PROGRAM ANNOUNCEMENT

I. GENERAL INFORMATION

1. Agency Name

Naval Medical Logistics Command (NMLC)

2. Funding Opportunity Title

Conduct of Clinical Trials to Facilitate the Development and Approval of Novel Countermeasures (vaccines, devices, drugs) for Use by the Warfighter.

3. Sponsor's Name

Naval Medical Research Unit Six Lima (NAMRU-6)

4. Funding Opportunity Number

N62645-PA-20-1

5. Catalog of Federal Domestic Assistance (CFDA) Number

12.340

6. Catalog of Federal Domestic Assistance (CFDA) Title

Naval Medical Research and Development

7. Application Submission Deadline

The application submission deadline is: 10:00 A.M. Eastern Time, 08 November 2019.

8. Funding Decision Date

The Government plans to make a funding decision by: 22 November 2019.

Each applicant will receive notification of the funding decision.

9. Funding Opportunity Description

i. Program Description

The goal of this Cooperative Agreement is to engage in a collaborative research and development (R&D) effort to support the research mission of NAMRU-6. The collaborative R&D effort will include conducting clinical trials, and epidemiologic studies in support of clinical trials, so products can be approved/cleared by the U.S. Food and Drug Administration (FDA) for use by the warfighter.

To accomplish these goals, the collaborative efforts will involve two research focus areas: 1) Clinical Research for Vaccines, Drugs and other Biologics and 2) Clinical Research for Novel Rapid Diagnostic Devices for FDA clearance. For drugs and vaccines, we anticipate conducting Phase 2 through 4 clinical trials.

ii. Award Description

The intent of this award is to fund an organization that can provide collaborative assistance with manpower including but not limited to (scientists, physicians, research associates, research assistants, laboratory aides, nurses, clinical trials staff, program managers, research coordinators and technicians) and materiel (initial regulatory FDA/local authorities applications, start up planning/team training, laboratory testing, statistical analysis support/reports, clinical monitoring and quality assurance/control, writing of the study final report, study site facility rental, medical indemnity/liability insurance, computer and communications devices such as laptops, tablets and cellphones, hardware for data server/network, internet service, mobile data services, subject recruitment, investigational product importation fees, research supplies, equipment, study personnel travel/transportation and research subject compensation) for research efforts focusing on the conduct of clinical trials and biomedical research in the field of infectious diseases and global health. For handling of specific study data, as required by the sponsor, the awardee may be provided Government Furnished Equipment, which the awardee must track and periodically report accountability throughout the agreement. Clinical trials will focus on the development and evaluation of preventive and therapeutic countermeasures and diagnostic/detection devices. The goal of the collaborative research is to conduct clinical trials to deliver life-saving products, knowledge, technology, and medical materiel that sustain the effectiveness of the uniformed service members. The award will be issued as a cooperative agreement between the awardee and the Government (NAMRU-6). The awardee will collaborate with NAMRU-6 to develop and implement clinical studies, scientific research efforts, and share substantial programmatic involvement. NAMRU-6 will provide program direction and scientific focus directly and through the Grants Officer Representative (GOR). Research activities under this cooperative agreement may take place either at NAMRU-6 laboratories or extramural locations in different sites in Peru.

Collaborative research personnel provided by the awardee must have the necessary work permits/visas, medical qualifications and security clearances in place for access to NAMRU-6 facilities and Information Technology (IT) networks. Likewise, research personnel provided by the awardee must have all clearances and be medically qualified to work in facilities that are part of the collaborative effort outside of NAMRU-6. Collaborative research personnel provided by the awardee must be equipped with tablets, laptops, cellphones and appropriate support services necessary to communicate and interface with Department of Defense data management systems. The study site provided by the awardee must meet the physical security standards as required in FDA regulated studies. The awardee must have the capacity to award sub-grants and subcontracts as needed to meet research and development needs. It is critical that the awardee must possess the ability to conduct clinical trials in Peru. More specifically, the awardee must be certified by the General Office for Research and Technology Transfer (OGIT in Spanish); this entails being registered at the Peruvian Clinical Trial Registry (REPEC) to conduct clinical trials in the field of infectious diseases. The awardee shall have at least one active trial site approved and registered in Peru at the time of selection.

iii. NAMRU-6 Award Research Focus Areas

NAMRU-6 has already begun research activities toward testing and evaluating rapid diagnostic tests, drugs, and vaccines targeting infectious diseases of military importance. For the warfighter to benefit from novel products, these countermeasures must be approved by the FDA. The product discovery and development pipeline is divided into pre-clinical studies and clinical trials from Phase 1 through Phase 4. NAMRU-6's focus areas involve the conduct of clinical studies that will advance these medical products toward FDA approval/clearance.

