



THE CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS AWARD GUIDE FOR FUNDED INVESTIGATORS

December 2015
revision

****UPDATES****

Effective October 1st, 2014 the process related to Safety and Environmental Documents and Approvals has changed which is reflected in this version. If you have an award made before October 1st, 2014 and have questions related to this, please contact your Science Officer.

Effective November 2015, the final project report should be submitted electronically no later than 120 days following the end of the grant. Note, however, that awards made prior to November 2015 retain the requirement to submit final project reports no later than 90 days following the end date of the award.

Effective November 2015, awardees must notify the USAMRAA Grants Officer, in writing, at least 30 calendar days prior to the expiration date of the award of their desire to extend the award period of performance without additional funds. This is a change from the prior 10 day requirement.

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Introduction

I. Overview

This guide is intended for investigators who have been recommended for funding through the Congressionally Directed Medical Research Programs (CDMRP). This document provides detailed information regarding various regulations and requirements related to the award. The Principal Investigator (PI) of an application selected for award is responsible for adhering to these regulations and requirements and working efficiently with the various Department of Defense (DoD) staff members, as needed. The information provided in this guide is divided into three sections, based on the primary phases of the award process (Figure 1).

- 1. PHASE I – Scientific Assessment and Execution of Assistance Agreements:** After notification from the United States Army Medical Research Acquisition Activity (USAMRAA) Grants Officer that an application has been recommended for funding, the application enters a pre-award phase. This phase includes a scientific assessment of applications recommended for funding and award negotiations. It involves communication between the PI and a Grants Officer's Representative (GOR) assigned to the award or a Science Officer working on behalf of the GOR. This phase also includes negotiations between the PI's institution and the USAMRAA Grants/Contract Specialist, as well as PI interaction with the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP) for review of the use of animals and human subjects. Communication with other USAMRMC offices may occur as needed. USAMRAA is the contracting office under the USAMRMC and the only office which can issue an award. The pre-award phase concludes with the issuance of an Assistance Agreement. The Assistance Agreement is the official award document.
- 2. PHASE II – Award Management:** Applications enter an active award phase once negotiations have been completed and an award has been issued. During this phase, the GOR or Science Officer will actively monitor and manage the award from a scientific perspective. The PI and the recipient institution will be responsible for adhering to all the terms and conditions set forth in the award including submission of technical progress reports, financial reports and patent reports. The recipient will also be required to notify the Science Officer and, in some cases, the Grants/Contract Officer of any changes that might impact the planned progress of the project.
- 3. PHASE III – Award Closeout:** This is the phase during which the award is closed out. The Post-Award phase begins at the end of the award performance period, and involves the submission of a final technical progress report, patents and inventions disclosure and other final reports to document the products and outcomes that have resulted from the DoD-funded study.

Award Management Cycle

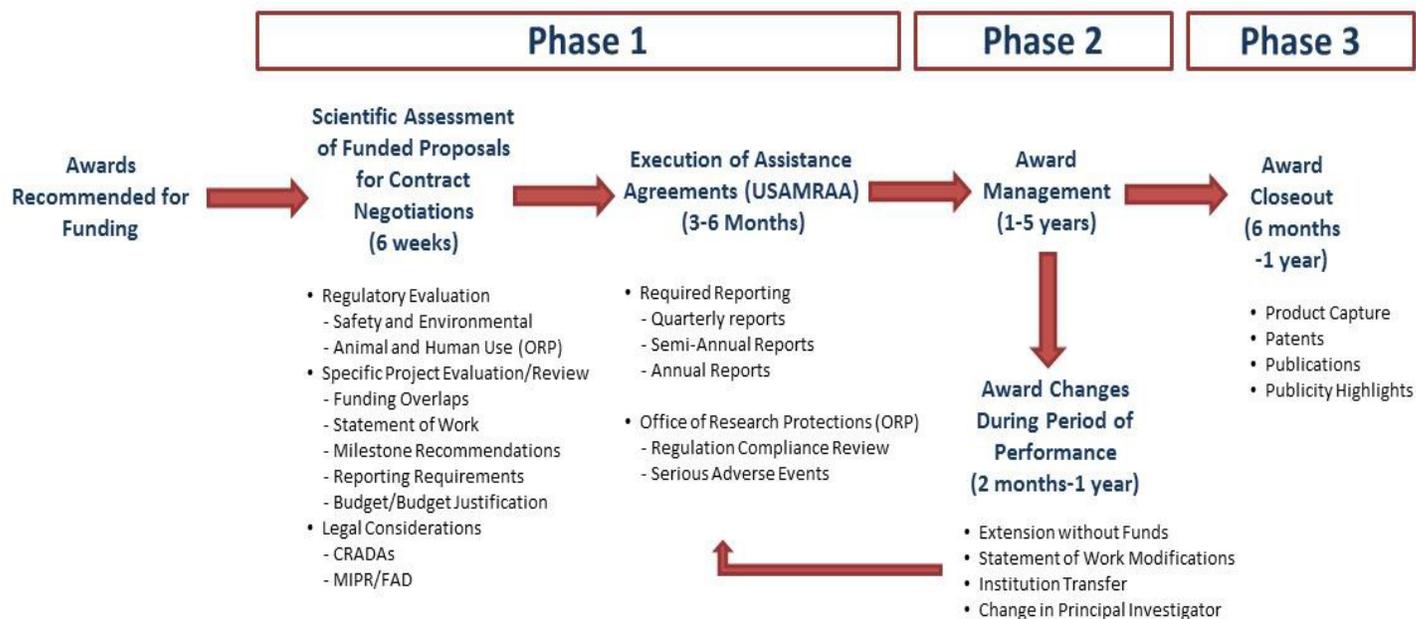


Figure 1. The CDMRP Award Management Cycle

II. Roles and Responsibilities of USAMRMC Participants

Negotiation, execution, and management of research awards are a collaborative effort between CDMRP, USAMRAA, ORP, and other USAMRMC offices. No single office can specialize in all the requirements of application submission, contracting laws, and regulatory requirements. Just as institutions of higher learning have separate laboratories, offices of sponsored research, and Institutional Review Boards (IRBs), we have separate offices located in separate buildings. The following list of participants represents key individuals involved in the management of the award.

