Program Announcement

U. S. Army Medical Research and Materiel Command (USAMRMC)

Telemedicine and Advanced Technology Research Center (TATRC)

Joint Program Committee 1 – Medical Simulation, Education, & Training for Systems Development and Integration (JPC1-MedSim)

Combat Casualty Training Consortium (CCTC)

Funding Opportunity Number:

W81XWH-10-JPC-MedSim-CCTC

I. Funding Opportunity Description

A. *Summary of Purpose*

The primary purposes, but not exclusive, of the Program Announcement (PA) are to 1) conduct research using models such as animals/live tissue and simulation-based systems to replicate the performance of life saving procedures and skills identified in the Critical Research Areas (Section D), 2) compare animal/live tissue models that may be used currently for training and education with those of technology-driven, simulation-based systems and provide detailed gap analysis of differences in training and education effectiveness and why for each of the respective procedures and skills identified in the Critical Research Areas (Section D), 3) either a) validate current published peer reviewed metrics and/or evaluation criteria used to objectively access and score effectiveness of training to actual performance on humans using any model (animal, live tissue, and/or simulation based system) or b) create new metrics and/or evaluation criteria based upon research performed that replicates the performance of the procedures and skills identified in the Critical Research Areas (Section D), 4) verify and validate the findings of the critical steps, important steps, and metrics and/or evaluation criteria by a team independent of the ones performing the research of replicating the performance of the life saving procedures and skills identified in the Critical Research Areas (Section D), and 5) propose training curriculum(a) for the respective procedures and skills identified in the Critical Research Areas (Section D). Emphasis should be on trauma training and critical life saving procedures relevant to military training, particularly where the use of animals/live tissue are used for training and education as a component of learning life saving procedures and skills.

B. *Program History and Objectives*

The Joint Program Committee 1 – Medical Simulation, Education, & Training for Systems Development and Integration (JPC1-MedSim) was established in fiscal year 2010 (FY10) to provide programmatic funding recommendations for DoD Health Affairs medical research dollars related to medical education and training efforts to advance the development and integration of simulation-based training systems.

The Armed Forces Simulation Institute for Medicine (AFSIM) is being formed as a committee (1) to provide relevant information to the JPC1-MedSim regarding, for example, medical modeling, education, training, and technology systems updates and (2) to integrate Combat Casualty Training Consortium Research and Development (R&D) efforts, as identified in this Program Announcement (PA), and potential future related R&D efforts, e.g., a Practice Based Consortium and a Patient Focused Consortium. The JPC1-MedSim considers this information plus relevant white papers and additional inputs to develop strategic plans for potential funding opportunities. The AFSIM may also assist in overseeing research efforts, curricula development, metrics creation, gap analysis, validation studies, as well as the advanced development of products.

This Program Announcement (PA) seeks to establish a Combat Casualty Training Consortium (CCTC). The US Army Medical Research and Materiel Command (USAMRMC) is soliciting full proposals to address the needs identified below. The results of these efforts are intended to ensure and sustain combat readiness and save lives through well validated training methodologies.

The CCTC, which is intended to be formed as a result of awards made in response to this PA, is focused on militarily relevant trauma training. In the short-term (1-2 years), the CCTC seeks to validate both live tissue training methodologies and simulator based training alternatives, with the goal of making a statistically valid comparison of their effectiveness and transfer. This will require applications of metrics developed and validated by the sub-awardees and overseen by the CCTC and guided by military Subject Matter Experts (SMEs). Mid-term goals (up to 3 years) include evaluation of training retention and identification of existing simulator gaps for the purpose of future research and development of simulator systems that have the potential to replace the presumed gold standard of animal/live tissue training. Long-term goals, which may be recognized in future Program Announcements, include the development of validated and standardized core curricula in collaboration with military training organizations and research and development of more advanced simulator systems. Future

funding opportunities may be considered, starting in FY11, to expand this research as needs and performance warrant.

Full proposals will be reviewed by an independent scientific peer review panel, and qualified projects will be selected for funding by a programmatic review panel. If the research is determined not relevant to the Critical Research Areas identified in this PA, the Government reserves the right to reject any proposal. The Government also reserves the right to not review full proposals that do not conform to criteria identified under the Consortium & Lead section below (Section C). Applications to this Program Announcement must provide research plans, Statements of Work (SOW), and budgets for each of the respective Critical Research Areas proposed. These Critical Research Areas will be addressed in Section D of this Program Announcement. The Government reserves the right to evaluate and select some or all components of the full proposal in order to maximize the strength of the proposal, team, and facilities to meet the overall objectives of effective research, creation of metrics and curricula, and validation studies.

C. *Consortium & Lead*

For the purposes of this Program Announcement, a consortium is defined as an association of two or more academic institutions, professional societies, companies, organizations or government entities (or any combination thereof) with the objective of participating in a common activity or pooling their resources for achieving a common goal. Each consortium must have a lead member, hereinafter referred to as the "Lead" or "Applicant", which will be responsible for all requirements attendant to the submission to this Program Announcement. Most likely, the Lead will be from an academic organization (e.g. University) or nationally recognized medical professional society that sets guidelines for its members. The Lead must assemble a CCTC Advisory Board (referred to hereinafter as the "Board") and obtain Letters of Intent (LOI) from these potential Board members. A full proposal must be submitted by the Lead member of the consortium and must include the other members who are overseen by the consortium as sub-awardees. The Board members should include individuals who have expertise in academic live tissue training, academic medical training (such as students and/or residents), military medicine, combat medicine, industry (such as in medical simulation and/or medical education), veterinary medicine, human factors and/or psychometrics, medical education curricula and development, and appropriate medical specialty knowledge for respective area of research, study, and curriculum development.

Expectations of the Advisory Board Members include, but are not limited to, 1) function as recruiters, 2) provide guidance on Institutional Review Board (IRB) and animal/live tissue processes and protocols, 3) assist in reviewing the raw data from the research and provide guidance on the analysis and interpretation of the data, 4) review the metrics/evaluation criteria as a result of the research and provide input, 5) advise on validation and verification plans, 6) approve proposed validation and verification plans, and 7) assist in distribution of results to professional organizations, such as testing and certification boards (e.g., but not limited to, the American Board of Surgery, American Board of Emergency Medicine, and American Board of Anesthesiology).

Consortium members may be added after award, based upon submission of a revised statement of work, revised budget, and upon approval of the Grants Officer Representative (GOR) and Grants Officer. Protocols may be modified under the same conditions, subject to the regulatory requirements addressed later in this PA.

Full proposals will NOT be reviewed unless they conform to the following:

- The Applicant must be an extramural (non-Governmental) organization, and one of the Principal Investigators must be from that extramural organization. Subawardee(s) may be intramural or extramural. Inclusion of military medical organizations with knowledge of the Critical Research Areas identified later in this PA is highly recommended;

- The proposed CCTC must include an "Association for Assessment and Accreditation of Laboratory Animal Care International" (AAALAC) accredited veterinary research facility;
- The Applicant must address all three Critical Research Areas of research in the submitted proposal: 1) Trauma Hemorrhage Skills, 2) Trauma Airway Skills, and 3) Emergency Medical Skills;
- The Applicant must identify budgets, hypothesis(es) of research, milestones and deliverables and information on PIs, Co-PIs, facilities, and subawardee(s), on each of the three Critical Research Areas to which they are applying. It is understood that selection of specific military PIs, co-PIs, facilities and sub-contractors may take place after award, but the Applicant must provide intent by providing a Letter of Intent(s) and preliminary budget(s) from anticipated partners;
- The proposal must provide detailed information regarding study designs and research methodologies. Study designs need to include proven, peer reviewed, systematic approach processes and referenced sources. Methodologies must be based on gathering observable, empirical and measurable evidence subject to specific principles of reasoning. A scientific method consists of the collection of data through observation and experimentation, and the formulation and testing of hypotheses.