Clinical Research for Vaccines, Drugs and other Biologics: Before a vaccine and/or a drug or biologic product can be used either to prevent and/or treat an infectious disease, their safety and efficacy must be demonstrated through adequate and well-controlled clinical studies. A well-controlled clinical study allows for sound decisions to advance a compound/new candidate vaccine to the next stage of clinical development. To date, NAMRU-6 has been involved in the development of several investigational vaccine products to prevent infectious diseases that are of military importance. These infectious diseases include *Plasmodium falciparum* and *Plasmodium vivax* malaria, diarrheal diseases caused by *Enterotoxigenic E. coli* (ETEC), and *Campylobacter jejuni*, enteric viruses such as norovirus, influenza, dengue and other arboviruses, among others. These products have gone from early discovery to Phase

1/4 clinical testing in humans. Our investigators are also pursuing novel therapeutic modalities, new delivery platforms and improved drug regimens that can be evaluated and used in endemic areas for the treatment and prevention of infectious diseases. Malaria, diarrheal diseases, influenza, dengue fever, Zika virus, chikungunya and other arboviral infections, wound infections, respiratory infections, urinary tract infections and sepsis due to multidrug resistant bacteria and neglected diseases, such as leishmaniasis, are a known threat to military operations and readiness. NAMRU-6 also intends to conduct clinical research studies to evaluate and optimize the dose and schedules of existing, FDA-approved antimicrobial drugs/regimen to enhance the treatment of military personnel afflicted with these infections in the deployed setting to enable their rapid return to duty. The testing and development of novel drugs and biologics for treating and preventing these diseases would greatly enhance force health protection for the warfighter while deployed in the area of operation.

Clinical Research for Novel Rapid Diagnostic Devices for FDA clearance: Rapid diagnostic devices capable of testing for multiple infectious disease pathogens would be important assets for the US military. These devices can facilitate point-of-care testing for the enhanced, rapid and optimal clinical management of military members afflicted with infectious diseases in the deployed setting. These devices can also be used for infectious disease surveillance and outbreak investigations. Manufacturers of these rapid diagnostic devices must submit premarket notification to the FDA if they intend to market such devices in the U.S. A medical device is cleared by the FDA if well-controlled clinical studies demonstrate that it is substantially equivalent to another device which is legally on the market. NAMRU-6 has been engaged in the clearance of multiple point-of-care rapid diagnostic tests, such as the CL-Detect for cutaneous leishmaniasis, and Biofire FilmArray Global Fever Panel for detecting viral and bacterial etiologies of acute febrile syndromes. NAMRU-6 intends to advance the development of rapid diagnostic devices for other infectious diseases that are important to the military such as dengue, Zika and chikungunya virus infections and other vector-borne diseases, and multidrug resistant bacterial pathogens by testing and evaluating such devices in austere environments.

iv. General Information

The mission of NAMRU-6 is to conduct biomedical research in infectious diseases that is responsive to U.S. Navy requirements and develop knowledge, technology, and medical materiel that sustain the effectiveness of the uniformed service members through respectful cooperation with our collaborators. NAMRU-6 research focuses on the most relevant infectious disease threats to operational forces. Our researchers have conducted studies on the epidemiology, pathogenesis and prevention of viral, parasitic and bacterial diseases. For many years, NAMRU-6 has been engaged in collaborative efforts devising materiel solutions to mitigate the detrimental effects of infectious diseases on military operations around the globe. NAMRU-6's current top priority is to test and evaluate novel vaccines, drugs, and diagnostic devices to protect the warfighter from pathogens that cause diarrheal diseases, emerging and re-emerging viral diseases such as dengue, Zika and chikungunya, and parasitic diseases such as malaria and leishmaniasis.

For the warfighter to benefit from novel products, these countermeasures must be approved by the FDA. The product discovery and development pipeline is divided into Pre-Clinical and Clinical studies, with Clinical studies going from Phase 1 through Phase 4.

Clinical Research for Vaccines, Drugs and other Biologics:

This award will provide scientific and program management support for clinical research studies focused on evaluating the safety and efficacy of new drugs and vaccines, to facilitate and accelerate the process of FDA approval, acquisition and fielding of novel products. These will facilitate the transition of lifesaving vaccine and drugs from the bench to the clinics that are critical for the warfighter. During the performance period, the awardee will work collaboratively with NAMRU-6 towards advancing current products in its research portfolio to more advanced clinical testing and possible licensure while also assisting in devising new concepts and backup strategies for the current products.

Clinical Research for Novel Rapid Diagnostic Devices for FDA clearance:

This award will provide scientific and program management support for clinical research studies to facilitate and accelerate the process of FDA clearance, acquisition and fielding of novel rapid and accurate diagnostic devices that can improve the clinical management of US troops who are deployed in field settings where access to traditional reference laboratory capabilities are limited. During the performance period, the awardee will work collaboratively with NAMRU-6 towards advancing current products in its research portfolio to more advanced clinical testing and FDA clearance while also assisting in devising new concepts and backup strategies for the current products.

v. Summary of Responsibilities

Awardee responsibilities for the two focus areas are as follows:

1. Clinical Research for Vaccines, Drugs and other Biologics: Conduct Clinical Trials in the field of infectious diseases to evaluate the safety and efficacy of vaccines, drugs and other biologics as per Good Clinical Practices (cGCP), International Council for Harmonization (ICH) guidelines and Peruvian Clinical Trial Regulation (Decreto Supremo (DS) Nº 021-2017-SA). These studies will include clinical trials that optimize existing FDA-approved drug regimens to enhance the treatment and prevention of infectious diseases. The awardee's tasks will include but are not limited to the following:

    - Identification, development, approval and implementation of clinical study sites that meet FDA standards and are certified by the General Office for Research and Technology Transfer (OGIT), if required;
    - Identification and provision of principal investigators (PIs), associate investigators (AIs) and other essential study personnel;
    - Development and implementation of regulatory strategies;
    - Development, implementation and management of a budget and clinical trial finances;
    - Development, approval and implementation of study protocols, informed consent forms (ICFs), case report forms (CRFs), standard operation procedures (SOPs), manual of operation procedures (MOPs), manual of laboratory procedures (MLPs) and other regulatory documents for study execution;
    - Development and execution of statistical analysis plan (SAP); generate statistical analysis reports;
    - Execute scientific and administrative aspects/tasks in support of each clinical trial;
    - Support and obtain Peruvian Ministry of Health (MOH), Regional and local institutional review board (IRB) approvals;
    - Select, hire and coordinate efforts with local clinical laboratories, in accordance with the study protocols;
    - Follow all guidelines and regulations for handling of investigational products, in accordance with the Investigational Brochure (IB) or any similar required document;
    - Assure test product accountability;
    - Support all activities for data analysis such as data collection/acquisition, data management, and quality control/quality assurance;
    - Conduct study audits/clinical monitoring;
    - Provide computer/communication devices/internet services and mobile data services in support of conducting and executing clinical trials;
    - Facilitate and support the writing of monthly, annual and final reports, including final reports for submission to the FDA;
    - Interact and coordinate with the research administrative program (RAP), clinical trial unit (CTU), and other science or administration departments (as needed) at NAMRU-6 and collaborating agencies; and,
    - Support NAMRU-6 in finding industry/pharma collaborators to execute clinical trials in this focus area.

2. Novel Rapid Diagnostic Devices for FDA clearance: Conduct clinical trials in the field of infectious diseases to evaluate and test novel diagnostic devices as per Good Clinical Practices (cGCP), International Council for Harmonization (ICH) guidelines and Peruvian Clinical Trial Regulation (DS Nº 021-2017-SA). The awardee's tasks will include but are not limited to the following:

    - Identification, development, approval and implementation of clinical study sites that meet FDA standards and are certified by the General Office for Research and Technology Transfer (OGIT), if required;
    - Identification and provision of principal investigators (PIs), associate investigators (AIs) and other essential study personnel;
    - Development and implementation of regulatory strategies;
    - Development, implementation, and management of a budget and clinical trial finances;
    - Development, approval, and implementation of study protocols, informed consent forms (ICFs), case report forms (CRFs), standard operation procedures (SOPs), manual of operation procedures (MOPs), manual of laboratory procedures (MLPs) and other regulatory documents for study execution;
    - Development and execution of statistical analysis plan (SAP); generate statistical analysis reports;
    - Execute scientific and administrative aspects/tasks in support of each clinical trial;
    - Support and obtain Peruvian MOH, Regional and local IRB approvals;
    - Select, hire and coordinate efforts with local clinical laboratories, in accordance with the study protocols;
    - Follow all guidelines and regulations for handling of investigational products, in accordance with the Investigational Brochure (IB) or any similar required document;
    - Assure test product accountability;
    - Support all activities for data analysis such as data collection/acquisition, data management, and quality control/quality assurance;
    - Conduct study audits/clinical monitoring;
    - Provide computer/communication devices/internet services and mobile data services in support of conducting and executing clinical trials;
    - Facilitate and support the writing of monthly, annual and final reports, including final reports for submission to the FDA;
    - Interact and coordinate with the research administrative program (RAP), clinical trial unit (CTU) , and other science and administrative departments (as needed) at NAMRU6 and collaborating agencies; and,
    - Support NAMRU-6 in finding industry/pharma collaborators to execute Clinical Trial in this focus area.

vi. Oversight of Research Activities Under the Cooperative Agreement

The NAMRU-6 GOR will provide oversight of research activities covered under the cooperative agreement. The GOR will coordinate with program managers (PMs) from each NAMRU-6 department, as required by the research studies. The PMs will coordinate with project investigators to stay abreast of progress toward meeting established milestones.

vii. Use of Human Subjects / Human Biological Substances

Research activities utilizing human subjects and biological substances are a core requirement of this agreement. All Federal and Department of Defense (DOD) regulations must be met as applicable. Applicable laws and directives are rigorous and detailed. Regulatory support activities required under this agreement include, (1) FDA filings in support of Investigational New Drug (IND) and similar applications, (2) compliance with Sponsor requirements, (3) preparation and submission of protocols, reports and supporting materials in support of new and ongoing Institutional Review Board (IRB) reviews and DoD-mandated scientific reviews (SRB-reviews), and (4) as needed, some DoD-funded research involving

human subjects requiring Human Research Protection Officer (HRPO) review in accordance with DoD Federal Acquisition Regulation Supplement (DFARS) Protection of Human Subjects in Research directives. A minimum of 3-months and additional submission requirements will be needed for studies requiring HRPO review.

