The Congressionally Directed Medical Research Programs: Guide for Funded Investigators

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CHAPTER 1: INTRODUCTION

Overview

This Guide for Funded Investigators is intended for principal investigators (PIs) whose applications have been recommended for funding via an assistance agreement through the Congressionally Directed Medical Research Programs (CDMRP). This document provides detailed information regarding various regulations and requirements related to the award. The PI of an application recommended for funding is responsible for adhering to these regulations and requirements and working efficiently with the various Department of Defense (DOD) personnel, as needed. The information provided in this guide is divided into sections based on the primary phases of the award management cycle (Figure 1).

PHASE I – Pre-Award Negotiations

After notification from the U.S. Army Medical Research Acquisition Activity (USAMRAA) Grants Officer (GO) that an application has been recommended for funding, the application enters pre-award negotiations. This phase includes:

- Science Officer (SO) assessment of applications recommended for funding.
- Communication between the PI and a CDMRP Grants Officer's Representative (GOR) assigned to the award, or an SO working on behalf of the GOR.
- Negotiations between the PI's institution, specifically the institution's Business Official from the Sponsored Programs Office (SPO) or other similarly named office, and the USAMRAA Grants Specialist (GS).
- As applicable, PI interaction with the U.S. Army Medical Research and Development Command (USAMRDC) Office of Human and Animal Research Oversight (OHARO) for review of all DOD-funded use of animals, human data/cells/cell lines/specimens, and/or human subjects.

Communication with other USAMRDC offices may occur as needed. USAMRAA is the contracting office under the USAMRDC, and it is the only office that can execute an award. Phase 1 concludes with the distribution of an assistance agreement (i.e., the official notice of award).

Please note: This guide does not discuss unique situations that may arise with Small Business Innovation Research/Small Business Technology Transfer awards, or other contracts.

PHASE II – Active Award Management

Applications enter active award management, also referred to as the period of performance (POP), once the assistance agreement has been distributed to the PI and institutional SPO. During this phase, the GOR and/or SO actively monitor and manage the award from a technical perspective. The PI and the recipient institution are responsible for adhering to all the terms and conditions set forth in the award, including, but not limited to, submission of annual technical progress reports and annual financial reports, maintaining compliance with OHARO regulations (as appropriate), and patent reports. The recipient is also required to notify the SO and/or GS of any changes that might impact the planned progress of the project (loss of resources, significant delays in obtaining animal- or human-use approvals, PI moving to a new institution, etc.).

PHASE III – Award Closeout

The award closeout begins once the POP expires, and primarily involves the submission of a final technical progress report, a patents and inventions disclosure form, and final financial reports.

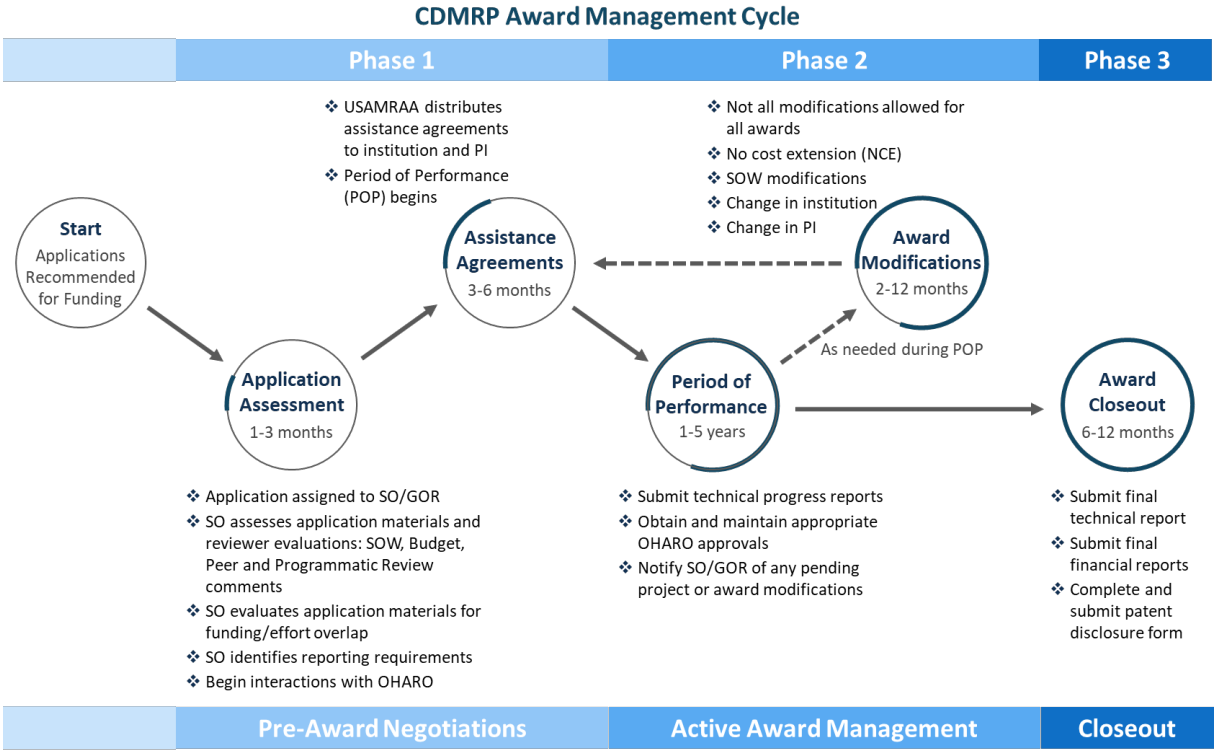


Figure 1. Graphical representation of an award life cycle, beginning when the award is first recommended for funding and ending at the award closeout. The milestones represented within the graphic are the most common actions that may occur for any given award, but not all milestones will occur for all awards. This is not intended as an all-inclusive representation of all possible activities.

Roles and Responsibilities of USAMRDC Participants

Negotiation, execution, and management of research awards requires a collaborative effort between CDMRP, USAMRAA, OHARO, and other USAMRDC offices. No single office can specialize in all requirements of application submission, contracting laws, and regulatory requirements. Just as institutions of higher learning have separate laboratories, an SPO, and Institutional Review Boards (IRBs), USAMRDC has separate offices located in separate buildings. CDMRP is the program office that manages and executes the program cycle from investment strategy through award execution. USAMRAA is the contracting office that executes awards, and reviews and approves any modifications. OHARO is the regulatory office that ensures all research projects and investigations involving animals, human subjects, human cadavers, and/or human anatomical substances (including human cell lines and analysis of human data) are conducted in accordance with applicable federal and DOD-specific laws and policies.

The following list of participants represents key individuals involved across the phases of award management. Figure 2 demonstrates the primary lines of communication between the different individuals and offices involved in the award management cycle.

CDMRP Participants

Science Officer

The SO is a CDMRP staff member selected for their technical knowledge and scientific expertise to manage awards recommended for funding. The SO serves as a liaison for the PI, maintaining the proper flow of information between the recipient institution, the PI, CDMRP, USAMRAA and other offices within USAMRDC, such as OHARO and the Deputy Chief of Staff for Information Management. The SO is the primary point of contact for the PI on all matters related to the CDMRP-funded project's execution, and general award management questions for the lifetime of the award. Additionally, the SO is the primary source of information for the program office on all matters regarding the award, including notable accomplishments resulting from the CDMRP-funded project. If the SO and the GOR (see below) on an award are not the same person, the SO works on behalf of the GOR.

Grants Officer's Representative

The GOR is a federal government employee at CDMRP appointed by USAMRAA for their technical knowledge and subject matter expertise to assist the GO in administering awards, as necessary. On any particular award, the SO and the GOR may or may not be the same person.

USAMRAA Participants

Grants Officer

The GO is a federal government employee within USAMRAA. The GO is the only person with authority to commit funds, enter into agreements, approve award modifications, and/or make official decisions affecting the cost and/or terms and conditions of awards.