A. Science Officer (SO)

CDMRP is the program office that manages and executes the program cycle from investment strategy to award execution. The Science Officer is a CDMRP staff member selected for his/her technical knowledge and scientific expertise to scientifically manage awards selected for funding. The SO will act as a liaison, maintaining the proper flow of information between the recipient institution, the PI, CDMRP, USAMRAA and other offices within USAMRMC, such as ORP and Information Management (IM). The SO is the

primary point of contact for the PI on all scientific matters and general questions for the lifetime of the award. In addition, the SO is the primary source of information for the program office on all matters relating to the award to include notable accomplishments during the period of performance. If the SO and the Grant Officers Representative (see below) on an award is not the same person, the SO works on behalf of the Grant Officers Representative.

B. Grant Officers Representative (GOR)

The GOR is a Federal government employee (or Federal equivalent) appointed by USAMRAA for his/her technical knowledge and subject matter expertise. On any particular award, the Science Officer and the GOR may be the same person.

C. Contract Specialist/Grants Specialist (CS/GS)

The CS/GS is a Federal government employee within USAMRAA who is assigned to assist the USAMRAA Grants Officer with award-related issues. The USAMRAA Grants Officer is the only person who can commit funds and/or approve changes. The CS/GS is the primary point of contact for business and/or non-scientific award related issues. All communications with the CS/GS should be directed through the recipient institution's Business Office.

D. ORP (ACURO/HRPO) Reviewers

ORP regulatory personnel are research protection scientists who may request additional documentation related to the use of animal or human subjects. They review documentation for compliance with Army, DoD and host National Federal Regulations, and will issue DoD–required approvals prior to the initiation of the research with animals or humans.

E. Program Sponsor Representative (PSR)

The PSR is a government representative designated by a program office outside of CDMRP, such as a Research Area Directorate, for a given award (generally an award with direct military interest) to serve as a technical resource in support of award management. A PSR works directly with the CDMRP Science Officer to facilitate success of the award. It is important to note that PSRs work through the CDMRP Science Officer with respect to the award, and therefore all correspondence shall include the assigned SO (and GOR as necessary).

Chapter 1: Scientific Assessment and Execution of Assistance Agreements

I. The Funding Notification Letter

A. What is the Funding Notification Letter?

At the conclusion of the review process, applications are selected and recommended for funding. The USAMRAA office notifies the selected investigators and their respective institutions via a Funding Notification Letter. The Funding Notification Letter, peer review summary statement, and program information paper are posted in the CDMRP electronic receipt portal (<https://ebrap.org>) for easy access by the PI and his/her institution's Business Official. PIs and Business Officials are electronically notified that these documents are posted and available.

The Funding Notification Letter is an important pre-award document that informs the PI and his/her Business Official of the steps in the award process, including the submission of required pre-award documents. The letter provides specific instructions for updating information and uploading documents, as well as a deadline for completing these actions. Following receipt of this letter, the CDMRP Science Officer assigned to manage the award will contact the PI to provide guidance to him/her through the pre-award phase.

B. Information Requested in the Funding Notification Letter

PIs are responsible for responding to post submission questions and uploading the required award documents requested in the Funding Notification Letter via the CDMRP electronic receipt portal (<https://ebrap.org>).

Required documents:

Note! For awards made after October 1st 2014, the initial Safety and Environmental documents requested in prior years are no longer required for every award. The USAMRMC Surety and Environmental (SE) Office will follow up with individual awardees as required.

i. Updated Support Information

The Previous, Current and Pending Support (PCPS) is a document detailing all past, existing /current, and pending support for the PI and key personnel. Although PCPS information is submitted with the initial application, an updated / more current PCPS is required with the pre-award documents to reflect any changes between the application submission date and the time the Funding Notification Letter is sent. There is no specific format required by the DoD for the PCPS but, at minimum, the PCPS should include all previous (award period of performance ending within the past 5 years), current, and pending research support

information, including:

Title of award/support:

Supporting agency:

Name/contact info of agency's procuring Contracting/Grants Officer:

Performance period:

Level of funding:

Level of effort (in percentage or calendar months):

Brief description of project goals:

Potential Overlap:

The PCPS should clearly indicate whether the proposed project overlaps with other existing and pending research projects. CDMRP's position on research duplication and procedures to avoid duplication can be found on the CDMRP website: <http://cdmrp.army.mil/funding/researchDup>. If there is no overlap, clearly state as such under each project listed on the PCPS. Total level of effort for all supported research, including the pending DoD-supported project, cannot exceed 100%.

Note! It is essential that the PCPS be accompanied by a cover letter signed by a business official certifying that the information is current and accurate, and, if necessary, it should address any scientific or financial overlap issues. The cover letter should be the first page of the PCPS and it should be submitted as a single, continuous document.

ii. **Documents related to the Use of Animals, Human Subjects and the Use of Human Specimens**

Any award involving the use of animals or human subjects will require review and approval by the USAMRMC ORP prior to beginning any animal or human subject work. The ORP review and approval is in addition to an institution's local review and approval. Additional information about the role of the ORP and the documents required for ORP review can be found in Chapter 2, section I.A.

The Science Officer assigned to the award guides the PI as to which approvals are needed for the award and works with the PI to obtain these approvals during the pre-award phase. For additional information regarding ORP requirements and the most common scenarios encountered during the review of the use of animal and human subjects please see the ORP requirements section in Chapter 2. Any supporting documents for ORP approval are to be submitted through the CDMRP electronic portal (<https://ebrap.org>); PIs should also inform their Science Officer by email when documents have been submitted.

II. What are Award Negotiations and Who is Involved?

Award negotiation is a multi-step process that occurs between the time an application has been recommended for funding and when the award is made. The award negotiation process involves:

A. The Pre-Negotiation Phase

The CDMRP Science Officer assigned to the award contacts the PI, facilitates collection of the initial documents required as stated in the Funding Notification Letter, and conducts a technical review of the application in order to provide pertinent information to the USAMRAA Grants Officer prior to initiation of negotiations.