10. Point(s) of Contact

Questions of a technical or business nature should be submitted in writing to the NMLC Grants Officer via email at jennifer.m.mcmurry.civ@mail.mil and jaclyn.p.svincek.civ@mail.mil. Please cite the funding opportunity number in the subject line.

The deadline for the submission of questions is 10:00 AM Eastern Time on 22 October 2019.

Amendments or revisions to the funding opportunity will be posted to the following web page: Grants.gov (http://www.grants.gov/). It is the applicant's responsibility to monitor the website for any amendments or revisions.

11. Funds Available and Anticipated Number of Awards

NMLC intends to award a single Cooperative Agreement for a single 60 month period of performance (divided into five 12-month budgets) to the awardee for collaborative efforts with NAMRU-6 on the clinical trials. Funding will be provided on the base award (and added incrementally) to provide for the personnel and research materiel that is necessary for the collaborative research being conducted under the cooperative agreement. All direct and indirect costs of any sub-award (sub-grant or sub-contract) must be included in the total direct costs of the primary award. Research, Development, Testing and Evaluation (RDT&E) funds are anticipated for this requirement.

The maximum allowable funding for the entire 60 month base period is $41,822,342.40, inclusive of direct and indirect costs. Funding is planned as follows:

Budget Period	**Amount**
12 Month Budget Period 1	$7,877,429.37
12 Month Budget Period 2	$8,113,752.27
12 Month Budget Period 3	$8,357,164.83
12 Month Budget Period 4	$8,607,879.78
12 Month Budget Period 5	$8,866,116.15
Total	$41,822,342.40

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

- Salary to include administrative support
- Research supplies
- Equipment and equipment maintenance
- Clinical research costs, including research subject compensation
- Support for developing and maintaining collaborations
- Assistance and collaboration with writing and submitting manuscripts and reports
- Travel between collaborating institutions
- Travel costs to attend scientific/technical meetings
- Other direct costs as described in the Application Instructions for the budget

II. ELIGILIBLITY INFORMATION

1. Eligibility

All Qualified sources from academia and industry may submit applications under this funding opportunity. Historically Black Colleges and Universities (HBCUs) and Minority Institutions (MIs) are encouraged to submit applications and join others in submitting applications. However, no portion of this funding opportunity will be set aside for HBCU and MI participation.

Federally Funded Research & Development Centers (FFRDCs), including Department of Energy National Laboratories, are not eligible to receive an award under this funding opportunity. Cost sharing/matching is not an eligibility requirement.

The awardee shall have at least one active trial site approved and registered in Peru at the time of selection.

2. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management (SAM)

Applicant organizations and all sub recipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an "Active" status to submit applications through the Grants.gov portal. Applicant organizations shall verify the status of their Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Refer to the General Application Instructions for further information regarding Grants.gov requirements.

The Federal Funding Accountability and Transparency Act of 2006 (Public Law 109-282), as amended by Section 6202 of Public Law 110-252, requires that all agencies establish requirements for awardees reporting information on sub-awards and executive total compensation as codified in the award provision in appendix A to 2 CFR part 170, "Reporting subaward and executive compensation information (refer to REP Article IV. Reporting on subawards and executive compensation. (September 2017)) in the DoD R&D General Terms and Conditions July 2018. Any company, non-profit agency or educational institution that applies for financial assistance as either a prime or subrecipient under this funding opportunity must provide information in its application that describes the necessary processes and systems in place to comply with the reporting requirements identified in 2 CFR 200.330.

III. APPLICATION AND SUBMISSION INFORMATION

Please refer to the separate Application Instructions document.

IV. EVALUATION INFORMATION

1. Review and Selection Process

The award decision will be based on a competitive selection of the application resulting from a three-tier review process.

The first tier is a completeness review that ensures that the application provides support of all research focus areas outlined in Section I.9.iii of this Program Announcement. Failure of an application to document support of all research focus areas may (at the discretion of the Grants Officer) cause an application to not be forwarded for the peer and programmatic reviews and therefore, not be eligible to be funded.

The second tier is a peer review of applications against established criteria for determining technical merit, as identified below in paragraph 2.

The third tier is a programmatic review that compares applications to each other and makes a recommendation for funding to the Commanding Officer (NAMRU-6), for concurrence, and then to the NMLC Grants Officer for award processing.

2. Review Criteria

A. Peer Review

To determine technical merit, all applications will be evaluated according to the criteria listed below. Criteria 1 through 3 are of equal importance, and when combined, are more important than Criteria 4.

1) Overall scientific and technical merits of the application;
2) Military relevance and contributions of the proposed effort;
3) The applicant's capabilities, related organizational experience, previous work, facilities, techniques, key personnel (qualifications, capabilities and experience) or unique combinations of these which are integral factors for achieving the proposed objectives; and
4) Budget: Whether the budget is appropriate for the proposed effort and within the funding limitation of this funding opportunity.