RESPONSIBILITIES OF THE LEAD

1. The Lead is responsible for all requirements of the award. The Lead has oversight of the project (approval of the budgets, milestone deliverables, etc.) of the organizations that participate in the research, study, and development including independent validation of prototypes and curriculum. Documentation of approvals will be forwarded to TATRC;
2. The Lead is responsible for project deliverables and for maintaining a detailed project plan, which will guide the progress of the project;
3. The Lead will appoint a Project Manager for all elements or parts of the three (3) Critical Research Areas. The Project Manager will have responsibility to the Lead for the day to day management of all aspects of the project to include any and all subawardee activities and will report directly to the Lead. This identified Project Manager will be a second Point of Contact (PoC) for the Government GOR;
4. The Lead must provide a preliminary Charter for the CCTC, including all anticipated members as well as Letters of Intent (LOI) from proposed members to enter into appropriate collaboration agreements. The Charter must identify the roles, relationships, responsibilities, decision making procedures and expectations of members of the CCTC. The contact information of these anticipated members must include their full name, credentials (if applicable), organization name, and work title.
    - NOTE: Access to, and integration with, existing military training programs, systems and personnel is optimal but contingent on military training institution approval. Access cannot be assumed and may not be possible for all research studies. Collaboration with military organizations may require development of an MOA under a Cooperative Agreement or a Cooperative Research and Development Agreement (CRADA), in accordance with DOD regulations. The point of contact in this regard is Mary Rico at mary.rico@amedd.army.mil.
    - The CCTC should be prepared both to defray study costs incurred by military organizations during collaborative studies and to provide/arrange a civilian training environment and subjects when military resources are not available. For studies requiring training systems that are not already in use, those systems may need to be acquired by the proposing organization, whether the study is at a civilian or military site;
5. The Lead must provide an outline and budget for each of the Critical Research Areas (Section D) as part of the submission, and anticipated milestones & deliverables. There should be complete budgets and Statements of Work for each of the Critical Research Area components as well as a total (combined) budget;

6. The Lead will be responsible for the financial management of the research, and will manage the research in accordance with accepted project management techniques. The consortium may choose to take advice from third parties. The Lead must notify the Grants Officer Representative (GOR) and Grants Officer of changes to budgets, Board members, Principal Investigators, Project Managers, as well as changes to contractors. The Government reserves the right to approve or disapprove any new member to the Consortium and/or key members to the Critical Research Area teams, such as Principal Investigators;
7. The Lead will provide a list of proposed CCTC members who will advise, manage, and assure all ethical, Human Subject, Animal subject, and IRB protocols;
8. The proposal must include an outline for verification and validation studies of the proposed critical steps, methodology and proposed metrics from the research. It is not expected that the Applicant provide the full validation and verification plans within the submitted proposal.
    - Verification and validation needs to be conducted by a Principal Investigator (PI) not associated with the research and metrics development team. It is also strongly advised that the PI conducting the verification and validation study is not from the same institution/organization that is conducting the research and creating the metrics.
    - The proposal must include an outline of anticipated critical steps, proposed metrics and/or evaluation criteria, and comparative studies e.g., 1) studies specifically regarding the fidelity of animals/live tissue and why using these models transfers to the treatment of real patient procedures and 2) animal/live tissue compared to current simulation systems and what are the pros and cons of using the respective systems;
9. The Lead must assure completion of all IRB protocols and the coordination of studies from the various institutions / organizations where animal/live tissue and human subjects are used and provide updates in reports.

DESCRIPTION OF RESEARCH NEEDS

As stated in the Summary section of this Program Announcement, the primary purposes of the CCTC, but not exclusive, are to 1) conduct research using models such as animals/live tissue and simulation-based systems to replicate the performance of life saving procedures and skills identified in the Critical Research Areas (Section D), 2) compare animal/live tissue models that may be used currently for training and education with that of technology-driven, simulation-based systems and provide detailed gap analysis of differences in training and education effectiveness and why for each of the respective procedures and skills identified in the Critical Research Areas (Section D), 3) either validate current published peer reviewed metrics and/or evaluation criteria used to objectively access and score effectiveness of training to actual performance on humans using any model (animal, live tissue, and/or simulation based system) or create new metrics and/or evaluation criteria based upon the identification of critical and important steps which was performed during the research of replicating the performance of indicated procedures and skills in the Critical Research Areas (Section D), 4) validate and verify the findings of the critical steps, important steps, and metrics and/or evaluation criteria by a team independent of the ones performing the research of replicating the performance of the life saving procedures and skills identified in the Critical Research Areas (Section D), and 5) propose training curriculum(a) for the respective procedures and skills identified in the Critical Research Areas (Section D).

The CCTC should be knowledgeable of military education and training needs, especially those of the combat medic. The CCTC should include sub-award organizations from academia, the DOD (organizations which conduct combat medicine/surgical training using animal/live tissue), veterinarians, government, and industry, and should include medical educators, human factors specialists, psychometricians, medical specialists from respective area of research, study, and curriculum development, and relevant medical professional organizations.

Various training methodologies are used, some of which include use of live animals, some form of live tissue, some form of standardized patients, and some form of a simulation-based training systems.

The CCTC should focus on Pre-hospital Trauma, Tactical Combat Casualty Care (TCCC), Combat Medicine, and emergency response particularly as these clinical environments relate to the work of physicians, residents, graduate medical education professionals, Emergency Medical Technicians, Air Force Para-jumpers, Navy Corpsmen, and Damage / Resuscitation specialists.

The CCTC should have the capability to conduct live animal tissue studies, to conduct requirements review(s) and gap analyses, to design curricula, and to conduct validation studies. The CCTC should identify Principal Investigators capable of performing validation studies of the critical steps / important steps and the metrics/evaluation criteria that were discovered during the research. Critical steps are deemed acceptable and/or determined by peer reviewed publications and can be defined by a diversified group of Subject Matter Experts (SMEs) who would be able to defend them amongst their peers. Critical steps are the cognitive knowledge and technical skills that must occur during a specialized skill or procedure. Steps with direct impact to the published Morbidity and Mortality outcomes of performing these specialized skills and procedures need to be considered as "critical". It should be noted that use of the term "task" is sometimes used instead of "step". For the purpose of this PA they are interchangeable when specifically addressing the Critical Research Areas.

Important steps are deemed acceptable and/or determined by peer reviewed publications and can be defined by a diversified group of SMEs who would be able to defend them amongst their peers, but are the cognitive and/or technical steps that are typically technique related. These steps may not be taught the same way from organization to organization but are essential to complete the specialized skill or procedure. These PIs should report directly to the Lead or a member identified by the Lead and the Project Manager of the CCTC.

The Lead and CCTC Board members must oversee the conduct of studies and research. The studies and research include, but are not limited to, the performance of specialized skills / procedures (identified in Critical Research Areas – Section D) and documentation of the critical steps and the important steps. The Lead and CCTC Board members will either confirm the existence of validated metrics and/or evaluation criteria or develop metrics and/or evaluation criteria that would meet current testing or credentialing board standards (examples, but not limited to, the American Board of Surgery, American Board of Emergency Medicine, and American Board of Anesthesiology) and expectations of one considered as an eligible applicant who would qualify to perform these procedures/specialized skills on their own. The anticipation is that the model used to perform these procedures/specialized skills will be on animals/live tissues. It is anticipated that this portion of the research will be completed by sub-award Principal Investigators and their multi-center team.

The Lead and CCTC Board members must oversee the comparison of performing the same procedure/specialized skill using simulation-based training systems designed to educate and train the respective procedures/specialized skills. Identification and documentation of gaps between the models need to be reported. Detailed information on the gaps, e.g., the level of fidelity of the difference between the models, must be reported.

The research and studies must be performed for all three critical areas: 1) Trauma Hemorrhage Skills, 2) Trauma Airway Skills, and 3) Emergency Medical Skills. The Lead and the CCTC should provide data and information to 1) demonstrate the need for live tissue training, i.e., what steps and metrics that only live tissue could answer, 2) identify which current simulation-based systems are able to address the steps identified from the research instead of live tissue, and 3) identify what critical steps and metrics are needed to assess those steps and why.