Grants Specialist

The GS is a federal government employee within USAMRAA assigned to assist the GO with award-related issues. The GS is the primary point of contact for business and/or non-scientific award-related issues. All communications with the GS should be directed through the recipient institution's SPO. All official negotiations of the budget, terms, and conditions of any resulting award will be limited to the institution's SPO/Business Official and the GS or GO.

Procurement Technician

For the purposes of the award management, the USAMRAA Procurement Technician is responsible for processing invoices submitted by the institution and distributing assistance agreements and award modifications via email. The Business Official and the PI rarely will communicate actively with Procurement Technicians.

OHARO Participants

Office of Human and Animal Research Oversight Personnel

The OHARO is comprised of three offices: the USAMRDC Animal Care and Use Review Office (ACURO), the USAMRDC Office of Human Research Oversight (OHRO), and the USAMRDC Institutional Review Board Office (IRBO). Discussion of the IRBO is outside the scope of this guide. Regulatory personnel from the ACURO and OHRO are research protection scientists who conduct an administrative review of protocol documentation for compliance with Army, DOD, and host country National Federal Regulations

(as needed), and they will issue DOD-required approvals prior to the initiation of DOD-funded research with animals, human data/specimens, and/or humans. During pre-award negotiations and award POP, the ACURO and OHRO reviewers may request additional documentation related to OHARO-regulated activities to ensure the submitted protocols are compliant with the relevant regulations.

Other Participants

Program Sponsor Representative

The Program Sponsor Representative (PSR) is a government representative designated by a program office outside of CDMRP, such as a Joint Program Committee/Program 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 SO to facilitate success of the award. It is important to note that PSRs work through the SO with respect to the award and, therefore, all correspondence shall include the assigned SO (and GOR, as necessary).

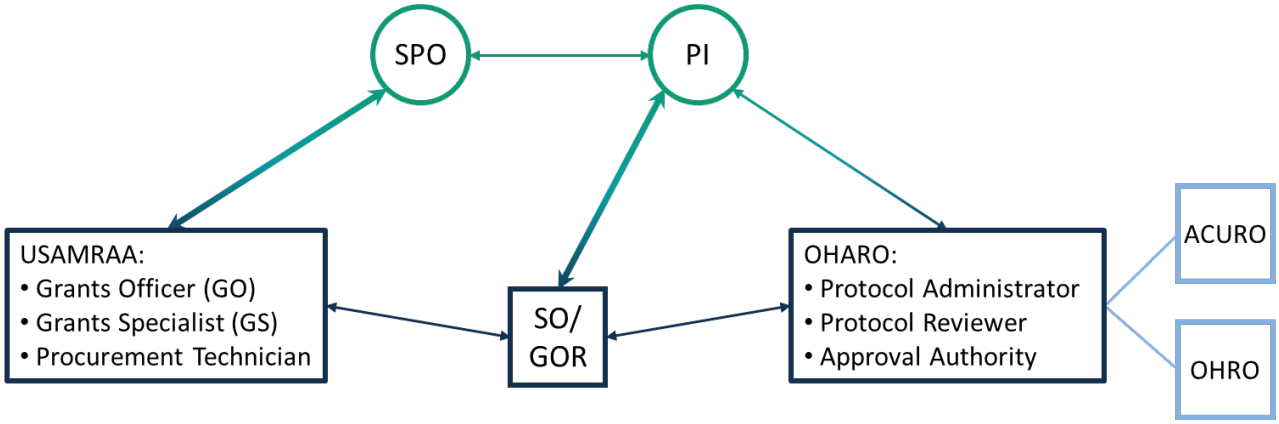


Figure 2. Primary lines of communication that open during pre-award negotiations and continue through the life of an award. The green circles represent individuals/offices at the awardee's institution (i.e., the Business Official within the Sponsored Programs Office [SPO] and the principal investigator [PI]). The blue rectangles represent individuals/offices within the DOD with whom the SPO and PI will interact. The arrows indicate the appropriate lines of communication between each individual/office. The SPO interacts with USAMRAA on behalf of the PI. All official communication regarding negotiations and award modifications must be communicated through these two offices. The PI's primary point of contact for all technical/scientific aspects of the project is the SO/GOR. The PI should keep the SO informed of all changes that may affect the CDMRP-funded project. The PI may also interact with individuals from either or both OHARO offices (light blue boxes; ACURO and/or OHRO) and will directly communicate with individuals from the respective office(s), as needed to obtain the appropriate regulatory approvals. This graphic does not necessarily represent all institutional or DOD individuals/offices that may be involved with award execution or management.

CHAPTER 2: APPLICATION ASSESSMENT AND EXECUTION OF ASSISTANCE AGREEMENTS

The Funding Notification Letter

What is the Funding Notification Letter?

At the conclusion of the review process, applications are selected and recommended for funding. The GO notifies the selected PIs and their respective SPOs 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 (eBRAP, https://ebrap.org) for the PI and the institutional Business Official. PIs and Business Officials are electronically notified when these documents are posted and available.

Please note: In addition to being available through eBRAP, the program information paper is also typically available on a CDMRP program's website after Programmatic Review. The information paper contains application submission and funding metrics for the recently completed funding cycle and a brief description of the review process.

The Funding Notification Letter is an important pre-award document that informs the PI and 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 to eBRAP, including a deadline for completing these actions. In some cases, the Funding Notification Letter may contain additional information about funding restrictions (e.g., stating the project is only being partially funded) or additional conditions that need to be meet before an award can be made. After a PI is notified about the funding status of their application, the SO assigned to manage the award will contact the PI to provide additional guidance regarding the pre-award phase.

Information Requested in the Funding Notification Letter

Completion of Post-Submission Questions

PIs are responsible for responding to the post-submission questions as directed in the Funding Notification Letter. The responses to these questions are primarily used by the SO assigned to the award as a first introduction to the award, and to help the SO identify potential items that may require prioritized attention (e.g., if the PI anticipates moving to a new institution during pre-award negotiations).

Updated Support Information

The Previous, Current, and Pending Support (PCPS) is a document detailing all funding that has ended in the past 5 years, active/current funding, and all pending support for the PI and key personnel. Although the PCPS information is submitted with the initial application, an updated PCPS is required with the pre-award documents to reflect any changes that went into effect after application submission (e.g., funding that had previously been listed as "pending" is now "current," or additional applications have been submitted in the interim). The updated PCPS should list the CDMRP-funded award(s) currently under pre-award negotiations, and all other proposals currently under review or pending award.

There is no specific format required by the DOD for the PCPS, but the PCPS should include the following information for each funding source listed:

- Title of project

- Project number
- Brief description of project goals
- Specific Aims/Tasks
- Period of performance (month/day/year – month/day/year)
- Level of effort (in percentage or calendar months)
- Supporting agency
- Supporting agency POC (name and contact information)
- Description of any real or perceived overlap with the CDMRP-funded project

The PCPS should clearly indicate whether any listed project has scientific or financial overlap with other existing and/or pending research projects. CDMRP's position on research duplication and procedures to avoid duplication can be found on the CDMRP website: https://cdmrp.health.mil/funding/researchDup. If there is no overlap, this should be stated clearly under each project listed on the PCPS. If another project on the PCPS has a title and/or specific aims that sound similar, but the PI believes it is not duplicative with the CDMRP-funded project, the PI is encouraged to describe how the other project is distinct. Total level of effort for all active research, including the pending CDMRP-funded project, cannot exceed 100% or 12 calendar months. The PCPS for the PI and all other key personnel are evaluated for potential duplication of funding and over-commitment of effort. CDMRP personnel have access to proposals from federal partners (i.e., the National Institutes of Health [NIH] and the Department of Veterans Affairs [VA]) and may communicate with foundations and other organizations that also fund research.