B. The Negotiation Phase

The negotiation phase begins when the USAMRAA Contract Specialist/Grants Specialist (CS/GS) assigned to the award sends a Request For Information (RFI) to the PI's institution. The RFI may request items and clarifications related to the Science Officer's technical review, and/or related to USAMRAA's contractual and administrative requirements. This can be a complex process and the PI and his or her business official should allow several weeks/months for business office communications. **While the average time from Funding Notification Letter to award is approximately 3-6 months, all awards will be made by the date described in the awards notice section of the respective Program Announcement. All awards are issued by USAMRAA.**

Note! If the awardee is an institution of higher education, hospital, or other non-profit organization, the recipient may incur pre-award costs up to 90 calendar days prior to the start date of the award agreement in accordance with the DODGAR Part 32.25(d)(2)(i). Pre-award costs as incurred by the recipient must be necessary for the effective and economical conduct of the project, and the costs must be otherwise allowable in accordance with the appropriate cost principles. Pre-award costs are incurred at the recipient's risk. The incurring of pre-award costs by the recipient does not impose any obligation on the Government in the absence of appropriations, if an award is not subsequently made, or if an award is made for a lesser amount than the recipient expected. Pre-award costs with for-profit organizations require prior written approval from the USAMRAA Grants Officer.

III. Revisions/Clarifications that may be Requested During Negotiations

A. Statement of Work (SOW) Revisions

USAMRAA may request a revised SOW during negotiations. All revisions will be within the scope of the original application and often include requests to define missing ORP approval steps and estimated number of animal and human subjects in relevant tasks. The SOW should be a sufficiently detailed document that clearly defines the project strategy to include methodology and a timeline. Progress will be evaluated against the

SOW during the review of technical progress reports. To view examples of recommended SOW formats, visit the “Generic Forms for Application Submission” section on the CDMRP electronic portal, <https://ebrap.org/eBRAP/public/Program> PIs should select the example that best aligns with their award type.

B. Budget Revisions

USAMRRA may request a revised budget if inconsistencies with direct or indirect costs are identified, requested costs are deemed inappropriate or unallowable, or if further cost justification is needed. Ensure all revised documents contain sufficient justification for all requested funds.

C. Previous, Current and Pending Support (PCPS)

USAMRAA will require a cover letter signed by a business official to accompany the PCPS if one is missing from the original submission. The signed letter serves as the institution’s certification that the reported information is current and accurate. USAMRAA may request that additional details be provided on the PCPS if critical information was omitted (e.g. dates and level of effort) or if suspected overlap is identified during the review process. Please refer to the CDMRP position on research duplication on the CDMRP website, <http://cdmrp.army.mil/funding/researchDup>.

D. Office of Research Protections (ORP) Related Considerations

i. General ORP Considerations for Awards with Animal or Human Use

During negotiations, the Science Officer assigned to the award will help guide the PI as to which approvals are needed for the award and will begin working with the PI to obtain these approvals during the pre-award phase.

Animal use investigators are encouraged to visit the USAMRMC Animal Care and Use Review Office webpage when developing animal use protocols,

https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro

Investigators conducting human research are encouraged to visit the USAMRMC Human Research Protection Office (HRPO) webpage,

https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo, and

also the HRPO frequently asked questions page,

https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.orp_faq,

prior to submitting protocols to their Institutional Review Boards (IRBs).

Please refer to Chapter 2 section I.A for further details on the ORP review process.

ii. Clinical Trials

If the application and SOW indicate the funding will support a clinical trial, key points will be addressed during the pre-award processes to facilitate the success of the trial. When preparing revised award documents such as the SOW, budget and/or clinical protocol, investigators are encouraged to review the “HRPO Submission Form

– Human Subjects Research” found at the following website:

https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

In addition, investigators should consider the following additional points:

- Inclusion of a study coordinator as personnel on the research team. This person shall contribute an appropriate level of effort. This is particularly important when the clinical trial involves multiple performance sites.
- Inclusion of personnel, as a collaborator or as part of the key research team, experienced in IRB submission and approval to assist in the development, approval process, and implementation of the trial.
- Inclusion of an experienced statistician, as a collaborator or as part of the key research team, to make sure the study is adequately powered to address the study aims (for Phase II/III trials).
- The inclusion in the SOW of various timelines for approvals applicable to the use of human subjects, including an FDA IND/IDE submission time line (if necessary) and/or preparation time for the protocol, consent forms, patient recruitment forms with the appropriate DoD language and guidelines.

IV. Execution of the Award Agreement and the Terms and Conditions of the Award

USAMRAA awards Assistance Agreements (grants and cooperative agreements) as a result of applications received under a variety of funding opportunity types, including the USAMRMC Broad Agency Announcement (BAA) and CDMRP program announcements. Assistance Agreements are subject to a variety of Federal Regulations and policies, including the Office of Management and Budget circulars. The governing DoD regulatory document is the DoD Grant and Agreement Regulations (DODGARs) (DOD 3210.6-R). For more information on the DODGAR, visit <https://www.usamraa.army.mil/index.cfm?ID=12&Type=3>.

A. Official Notification and the Start of the Award Period of Performance

Once negotiations are complete, a USAMRAA Procurement Technician sends the signed award document via email to the Business Official, with the PI copied. The email includes a subject heading similar to “Award W81XWH-##-#-#### (Award log number), Institution name.” The USAMRAA sender’s name and email address may be unfamiliar; however the importance of the attached document cannot be overstated. The attachment is the **Assistance Agreement** which contains the terms and conditions that govern the award, including recipient responsibilities, prohibition of certain types of research, and technical and financial reporting requirements. Other critical information is also included. This document should be saved in a readily accessible location, it **is the award**.