ANTICIPATED DELIVERABLES OF THE CONSORTIUM

It is the intention that all data, results, outcomes, metrics/evaluation criteria, proposed curriculum(a), gap analysis based upon the research and validation/verification studies and data from these studies are to be public and shared. To protect the rights and privacy of individuals who participate in sponsored research, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that

could lead to deductive disclosure of the identity of individual subjects. The Government recognizes the need to protect patentable and other proprietary data and the restrictions on the sharing of data that may be imposed by agreements with third parties. In this regard, note that under the Bayh-Dole Act, grantees have the right to elect and retain title to subject inventions developed with Federal funding. It is not the intent of this PA to discourage, impede, or prohibit the development of commercial products from federally funded research. However, it should be noted that, for purposes of this PA, the Government does not support the production of data that cannot be shared. If patent protection is being sought, data still can be shared in a timely manner.

Reports, data, and meetings are required. Each award instrument will state the necessary reports due to the Government. Reporting requirements may include, but are not limited to, the following:

- Provide quarterly reports that outline the accomplishments and progress for that period on all Critical Research Areas of interest: 1) Trauma Hemorrhage Skills, 2) Trauma Airway Skills, and 3) Emergency Medical Skills. Areas that must be addressed on report:
    - Data from the research on the identified critical steps, important steps and techniques necessary to successfully perform procedures/skills indicated in the Critical Research Areas. The intent is that these identified steps and techniques will either confirm existing curriculum for the respective procedure/skill or may suggest changes to amend existing curriculum(a). In some instances creation of curriculum(a) may be required;
    - Metrics/evaluation criteria upon which to objectively measure assess success of completing the procedure/skill with positive patient outcomes and performance assessment. Correlation of the metric/evaluation criteria with the anticipated modality on which training and education will be performed;
    - Gap analysis information regarding critical steps and techniques necessary to achieve success for education and training that only live tissue can provide currently. Explain the rationale in detail on why the training is necessary to occur on animals/live tissue rather than simulation-based systems;
    - Proposed curriculum. NOTE: design and validation studies of curriculum are optional.
- Quarterly Standard Form Report, SF 425, Federal Cash Transaction Report, used for grants and cooperative agreements that track the expenditure of funds on the project.
- Provide data (data may be in embedded spreadsheet as well as displayed as graphs) and results of the independent validation results which must include verification of the critical steps, important steps, and metrics and/or evaluation criteria of the animal/live tissue research for the respective procedure(s) / skill(s). Provide analyzed data in the respective quarterly reports as well as in the final report;
- Provide system requirements for all medical simulation-based systems intended for each curriculum developed. A specification sheet with hardware needs and software modules must be provided;
- The CCTC must meet as a group a minimum four (4) times per year, preferably quarterly. One session must be an "open" session in a public forum, one session must be "closed," specifically to the AFSIM and JPC-1 MedSim, and the other two among the CCTC (NOTE: Government representatives may attend any and all meetings). The Lead is responsible to submit formal minutes from these meetings with the appropriate report (quarterly, annual, or final) with respect to when the meeting was held;
- Provide a proposed curriculum(a) (draft) for each of the three Critical Research Areas based upon the research. The Government anticipates this report will be in the final report or one of the quarterly reports prior to the final report;

- Provide potential plans regarding routes of delivery of the data and mechanisms for implementing potential future curriculum that could be used for certification and/or credentialing bodies / organizations;
- Provide in the appropriate report (quarterly, annual, or final) proposed abstracts / manuscripts of the research being prepared for peer review publication;
- Provide copies of all scientific publications and presentations as a result of this funding;
- Provide a transition plan of the anticipated curriculum(a) to the users; that is, training programs, and respective authorized certification bodies. Provide an anticipated validation plan of a proposed standardized curriculum based upon this project's findings;
- Provide quarterly, annual and final reports on progress and details of findings, including milestones, deliverables, budgets, personnel changes, summaries of scientific issues, accomplishments and human research usage during the project, and any problems existing at time of completion of project;
- Presentation by the Principal Investigator (PI) at a TATRC Product Line Review (PLR) of Subject Matter Experts selected by the TATRC. The format will be prescribed by the government, but the presentation should provide summary and detailed status of a project. Travel and other costs related to PLR attendance should be included in the budget submission;
- Demonstration of the efforts as a result of this funding. Demonstrations may be in person or through video or on-line presentations.

A listing of potential active duty military Subject Matter Experts for the respective Critical Research Areas may be requested by E-Mail to TATRC at JPCWorkingGroup@TATRC.org. Requests made within seven (7) business days prior to full proposal submission date may not be honored. [Please allow approximately five (5) business days for response.]

The three (3) Critical Research Areas to be addressed by the CCTC are described within the next section (Section D, Critical Research Areas). The CCTC Lead is ultimately accountable, but it is assumed that the research in the Critical Research areas will be managed and directed by Principal Investigators, Co-PIs, and their respective organizations as accepted by the CCTC.

D. *Critical Research Areas*

Proposals must meet, at a minimum, the criteria for decreasing the need for animals/live tissues use during medical education and training. Proposals must meet the criteria for comparing current simulation-based systems (which might be used to train the indicated procedures/skills) to that of animals / live tissues by comparing the identified critical steps and techniques and the metrics/evaluation criteria. In addition, the DoD requires critical lifesaving medical skills (cognitive & psychomotor) at all levels of care, from combat medicine through definitive care at Medical Treatment Facilities (MTF). In the civilian world it would represent the initial point of contact with the patient in the field, the transportation, through the definitive care and treatment to what constitutes a Level II Trauma facility. These skills require hands-on practice, both to acquire and to maintain currency and competency. Each of the three Critical Research Areas emphasizes medical training systems both 1) to improve training effectiveness and 2) to reduce reliance on animal/live tissue training. The Statement of Work (SOW) for this PA should be focused on the first medical care that a Wounded Warrior receives and, by extension, should also be applicable towards civilian patients needing such procedures. Each Critical Research Area addressed should include expertise from 1) academic organization(s), 2) professional societies, 3) active military healthcare professionals, 4) industry, and 5) thought leaders. The SOW of the CCTC predominately concentrates on three (3) Critical Research Areas: 1) Trauma Hemorrhage Skills, 2) Trauma Airway Skills, and 3) Emergency Medical Skills. The Applicant must propose effort in all three of the Critical Research Areas (Trauma Hemorrhage Skills, Trauma Airway Skills, and Emergency Medical Skills).

OBJECTIVES FOR ALL CRITICAL RESEARCH AREAS:

1. Identify/develop metrics upon which to assess proficiency, regardless of whether using animal/live tissue or simulation based systems;

2. Perform research and studies comparing animal/live tissue training versus simulation-based system platforms;

3. Conduct research and studies using animal/ live tissue and simulation-based systems. Provide a detailed plan including the research methodologies intended to identify critical steps and important steps based upon currently accepted doctrine from professional organizations, peer reviewed journals, and board standards for the procedures and specialized skills addressed in the Critical Research Areas as well as plans for the creation and assessment of metrics for critical steps, important steps, and other important components, and how to validate those critical steps & metrics;

4. Conduct research to understand the critical steps, the important steps, cognitive factors, and potential errors a novice, intermediate, or expert might make, as they progress through an established curriculum(a) to better prepare an individual(s) to perform such procedures/skills in the field, either individually or as a team. The anticipated outcome is to train to proficiency (or competency) of any given procedure. Research, analysis, and documentation of these critical steps must relate to the Critical Research Areas being studied.

5. Conduct research to (1) validate the capabilities of live tissue training platforms and (2) validate transfer of skills to human subjects;

6. Identify the simulation-based training systems that offer training that is as effective as, or better than, animal /live tissue training. Document clearly the gaps between live tissue training and simulation-based training systems, when animal/live tissue training is concluded to be superior to simulation-based training;

7. Identify simulation-based training systems, technologies and/or methodologies that offer advantages and benefits that (a) are identical or superior to those of animal/live tissue training yet (b) reduce (short term) and replace (long term) the requirement for animal/live tissue training.