B. Programmatic Review

The following equally weighted criteria will be used by programmatic reviewers to make the funding recommendation.

1) Ratings and evaluations of the peer reviewers;
2) Programmatic relevance;
3) Adherence to the intent of the funding opportunity; and
4) Evaluation on the cost of their solution(s) based on the work to be performed in accordance with the scope of this project and organizational experience.

V. AWARD ADMINISTRATION INFORMATION

1. Administrative Requirements

Organizations must register in Grants.gov to submit applications through the Grants.gov portal. The registration process may take several weeks, so organizations should register as soon as possible.

All applicants must:

- Be registered as an Entity within the SAM (http://www.sam.gov) and receive confirmation of an "Active" status before submitting an application through Grants.gov;
- Maintain an active SAM registration with current information at all times during which it has an active Federal award or an application under consideration by any agency;
- Provide its DUNS number in each application it submits to the agency;
- Have the management capability and adequate financial and technical resources, given those that would be made available through the cooperative agreement, to execute the program of activities envisioned under the cooperative agreement;
- Have a satisfactory record of executing such awards (if a prior recipient of an award); and
- Be otherwise qualified and eligible to receive a cooperative agreement under applicable laws and qualifications.

Prior to making an assistance agreement award where the Federal share is expected to exceed the simplified acquisition threshold, as defined in 2 CFR 200.88, over the period of performance, the Federal

awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant organization may review FAPIIS and submit comments to FAPIIS on any information about the organization that a Federal awarding agency previously entered and is currently available in FAPIIS.

The Federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when determining a awardee's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGARs), Section 22.415.

2. Certifications

A. Representations for Assistance Agreements

The applicant that is selected for award will be required to complete NMLC's Representations Form during the negotiations process. This form will be sent to the applicant who is selected for award by the NMLC Grant's Officer.

B. Certification Regarding Lobbying Activities

Cooperative Agreement awards greater than $100,000, under Title 31, United States Code (U.S.C.), Section 1352 (PL 101-121, Section 319), require a certification of compliance with a national policy mandate concerning lobbying. Grant and Cooperative Agreement applicants shall provide this certification by electronic submission of SF424 (R&R) as a part of the electronic application submitted via Grants.gov (complete Block 17). The certification applies to each applicant seeking federal assistance funds exceeding $100,000.

CERTIFICATION REGARDING LOBBYING ACTIVITIES

Certification of compliance with the national policy requirement regarding lobbying activities is required from all awardees of awards over $100,000. Submission of this certification is required by 31 U.S.C. 1352 and is a prerequisite for making or entering into an award over $100,000. Complete SFLLL (Disclosure of Lobbying Activities), if applicable, and attach to Block 18 of the SF424 (Research & Related) (Application for Federal Assistance) Form.

Certification for Contracts, Grants, Loans, and Cooperative Agreements

By signing an application, the applicant certifies, to the best of his or her knowledge and belief, that:

(1) No Federally appropriated funds have been paid or will be paid by or on behalf of the under-signed, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federally appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award

documents for all subawards at all tiers (including subgrants, and contracts under grants, loans, and cooperative agreements) and that all sub awardees shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by 31 U.S.C. 1352. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

3. Funding

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

4. Government Obligation

Only a warranted Grants Officer may obligate the Government to the expenditure of funds for an award under this funding opportunity. The Government does not fund preparation of applications or support research that is inferred from discussions with technical program officers.

5. Maximum Obligation

NMLC does not modify awards to provide additional funds for such purposes as reimbursement for unrecovered indirect/facilities and administrative costs resulting from the establishment of final negotiated rates or for increases in salaries, fringe benefits, and other costs.

VI. OTHER INFORMATION

1. Government Property/Government Furnished Equipment (GFE) and Facilities

Government research facilities, laboratory equipment and IT equipment (desktop computers, laptop computers, and mobile devices) are available and should be considered as potential government-furnished equipment/facilities. The use of these facilities, equipment and IT devices are authorized, provided the personnel requiring the use of this equipment have the necessary training and security clearances in place.

2. Security Classification

To facilitate intra-program collaboration and technology transfer, the Government will attempt to enable technology developers to work at the unclassified level to the maximum extent possible. If access to classified material will be required at any point during performance, the applicant must clearly identify such need in the Technical Volume.

Note: Normally, work under an assistance agreement does not require access to classified material.