B. Important Terms and Conditions Contained in the Award Agreement

The Award Agreement will contain in full text or incorporate by reference all the terms and conditions that are applicable to the award. Brief descriptions of the key terms and conditions specifically applicable to the PI's responsibilities are found below:

i. Technical Progress Reports and Publications

The Assistance Agreement specifies the required format and frequency of the Technical Progress Reports to be submitted, so as to maintain the award agreement in good standing. These requirements include, but are not limited to:

- Technical reporting requirements (to include annual, and biannual or quarterly progress reports as identified in the Assistance Agreement)
- Patents and inventions reporting requirements
- Financial reporting requirements
- Manuscripts/Reprint requirements
- Training materials used, developed, or maintained under an award

ii. Research Protection Prohibitions

These "prohibition" Terms and Conditions, clearly state the DoD and USAMRMC requirements for approval of research involving animals, human anatomical substances, human subjects and cadavers, permitted or prohibited under the award or its subawards. For permitted types of research, these terms and conditions also stipulate that the research may not begin until the USAMRMC's Office of Research Protections (ORP) provides an official determination and/or authorization, via separate communication, that the research may proceed.

C. Other Types of Award Arrangements

In addition to Assistance Agreements, there are other means to establish appropriate funding vehicles when DoD facilities or other Federal agencies are involved in the project. These include the Military Interdepartmental Purchase Request (MIPR) or a Funding Authorization Document (FAD). The MIPR is a mechanism to transfer funds within different agencies of the government. It is required in place of an Assistance Agreement when an award or sub-award is to be made to a U.S. Federal Government Agency from another U.S. Federal Government Agency. A FAD is used in place of an Assistance Agreement when an award is made within the same U.S. Federal Government Agency. The USAMRMC Resource Management is the office that oversees MIPRs and FADs; however, you are encouraged to direct any questions related to MIPRs/FADs to your Science Officer.

Chapter 2: Award Management - Policies and Procedures for the Period of Performance

I. PI/Recipient Responsibilities

This section outlines some of the expectations from the PI during the award period of performance. The Science Officer is the PI's primary point of contact for all scientific matters for the lifetime of the award. The Science Officer serves as the liaison to other offices within USAMRMC.

A. The Office of Research Protections (ORP) Regulatory Review

i. ORP Overview

Description: The ORP ensures that all USAMRMC research projects and investigations involving human subjects, human cadavers, human anatomical substances and/or animals are conducted in accordance with Federal, State, DoD, Army, USAMRMC, and international laws and regulatory requirements. The ORP has four major subordinate offices, the [Human Research Protection Office \(HRPO\)](#), the [Clinical Investigations Review Office \(CIRO\)](#), the [Institutional Review Board Office \(IRBO\)](#) and the [Animal Care and Use Review Office \(ACURO\)](#).

Location: For more information on the role of each office, visit the ORP website, https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.overview. ORP forms are also available for download from CDMRP electronic receipt portal <https://eBRAP.org>.

ii. PI/Recipient Interaction with the ORP

PIs and organizations may not use or subcontract for the use of laboratory animals, human subjects, human cadavers, human anatomical substances, and/or human data until applicable regulatory documents are reviewed and approved by USAMRMC to ensure that DoD regulations are met. Non-compliance may result in the termination of the award and/or the return of funds used to support the unapproved research. Written approval to begin research or subcontract for animal or human research under an applicable protocol will be issued from ORP independently from the award agreement. ORP approval may be granted before or after the official start of the award; however, the approval must be obtained prior to the initiation of any tasks involving laboratory animals, human subjects, human cadavers, human anatomical substances, and/or human data. In general, allow a minimum of 2-3 months for animal and/or human subjects' regulatory reviews.

The award PI and/or the animal or human subjects protocol PI will work with the CDMRP Science Officer and an ORP Review Scientist to prepare all regulatory documentation and ensure research compliance prior to the initiation of human- or animal or human-related research tasks. Depending on when ORP approvals are needed for the project, the collection of documents and the ORP review process may begin during the pre- or post-award stage.

Note! For certain awards e.g. projects comprised of an intervention-based clinical trial, payments may be limited to an initial period, pending receipt of appropriate approvals. Further payments may be restricted until the recipient provides copies of the HRPO, IRB, and IND or IDE approvals to the Grants Officer. The recipient must be in full compliance with all other terms and conditions of the award prior to the approval of further payments.

iii. **ORP Review Types**

The Science Officer and the ORP Review Scientist will work with the PI to help determine which types of approvals will be needed for the award. Additional information regarding the documents/forms required for various types of research can be found on the ORP subordinate offices' websites or within the CDMRP submission portal account. It is recommended that the PI familiarize themselves with some of the most common scenarios encountered during the review of animal and human subjects, described below:

a. **Animal Use**

If there is animal use involved in the project, the PI is required to complete and submit animal documents for review by ORP's Animal Care & Use Review Office (ACURO). The ACURO will not review any protocols that have not already been approved by your IACUC. More information about ACURO can be found at:

https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro

Documents required by the ACURO office include:

- **ACURO Appendix**

The ACURO appendix is a protocol-at-a-glance document used by the ACURO staff during the review process. Both versions (Abbreviated or Full) are available on line at the ACURO website:

https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.acuro&rn=1. If the IACUC-approved protocol(s) ONLY describe(s) animal studies funded by the DoD award, submit the IACUC-approved version of the protocol(s) and a separate copy of the Abbreviated version of [ACURO Animal Use Appendix abbreviated version](#) for each

protocol. If the IACUC-approved protocol(s) describe(s) any additional animal studies or experiments NOT funded by the DOD award, submit the IACUC-approved version of the protocol(s) and a separate copy of the [full version of ACURO Animal Use Appendix](#) for each protocol. The full version appendix must only describe those experiments and/or procedures being funded by the DoD award. ACURO's approval will only cover the work described in the appendix.

- **Institutional Animal Care and Use Committee (IACUC) approval document**
- **A copy of the full IACUC approved animal protocol**

Note! Animal use review will not commence until all required documents are received via ACURO's central email box (usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil).

b. Human subjects, anatomical substances, and cadavers

There are various categories of research that may involve human subjects and/or biological samples and data from human subjects. Brief descriptions of these categories are below. More information about HRPO can be found at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

1. Retrospective Human Anatomical Substance Use

Studies using previously collected human anatomical substances such as human cell lines or human samples from public repositories generally require a **Research Involving the Use of Data/Specimens form** and a determination **letter from the local IRB Office or designee regarding the use of samples in the DoD study**. The data/specimens form can be downloaded from the CDMRP electronic receipt portal <https://eBRAP.org>.