8. Identify/develop metrics upon which to assess proficiency, regardless of whether using live tissue or simulation based systems;

9. Assure research and metrics and/or evaluation criteria apply to multiple skill levels of clinicians and healthcare professionals with emphasis on the combat medics. Future anticipated services, products, and/or curriculum for education and training of the proposed procedures/skills must address the different medical disciplines as well as level(s) of education and experience;

10. Determine capability of training and education, whether using animal/live tissue or simulation based systems, to transfer cognitive and psychomotor skills to the actual delivery of care to optimize patient outcome.

ANTICIPATED DELIVERABLES FOR ALL CRITICAL RESEARCH AREAS:

1. The Lead should provide the following information, as it becomes available in the conduct of research, in periodic, e.g., quarterly, annual, and final technical reports.

- Outcomes of research using (a) live tissue, (b) simulation-based systems, or (c) combined on the specific procedures/skills identified;

- Summary and detailed analysis, based upon the research that identifies the critical steps and important steps that can be accomplished by current simulation-based systems and the critical steps and important steps that cannot. For simulation-based systems identified, the analysis must also discuss the anatomical, physiological, pathological, pharmacological, etc. reason(s) (a) why the current simulation-based systems identified are concluded to be inadequate and (b) justify the use or not of animals/live tissue in medical modeling, simulation, education and training within all three Critical Research Areas based upon the research performed, especially in the comparative portion of the research;
- Metrics/evaluation criteria on both the critical steps of the procedure / skills and on other important steps as identified by subject matter experts as well as independent validation teams;
- Template of a proposed common curriculum methodology, which could serve as a standard approach to curriculum development;
- Results of a gap analysis identifying deficiencies of simulation based training systems and why the team believes they are either inferior to, equal to, or superior than, live tissue training. Provide details on features, functions, steps, and/or technologies that limit simulation-based systems for education and training of the specified procedures/skills if applicable;
- Report of the identified and/or developed simulation-based training systems and technologies and/or methodologies that (a) offer identical or superior advantages and benefits to those offered by live tissue training and (b) reduce (short term) and replace (long term) the requirement for live tissue;
- Report of an evaluation on training retention with the use of animal/live tissue(s) to the respective procedure / skill, including a hypothesis on "why" there may be variations in training retention, e.g., whether it is due to the steps to be learned, the type of animal/live tissue being used, and/or the learner type, e.g., group demographics;
- Report of study results -- validated preferred but hypothesis driven accepted -- of the transfer of cognitive and psychomotor skills to the actual delivery of care via live tissue and/or simulation-based-system(s), to optimize patient outcomes;
- Report of the users' subjective experience using live animals and simulation-based training systems to include at least an assessment of utility, realism, sense of urgency and confidence from training;
- Report of study results of what simulation-based training systems contribute towards realistic training, with measureable effectiveness in education and training that can reduce reliance on live animals.
- Published report(s) of results in a reputable peer-reviewed journal. All manuscripts and abstracts from data and results generated by the funding of this project need to be submitted in the respective quarterly reporting period. This should be coordinated with the Lead and Project Manager on who is responsible for actual submissions;
- Propose a curriculum(a) aimed at training and education of the identified procedures and skills outlined in the critical research areas of the PA, which may be considered for incorporation and adopted by organizations and/or societies that set guidelines, provide continuing education credits, or who oversee the credentialing and certification of individuals who perform the identified procedures/skills.

1. TITLE. TRAUMA HEMORRHAGE SKILLS

DESCRIPTION. The DoD requires critical lifesaving trauma hemorrhage skills (cognitive & psychomotor) at all levels of care, from combat medicine through definitive care at MTFs, academic hospitals, and facilities responsible for addressing and treating the respective pathologies. These skills require hands-on practice, both to acquire and to maintain currency and competency. Various training methodologies are in use, some of which

include the use of live animals. Applicants should address the use of animals and/or live tissue for medical training and education purposes for the following procedures/skills:

- Trauma Hemorrhage Skills:
    - hemorrhage control to include both tourniquet placement and hemostatic agent use,
    - fluid resuscitation due to blood loss,
    - amputation management,
    - multi-hemorrhage management,
        - should include intra-abdominal and intra-thoracic hemorrhage

Scientific / technological progress has been made in the development of simulation-based training systems for medicine, but many have not been validated to train effectively the gamut of skills related to treatment of traumatic hemorrhage. Additionally, the metrics and evaluation(s) still have substantial subjectivity, which makes it difficult to replicate training scenario(s).

The Principal Investigators, in coordination with the CCTC Board members, must address at least the following: (a) Internal hemorrhage, (b) open wound(s) with hemorrhage, and (c) use of appropriate instruments / tools based upon treatment options at the different levels of care. The CCTC may determine the animal/live tissue model and simulator technologies for study, in collaboration with military experts. At least three (3) of the five (5) trauma hemorrhage skills areas must be studied; four (4) or more are preferred.

Varied healthcare professionals deal with hemorrhage management; research and studies on live tissue must reflect the needs of the various healthcare levels (combat medic through physician). Research will include metric / evaluation criteria for critical procedural steps or skills. Applicants will include an evaluation of training retention and critical skills transferability from live tissue / simulator to patient outcome. Also identify existing simulator gaps for the purpose of future research and simulation development. Existing uniform results or outcomes of commonly performed procedures may be used to minimize variation in specific disciplined guidelines

SPECIFIC ANTICIPATED DELIVERABLES FOR TRAUMA HEMORRHAGE SKILLS.

These additional deliverables for trauma hemorrhage skills should be included in the final report unless otherwise specified:

- Specifics to the choice of animals/live tissue, as well as simulation based systems that were included in the research;
- Specific instruments used in the indicated procedures/skills used during the research;
- Specific material used to represent blood (if not blood) for both the animal/live tissue scenarios and the simulation based systems;
- Specific mechanisms, such as valves, tubing, etc, used to control the rate, pressure, and amount of blood used to simulate the scenarios indicated;
- Conditions and/or environment(s) in which the scenarios were researched and/or administered. Approximate temperatures and other potential environmental factors that have impact on real life hemorrhage scenarios should be addressed. NOTE: this should be included in quarterly, annual, and final reports.

2. TITLE. TRAUMA AIRWAY SKILLS

Description. The DoD requires critical lifesaving airway skills (cognitive & psychomotor) at all levels of care, from combat medicine through definitive care at MTFs, academic hospitals, and facilities responsible for addressing and treating the respective pathologies. These skills require hands-on practice, both to acquire and to

maintain currency and competency. Various training methodologies are in use, some of which include use of live animals. Applicants should address the use of animals and/or live tissue for medical training and education purposes for the following procedures/skills:

- Trauma Airway Skills:
    - chest tube insertion;
        - for both pneumothorax and hemothorax scenarios
    - intubation skills;
    - cricothyroidotomy;
    - needle decompression of the thorax;
    - placement of chest seal;
    - pericardiocentesis.

Simulation-based systems that address Trauma Airway Skills probably are more mature than systems that address other procedures/skills in this Program Announcement. However, current metrics/evaluation criteria addressing the above procedures/skills have not necessarily been validated, especially in comparison to animal/live tissue. Additionally, there are very few -- some may argue no -- simulation-based training systems that address all of these procedures/skills. A medical education organization may have to use numerous simulation systems to address the procedures/skills in comparison of using only one animal/live tissue trainer.

The CCTC may determine the animal model and simulator technologies for study, in collaboration with military experts. At least five (5) of the six (6) trauma airway skills areas must be studied. More than one skill may be evaluated in a particular study.

Consideration for study of more than one type of medical professional is encouraged.

SPECIFIC ANTICIPATED DELIVERABLES FOR TRAUMA AIRWAY SKILLS.

These additional deliverables for trauma airway skills should be included in the final report unless otherwise specified:

- Report the specifics to the choice of animal/live tissue as well as simulation-based systems included in the research;
- Report the specific instruments that were used in the indicated procedures/skills that were used during the research. Make sure sizes, such as French size of chest tube for pneumothorax and for hemothorax, or needle gauges are clearly defined;
- Report what devices were used to produce / replicate the various scenarios, such as to represent the pressure for the pneumothorax and needle decompression, the blood in the pericardial sac for the pericardiocentesis, etc.;
- Report what physical signs, vital signs (and how taken with what instrument), and other indicators of differential diagnosis as well as treatment were used during the animal/live tissue research as well as the simulation based system;
- Report the conditions and/or environment in which the scenarios were researched and/or administered. Approximate temperatures, altitudes, other potential environmental factors that might impact on real life traumatic airway scenarios should be addressed.