3. Use of Human Subjects in Research

A. Applicable Regulations

Human Subjects: The performance of research involving human subjects shall be conducted in accordance with The Common Federal Policy for the Protection of Human Subjects codified by the Department of Health and Human Services at 45 CFR 46 Part A, and implemented by the Department of Defense with 32 CFR 219 “The Common Rule,” 10 USC 980 “Limitation on Use of Humans as Experimental Subjects,” Department of Defense (DoD) Instruction 3216.02 “Protection of Human Subjects

and Adherence to Ethical Standards in DoD-Supported Research," and Secretary of the Navy Instruction 3900.39D (series) "Human Research Protection Program," as well as other applicable federal and state law and regulations, and Department of the Navy guidance. The awardee must be cognizant of and abide by the additional restrictions and limitations imposed on the DoD regarding research involving human subjects, specifically as they regard vulnerable populations, recruitment of military research subjects, and informed consent and surrogate consent, and chemical and biological agent research. Food and Drug Administration regulation and policies may also apply. Department of the Navy, Human Research Protection Program (DON HRPP) guidance for human subject research is located at https://www.med.navy.mil/Pages/InfoViewPage.aspx?ItemID=6.

Any human subject research to be conducted under this cooperative agreement requires a Human Research Protection Officer (HRPO) approval. No funds are to be expended until the HRPO review has been received by the NMLC Grants Officer and a subsequent modification has been issued to the assistance agreement to list the approved human subject research protocol by name.

Example from the terms and conditions of a NMLC assistance agreement award:

"Human subject research is not allowed under this award, except under the protocol(s) named below:

A. Protocol A.
B. Protocol B."

When a HRPO review has been received by the NMLC Grants Officer, the research protocol will be added to this list in the award terms and conditions and thereby lifting the restriction on human subject research under the named protocols only.

B. Required Assurances

The objectives of the award to Conduct of Clinical Trials to Facilitate the Development and Approval of Novel Countermeasures (vaccines, devices, drugs) for Use by the Warfighter dictate that there will be Human Subject Research conducted by the successful awardee. Therefore the awardee must possess the following assurances:

- An active (i.e., not expired) Federal-wide Assurance (FWA) appropriate for research to be conducted under the award. The FWA shall remain active for the duration of the award. The FWA is issued by the Department of Health and Human Services.

C. Intramural Research

Intramural research is research (or services supporting the research) conducted by one or more government agencies using Government facilities with Government staff (to include Principle Investigators) and under Government protocols and a Government IRB.

The awardee must complete the following requirements prior to the performance of research involving human subjects or expenditure of funding on such effort (whichever occurs first):

- The awardee shall rely on the Government organization's designated IRB as the IRB of record for the research to be supported under the award. The awardee shall enter into a DoD Institutional Agreement for IRB Review (IAIR) with the designated Government organization. The IAIR will apply to all human subject research supported under the specific study(s). The IAIR shall be executed by the parties no later than 30 days after the effective date of the award, or before commencement of performance of research involving human subjects or expenditure of funding, whichever occurs first.
- Awardee personnel providing support under the award shall complete initial and ongoing research ethics and human subject protections training appropriate to each individual's level of

involvement, duties, and responsibilities. Specific training requirements will be directed by the designated Government organization.

- The awardee shall obtain written notice from the designated Government organization that: (i) awardee and/or partner personnel identified as supporting human subject research under the award have been added to the applicable research protocol; (ii) performance of the protocol has been approved by the designated Government organization's Institutional Official and that performance may begin; (iii) a determination that the protocol meets exemption criteria including the exemption category or classification of research risk (e.g., minimal risk); (iv) confirmation of continuing acceptability of the awardee and/or partner's assurances; and (v) Human Research Protection Official (HRPO) review of the protocol has been completed. Awardee personnel shall not commence performance of research involving human subjects until stated notice is received.
- The awardee shall notify the designated Government organization of personnel changes under the award. New personnel that will perform research involving human subjects will be required to complete applicable training and will be added to the applicable research protocol(s) as discussed above.

The awardee shall supplement administrative efforts by the designated Government organization to ensure compliance with the listed requirements for intramural research. This includes identifying contract personnel that contribute to the required human subject research under the award and maintaining records of training and other documentation to demonstrate compliance with human research protection requirements under the award. The awardee shall also assist with the continuing review of the human subject research that is necessary under the award.

Failure of the awardee to comply with the listed requirements for intramural research will result in the issuance of a stop-work order to immediately suspend, in whole or in part, work and further payment under this award or will result in other issuance of suspension of work and further payment for as long as determined necessary at the discretion of the Grants Officer.

The listed requirements for intramural research are applicable to and shall be included in all subawards made by the awardee's administrator to organizations that may conduct human subject research.

D. Extramural Research

Extramural research is research that is funded by the Government, but that is conducted using awardee or subawardee facilities with awardee or subawardee staff (to include Principal Investigators) and under the awardee or subawardee's protocols and IRB.

If the awardee or subawardee is conducting extramural research involving human subjects, it must complete the following requirements prior to the performance of research involving human subjects or expenditure of funding on such effort (whichever occurs first):

The awardee or subawardee must submit the following documents (if applicable) for review by the designated Government organization's HRPO:

- IRB Approval Letter or IRB Exemption Determination Letter
- IRB Risk level Determination for Non Exempt Research (Minimal or Greater than Minimal Risk)
- IRB Approved Protocol for Non Exempt Research
- IRB Approved Informed Consent Form for Non Exempt Research (or documented exemption in protocol)

The awardee or subawardee must receive written notice that the research has been reviewed by the designated Government organization's HRPO and that performance may begin.