Please note: It is essential that the PCPS be accompanied by a cover letter signed by a Business Official certifying the information is current and accurate and, if necessary, addressing any scientific or financial overlap issues. The cover letter should be the first page of the PCPS, which should be submitted as a single, continuous document.

Pre-Award Negotiations

Pre-award negotiations is a multi-step process that occurs between the time when an application has been recommended for funding and when the assistance agreement is distributed. The pre-award negotiation process involves the communications and activities outlined below.

SO/PI Communications

The SO is the primary point of contact for the PI. During the initial stage of negotiations, the SO assigned to the project contacts the PI, facilitates collection of the initial required documents as stated in the Funding Notification Letter, and conducts a technical review of the application. This technical review is not another review of the scientific merit. Rather, the SO is assessing items such as, but not limited to: Does the budget seem appropriate for the types of studies proposed? Is the Statement of Work (SOW) an accurate representation of the studies proposed? Is there any evidence for scientific overlap between the project under pre-award negotiations and any other project listed in the PCPS? What type of OHARO approvals are needed?

Once the SO completes the technical review of the application, it is forwarded to USAMRAA to provide pertinent information to the GS and/or GO to support the official pre-award negotiations between USAMRAA and the Business Official from the institution's SPO.

USAMRAA/SPO Negotiations

The official pre-award negotiations begin when the GS assigned to the project sends a Pre-Award Information Request (PAIR) to the recipient institution's SPO. The PAIR may include requests for items and clarifications related to the SO's technical review, and/or related to USAMRAA's contractual and administrative requirements. The response to the PAIR must be sent to the GS from the Business Official. The GS is the primary point of contact for the SPO/Business Official. If the PI has any questions regarding the PAIR, they may either ask their SO or have their Business Official ask the GS; however, PIs should not directly contact the GS themselves. Pre-award negotiations can be complex; therefore, the PI and the SPO should allow several weeks or months for communications.

While the average time from Funding Notification Letter to award is approximately 3-6 months, all awards will be made no later than the date described in the respective Program Announcement. All assistance agreements are distributed by USAMRAA and are made to the institution, not to the individual PI.

Please 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 POP, in accordance with DOD regulations. 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 associated with for-profit organizations require prior written approval from the GO.

Revisions/Clarifications That May Be Requested During Negotiations

Statement of Work Revisions

Either the SO or GS may request a revised SOW during negotiations. All revisions should be within the scope of the original application and will often include requests such as adding missing OHARO approval steps, including all studies described in the application, providing estimates for numbers of animal and/or human subjects, etc. The SOW should be a sufficiently detailed document that clearly defines the project strategy, to include general methodology and an appropriate timeline. Progress will be evaluated against the SOW during the review of technical progress reports. For additional suggestions on creating or revising an SOW, visit the "Generic Forms for Application Submission" section on the eBRAP website, https://ebrap.org/eBRAP/public/Program.htm. PIs should select the example that best aligns with their award type.

Budget Revisions

The GS 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 the requested funds.

PCPS Clarification

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 additional details regarding the PCPS if critical information was omitted (e.g., dates, level of effort, etc.) or if potential overlap is identified.

OHARO-Related Considerations

Obtaining OHARO approval (either from the ACURO and/or OHRO) is a separate process that can occur parallel to pre-award negotiations (i.e., a PI is ***not*** required to obtain the ACURO/OHRO approval ***before*** the assistance agreement is distributed). However, if a PI will use DOD funds for animal studies and/or research involving the use of human data (publicly available or otherwise), non-commercially available human cell lines, human anatomical substances (HAS), and/or human subjects, the PI is strongly encouraged to submit the documents needed for OHARO review as soon as possible after they receive the Funding Notification Letter. This will minimize delays in starting work on the project due to waiting for OHARO review and approval. The SO assigned to the award will help guide the PI as to which OHARO approvals are needed for the project and will begin working with the PI during the pre-award negotiations to obtain the appropriate documents required for the OHARO review and approval processes. The details of OHARO review and approval are provided in the next chapter.

Clinical Trial Considerations

If the application and SOW indicate the funding will support a clinical trial, key points will be addressed during the pre-award negotiations to facilitate the success of the trial. When preparing revised award documents such as the SOW, budget, and/or clinical protocol, PIs and/or relevant study personnel are strongly encouraged to review the "Information for Investigators – Human Subjects Research" and "OHRO Submission Form – Human Subjects Research" documents found on the OHRO website: https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo. These documents contain important information for investigators and are intended to help streamline the OHRO submission and review processes.

In addition, PIs may consider the following additional points, as resources permit:

- Including a study coordinator as personnel on the research team, at an appropriate level of effort. This is particularly important when the clinical trial involves multiple performance sites.
- Including personnel, as a collaborator or as part of the key research team, experienced in IRB submission and approval to assist with the protocol development, approval process, and implementation of the trial.
- Including an experienced statistician, as a collaborator or as part of the key research team, to ensure the study is adequately powered to address the study aims (for Phase II/III trials).
- Adding to the SOW timelines for applicable approvals for the use of human subjects. This could include appropriate U.S. Food and Drug Administration (FDA) submission milestones (e.g., investigational new drug [IND] or investigational device exemption [IDE] submissions) and/or setting aside adequate time to prepare and obtain approval of the protocol, consent forms, and patient recruitment forms, ensuring they contain any required DOD/Army-specific language.

Execution of the Assistance Agreement

USAMRAA issues assistance agreements (grants and cooperative agreements) as a result of applications received under a variety of funding opportunity types, including the USAMRDC 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 Department of Defense Grant and Agreement Regulations (DODGAR; DOD 3210.6-R). For more information on the DODGAR, visit https://usamraa.health.mil/Pages/Resources.aspx.

Official Notification and the Start of the Award Period of Performance

Once negotiations are complete, a USAMRAA Procurement Technician distributes the signed assistance agreement via email to the institutional SPO/Business Official with the PI copied. The email includes a subject heading similar to "Award HT9425-##-#-#### (Award log number), Institution name." The USAMRAA Procurement Technician's name and email address may be unfamiliar; however, the importance of the attached document—the assistance agreement—cannot be overstated. The assistance agreement 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, as it is the official notice of award.

Please note: Prior to 01 October 2022 all new assistance agreements and award modifications utilized award numbers that began with W81XWH rather than HT9425.

Terms and Conditions Contained with the Assistance Agreement

Please note: The information in this section is for informational purposes only and is not contractually binding. PIs and Business Officials should refer to the assistance agreement of a particular project for specific policy and guidance information.

The assistance agreement will contain in full text or incorporate by reference all terms and conditions that are applicable to the award. The following terms and conditions are incorporated by reference:

1) Division III - USAMRAA Addendum to the DOD R&D General Terms and Conditions and USAMRAA Programmatic Requirements

   The current version of the Division III terms and conditions is available at: https://usamraa.health.mil/Pages/Resources.aspx . The USAMRAA Addendum to the DOD R&D General Terms and Conditions provides additional content relevant to USAMRAA awards for sections of specified articles from those general research terms and conditions.

2) DOD R&D General Terms and Conditions

   The current version of the general DOD terms and conditions is available at: https://www.nre.navy.mil/work-with-us/manage-your-award/manage-grant-award/grants-terms-conditions . These general terms and conditions implement Office of Management and Budget (OMB) guidance, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards," published in the Code of Federal Regulations (CFR) at 2 CFR part 200 and implemented by the DOD at 2 CFR part 1104, "Interim Grants and Cooperative Agreements Implementation of Guidance in 2 CFR part 200" (79 FR 76047, December 19, 2014, as amended at [updated for each current version of document]).

PIs and Business Officials should be familiar with the content of the assistance agreement and the terms and conditions described above as they contain important information for submitting requests for payments, prior approval requirements, requesting no-cost extensions, reporting requirements, award closeout requirements, etc.