3. TITLE. EMERGENCY MEDICAL SKILLS

Description. For this Program Announcement in this Critical Research Area, only two Emergency Medical Skills are addressed.

The cholinergic crisis study requires collaboration with the US Army Medical Research Institute of Chemical Defense (USAMRICD) Chemical Casualty Care Division (CCCD) which employs a demonstration of anesthetized physostigmine treated African-Green monkeys to stimulate a cholinergic crisis as would be seen from nerve agent exposure. Other exercises are performed with some of the current mannequin technologies. CCCD may be accessed at https://ccc.apgea.army.mil and the telephone is (410) 436-2230, Dr. Charles G. Hurst. Study performance at that site is possible if it can be arranged with minimal perturbation of military training and approval by USAMRICD.

The military typically has used ferrets (Army) or cats (Navy) for neonatal intubation training. The Government encourages research performed on pediatric intubation be conducted at a civilian institution. Applicants need to address the use of animals and/or live tissue for medical training and education purposes for the following procedures/skills:

- Emergency Medical Skills.
    1. cholinergic crisis using physostigmine as a nerve agent stimulant,
        a. (Cholinergic Crisis) The study must employ the existing African-Green monkey AALAC approved protocol in place for both the live tissue and simulator component with emphasis on physical examination findings;
    2. pediatric and neonatal intubation.

SPECIFIC ANTICIPATED DELIVERABLES FOR EMERGENCY MEDICAL SKILLS.

For the following, the additional deliverables for trauma hemorrhage skills may be included in the final report unless otherwise specified:

- (Cholinergic Crisis) Identify optimal use and benefits of advanced simulator systems in education and performance scenarios outside the scope how the animals are currently used;
- Preliminary report on progress regarding the cholinergic crisis and associated metrics one year after contract award.
- (Pediatric and Neonatal Intubation) Identify optimal use and benefits of advanced simulator systems in education and performance scenarios outside the scope how the animals are currently used.

E. *TATRC Award Description*

Anticipated Instrument Type(s)
USAMRMC implements its extramural research program predominantly through the award of 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. The supporting contracting office, the US Army Medical Research Acquisition Activity (USAMRAA), will negotiate and award proposals selected for funding. It is anticipated that this Program Announcement will result in the award of a cooperative agreement(s).

F. *Eligibility*

All individuals, regardless of ethnicity, nationality, or citizenship status, may apply as long as they are employed by, or affiliated with, an eligible institution. Principal Investigators (PIs) must be independent investigators at any academic level that possess the skills, knowledge, and resources necessary to carry out the proposed research.

Eligible Extramural Institutions include not-for-profit, non-profits, public, and private organizations, such as universities, colleges, hospitals, laboratories, for-profit businesses (small businesses, large corporations for example), and commercial firms (a profit or fee is not allowable on grants or cooperative agreements). Historically Black Colleges and Universities/Minority Institutions (HBCU/MI) are encouraged to submit proposals for review and funding consideration under this announcement.

Intramural organizations are not eligible to be the Lead awardee. Intramural organizations may be consortium members if they represent less than 30% of the dollar value of the consortium work. Intramural organizations include Department of Defense (DoD) activities, e.g., DoD laboratory, medical treatment facility (MTF), DoD activity embedded within a civilian medical center, Program Executive Office (PEO), Program Manager (PM), or Research, Development, and Engineering Center (RDEC).

G. *Funding*

The amount available for funding for the FY10 CCTC is approximately $15.2 million. One (1) to three (3) awards are anticipated. Multiple consortia may be funded to address individual Critical Research Areas. Projects requiring lower levels of funding may also be proposed and are encouraged. Reasonableness of budget for the proposed research is a component of the peer review evaluation process. Strong justification must be provided to support the requested budget. The maximum period of performance is anticipated not to exceed three (3) years. Additional work, within scope, may be considered based upon the needs of the Government. These funds must be applied across the three Critical Research Areas: Trauma Hemorrhage Skills, Trauma Airway Skills, and Emergency Medicine Skills. The Government reserves the right to fund individual Critical Research Areas within a consortium proposal. All funding is contingent upon annual renewal and meeting milestones and deliverables. There is no minimal or maximum funding amount for each of the individual Critical Research Areas, but total funding across all three Critical Research Areas shall not exceed $15.2 million.

The Lead applicant must identify the details of the budgets for each and all of their subawardee(s). Government approval is required prior to addition of any new subawardee.

Within the guidelines provided in the Application Instructions, funds can cover:

Salary
Supplies
Capital Equipment
Research-related subject costs
Travel to scientific/technical meetings
Travel between collaborating institutions
Travel to required meetings, i.e. Product Line Review [PLR] and/or Integrated Product Team
Indirect costs (intramural organizations will not be allowed indirect costs)
Other direct costs
Subawardee costs

H. *Award Administration*

The transfer of an award to another institution is strongly discouraged. Approval of a transfer request from an institution will be at the discretion of the Grants or Contracting Officer. Funding for Clinical Trials will not be supported.

1. Site Visits

During the performance period of a subsequent award the PI is encouraged to visit USAMRMC laboratories and institutes to discuss related work with USAMRMC scientists. Only visits or travel approved in the award budget will be reimbursed. Any additional visits must be funded through different sources. All PI visits must be coordinated through the Grant Officer Representative (GOR) prior to the visit.

USAMRMC laboratory personnel, as well as other DOD personnel, may request to visit the PI during performance of the funded project. The visits must all be coordinated with the GOR prior to the visit. The visits will be for technical discussion and monitoring of progress of the funded project.

II. Timeline for Submission and Review

Proposal submission consists of full proposal submission.

Full Proposal Submission Deadline: 11:59 p.m. Eastern time, 24 September 2010

Scientific Review: October-November 2010

Programmatic Review: November 2010

Full Proposals should be submitted at least 72 hours before the deadline. This will allow Grants.gov sufficient time to process full proposals, notify PIs of errors, and allow for resubmission of the revised application package prior to the deadline. Please plan ahead accordingly. *Initial full proposal submissions and any resubmissions received after the final deadline will not be evaluated.*

Awards are anticipated to be made during May 2011.

Questions related to the submission process for this announcement should be directed to Ms. Mary Rico at the U.S. Army Medical Research Acquisition Activity at mary.rico@amedd.army.mil

Questions related to the research area, administrative process (such as obtaining DUNS number) for this announcement should be directed to TATRC at JPCWorkingGroup@TATRC.org.

III. Submission Process & Application Instructions

Proposal submission is through a full proposal through Grants.gov (http://www.grants.gov/).
If there is a change in PI or organization after submission of the Proposal, the PI must contact the submission helpdesk at (703) 674-2500, ext. 207.

A. *Full Proposal Components and Submission*

A Full Proposal submission will not be considered if it does not conform to the following. Full proposals must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (http://www.grants.gov/). Refer to Grants.gov section described later.

Each proposal submission must include the completed Grants.gov application package of forms and attachments identified in http://www.grants.gov for the U.S. Army Medical Research Acquisition Activity (USAMRAA) Program Announcement.

In addition to the mandatory items (see Mandatory Full Proposal Forms) the application packet must include:

- Two letters from active military personnel familiar with animal/live tissue training and/or military educational and training programs;
- Three letters from medical centers: two from academic medical centers and one from a Department of Defense (DoD) medical center;
- The applicant must to provide a detailed GANTT chart (or equivalent) that maps out the milestones with dates. Refer to http://en.wikipedia.org/wiki/Gantt for an example of a GANTT chart. Proposals that request funding beyond the maximum available will not be considered.
- Detailed budget for each of the Critical Research Areas, the total of which must not exceed $15.2 Million, inclusive of direct and indirect costs;
- Documentation that assures qualifications of Principal Investigators, the organization's team, and the facilities including past performances of published articles within the area of animal/live tissue research or medical education curricula development, past work with DoD such as recipient grant, contract, or co-op agreement, and provide summary relevant current work (no more than 4 pages per person).