Failure of the awardee or subawardee to comply with the listed requirements for extramural research will

result in the issuance of a stop-work order to immediately suspend, in whole or in part, work and further payment under this award or will result in other issuance of suspension of work and further payment for as long as determined necessary at the discretion of the Grants Officer.

The listed requirements for extramural research are applicable to and shall be included in all subawards made by the awardee administrator to organizations that may conduct human subject research.

4. Biosafety and Biosecurity Requirements.

The awardee and all subawardees must comply with applicable provisions of DOD 6055.18-M, Safety Standards for Microbiological and Biomedical Laboratories, including ensuring compliance with standards meeting at least the minimum applicable requirements of the current edition of Centers for Disease Control and Prevention, “Biosafety in Microbiological and Biomedical Laboratories (BMBL),” and National Institutes of Health, “The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).” The NIH Guidelines are available at https://osp.od.nih.gov/biotechnology/biosafety-and-recombinant-dna-activities/.

5. Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

Applications which call for experiments using Recombinant or Synthetic Nucleic Acid Molecules and/or organisms and viruses containing Recombinant or Synthetic Nucleic Acid Molecules must include documentation of compliance with the National Institutes of Health "Guidelines for Research Involving Recombinant DNA Molecules". The NIH Guidelines are available at https://osp.od.nih.gov/biotechnology/biosafety-and-recombinant-dna-activities/.

Performance of experiments using Recombinant or Synthetic Nucleic Acid Molecules and/or organisms and viruses containing Recombinant or Synthetic Nucleic Acid Molecules, shall not begin until the awardee receives notice from the NMLC Grants Officer that NMLC has reviewed and accepted the awardee’s documentation.

In order for NMLC to accomplish that review, the awardee shall provide the following documentation as part of your Attachment 1 - Technical Volume.

a. A written statement that your entity is in compliance with NIH Guidelines. This statement should be made by an official of the institution other than the Principal Investigator and should be on university or company letterhead.
b. Evidence demonstrating that your proposed research protocol has been approved by an Institutional Biosafety Committee (IBC); and a copy of the Department of Health and Human Services (DHHS) Letter of Approval of the IBC, or the most recent letter from DHHS stating the IBC is in compliance with the NIH Guidelines.

The awardee will not receive a separate approval for the proposed research under this paragraph. If the applicant received the award based on a proposal including the two aforementioned items, the awardee can assume the NMLC Grants Officer has accepted that documentation. If such research is added later, the awardee will have to provide the two items of documentation listed above and a revised proposal. If this research is approved, you will receive a modification incorporating the revised proposal.

For research involving countries outside the United States, if the host country has established rules for the conduct of recombinant or synthetic nucleic acid molecule research, then the research must be in compliance with those rules. If the host country does not have such rules, the proposed research must be reviewed and approved by an NIH-approved IBC or equivalent review body and accepted in writing by an appropriate national governmental authority of the host country. The safety practices that are employed abroad must be reasonably consistent with the NIH Guidelines.

6. Organizational Conflicts of Interest

All Applicants and proposed sub-awardees must affirm whether they are providing Systems Engineering and Technical Assistance (SETA) or similar assistance to any NAMRU-6 technical office(s) through an active contract or subcontract. All affirmations must state which office(s) the applicant assists and identify the corresponding, prime assistance agreement/contract numbers. Affirmations shall be furnished at the time of application submission. All facts relevant to the existence or potential existence of organizational conflicts of interest (2 CFR 200.112 and 2 CFR 200.318(c)) must be disclosed. The disclosure shall include a description of the action the applicant has taken or proposes to take to avoid, neutralize, or mitigate such conflict. Applications that fail to fully disclose potential conflicts of interests or do not have acceptable plans to mitigate identified conflicts will be rejected without technical evaluation and withdrawn from further consideration for award. If a prospective applicant believes that any conflict of interest exists or may exist (whether organizational or otherwise), the applicant should promptly raise the issue with NMLC by sending his/her contact information and a summary of the potential conflict by e-mail to the Business Point of Contact in Section I, item 10 above, before time and effort are expended in preparing an application and mitigation plan. If, in the sole opinion of the Grants Officer after full consideration of the circumstances, any conflict situation cannot be effectively avoided or mitigated, the application may be rejected without evaluation and withdrawn from further consideration for award under this funding opportunity.

7. Project Meetings and Reviews

Project meetings and reviews will be conducted at the departmental level as well as in conjunction with scheduled reviews and meetings as required by the funding sponsors. For costing purposes, applicants should assume that most of these meetings will be at or near NAMRU-6 or other awardee or Government facilities. Interim meetings are likely, but these will be accomplished via video telephone conferences, telephone conferences, or via web-based collaboration tools.

8. Award Negotiations

Extramural research programs are implemented predominantly through the award of assistance agreements that are made to an organization, not to the individual Principal Investigator(s) (PI[s]). A representative from NMLC will contact the business official authorized to negotiate on behalf of the PI's organization. The award start date will be determined during the negotiation process.