The terms and conditions also include Research Protection Prohibitions. These prohibition clauses clearly state the DOD and USAMRDC 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 the research may not begin until OHARO provides official authorization(s) that the research may proceed.

Please note: The specific contents and layout of an assistance agreement may change from one fiscal year to another and/or contain project-specific clauses or requirements. PIs with multiple awards—either across multiple fiscal years or within a single fiscal year—should familiarize themselves with each agreement.

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. Discussion of the nuances involved with these types of agreements are beyond the scope of this document. If any or all the funds for a project that has been recommended for funding will be used by DOD facilities and/or other federal agencies, this should be brought to the SO's attention as early in the award negotiations as possible to initiate the appropriate course of action.

Chapter 3: Interactions with the Office of Human and Animal Research Oversight

OHARO Overview

OHARO ensures that all USAMRDC-funded research projects and investigations involving animals, human subjects, human data, human anatomical substances (including human cell lines), and/or human cadavers are conducted in accordance with Federal, State, DOD, Army, USAMRDC, and international laws and regulatory requirements. OHARO has three major subordinate offices: the Animal Care and Use Review Office, the Office of Human Research Oversight, and the Institutional Review Board Office. This guide focuses on the ACURO and OHRO.

For more information on the role of each office, visit the OHARO website at: https://mrdc.health.mil/index.cfm/collaborate/research_protections.

Please note: Prior to July 2022, OHARO was called the Office of Research Protections, and OHRO was called the Human Research Protection Office.

PIs and recipient organizations may not use, or subcontract for the use of, animals, human subjects, human data, human anatomical substances (including human cell lines), and/or human cadavers until applicable protocol documents are reviewed and approved by OHARO 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 OHARO independently from the award agreement. OHARO approval may be granted before or after the award POP begins. However, the approval must be obtained prior to the initiation of any tasks involving animals, human subjects, human data, human anatomical substances (including human cell lines), and/or human cadavers. In general, PIs should allow for a minimum of 2-3 months for OHARO reviews, *in addition to* the time needed to obtain local Institutional Animal Care and Use Committee (IACUC) and/or IRB approvals for the DOD-funded work.

Please 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 IRB, OHRO, and FDA IND or IDE approvals to the GO. The recipient must be in full compliance with all other terms and conditions of the award prior to the approval of further payments.

OHARO Review Types

The SO and OHARO personnel will work with the PI to determine which types of OHARO reviews and approvals are required for each project. Depending on when OHARO approvals are needed for the project, the collection of documents and the OHARO review process may begin during pre-award negotiations or during the POP. Although this guide is updated periodically, PIs should refer to the pertinent OHARO website(s) for the most current forms and information. The following sections and Figure 3 outline the basic interactions between a DOD-funded PI and OHARO. However, most projects have their individual nuances. PIs are strongly encouraged to engage with their SOs early in the pre-award negotiation phase to determine the specific requirements for a given project.

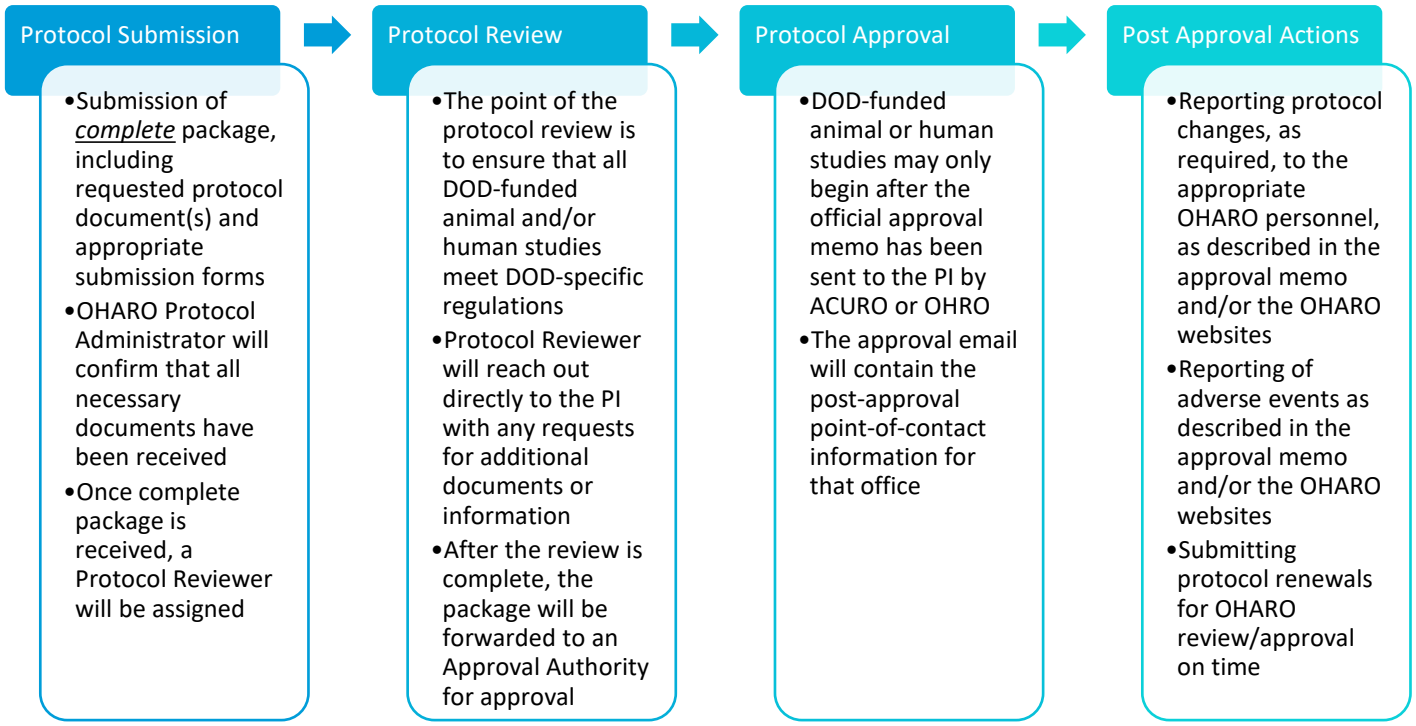


Figure 3. General process overview of protocol submission and review by the Office of Human and Animal Research Oversight (OHARO). Although the Animal Care and Use Review Office (ACURO) and Office of Human Research Oversight (OHRO) are separate offices guided by their own policies and regulations, they follow a similar protocol submission and review workflow. PIs are encouraged to provide prompt and accurate responses to inquiries from either office to facilitate the protocol submission and review processes. As a rule, the SO has no direct role in these processes, but is available as a resource if any questions or concerns arise from either the PI or the OHARO.

Animal Care and Use Review Office

If DOD funds will be used for live animal studies, the PI is required to receive approval from the ACURO before any DOD funds are used for such studies. The ACURO will not review any protocols that have not already been IACUC-approved. The PI should visit the ACURO website to learn more about the ACURO's processes, and for resources such as Frequently Asked Questions, more detailed instructions, the current ACURO Appendix form, and other news and guidance documents, https://mrdc.health.mil/index.cfm/collaborate/research_protections/acuro.

PIs must submit the documents listed below to the ACURO for their review and approval. Documents can either be uploaded via the PI's eBRAP account (preferred) or submitted via email to the ACURO mailbox at usarmy.detrick.medcom-usamrmc.other.acuro@health.mil. Other project personnel, collaborators, et al. have the option of uploading the necessary documentation via eBRAP by utilizing the Regulatory File Drop Off. The "eBRAP Regulatory File Drop Off Instruction Guide" provides step-by-step instructions for how to do this, and it is located on the eBRAP Funding Opportunities & Forms page at https://ebrap.org/eBRAP/public/Program.htm.