Note! The PI must submit local IRB determination documents immediately for mechanisms limited to exempt/expedited research, as defined by the Program Announcement.

2. Exempt Research

Other research considered exempt, as defined in the 32 CFR 219.101 and listed on ORP's website at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.orp_faq requires submission of a **Research Involving the Use of Data/Specimens form and study determination letter from the local IRB Office or designee**. The Data/Specimen form can be downloaded from the CDMRP electronic receipt portal <https://eBRAP.org>.

3. Human Subjects

If the proposed research involves the use of human subjects, the PI is required to submit documents for the review of human subjects to HRPO. Additional information regarding definitions, categories, and resource information for Human Subjects Research can be found at https://mrmc.amedd.army.mil/assets/docs/orp/hrpo_information_for_investigators_050712.pdf. HRPO will typically only review documents that have prior approval from an institutional IRB. For complex protocols, HRPO may perform a pre-review. Please be aware, HRPO requires specific Army and/or DOD language in the documents. The PI will be contacted by an administrative coordinator with the USAMRMC ORP HRPO. This person is responsible for conducting an initial assessment of human research applications submitted to the HRPO to ensure all necessary documentation is received and will guide the PI on requirements for a particular study.

Documents required for HRPO review include but are not limited to:

- IRB-approved detailed Human Subjects protocol
- IRB-approved informed consent documents
- IRB approval letter
- [The HRPO Human Research Protocol Submission Form](#)

Once all of the required documentation has been received, the administrative coordinator will send the file to an ORP Review Scientist for regulatory review.

Note! For awards with clinical trials, registration at the National Institutes of Health website, www.clinicaltrials.gov, is required in accordance with U.S. law.

4. Use of Human Cadavers for Research Development Test & Evaluation (RDT&E), Education or Training

All Army-supported research, development, testing and evaluation (RDT&E), education and training activities involving human cadavers require review and approval in accordance with the Army Policy for Use of Human Cadavers for Research, Development, Test and Evaluation, Education, or Training.

Details can be found at

https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.overview. “Cadaver” is defined as a deceased person or portion thereof, and is synonymous with the terms “human cadaver” and “post-mortem human subject” or “PMHS.” Activities involving human cadavers supported by the USAMRMC must be reviewed for compliance with the Army policy and approved by the ORP. If a study involves the use of human cadavers, the PI should contact both the Science Officer and ORP to obtain cadaver protocol

iv. **Notification of ORP approval**

Following successful completion of the review process, the PI will receive written approval to begin research from the appropriate subordinate ORP office.

Note! Notice of ORP approval is separate from the notice of award funding, and may occur either before the award is issued, or during the active award period. Sites should not construe ORP approval received prior to award as a commitment for any award funding.

A copy of the ORP approval will be provided to the USAMRAA for the official file. This ORP approval is contingent on the PI complying with all reporting and notification requirements as outlined in the approval letter. All amendments, including administrative changes and minor amendments, must be submitted to ORP for review and approval prior to initiation.

B. ORP Continuing Reviews (Animal or Human Subjects Protocol)

Animal Use: As outlined in the ACURO approval letter, there are numerous continuing review requirements throughout the life of the award. De novo renewals of protocols must be submitted to the ACURO for review as soon as possible after IACUC approval. De novo renewals must be accompanied by a new, updated animal use appendix and IACUC approval document. Adverse events, protocol violations, or noncompliance must be reported within five days of discovery with follow up as requested by ACURO.

Human Use: In accordance with the requirements identified in the ORP approval memo for the study, continuing review materials (e.g. annual reviews), major modifications to protocols, and reportable events reviewed by an institutional IRB must be submitted to ORP for approval prior to implementation. A copy of the continuing review approval notification by the institution must be submitted to the ORP as soon as possible after receipt of approval. Please note that the ORP also conducts random audits at the time of continuing review and additional information and documentation may be requested.

C. Project Technical Performance Reporting

Technical progress reports are required per the terms and conditions of the award. The Assistance Agreement will specify the required frequency of reports (i.e., annual, quarterly, etc.). More information about the various types of reports is detailed below. The importance of the reports to decisions relating to continued support and/or direction of the research cannot be over-emphasized.

i. **Information Management (IM) Office and Report Correspondence**

Personnel in the IM office may send report reminder emails, delinquent report emails, and report approval/disapproval notification emails. If there are questions or concerns regarding the report, the PI should contact the CDMRP Science Officer rather than IM staff.

ii. **Report Preparation**

Technical progress reports shall be prepared in accordance with the Research Performance Progress Report (RPPR). The RPPR is the uniform format for reporting performance progress on Federally-funded research projects and research-related activities. Report templates are available for download from the Funding Opportunities and Forms tab of the CDMRP electronic receipt portal under Progress Report Formats (<https://eBRAP.org>).

a. **Technical Reporting Requirements**

For a detailed list of required report elements, the PI should refer to the Assistance Agreement for the award. For additional documents that must be submitted with your report, including a sample cover and Standard Form 298, visit, https://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.technical_reporting. Additionally, templates for report types to include annual, final and quarterly are available for download at the sites listed elsewhere in this section.

All awards will require, at a minimum, annual and final technical reports.

- 1. Annual Reports:** Annual reports shall be prepared in accordance with the Federal-wide RPPR and shall provide a complete summary of the research results (positive or negative) to date in direct alignment to the approved Statement of Work. An annual report shall be submitted within 30 calendar days of the anniversary date of the award for the preceding 12 month period. If the award period of performance is extended by the USAMRAA Grants Officer, then an annual report shall still be submitted within 30 days of the anniversary date of the award with a final submitted at the end of the extension period. For questions regarding requirements for a particular award, please contact the CDMRP Science Officer.