Only an appointed NMLC Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government should be inferred from discussions with any other individual. Any pre-award costs associated with a research effort are made at an organization's own risk. The incurring of pre-award costs by an organization does not impose any obligation on the Government in the absence of appropriations, if an award is not made, or if an award is made for a lesser amount than an organization expected.

9. Reporting Requirements for Awards

The Government requires periodic reports to be submitted to continue the research and funding through the entire period of performance. Specific reports required by the Government will be described in the award and may include: quarterly, mid-term, annual, and final research progress reports; fiscal reports; non-exempt human studies reports; and animal use reports.

10. Equipment

Unless otherwise specified in the award, the title to equipment or other tangible property purchased with Government funds will vest in institutions of higher education or with non-profit organizations whose primary purpose is conducting scientific research. Normally, the title will vest in the awardee if vesting will facilitate scientific research performed by the organization for the Government. Title to equipment or other tangible property purchased by for-profit organizations will conditionally vest in the organization

subject to the requirements of 2 Code of Federal Regulations (CFR) part 200. However, if the award is subsequently transferred to a new organization, the Department of Defense (DoD) reserves the right to require the transfer of equipment purchased with the award funds to the Federal Government or to an eligible third party.

11. Inquiry Review

If an application is not recommended for funding, the organization or PI may submit an inquiry within 30 business days after the date on which the funding status notification email for that application is sent. The inquiry must specifically address a factual or procedural error that is believed to have occurred during review of the application. Inquiries in response to funding decisions should be submitted to the NMLC Grants Officer via email at jennifer.m.mcmurry.civ@mail.mil and jaclyn.p.svincek.civ@mail.mil. Please cite the funding opportunity number in the subject line.

An inquiry review panel will determine whether a factual or procedural error occurred in either peer or programmatic review and, if so, recommend corrective action where appropriate. Considering the recommendation of the inquiry review panel, a final determination will be made by the NMLC Grants Officer and is not subject to appeal. Questions related to the inquiry review process prior to or after submitting an inquiry should be directed to the NMLC Grants Officer via email at jennifer.m.mcmurry.civ@mail.mil and jaclyn.p.svincek.civ@mail.mil. Please cite the funding opportunity number in the subject line.

12. J-1 Visa Waiver

Each organization is responsible for ensuring that the personnel associated with any application recommended for funding are able to complete the work without intercession by the DoD for a J-1 Visa Waiver on behalf of a foreign national in the United States under a J-1 Visa.

13. Clinical Trial Registry

PIs are required to register clinical trials individually on www.clinicaltrials.gov using a Secondary Protocol ID number designation of “NMLC-NMLC Award Number” (e.g., NMLC-N62645-20-1-XXXX). If several protocols exist under the same application, the Secondary Protocol ID number must be designated “NMLC-NMLC Award Number-A, B, C, etc.” (e.g., NMLC-N62645-20-1-XXXX-A). Clinical trials must be registered prior to enrollment of the first patient. All trials that meet the definition on the National Institutes of Health database (see http://prsinfo.clinicaltrials.gov/, click on “Data Element Definitions”) are required to register. Failure to do so may result in a civil monetary penalty and/or the withholding or recovery of grant funds as per U.S. Public Law 110-85.

14. Title to Inventions and Patents

The awardee has patent rights in Subject Inventions, as defined in 37 CFR 401.2, in accordance with 37 Code of Federal Regulations (CFR) part 401, subject to the requirements of 37 CFR 401.14. The Federal government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any Subject Invention. Furthermore, the Federal Government, IAW 37 CFR part 401 has the right to reproduce, publish or otherwise use the data first produced under an award and to authorize others to receive, reproduce, publish or otherwise use such data for Federal purposes. Data will be delivered to the Federal Government IAW the agreement, but not less than annually. The awardee may copyright any work subject to copyright protection. The DoD reserves a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes and to authorize others to do so.

15. Administrative and National Policy

This award is governed by the guidance in Title 2 Code of Federal Regulations (CFR) part 200, "Uniform

Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards," as modified and supplemented by the Department of Defense's (DoD) interim implementation found at 2 CFR part 1103, "Interim Grants and Cooperative Agreements Implementation of Guidance in 2 CFR part 200" (79 FR 76047, December 19, 2014), all of which are incorporated herein by reference and the articles below.

Provisions of Chapter I, Subchapter C of Title 32, CFR, "DoD Grant and Agreement Regulations (DoDGARs)," other than parts 21, 22, 32, 33 and 37, continue to be in effect and are incorporated herein by reference, with applicability as stated in those provision.

This award is subject to the Department of Defense (DoD) Research and Development (R&D) General Terms and Conditions (July 2018).

16. NMLC Assistance Agreement Terms & Conditions

The following terms and conditions (T&Cs) apply to assistance agreement awards made by NMLC:

T&Cs for Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations
T&Cs for For-Profit Organizations
T&Cs for Foreign Institutions

These T&Cs are located at http://www.med.navy.mil/sites/nmlc/Pages/DBU-RnG.aspx**.**