B. *Mandatory Full Proposal Forms*

Each submission must include the completed package of forms identified at http://www.grants.gov/ for this Program Announcement/funding opportunity. The Package includes: SF 424 Research & Related (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 Sub-award Budget Attachment(s) Form is to be used as needed. **NOTE: All Attachments that require signatures must be filled out electronically, printed, signed, scanned and then uploaded as an Attachment to the full proposal as a .PDF file.**

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, 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 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 Grant ID 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 (PD)/Principal Investigator (PI).

- **Block 6 – Employer Identification.** Enter the Employer Identification Number (EIN) or Tax Identification Number (TIN) 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, and city). Enter N/A for not applicable.
- **Block 13 – Proposed Project.** The start date should be 7 to 9 months from the deadline for application submission.
- **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 Organizational Representative (AOR).** 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. ***Hard copies of applications will not be accepted.***
- **Block 20** – Pre-application. **Not Applicable. No information is required.**

2. Research & Related Other Project Information Form

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 (limit one page) (Attachment 2**, located at http://www.grants.gov**; name "Abstract1.pdf").** 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 military health outcomes.

A sample technical abstract can be found at www.usamraa.army.mil/pages/pdf/2001_BAA_sample_technical_abstract.pdf. Please note limit of one page.

- **Block 7 – Project Narrative (limit 25 pages) (name "Narrative2.pdf")** – The Project Narrative includes the **Statement of Work** and the **Body of the Full Proposal** – in that order. There is no form for this information. **The attachments must be in PDF, 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 is 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 the Freedom of Information Act (FOIA)).

A series of relatively short statements should be included which correlate 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 **should not exceed two pages** of single-spaced typing.

Below is a suggested SOW format:

Task 1. Brief overview description of this task (timeframe, e.g., months 1-18):
1a. Description of subtask 1a (timeframe, e.g., months 1-3).
1b. Description of subtask 1b (timeframe, e.g., months 4-12).
1c. Description of subtask 1c (timeframe, e.g., months 1-18).

Task 2. Brief overview description of this task (timeframe, e.g., months 4-36):
2a. Description of subtask 2a (timeframe, e.g., months 4-12).
2b. Description of subtask 2b (timeframe, e.g., months 13-24).
2c. Description of subtask 2c (timeframe, e.g., months 25-30).
2d. Description of subtask 2d (timeframe, e.g., months 25-36).

The concise timeline should account for the duration by quarter (Q) or year and scheduling relationships of the major tasks identified in the descriptive SOW above.

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. 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 ideas and reasoning behind the proposed study.

    - An overview of the subject, issue and/or problem
    - Rationale for the proposed research
    - Theory under consideration
    - Thorough description and evaluation of the work done on the subject matter and argument to support position under review
    - 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 and Impact Statement.** State precisely how the proposed study is responsive to the health care needs and quality of life of members of the Armed Forces who are deployed and/or other populations of interest as appropriate for this solicitation. If a military population(s) will be used in the proposed project, describe the population(s), the appropriateness of the population for the proposed research, and the feasible of using the population. Explain how the proposed research study is aligned with the critical areas addressed in this funding opportunity. Discuss how the anticipated outcome is suitable for operation in a military field or clinical environment. State explicitly how the proposed study will have an impact on medical training, education and/or treatment. Provide the name of the institution and/or professional society with whom the validation study will be performed. Explain the potential clinical and operational applications, benefits, and risks.

6. **Public Purpose.** 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. If recruiting human participants, describe the recruitment process:

    - Methods for identification of potential volunteers, e.g., medical record review, obtaining sampling lists, health care provider identification, etc.
    - Description of compensation plan (should be fair and 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).
    - Type of consent to be used (informed, waived, or surrogate).
    - List the major inclusion and exclusion criteria of the study.
    - The number of participants that must be enrolled to properly power the proposed study, the number of participants that must be screened to meet the enrollment target number, and the plan for replacing participants who choose to drop out.
    - Describe plans for military populations use for the proposed research project.
    - Describe the study intervention. Briefly describe the data collection procedures and interaction(s) with the participants, detailing how frequently and for what duration the investigator will interact with the participant (e.g., initial interview, followed by weekly group psychotherapy sessions, each 50 minutes in duration, for 10 weeks).

8. Transition Plan. Provide information on the methods and strategies proposed to move the product to the next phase of development, e.g., larger study, additional clinical training applications, manufacturing plans, commercialization plans, military applications, etc., after the successful completion of the award. The plan should include details of additional potential funding sources, collaborations, other resources that will be used to provide this continuity of development, and a potential timeline for field deployment and/or commercialization.

- **Block 8 – Bibliography & References Cited (name "References3.pdf").** 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 PDF, in accordance with the formatting guidelines specified for full proposal preparation.

- **Block 9 – Facilities & Other Resources (name "Facilities4.pdf").** 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.

- **Block 10 – Equipment (name "Equipment5.pdf").** Include a description of existing equipment to be used for the proposed research project. There is no form for this information.

- **Block 11 – Other Attachments.** Include other items appropriate to the proposal.

    - **Multimedia Objects, Photographs, Illustrations, Graphs, etc. (name "graphs6.pdf").** 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 JPEG format only (no bitmaps or TIFF).
    - **Acronyms and Symbol Definition (name "Acronyms7.pdf").** 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 (name "Collaborations8.pdf").** 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 and assistance agreements of any portion of the program outlined in the proposal. Prior approval from both agencies must be secured for research to be undertaken under joint sponsorship. If the PI is a practicing clinician, the institutional support letter must clearly demonstrate a commitment to the clinician's research.
    - **Certificate of Environmental Compliance (name "COEC9.pdf").** Information regarding environmental compliance must be provided with the full proposal (**Attachment 3**, located at www.grants.gov**).**
    - **Research Involving Human Participants and/or Anatomical Substances (name "HRPO10.pdf").** Research Awards funded by the USAMRMC require a second tier review by the Human Research Protection Office (HRPO) for the use of human participants, the use of human data, and the use of human anatomical substances prior to implementation. Therefore, the PI must address all pertinent issues relating to the use of human participants and/or data in the proposed research. Include the required approvals, forms and information as specified on the HRPO website, https://mrmc.detrick.army.mil/rodorphrpo.asp Research Involving Human subjects and/or anatomical substances. Full proposals may be submitted without protocols for human use.

However, protocols and required institution approvals must be submitted not 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 time frame for submission of the appropriate protocols should be established during discussion/negotiations.

- **Research Involving Animals**. Research Awards funded by the USAMRMC require a second tier review for the use of animals prior to implementation. Therefore, the PI must address all pertinent issues relating to the use of animals in the proposed research. Include the required assurances, approvals, forms and description in the proposal addenda entitled "Research Involving Animals," as specified on the Animal Care and Use Review Office (ACURO) website https://mrmc.detrick.army.mil/rodorpaurd.asp. Research conducted under USAMRMC sponsorship that generates preclinical safety data intended to support a research or marketing permit for products regulated by the Food and Drug Administration must be in conformance with the Good Laboratory Practices. Full proposals may be submitted without protocols for animal use; **however, protocols and required institution approvals must be submitted not later than 60 days after award to ensure continuation of payments.** The contracting office may grant exceptions in situations where animal use is not expected to occur 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 discussion/negotiations.
- **Facility Safety Plan**. The facility safety plan is outlined in **(name "Safety11.pdf")** (**Attachment 4** located at http://www.grants.gov) and must be completed and included in the full proposal.
- **Representations & Certifications (name "RepCert12.pdf")**. 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 http://www.grants.gov.
- **Certifications and Assurances for Assistance Agreements (name "Compliance13.pdf").** The required Assurances are outlined in **Attachment 6,** located at http://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.

All attachments must be submitted in PDF format.

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.

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

- The Lead ("Applicant") of the Consortium Biographical Sketch (four- page limit)
- Project Manager of the Consortium Biographical Sketch (four -page limit)
- PI Biographical Sketch (four-page limit)
- PI Current/Pending Support
- Key Personnel Biographical Sketches (four-page limit each)
- Key Personnel Current/Pending Support

PI Biographical Sketch: Four-page limit. Named "Biosketch_LastName.pdf" in which "Last Name" is the last name of the PI.