2. **Final Reports:** A final report prepared in accordance with the Federal-wide RPPR and summarizing the entire research effort shall be submitted within 120 calendar days of the award performance end date. [Note: awards made prior to November 2015 retain the requirement to submit final project reports no later than 90 days following the end date of the award.] The final report shall provide a complete reporting of the research findings, appropriately citing specific data elements in the annual reports and appended publications.

Note! Please pay specific attention to the following reporting requirements:

- Distribution statement: Reports may be marked for limited or unlimited distribution. Reports not properly marked for limited distribution will be distributed as approved for public release. Please note the abstract provided in Block 14 of the SF 298 will be submitted to the Defense Technical Information Center (DTIC) for public distribution. DO NOT include any proprietary information in this public abstract.
- Publications: Only published or In-Press publications are acceptable as an outcome. All publications resulting from the research effort shall properly acknowledge DoD award support. For information on how to properly reference the award, see section III. below. Publications that clearly acknowledge DoD award support will appear on the CDMRP website.
- Training or Fellowship Awards: For training or fellowship awards, in addition to the required annual/final elements, a brief description of opportunities for training and professional development is required. Training activities may include, for example, courses or one-on-one work with a mentor. Professional development activities may include workshops, conferences, seminars, and study groups.
- Collaborative/Partnering Awards: For collaborative award mechanisms where separate awards are made to multiple investigators supporting a single project or effort, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI(s). Each report must be uploaded independently using the unique award number (e.g. W81XWH-XX-X-XXXX). A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site.

b. Other Technical Reporting Requirements

1. Department of Defense Annual Report on Animal Use: The Office of the Assistant Secretary of Defense for Research and Engineering (ASDR&E) requires DoD supported investigators to provide animal usage information (by fiscal year) throughout the life of the award. ACURO will notify the PI when the report database opens and provide instructions for the submission of data. Additional information on this requirement can be obtained from: Usarmy.detrick.medcom-usamrmc.other.acuro-data-call@mail.mil

2. Some awards will specify technical reporting more frequently than once a year and/or other forms of reporting. Additional reporting requirements may include:

i. Quarterly Technical Progress Report

Distinct from quarterly financial reporting, quarterly technical progress reports describe research project status with respect to the SOW. Quarterly reports are the most immediate and direct contact between the PI and the CDMRP Science Officer. The reports provide the means for keeping the USAMRMC advised of developments and problems as the research effort proceeds. Not all awards require reporting on a quarterly basis. If quarterly reporting is required for the project, there will be a term in the award. In general, awards with direct military interest and awards that involve a clinical trial will typically require technical reporting on a quarterly basis. Quarterly reports are submitted for the first three quarters of each year of the entire performance period of the award. A quarterly report for the fourth quarter is not required, as the annual technical report should incorporate all four quarters of progress. Each report shall be submitted electronically, within 15 days after the end of each quarter, to the appropriate offices specified in the award agreement. The Quarterly Technical Progress Report Format is required. Each item of the report format shall be completed. If there are questions about quarterly reporting requirements, contact the CDMRP Science Officer.

ii. Quad Charts

Submission of Quad charts will be specified in the Program Announcement and/or the award. Generally, awards with direct military interest will require quad chart submission. If there is a question about requirements under a particular award, contact the CDMRP Science Officer. Quad charts should be submitted as an appendix to the quarterly technical progress report document. The

Quad Chart template is a one-page PowerPoint file. A template is available for download from the Funding Opportunities and Forms tab of the CDMRP electronic receipt portal under Progress Report Formats (<https://eBRAP.org>). The template should be saved as a PDF file prior to submission.

c. Report Submission

Annual and Final reports are to be submitted electronically (PDF only) through the Electronic Report Submission (ERS) website (<https://ers.amedd.army.mil/>). Problems accessing the ERS site should be brought to the attention of the USAMRMC Help Desk at 301-619-2049.

Quarterly reports are not to be submitted through ERS and should be submitted in accordance with the instructions included in the award.

D. Financial Reporting

A Business Official from the recipient institution will be required to submit a Standard Form (SF) 425 Federal Financial Report (FFR). The submission of interim FFRs will be on a quarterly or annual basis, as stated in the award. A final FFR will be required to be submitted within 90 days of the end of the award performance period. USAMRAA requires that the recipient complete sections 1 – 9, section 10 (a) – 10 (o), and sections 11, 12, 13 and 14 of the (SF) 425. Institution business officials should visit the USAMRAA website <http://www.usamraa.army.mil/index.cfm?ID=12&Type=3> for more information.

E. Other Program Specific Obligations

Some awards may have additional reporting obligations associated with mandatory DoD-sponsored meetings or data submission requirements (e.g., External Advisory Boards or Government Steering Committees, In Progress review meetings, milestone meetings, data submission to the Federal Interagency Traumatic Brain Injury Research database). If there are questions or concerns, contact the CDMRP Science Officer.

II. Modifications to the Award during the Period of Performance

The PI and the recipient institution are obligated to abide by the terms and conditions in the award. Circumstances may arise that will require modifications to these terms and conditions. Any and all changes to the award terms and conditions require prior written approval from the USAMRAA Contract/Grants Officer. Provided below is a list of circumstances that could result in the need for an award modification. While the list is not intended to be all-inclusive, it does highlight the most frequent modifications. **To initiate any of these changes, the recipient institution's Business Official must submit a written request, either letter or email, to the CS/GS named in the award.** Requests are not approved until the recipient institution receives an official modification to the award.

Recipients shall request prior written approval from the USAMRAA CS/GS for each modification described below:

A. Change in SOW

Any changes in approach or the objectives of the project, as outlined in the approved Statement of Work (SOW), even if there is no associated budget revision, must be reviewed and approved prior to implementation of the change. A copy of the revised SOW should accompany the request. The revised SOW should clearly denote the revisions, additions, and/or deletions from the approved SOW referenced in the award document. Each proposed change in the revised SOW should be accompanied by a new timeline and followed by justifications and references. Any changes in the animal and/or human subject protocol must also be reviewed by the appropriate USAMRMC ORP office. All changes must be within the original scope of the project.