Documents required by the ACURO include:

1) Completed ACURO Appendix – The ACURO Appendix is a companion document to the IACUC protocol, identifying the DOD-funded work, and includes DOD-specific requirements. It is used by the ACURO staff during the review process. The Appendix is available from the ACURO website; ONLY the current version will be accepted by the ACURO. If a DOD-funded award is supporting multiple IACUC protocols, the PI must submit a completed Appendix for ***each*** protocol. The Appendix must reference only those experiments and/or procedures being funded by the DOD award. The ACURO's approval will cover only the work described in the Appendix.

   Please note: The ***protocol*** PI must sign the ACURO Protocol PI Assurances, which is the last page of the Appendix.

2) A copy of the IACUC approval document/notification for the protocol (providing only amendment approval is ***not*** sufficient).

3) A copy of the IACUC-approved animal protocol – If the IACUC-approved protocol describes ***only*** animal studies funded by the DOD award, then the PI only needs to submit the IACUC-approved version of the protocol. If the IACUC-approved protocol describes any additional animal studies or experiments ***not*** funded by the DOD award, the PI must submit the IACUC-approved version of the protocol with the DOD-funded work highlighted.

Please note: The ACURO review will not commence until **ALL** required documents are received.

Once the ACURO receives a complete submission package, the protocol(s) is assigned to an ACURO reviewer. The reviewer may request additional information or clarification. Once the reviewer's questions and requests have been addressed, the protocol(s) is assigned for a final review by an ACURO veterinarian. If the ACURO veterinarian has no follow-up questions or requests, the official ACURO approval memorandum is issued for the approved protocol(s). Only at that time may DOD-funds be used for the live animal studies covered under the approved protocol(s).

Office of Human Research Oversight

Document Submission to OHRO

There are several categories of research that require review and approval by the OHRO. The paragraphs below provide brief descriptions of the general categories of research that fall under the OHRO purview, and an overview of the documents the OHRO needs for the respective reviews. If DOD funds will be used for studies that involve one or more of the categories below, the PI is required to receive approval from the OHRO ***before*** any DOD funds are used for such studies. More detailed information about the OHRO can be found at https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo. PIs are strongly encouraged to read the "Information for Investigators – Research with Data/Specimens" and "Information for Investigators – Human Subjects Research" documents to better understand the OHRO's review requirements and processes.

PIs must submit the documents listed below to the OHRO for review and approval. Documents must be uploaded via the PI's eBRAP account. Other project personnel, collaborators, et al. have the option of uploading the necessary documentation via eBRAP by utilizing the Regulatory File Drop Off. The "Regulatory File Drop Off Instruction Guide" provides step-by-step instructions on how to do this, and it is located on the eBRAP Funding Opportunities & Forms page at https://ebrap.org/eBRAP/public/Program.htm.

Categories of research that fall under the OHRO purview:

A. Use of Established Human Cell Lines That Are Not Commercially Available

The OHRO will review and approve the use of all established human cell lines that are not commercially available. If a cell line cannot be purchased from a vendor like ATCC, the OHRO will conduct an administrative review of the human cell line use. Even if a cell line has been published, has been in use for many years, or is freely available from a public repository, the cell line is not considered commercially available by the OHRO's definition.

B. Secondary Use of Human Anatomical Specimens and/or Human Data (Publicly Available or Not)

PIs MUST submit a new, stand-alone protocol to their IRB that is specific to the secondary use of human specimens and/or data proposed for the DOD-funded project. This means the protocol covers ***only*** the DOD-funded **USE** of human specimens and/or data, and not the collection of the specimens. The OHRO will not review any protocols where the DOD-funded work has been added as an amendment to an existing protocol; this includes amendments to ongoing clinical protocols, umbrella biorepository protocols, or similar.

Please note: PIs should expect extended review times for DOD-funded research that involves the use of fetal tissue and/or human embryonic stem (HES) cell lines (if the cell lines are not among the list of NIH registered/approved HES cell lines) due to the laws and ethical issues involved with such research.

For the items listed in sections A and B above, the OHRO requires submission of:

1) The completed OHRO Submission Form – Secondary Research Involving the Use of Data/Specimens (and/or Cadaver Submission Form, if applicable).
2) A copy of the standalone protocol/protocol application, limited to the sources and research analyses as described in the approved SOW.
3) Documentation of an institutional regulatory office determination or IRB approval of the DOD-funded research activities. Self-determination or self-certification by the PI will not suffice for the OHRO review.

Please note: If the funding opportunity specified that research involving human subjects or specimens must be either exempt under Section 104(d) of the Common Rule (e.g., 45 CFR 46.104(d), 32 CFR 219.104(d)) or eligible for expedited review (45 CFR 46.110, 32 CFR 219.110, 21 CFR 56.110) (e.g., some Concept Awards contain this language), the PI must immediately submit the documents listed above via eBRAP in order to meet the Program Announcement requirements, and should inform their SO once they have done so.

C. Use of Human Subjects

If the DOD-funded research involves the use of human subjects, the PI is required to submit the IRB-approved protocol and supporting documents for the review of human subjects to the OHRO. Detailed information and submission requirements for the OHRO review of human subjects research are available on the OHRO website. PIs should be aware the OHRO requires specific DOD language in certain IRB-approved documents (e.g., the consent form). The most current guidance regarding these requirements is described in the "Information for Investigators – Human Subjects Research" document on the OHRO website.

Please note: Section 114 of the Common Rule requires that all institutions located in the U.S. engaged in multi-site, collaborative, cooperative research must rely upon approval by a single IRB for that portion of

the non-exempt research that is conducted in the U.S. The OHRO expects that multi-site studies receive review by a designated single IRB.

The core documents required for the OHRO review of human use protocols include, but are not limited to:

1) IRB-approved human subjects protocol specific to the DOD-funded activities;
2) IRB-approved informed consent documents;
3) IRB approval letter;
4) Completed "OHRO Submission Form – Human Subjects Research".

PIs should follow the guidance in the "OHRO Submission Form – Human Subjects Research" and submit additional supporting documents as directed by the form. The OHRO will typically review only documents that are IRB-approved.

Please note: PIs should expect extended review times for DOD-funded research involving large-scale genomic date (LSGD) collected from DOD-affiliated personnel. Disclosure of DOD-affiliated personnel's genomic data may pose a national security risk; accordingly, such research requires administrative, technical, and physical safeguards commensurate with risk, including the secondary use or sharing of de-identified data or specimens. The performer must obtain an NIH Certificate of Confidentiality from https://grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm. Additionally, the study must undergo security review and additional approvals by the OHARO, USAMRDC Headquarters, and DOD OHRO to ensure the adequacy of the proposed safeguards. These requirements do not apply to incidental participation of DOD-affiliated personnel in research that enrolls a broader population, and does not extend to research on targeted genes, genotypes, or phenotypes that are non-large-scale. DOD-affiliated personnel include Service Members, Reserve Service Members, National Guard members, DOD civilians, and DOD contractors.

Please note: For awards supporting Applicable Clinical Trials, registering the trial at www.clinicaltrials.gov is required in accordance with U.S. law. The registration information should be shared with the SO assigned to the award.

D. Use of Human Cadavers

All Army-supported Research, Development, Test and Evaluation (RDT&E), and education and training activities involving human cadavers require review and approval by the OHRO in accordance with the Army Policy for use of human cadavers; a PDF of the policy is available on the OHRO website. "Cadaver" is defined as a deceased person or portion thereof and is synonymous with the terms "human cadaver" and "post-mortem human subject." If a study involves the use of human cadavers, the PI must complete and submit to OHRO the "Cadaver Submission Form," available on the OHRO website, along with the required supporting documents.

The OHRO Review Process

Please note: The OHRO review of a protocol will not commence until a complete submission package is received for that protocol.

A PI may be asked by either their SO and/or an OHRO Protocol Coordinator to submit the documents outlined above during the negotiation phase. If the PI has questions about the submission process or the

requests for documents, they should engage with their SO and OHRO personnel to clarify the requirements for their specific project.