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 or supplementation of existing awards.

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:

- **Maximum Obligation:** The USAMRMC does not amend awards 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 award. 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 Department of Defense 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 one 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 the Product Line Review to include the Lead (Applicant), the Project Manager, and key Principal Investigators.**
- **Travel costs to attend one scientific/technical meeting.**
- **Travel costs associated with the execution of the proposed work.** If applicable, reasonable costs for travel between collaborating institutions should be included.
- **Travel to required meetings**. Funds for the PI to attend two Department of Defense military research-related meetings to be determined during the performance period.

Justification for all travel costs should be provided. Travel outside the United States, including between foreign countries, requires prior approval from the grant officer 60 days before travel, unless identified in the proposal that is part of the award.

Section E – Participant/Trainee Support Costs: This section is self-explanatory; follow the instruction in the form.

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.

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 – Sub award/Consortium/Contractual Costs: On the project's Research and Related Budget Form, enter the total funds requested for (1) all sub award/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 sub award must be included in the total direct costs of the prime 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.

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 http://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: (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 **"BudgetJust.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. **Provide a copy of your purchasing policy, which clearly sets forth competition requirements for your organization for the purchase of items and services.**

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 to 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 Sub Award Budget Attachment(s) Form (if applicable)

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

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

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

A description of services or materials that are to be awarded by subcontract or sub grant 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 sub awards:

- Identification of the type of award to be used (e.g., cost reimbursement, fixed price);
- Identification of the proposed subawardee or sub grantee, if known, and an explanation of why and how the subawardee or sub grantee was selected or will be selected;
- Whether the award will be competitive and, if noncompetitive, rationale to justify the absence of competition;
- The proposed acquisition price; and
- The applicant's cost or price analysis for the sub grant or subcontract proposed price.

C. *Formatting Guidelines*

Full proposals should be submitted no later than 8 September 2010 at 11:59 PM Eastern Time. An award decision should be rendered by the Government approximately 90 - 120 days after proposal due date. Forms and information supporting the submission of a full proposal are located at http://www.grants.gov.

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

- **Document Format:** All attachments must be in PDF.
- **Type Font:** 12 point, 10 pitch (Times New Roman)

- **Spacing:** Single-spacing between lines of text
- **Page Size:** Must be no larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
- **Margins:** At least 0.5 inch (1.27 cm) in all directions
- **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 must be submitted in JPEG format; bitmaps or TIFF formats are not allowed.
- **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.
- **Language:** English
- **Print Area:** 7.5 inches x 10.0 inches (19.05 cm x 25.40 cm).
- **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 application 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 application are encouraged.
- **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.

D. *Compliance Guidelines*

Compliance guidelines are designed to ensure the presentation of all Full proposals are organized and easy-to-follow. Scientific peer and military relevance 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 Full proposal rejection. Full proposals missing required components as specified in the Funding Opportunity will be administratively rejected.

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

- Project Narrative exceeds page limit.
- Project Narrative 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 is missing.
- Scientific Peer and/or Military Relevance Reviewer(s) have not declared a COI but are found to have involvement with the applicant prior to or during the review.

- FY10 JPC-1 and/or Joint Technical Committee Group-1 (JTCG-1) member(s) are named in the proposal.
- FY10 JPC-1 and/or JTCG-1 member(s) are found to be involved in any capacity in the proposal processes including but not limited to concept design, proposal development, budget preparation, and the development of any supporting document.
- FY10 JPC-1 and/or JTCG-1 member(s) communicated program priorities prior to the deadline for proposal submission listed in this program announcement.

Proposals that appear to involve any allegation of research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to perform an investigation and provide those findings to the Grants Officer for a determination of the final disposition of the application.

IV. Information for Full Proposal Review

A. *Full Proposals Review and Selection Process*

All full proposals will be evaluated by respected subject experts using a two-tier review process. The first tier includes a scientific peer review of proposals against established criteria for determining scientific merit. The second tier consists of a military relevance review of proposals against established criteria, as applicable, and a programmatic review that compares submissions to each other and then recommends proposals for funding based on scientific merit, military relevance, and the overall goals of the program.

The scientific peer, military relevance, and programmatic review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each tier review requires panelists to sign a non-disclosure statement attesting that proposal and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Institutional personnel and PIs are prohibited from contacting persons involved in the proposal review process to gain protected evaluation information or to influence the evaluation process. Likewise, persons involved in the proposal review process are prohibited from communicating the program priorities, other than what is listed in this program announcement, to PIs and/or being involved in the proposal development. Violations of these prohibitions will result in the administrative withdrawal of the institution's proposal. Violations by panelists or PIs that compromise the confidentiality of the scientific peer, military relevance, and programmatic review processes may also result in suspension or debarment of their employing institutions from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

The Government reserves the right to review all proposals based on one or more of the required attachments or supporting documentation, e.g., Military Relevance Statement.

B. *Review Criteria*

1. First Tier Review

Scientific peer review: All proposals will be evaluated according to the following criteria, which are in descending order of importance:

- **Impact**
  - How the results of the proposed study will affect the magnitude and scope of the AFSIM.
    - Proposed validation of training model. Training model is animal/live tissue, standardized patient(s), and/or simulation based system(s) (hypothesis might include combination of the models).

    - Transference of proposed metrics/evaluation criteria into curricula that end users might use for future certification / credentialing processes.
    - Proposed methodology of identification of gaps between respective training models.
    - Proposed rationale / soundness of research and methodologies for anticipated outcomes.
  - How the proposed research addresses each of the three Critical Research Areas.

- **Study Design**
  - How the scientific rationale and preliminary data, including critical review and analysis of the literature, and clinical evidence support the proposed study and its feasibility.
  - The theoretical or conceptual framework from which the study is premised
  - How the aims, hypotheses, experimental design, methods, data collection procedures, and analyses are developed.
  - How the logistical aspects of the proposed study, e.g., communication plan, data transfer and management, and standardization of procedures, meet the needs of the proposed study.
  - How the recruitment, informed consent, and screening processes for volunteers will be conducted to meet the needs of the proposed study.
  - How the organization's protocols and their facilities regarding animal/live tissue meet the needs of the proposed study.
  - How the inclusion, exclusion, and randomization criteria meet the needs of the proposed study.
  - How the inclusion, exclusion, and randomization of in vivo models and purposeful and efficient use of such models in the proposed study.
  - Evidence that the CCTC and Principal Investigator (PI) will have access to military populations required for the study, if applicable.
  - How the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.
  - How the data analysis plan is consistent with the study objectives.
  - How the proposed resources will be used to provide continuity of development/deployment and support the likelihood of success, if applicable.
- **Personnel**
  - How the study team's background and expertise are appropriate to accomplish the proposed work, i.e., statistical expertise, expertise in the disease/condition, and clinical studies.
  - How the levels of effort of the clinical team are appropriate for successful conduct of the proposed study.
  - How prior accomplishments within this area of research are appropriate. Referable research.
  - How the level of inclusion of a veterinarian and active military within the research.
  - How the proposed collaboration between independent investigators is likely to facilitate or greatly accelerate a significant achievement in this area of research and whether the proposal provides a clear and balanced plan outlining the contributions of each investigator to the overall synergy of the project.
  - How prior history and accomplishments working within a consortium are appropriate.
  - Past performance with DoD funded projects.

- **Environment**
  - AAALAC approved facilities.
  - How the research and academic infrastructure is appropriate for the proposed study with respect to research facilities, and availability of bio-statistical and computing support, and educational assessment expertise.
- **Budget**
  - How the budget is appropriate for the proposed research.
- **Intellectual Property**
  - How the intellectual and material property plan that is agreed upon by each participating institution is appropriate for the proposed study.

2. Second Tier Review

Programmatic review by JPC-1 MedSim: All proposals will be evaluated according to the following criteria, which are of equal importance.