B. Change in Principal investigator (PI) or Key Personnel

Any changes in PI and/or key personnel listed in the award must be reviewed and approved prior to implementation of the changes. Please note changes in PI for certain award types (i.e. training, fellowship, career development, or clinical trial) may not be allowed. Please see the Administrative Actions section of the original Program Announcement or reference the award terms and conditions for guidance specific to the award mechanism. The following documents may be requested in order to process a request:

- a. Letter from the current PI or key personnel stating he/she is relinquishing involvement as of a specific date, also signed by the Business Official
- b. Letter from the nominated PI accepting the award, also signed by the Business Official
- c. Bio-sketch of the nominated PI
- d. Past, current, and pending support information for the nominated PI
- e. Confirmation that the technical reporting for the award is up-to-date
- f. Complete contact information for the nominated PI

Note! Changes in statement of work or PI are subject to review by ORP for impact on animal or human use protocols.

C. Extended Absence

Any absence for more than 3 months or a 25 percent reduction in time devoted to the project by the approved PI or any key personnel specified in the award document must be reviewed and approved prior to implementation of the change. A clear justification and commitment to complete the approved SOW must accompany the request.

D. Funding Reallocation

Any reallocation of funds from a specified category within an approved budget to other

categories of expense must be reviewed by USAMRAA and may or may not require approval prior to implementation of the change. The awardee should reference the award terms and conditions for prior approval requirements specific to their award. As applicable, a clear justification and quotes must accompany a reallocation request.

E. Extension Without Funds

The recipient may initiate, without prior approval, a one-time extension without funds to the expiration date of the award for a period of up to 12 months, as long as the extension without funds does not involve a change in the approved objectives or scope of the project. The recipient shall notify the USAMRAA Grants Officer in writing at least 30 calendar days prior to the expiration date of the award. The notification shall state the additional time needed, the reasons for the extension, and the work to be completed during the extension period. The recipient must be current with all financial and technical reporting requirements and be in compliance with all other terms and conditions of the award. This one-time extension without funds may not be exercised merely for the purpose of using unobligated balances. An official modification to the award document must be issued by the USAMRAA Grants Officer to extend the period of performance. If a project is granted an extension, the USAMRMC ORP (HRPO/ACURO) approvals must continue to be obtained.

An additional extension without funds, beyond the initial 12 month period, requires a formal request by the Business Official. These requests must: 1) be signed by the PI and a Business Official, 2) indicate the specified period of extension, 3) include the reasons an extension is needed, and 4) include a detailed work plan, with milestones, to be performed during the extension period.

Note! The maximum obligation of the Government for support of this award will not exceed the amount specified in the award. In accordance with DODGAR Part 32.25(d) (2) (ii), the recipient is authorized to carry forward unobligated balances within the approved period of performance. Awards will not be modified 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. Award extensions with supplemental funding, or opportunities for competing renewals, are not CDMRP practices.

F. Award Transfer

The transfer of an award to another institution may be permissible under certain circumstances. The relinquishment and acceptance of the award to be transferred is a multistep and time-intensive process. The following documents must be prepared:

- a. Relinquishment letter or email from the recipient institution. This written notification must be from the Business Official and indicate the date of relinquishment.

- b. An acceptance letter or email from the new institution's Business Official.
- c. A statement indicating reasons for the transfer and any probable effects of the transfer on the work.
- d. Submission of the original application from the new institution. This includes a revised SOW stating only those tasks that need to be completed and a revised budget that does not exceed the funding level remaining on the award.
- e. An up-to-date technical progress report from the relinquishing institution.
- f. Required regulatory documents from the new institution, for awards made before Oct.1st 2014 or on a case by case basis.

The USAMRAA CS/GS will contact the relinquishing and accepting institutions with additional instructions as appropriate. USAMRAA will interact directly with the relinquishing institution to obtain and finalize financial and patent reporting. Please be aware that transfers may take 6 months or longer. USAMRMC ORP approvals need to be re-obtained after the IACUC and/or IRB approvals at the new institution have been secured and before any work with human or animal subjects can proceed at the new institution.

G. Early Termination

To request a termination date prior to the end of the period of performance, a letter from the current PI stating that he/she is relinquishing the award as of a specific date, signed by the Business Official, is required. The appropriate USAMRMC ORP office must also notified of early termination. Any unexpended funds will be returned to the government (i.e. de-obligated from the award.)

III. Publications and Intellectual Property

A. Press Releases/ Media Announcements

It is advised that the PI wait until negotiations are complete and the official award agreement is in place before announcing/issuing any award announcements. On occasion, the scope of work changes, personnel at research institutions change, or PIs decline some or all of an award prior to the official award notification. Once the award has been made, you are required to acknowledge that the DoD is funding the work, the appropriate CDMRP research program, and the award number (e.g. W81XWH-##-#-####). The award notice will contain a term indicating what information is required.

B. Manuscripts/Reprints, Meeting Abstracts

The recipient is encouraged to publish results of the research, unless classified, in appropriate media. Copies of all outcomes resulting from the research shall be forwarded to the CDMRP Science Officer and the USAMRAA CS/GS as they become available. To receive proper credit within the DoD award file, DoD support must be acknowledged (see section C. below).

C. Acknowledging the DoD

The PI is required to acknowledge the DoD sponsorship in manuscripts, book chapters, abstracts, posters, and oral presentations when the work is supported, in part or in whole, by the award. Specific guidance regarding award acknowledgement can be found in the terms and conditions for the award. Statements such as, " This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs through the (insert program name, e.g. Prostate Cancer Research Program) under Award No. (W81XWH-XX-X-XXXX)," are recommended. A further statement indicating "opinions, interpretations, conclusions, and recommendations are those of the author and are not necessarily endorsed by the Department of Defense" is also recommended.