Please note: As the SOW is used by the OHRO to aid their review of submitted protocols, it may be necessary for any requested SOW revisions to be complete before a PI is asked to submit their protocol documents for the OHRO review.

Once an entire submission package has been submitted for the OHRO's review of a protocol, the protocol will be assigned to an OHRO reviewer, or Human Subjects Protection Scientist (HSPS). The HSPS may request additional information or clarifications. Once the OHRO's questions and requests have been addressed, the protocol is assigned for a final review by an OHRO Approval Authority. If the OHRO Approval Authority has no follow-up questions or requests, the official OHRO approval memorandum is issued for the protocol. Only at that time may PIs begin using DOD funds for the studies covered under the approved protocol.

Please note: Several individuals and offices are included on the OHARO protocol approval notifications for their records and awareness: the PI, SO, GOR (if different from the SO), the PI's SPO/Business Official, the GS, and other research/administrative personnel that may have been included during the review process.

Please note: Notice of OHARO approval is separate from the notice of award funding and may occur either before the award is issued or during the award POP. Sites should not construe receiving OHARO approval prior to award start date as a commitment for any award funding.

Post-Approval Submissions to OHARO

OHARO approvals are contingent on the PI complying with all reporting and notification requirements as outlined in each protocol approval letter and posted on the ACURO and OHRO websites. The PI should make particular note of the circumstances and reporting timelines under which the ACURO and OHRO require notification of protocol amendments, adverse events, etc. Additionally, the onus is on the PI and the recipient institution to be cognizant of *de novo* renewal and continuing review dates of all ACURO- and/or OHRO-approved protocols, and to ensure that renewal documents are submitted in a timely fashion. The information below provides a brief overview of those requirements, but PIs should defer to the detailed, current information and guidance documents provided on the respective OHARO websites.

Please note: Maintaining current OHARO approvals is an important aspect of maintaining compliance with the terms and conditions of the DOD-funded award. Although OHARO strives to send timely reminders to PIs to submit required protocol renewal documents, the PI should not construe absence of such reminders as a waiver for meeting the stated submission timelines.

ACURO

De novo submissions

The ACURO approval expires 30 days after the IACUC-approved protocol's expiration date. Every time a protocol previously approved by the ACURO is approved as a complete rewrite by the IACUC, the ACURO will perform a full review. A rewrite submission must be submitted to the ACURO mailbox ***before*** the ACURO approval expires. The PI should include the following with their *de novo* review submission:

1) The IACUC-approved protocol;
2) A copy of the IACUC approval;
3) A completed ACURO Appendix, including the ACURO PI Assurances signed by the ***protocol*** PI.

As long as the *de novo* submission is received before the ACURO approval expires, animal work previously approved by the ACURO may continue as described in the previous version of the protocol. However, any DOD-funded changes or new experiments outlined in the rewritten protocol may not be implemented until the PI receives the ACURO approval.

Please note: Protocols not received within 30 days of the IACUC protocol expiration date will be considered inactive by the ACURO. If this occurs, the SO and GS will be notified that any animal work conducted after the IACUC expiration date is considered noncompliant. Protocols submitted more than 30 days after the IACUC protocol expiration date will be considered new submissions. Animal activities previously approved by the ACURO on the previous version of the protocol may **NOT** continue, and animal work cannot begin or continue until the PI receives approval from the ACURO.

Other reporting requirements
Institutions conducting DOD-funded RDT&E or training with animals must inform the ACURO in a timely manner of any of the following:

- Significant deficiencies
- Noncompliance
- Change in AAALAC international accreditation status, including probation
- Socially sensitive matters
- Adverse events
- Protocol suspensions

In general, most events should be reported to the ACURO as soon as possible, but not more than 5 business days after the event/official notification. PIs should refer to the "ACURO Reporting Guidance" document on the ACURO website for detailed descriptions of the events listed above and the procedures for reporting any such occurrences. The list above is not meant to be all-inclusive. If a PI is uncertain whether something must be reported to the ACURO, they should contact the ACURO Office Manager (usarmy.detrick.medcom-usamrmc.other.acuro@health.mil) and their SO to discuss.

When an IACUC approves significant changes/major modifications to the DOD-funded portion of a protocol that is subject to ACURO oversight, the ACURO must review and approve the changes before they can be implemented. Minor changes to the DOD-funded portions of animal protocols (e.g., changes to non-key personnel, decrease in animal numbers, etc.) do **NOT** require the ACURO review and approval prior to their implementations. The ACURO's definition of major and minor changes may differ from an institution's IACUC; therefore, PIs must refer to the "ACURO Protocol Change Guidance" document on the ACURO website for complete guidance as to which protocol changes do and do not require review and approval by ACURO. PIs should include the following documents for ACURO review of amendments:

1) A copy of the IACUC-approved amendment; if the PI's organization utilizes a revised protocol for amendment review, the PI must provide the revised protocol with all changes highlighted.
2) A copy of the IACUC approval for the amendment.

OHRO

The PI must provide the following post-approval submissions to the OHRO via email at usarmy.detrick.medcom-USAMRDC.other.hrpo-cr-documents@health.mil. Failure to comply could result in suspension or termination of funding. The SO should also be included on any such submissions. Additional details about the following items will be available in the initial OHRO approval memorandum that the PI receives from the OHRO. PIs should retain a copy of the memo in an easily accessible location and refer to it if/when any of the following events arise.

- Substantive modifications to the research protocol defined as a change in PI, change or addition of an institution, change to the reviewing IRB, elimination or alteration of the consent process, change to the study population that has regulatory implications (e.g., adding children, adding active duty population, etc.), significant change in study design (e.g., provides assistance to people who have served in the armed forces would prompt additional scientific review), and any modifications that could potentially increase risk to subjects must be submitted to the OHRO for approval prior to implementation.
- A copy of the IRB Continuing Review approval letter must be submitted to the OHRO as soon as possible after receipt of approval, if applicable.
- The final study report submitted to the IRB, including a copy of any acknowledgement documentation and any supporting documents, must be submitted to the OHRO as soon as all documents become available.

Please note: The OHRO conducts site visits as part of its responsibility for compliance oversight. The study team must maintain accurate and complete study records in a secure and confidential manner and make the records available to representatives of the USAMRDC. The OHRO may contact the study team for additional information and documentation for the purpose of routine study monitoring at any time during the award POP.

The following study events **MUST** be promptly reported to the OHRO by telephone (301-619-2165) or email (usarmy.detrick.medcom-USAMRDC.other.hrpo@health.mil).

- All unanticipated problems involving risk to subjects or others.
- Suspensions, clinical holds (voluntary or involuntary), or terminations of this research by the IRB, the institution, the sponsor, or regulatory agencies.
- Any instances of serious or continuing noncompliance with the federal regulations or IRB requirements.
- The knowledge of any pending compliance inspection/visit by the FDA, OHRO, or other government agency concerning this clinical investigation or research.
- The issuance of inspection reports, FDA Form 483, warning letters, or actions taken by any government regulatory agencies.
- Change in subject status when a previously enrolled human subject becomes a prisoner must be promptly reported to the USAMRDC OHARO OHRO. The report must include actions taken by the institution and the IRB.

Please note: Events or protocol reports received by the OHRO that do not meet reporting requirements identified above will be included in the OHRO study file but may not be acknowledged.

CHAPTER 4: AWARD MANAGEMENT – REPORTING REQUIREMENTS

There are several types of reporting requirements that may be required per the terms and conditions of the award. The assistance agreement will specify the nature and frequency of reports (i.e., annual, quarterly, etc.). All awards will require, at a minimum, annual and final technical reports. More information about the various types of reports is detailed below. The timely submission of complete and accurate reports is critically important for maintaining compliance with the award terms and conditions and helping inform certain decisions, such as those related to continued support and/or direction of the research.