- **Responsiveness to funding opportunity Critical Research Areas,**
- **Ratings and evaluations of the scientific peer reviewers,**
- **Military relevance,**
- **Review of Proposals against Compliance Guidelines,**
- **Programmatic relevance, and**
- **Program portfolio balance.**

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by the JPC-1 MedSim members and recommended for funding to the Commanding General, USAMRMC and Director, Defense Medical Research and Development Program, OASD (HA).

V. Administrative Information

A. *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).

B. *Administrative Requirements*

A recipient organization should meet certain minimum standards pertaining to institutional support, financial resources, and prior record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations. Investigators are cautioned that awards are made to organizations, not individuals. The Principal Investigator (PI) must submit a proposal through an organization and is employed by that organization 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 the investigators' credentials were examined and verifying the investigators are qualified to conduct the proposed study and use human research participants.

C. *J-1 VISA Waiver*

Organizations located outside of the U.S. may submit in response to this Program Announcement; however, it is the organizations' responsibility to ensure 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.

D. *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.

E. *Government Obligation*

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

F. *Integrity of Review Process*

The scientific peer review and programmatic review processes are conducted confidentially and anonymously to maintain the integrity of the merit-based selection process. Each tier of review requires panelists to sign a nondisclosure statement attesting that proposal and evaluation information will not be disclosed outside the panel.

Violations of the nondisclosure statement can result in the dissolving of a panel(s) and other correcting actions. Correspondingly, institutional personnel and PIs are prohibited from contacting persons involved in the proposal review process to gain protected evaluation information or to influence the evaluation process. Violations of this prohibition will result in the administrative withdrawal of the institution's proposal. Violations by panelists or PIs that compromise the confidentiality or anonymity of the scientific peer review and programmatic review processes may also result in suspension or debarment of their employing institutions from Federal awards.

G. *Award Negotiation*

A Contract or Grant Specialist and/or representative from the USAMRAA will contact the Contract Representative authorized to negotiate contracts and grants at the PI's institution. Award negotiations may include indirect rate agreement and discussions, reviews and justifications of issues related to the proposal. 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. The award start date will be determined during the negotiation process. The

USAMRMC implements intramural research programs through Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Documents (FADs).

H. *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.

VI. Instructions and Guidelines 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 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. A Facility Safety Plan must be approved by USAMRMC. **A list of institutions that have approved Facility Safety Plans** can be found at https://mrmc.amedd.army.mil/docs/rcq/sohd/Facilty_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 Facility Safety Plan. The specific requirements are 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 one not listed in the aforementioned website will be required.

C. *Research Involving Human or Animal Subjects*

Research Involving Human Subjects: ***Use of Human Subjects and Human Biological Substances: All DOD-funded research involving human subjects and human biological substances must be reviewed and approved by the USAMRMC Office of Research Protections, Human Research Protection Office (HRPO) in addition to local Institutional Review Boards (IRBs). The HRPO is mandated to comply with specific laws and directives governing all research involving human subjects that is conducted or supported by the DOD. These laws and directives are rigorous and detailed, and will require information in addition to that supplied to the local IRB.***

The PI must address pertinent issues relating to the use of human participants in the proposed research. Include the required approvals, forms and information as specified on the Human Research Protection Office (HRPO) website: https://mrmc.detrick.army.mil/rodorphrpo.asp

During the regulatory review process for research involving human subjects, the recommendations of the second tier Human Research Protection Office (HRPO) 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. TATRC regulatory personnel can provide a pre-review to assist with meeting HRPO requirements prior to submission to the IRB.

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

1. Requirements: Personnel involved in human subject's 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 .

The following must appear in the consent form:

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

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

In the event that a separate HIPAA authorization is required, representatives of the USAMRMC should be listed as one of the parties to whom private health information may be disclosed.

For Greater than minimal risk research, the following paragraph should 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.

3. 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, 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.

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 specific protocol.

4. Medical Monitor Requirement. An independent medical monitor must be identified in the protocol for all greater than minimal risk protocols. A CV or bio sketch and human subjects protection training is provided. The medical monitor must have no apparent conflict of interest. The medical monitor should 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 is described in the protocol and is 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 HRPO. 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 shall promptly report discrepancies or problems to the IRB and the HRPO. 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

5. 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 3216.2, 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.

6. 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.

7. 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 Military Code of Justice including incarceration and dishonorable discharge. For aviators, loosing flight status due to a physical or psychological concern is an issue.

8. Research Involving the Use of Animals: Research involving animals will be considered.

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 application. The Animal Care and Use Review Officer (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 "ACURO Animal Use Appendix for Research Involving Animals," which can be found on the ACURO website https://mrmc.amedd.army.mil/AnimalAppendix.asp. Allow 2 to 4 months for regulatory review and the approval processes for animal studies.

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

VII. INSTRUCTIONS FOR REPORTS

The Government requires reports to be submitted by each Principal Investigator 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.***

A. *Research Progress Reports*

Reporting requirements consist of quarterly and annual reports (for each year of research except the final year) that present 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 research funded through this Program Announcement should be included in the progress report. The Government reserves the right to request additional reports.

B. *Fiscal Reports*

Quarterly fiscal report requirements may include the Standard Form Report, SF 425, Federal Cash Transaction, used for grants and cooperative agreements to track the expenditure of funds on the research project.

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.

VIII. Helpful Information

A. *Contacts*

To view all funding opportunities offered by the USAMRMC, perform a Grants.gov basic search by selecting the "Find Grants Opportunity" tab and the insert 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.

Questions related to the submission process for this announcement should be directed to Ms. Mary Rico at the U.S. Army Medical Research Acquisition Activity at mary.rico@amedd.army.mil .

Questions related to the research areas, administrative process (such as obtaining DUNS number) for this announcement should be directed to TATRC at JPCWorkingGroup@TATRC.org.

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. Phone: 800-518-4726, Monday to Friday, 7:00 a.m. to 9:00 p.m. Eastern Time Email: support@grants.gov.

Deadline for invited, full proposal submission is 11:59 p.m. Eastern time on 8 September 2010. Therefore, there are approximately three hours during which the Grants.gov help desk will NOT be available. Proposals should be submitted at least 48-72 hours before the deadline so that Grants.gov can provide notification of errors and allow for resubmission of application package prior to the deadline. ***Proposals received after the deadline will not be evaluated.***

Grants.gov will notify Principal Investigators (PIs) of changes made to this Funding Opportunity 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 (http://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 be consulted to the extent practical for the same purpose.

C. *Commonly Made Mistakes*

- Not obtaining or confirming the organization's DUNS number (https://eupdate.dnb.com/requestoptions.asp?cm_re=HomepageB*TopNav*DUNSNumberTab) well before the proposal submission deadline.
- Not obtaining or confirming the organization's registration with the Central Contractor Registry (CCR) (http://www.ccr.gov/) well before the proposal submission deadline.
- Failing to request "send me change notification emails" from Grants.gov (http://www.grants.gov/).
- Not contacting help desks until just before or after deadlines.
- Not completing the Proposal submission before the mandatory deadline.
- Using an incorrect grants.gov application package to submit a proposal through grants.gov. Each 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 Sub award 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 full proposal by submission deadline.

IX. GRANTS.GOV INFORMATION

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 PA to be submitted through Grants.gov. This requires that Organizations register in Grants.gov to submit proposals through the Grants.gov portal. Individual Principal Investigators (PI)/Project Directors (PD), Project Managers (PM) DO NOT register; however, the Authorized Organizational Representative (AOR) is required to register.

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. ***The registration process can take several weeks, so please register as soon as possible.*** 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 the Central Contractor Registry (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 (http://dnb.com/ccr/register.html).

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. ***As CCR registrations do expire; PIs should verify the status of 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, 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 (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 http://www.dlis.dla.mil/Forms/Form_AC135.asp.

3. AOR must be registered with Grants.gov: Before submitting a proposal, organization representative needs to register to submit on behalf of the organization at Grants.gov - http://apply07.grants.gov/apply/OrcRegister. An organization's E-Business Point of Contact, 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 http://apply07.grants.gov/apply/OrcRegister to obtain a username and password. The AOR must then register with Grants.gov for an account at http://apply07.grants.gov/apply/OrcRegister. 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.