D. Intellectual Property

i. Title to subject inventions

In accordance with the Bayh-Dole Act (Title 35, United States Code, Sections 200 et seq.), the recipient and collaborators may elect to retain title to their subject inventions, but the U.S. Government shall, at a minimum, retain non-exclusive rights for the use of such inventions. Requirements in the award concerning the reporting of subject inventions must be followed. The recipient shall use the Interagency Edison (<http://www.iedison.gov/>) for filing of Patent Application and Invention Disclosure.

ii. Patent and Inventions reporting

The recipient shall electronically file Invention Disclosures and Patent Applications using the Interagency Edison (iEdison) system through the National Institutes of Health (<https://s-edison.info.nih.gov/iEdison>) within the times specified for reporting. In addition, inventions made during the year shall also be reported annually (within 30 days of the anniversary date of the award) on a DD Form 882, "Report of Inventions and Subcontracts." If there are no inventions during the year, no annual DD Form 882 is required. The DD Form 882 can be accessed at <https://www.usamraa.army.mil/index.cfm?ID=12&Type=3#Forms>. A final DD Form 882 is required and shall be submitted electronically within 90 days of end of the term of award. List all inventions made during the term of the award or state "none," as applicable. The award will NOT be closed until all reporting requirements have been met.

E. Data Sharing of Research Results

It is the intent of the CDMRP that data and research resources generated by DoD- funded research be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. Expectations for sharing of data and research resources apply to all basic research, clinical studies, surveys, and other types of research funded by the CDMRP. This includes all data and research resources generated during the project's period of performance. It is critically important to share unique data and research resources that cannot be readily replicated, including but not limited to the following:

Unique Data means data that cannot be readily replicated. Examples of unique data include large surveys that are expensive to replicate; studies of unique populations, such as patients to whom access is not widely available; studies conducted at unique times, such as during military conflict; studies of rare phenomena, such as rare diseases.

Final Research Data means recorded factual material commonly accepted in the scientific community as necessary to document and support research findings. These are not the summary statistics or tables; rather, final research data are the data on which summary statistics and tables are based. Final research data do not include laboratory notes or notebooks, partial datasets, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens.

Research Resources include, but are not limited to, the full range of tools that scientists and technicians use in the laboratory, such as cell lines, antibodies, reagents, animal models, growth factors, combinatorial chemistry, DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines.

Note! For additional information on CDMRP expectations for data-sharing, refer to the document titled "Congressionally Directed Medical Research Programs: Policy on Sharing Data and Research Resources," available on the CDMRP electronic receipt portal under Reference Material <https://ebrap.org/eBRAP/public/Program>

IV. Other Award Phase Considerations

A. Leave Policies

i. Maternity/Disability

Please refer to your institution's policy on leave. The PI and key personnel are employees of the recipient institution and, therefore, all leave arrangements are under the purview of the institution. Please note that an absence of the PI or any key personnel named in the award for a period of more than 3 months may require that a replacement is named. Changes in PI require prior approval by the USAMRMC Grants Officer. Information regarding extended absence requests and/or changes in PI can be found in Chapter 2 section II.

ii. Sabbaticals

Absences for a period of more than 3 months require Grants Officer's approval and a modification to the award. Please note that an absence of the PI or any key personnel named in the award for a period of more than 3 months may require that a replacement be named. Sabbatical requests must be signed by the recipient institution and sent to the USAMRAA CS/GS. A clear justification and commitment to complete the approved SOW must accompany the request. Requests will be approved by the USAMRAA Grants Officer on a case-by-case basis.

B. Disputes/Misconduct and Suspension/Termination

i. Disputes and Appeals

Disagreements regarding award-related issues between the recipient and the USAMRAA Grants Officer shall be resolved in accordance with the DODGAR, 32 CFR 22.815. Reference DODGAR part 22.815 for additional information.

ii. Suspension/Termination

The USAMRAA Grants Officer may terminate or suspend, in whole or in part, the award by written notice to the recipient upon a finding that the recipient materially failed to comply with the terms and conditions of the award, if the recipient materially changed the objective of the award, or if appropriated funds are not available to support the program.

Chapter 3: Award Close-Out

I. Final Reporting Requirements

A. Final Technical Progress Report

A final report prepared in accordance with the Federal-wide RPPR and summarizing the entire research effort shall be submitted within 120 calendar days of the award performance end date. Refer to Chapter 2 section I.C for details regarding technical reporting requirements.

B. Final Patent and Invention Disclosure

A final invention report is due within 90 days of the end of the award period. Refer to Chapter 2 section III D for details regarding title to subject inventions and the DD Form 882 Report of Inventions.

C. ORP Protocol Closures

Once USAMRMC support for a project has ended, no further review of the protocol will be conducted, and the ORP protocol file will be closed. ACURO requires notification that the DoD-funded animal work has been closed. If a clinical protocol has been completed at the institution, ORP-HRPO will require a copy of the IRB closure documents. If the protocol is ongoing after USAMRMC support has ended, ORP-HRPO will request a statement of current study status from the PI and verification of no outstanding ORP reports prior to closing the protocol file.

D. Financial Reporting

A final SF 425 FFR shall be submitted within 90 days of the end of the award period. For final FFRs, the reporting period end date shall be the end date of the award period. The institution's Business Office should visit the USAMRAA website, <http://www.usamraa.army.mil/index.cfm?ID=12&Type=3>, for more information.

II. Product/Outcome Follow-up

Following submission of the final technical progress report, it is strongly encouraged that the PI(s) send the CDMRP Science Officer any follow-up information regarding pending products/outcomes resulting from the award.

CDMRP and/or contract support staff may contact award recipients post-award for the purpose of research outcome follow-up. Please ensure updated contact information is provided to the Science Officer and is up-to-date in the CDMRP electronic portal account.

Resources

Applicable Links:

USAMRAA Home Page: <https://www.usamraa.army.mil>

Federal-Wide Research Terms and Conditions: <http://www.nsf.gov/awards/managing/rtc.jsp>

USAMRMC Researcher Resources:

https://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.overview

Office of Research Protections:

https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.overview

CDMRP electronic receipt portal for awards made prior to FY14: <https://cdmrp.org/>

CDMRP electronic receipt portal for awards made FY14 - present: <https://ebrap.org/>

CDMRP Funding Opportunities and Forms: <https://ebrap.org/eBRAP/public/Program.htm>

Electronic Technical Progress Report Submission Portal: <https://ers.amedd.army.mil/>