Annual and Final Technical Report Preparation

Annual and final technical progress reports shall be prepared in accordance with the Federal-wide Research Performance Progress Report (RPPR), the uniform format for reporting performance progress on Federally funded research projects and research-related activities. Detailed descriptions of the reporting requirements can be found on the USAMRDC Technical Reporting Requirements website at https://mrdc.health.mil/index.cfm/resources/researcher_resources/reporting/technical. For convenience, PIs can find copies of the annual and final report templates on the Funding Opportunities & Forms tab at https://ebrap.org/eBRAP/public/Program.htm, under Progress Report Formats. All annual and final technical reports must be submitted in PDF form via eBRAP with a front cover and Standard Form 298 (SF298). Blank copies of the appropriate front cover pages and SF298 are also available from the USAMRDC Technical Reporting Requirements website. The following are a few items from the Technical Reporting Requirements website that PIs are encouraged to pay particular attention to when composing the annual and final technical reports:

- Choose the appropriate distribution statement and accompanying front cover templates. A full description of the statements is on the Technical Reporting Requirements website. Reports marked as "Distribution is unlimited" will be approved for public release and will be available through search engines. PIs may choose the "Distribution authorized to U.S. Government agencies only" statement if an annual or final technical report contains unpublished data.
- Use the same heading and subheadings that were used in the approved SOW when stating the goals of the project under section 3, "Accomplishments." If the application/SOW listed milestones and/or target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.
- Describe all (1) major activities, (2) specific objectives, and (3) significant results or key outcomes/conclusions (both positive and negative) when discussing what was accomplished under each of the stated goals for that reporting period. The discussion should also include pertinent data and graphs, as appropriate, in sufficient detail to explain any significant results achieved and a succinct description of the methodology used. As the project progresses to completion, the reporting emphasis in this section should shift from reporting *activities* to reporting *accomplishments/conclusions*.
- For training or fellowship-type awards, a brief description of opportunities for training and professional development is also required under section 3, "Accomplishments." Training activities may include (but are not limited to) courses or one-on-one work with a mentor. Professional development activities may include workshops, conferences, seminars, and study groups.
- Provide only the citations for journal publications that report on work accomplished towards the approved SOW.

- Ensure that each annual and final technical report includes ALL sections outlined in the report table of contents. If there is nothing significant to report, PIs should state "Nothing to Report" rather than skipping a section, deleting it, or leaving it blank.

An annual technical report shall be submitted no later than 30 calendar days after the anniversary date of the award for the preceding 12-month period (e.g., for an award that began on September 30, the annual technical reports will be due October 30 of the subsequent years). If the award POP is extended by the GO, an annual technical report shall still be submitted no later than 30 calendar days after the anniversary date of the award, with a final technical report submitted at the end of the extension period.

Please note: Depending on the timing involved with processing and distributing a no-cost extension (NCE) award modification, the PI may or may not receive the typical automated reminder emails for the submission of the annual technical report. Under this circumstance, it is the PI's responsibility to ensure the technical report is still submitted via eBRAP no later than 30 days after the anniversary date of the award.

A final technical report summarizing the research effort over the entire POP, including all work completed during any NCE(s), shall be submitted no later than 120 calendar days after the award POP end date. The final technical report shall provide a complete reporting of all research findings in direct alignment with the approved SOW. Additionally, any work outlined in the SOW that was not completed should be explained.

Please note: Awards made prior to November 2015 retain the requirement to submit final technical reports no later than 90 calendar days after the award POP end date.

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 via eBRAP independently using the unique award number (e.g., HT9425-XX-X-XXXX). A duplicative report is acceptable; however, the front cover should be unique to each investigator, and the tasks and accomplishments shall be clearly marked with the responsible PI and research site.

The PI should contact the SO with any questions regarding the reporting requirements for a particular award.

Other Technical Reporting Requirements

Quarterly Technical Reports

The assistance agreement will specify in the award terms and conditions if additional technical reporting is required. In general, awards with direct military interest or awards that fund a clinical trial or human subject recruitment may require quarterly technical reports that describe research progress with respect to the SOW. Quarterly technical reports are the most immediate and direct contact between the PI and the SO. The reports provide the means for keeping USAMRDC advised of developments and problems as the research effort proceeds. Quarterly reports are submitted for the first three quarters of each year through the entire POP of the award. PIs do not submit quarterly technical reports for the fourth quarter, as the annual technical report will incorporate all four quarters of progress for that year.

A reporting quarter begins with the start date of the award POP and restarts annually from that date for the entire award POP. Each quarterly technical report must be submitted no later than 30 days after the end of each quarter. Automated emails will be sent to the PI approximately 15 days before the quarterly report is due. A template for the Quarterly Technical Progress Report Format can be found at https://ebrap.org/eBRAP/public/Program.htm, under Progress Report Formats. The PI should contact the SO with any questions regarding quarterly technical reporting requirements.

Quad Charts

The assistance agreement will specify in the award terms and conditions if quad charts are required. Generally, awards with direct military interest will require quad chart submission. If required, quad charts should be submitted as an appendix to the quarterly technical progress report. The quad chart template is a one-page PowerPoint file and is available at https://ebrap.org/eBRAP/public/Program.htm, under Progress Report Formats. The PI should contact the SO with questions regarding any quad chart reporting/submission requirements.

Technical Report Submission

All technical reports and any appendices should be saved as a PDF prior to submission and submitted electronically via the PI's eBRAP account. For help with uploading technical reports to eBRAP, Business Officials and/or PIs should read the "Technical Reports Instructional Guide," available on the Funding Opportunities & Forms page at https://ebrap.org/eBRAP/public/Program.htm, under Resources and Reference Material. Technical problems with accessing the eBRAP site or uploading technical reports should be directed to the Help Desk at 301-682-5507 or help@eBRAP.org.

Other Reporting Requirements

Financial Reporting

Please note: The information regarding financial reporting provided in this section is for informational purposes only and is not contractually binding. PIs and Business Officials should refer to the award-specific assistance agreement for official policy and guidance information.

Details regarding Financial Reporting requirements are incorporated by reference into the assistance agreement, with the Division III - USAMRAA Addendum to the DoD R&D General Terms and Conditions, available at https://usamraa.health.mil/Pages/Resources.aspx. More general financial information is also incorporated by reference into the assistance agreement and can be found in the DOD Research and Development General Terms and Conditions at https://www.nre.navy.mil/work-with-us/manage-your-award/manage-grant-award/grants-terms-conditions. Business Officials and PIs should be sure to refer to the terms and conditions that are specific to the fiscal year in which their assistance agreement was issued.

In general, a Business Official from the recipient institution will be required to submit a Standard Form 425 Federal Financial Report (SF425) according to the frequency and due dates specified in the appropriate award terms and conditions. For most awards, the Federal Financial Reporting period end dates fall on the end of the calendar year for annual reports (12/31/XXXX). An annual SF425 should be submitted via eBRAP no later than 90 days after the end of the calendar year. A final SF425 will be required to be submitted no later than 120 days after the end of the award POP. USAMRAA requires the recipient to complete sections 1-9, section 10 (a) – 10 (o), and sections 11, 12, 13, and 14 of the SF425. Business Officials should visit https://usamraa.health.mil/Pages/SF425.aspx for more information and to access the downloadable SF425 with instructions.

Public Health Service Inclusion Enrollment Reporting

The DOD was directed by the U.S. Senate Appropriations Subcommittee on Defense to develop a plan to ensure the appropriate representation of women and minorities in its extramural research in Congressional report 115-290, page 213, which accompanied H.R. 6157, the Department of Defense Appropriations Act of 2019. The report stated that CDMRP shall work in coordination with the NIH to develop a plan that provides for: "(1) representation of women and minorities in each clinical trial, as well as the data on specific challenges researchers face in seeking to include women and minorities in their studies; (2) examination of biological variables, including the appropriate analysis of differential outcomes by sex, in clinical research; (3) practice of making clinical findings, subgroup analyses, and data publicly available, as appropriate and applicable; and (4) requirements (including, but not limited to, programmatic controls) and updated guidelines to ensure the appropriate representation of women in clinical research. Outcomes should also be analyzed for potential sex differences." As a result, CDMRP established as policy that women and individuals from minority groups be included in all CDMRP-funded clinical research studies, unless there is a clear, justifiable rationale that it is inappropriate with respect to the health of the subjects or the purpose of the research.

