtained from:

EOP Publication Office
New Executive Office Building
725 17th Street, NW, Room 2200
Washington DC 20503

Telephone: 202-395-7332
Website http://www.whitehouse.gov/omb

3. The contracting/grants office may contact offerors whose proposals are selected for funding for specific certifications and statements required by Federal statutes and regulations. Failure to include all required information and completed forms with submission of the full proposal could delay the award process.

4. Code of Federal Regulations can be found at www.gpoaccess.gov/cfr.

5. Department of Defense Grants and Agreements Regulations can be found at http://www.dtic.mil/whs/directives/corres/html/321006r.htm.