Starting in FY21, all CDMRP-funded clinical research projects (i.e., any non-exempt studies that include the use of human data, human specimens, and/or human subjects) are required to include a strategy for the inclusion of women and minorities appropriate to objectives of the study, including a description of the composition of the proposed study population in terms of sex, racial, and ethnic group, and an accompanying rationale for the selection of subjects. Additionally, the terms and conditions for any award that funds clinical research will include reporting requirements for inclusion enrollment data updates. The CDMRP Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, and a template for the Public Health Service Inclusion Enrollment Report can be found at https://ebrap.org/eBRAP/public/Program.htm.

Other Program-Specific Reporting

Some awards may have additional reporting obligations associated with mandatory DOD-sponsored meetings or data submission requirements. These may include External Advisory Boards or Government Steering Committees, In Progress Review meetings, milestone meetings, or data submission to the Federal Interagency Traumatic Brain Injury Research (FITBIR) database. These requirements will be specified in the Program Announcement and the terms and conditions of the assistance agreement. If there are questions or concerns regarding any program-specific reporting requirements, the PI should contact the SO.

Chapter 5: Modifications to the Award During the Period of Performance

The PI and the recipient institution are obligated to abide by the award-specific terms and conditions. Circumstances may arise that require modifications to these terms and conditions. All changes to the assistance agreement terms and conditions require prior written approval from the GO. Provided below is a list of circumstances that could result in the need for an assistance agreement modification. While the list is not intended to be all-inclusive, it does highlight the most frequent modifications. To initiate the process, the recipient institution's Business Official must submit a written request, via email, to the GS named in the award, with the SO copied on the correspondence for awareness. Approval of any submitted request is not guaranteed, and requests are not approved until the recipient institution receives an official award modification from USAMRAA.

Common modification requests that require prior written approval from the GS

Change in SOW

Any changes in the approach or the objectives of the project, as outlined in the approved SOW, must be reviewed and approved by the SO ***prior*** to implementation of the change, even if there is no associated budget revision. A copy of the revised SOW should accompany the request. The revised SOW should clearly denote the revisions, additions, and/or deletions from the previously approved SOW. As necessary, an updated timeline should be provided for each proposed change, and the changes should be accompanied by justifications and references. Any changes in the animal and/or human subject protocol(s) must also be reviewed and approved by the appropriate OHARO office. All changes must be within the original scope of the project.

Change in PI or Key Personnel

Any changes in PI and/or key personnel, including significant changes to effort, must be reviewed prior to implementation of any changes. Changes in PI for certain award types (e.g., Career Development or Clinical Trial Awards) may not be allowed. Any such restrictions will be stated in the original Program Announcement and the award terms and conditions. To inquire about a change in PI or key personnel, the Business Official shall provide the GS with a detailed description and justification of the requested change(s). The GS will provide additional instructions, as appropriate.

Institution 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. To request an award transfer, the Business Official must provide the GS with a detailed justification for the award transfer, an official relinquishment letter signed by the Business Official, and contact information for the PI and Business Official at the new institution.

Please note: Award transfers are not permitted during the last year of the award POP or during any extension thereof. If the PI of an award is moving to a new institution, the Business Official of the original institution should contact the GS to discuss the viable options.

If the GS decides to move forward with transferring the award to a new institution, the 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. Additionally, ACURO and/or OHRO must review and approve all protocols once the IACUC and/or IRB approvals at the new institution have been secured, and before any work with animals, human data, HAS, and/or human subjects can start at the new institution.

No-Cost Extension

The recipient may initiate a one-time NCE to the expiration date of the award, for a period of up to 12 months, if the NCE does not involve a change in the approved objectives or scope of the project. Although prior approval from the GO for an initial NCE is not required, the Business Official shall notify the GO or the GS in writing at least 30 calendar days before the expiration date of the award. The notification shall state how much additional time is needed and confirm that no additional funds are being requested. The recipient must be current with all financial and technical reporting requirements and compliant with all other terms and conditions of the award. This one-time NCE may not be exercised merely for the purpose of using unobligated balances. An official modification to the award document will be issued by the GO to extend the POP. PIs must maintain current OHARO (ACURO/OHRO) approvals during the NCE period.

Any subsequent NCEs require prior approval from the GO. The Business Official shall submit a written request to the GO or GS assigned to the award no later than 30 days prior to the expiration date of the award. The written request should address the reason for the extension, how much additional time is needed, and a status update outlining the remaining tasks to be completed. The GS may request a revised budget for the NCE period reflecting the unexpended funds.

In addition, all financial (SF425) and technical progress reports (quarterly and/or annual) to date should be submitted. All human and/or animal protocols and continuing reviews should be up to date with appropriate approvals in place.

Please 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 POP. 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.

Funding Reallocation

Federal regulations allow grant and cooperative agreement recipients to “re-budget” funds across direct cost categories unless the federal agency chooses to prohibit such authority. The DOD has opted to give assistance agreement recipients this budgetary flexibility. Per regulation 2 CFR §200.308(a): “The Federal awarding agency may, at its option, restrict the transfer of funds among direct cost categories or programs, functions, and activities for Federal awards in which the Federal share of the project exceeds the Simplified Acquisition Threshold and the cumulative amount of such transfers exceeds or is expected to exceed 10 percent of the total budget as last approved by the Federal awarding agency. The Federal agency cannot permit a transfer that would cause any Federal appropriation to be used for purposes other than consistent with the appropriation.”

Extended Absence

The Business Official and PI should first refer to any institutional policies on extended leave, including maternity, disability, and sabbatical leave. Absences for a period of more than 3 months require the GO's approval and may require an award modification. At the discretion of the GO, an absence of the PI or any key personnel named in the budget for a period of more than 3 months may require that a replacement be named. Any changes in PI require prior approval by the GO.

Early Termination

To request a termination date prior to the end of the POP, the Business Official should submit to the GS a letter from the current PI stating they are relinquishing the award as of a specific date. The letter should be signed by both the PI and the Business Official. The appropriate OHARO office(s) must also be notified of early termination. Any unexpended funds will be returned to the government and de-obligated from the award.

Other Award Management Considerations

Disputes and Appeals

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

Suspension/Termination

The GO 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 6: PUBLICATIONS AND INTELLECTUAL PROPERTY

Please note: The information in this chapter is for informational purposes. PIs and Business Officials should consult the award-specific terms and conditions referenced in the assistance agreement for more detailed information about any of these items.

Press Releases/ Media Announcements

It is advised that the PI wait until negotiations are complete and the assistance agreement distributed 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, any press releases or media announcements must acknowledge that: the DOD is funding the work, the appropriate CDMRP research program, and the award number (e.g., HT9425-XX-X-XXXX). PIs can refer to their assistance agreement, and the terms and conditions referenced therein, to find additional information about how to appropriately cite DOD funding.

Acknowledgement of DOD Support in Award Outcomes

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 SO and the USAMRAA GS as they become available. The PI is required to acknowledge the DOD funding in manuscripts, book chapters, abstracts, posters, and oral presentations when the work is supported, in part or in whole, by 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. (HT9425-XX-X-XXXX)," are recommended. A 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. Publications that clearly and appropriately acknowledge DOD support will appear on the CDMRP website.

Intellectual Property

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 referenced in the terms and conditions of the assistance agreement concerning the reporting of subject inventions must be followed. Invention Disclosures and Patent Applications shall be filed electronically using the Interagency Edison (iEdison) system through the National Institute of Standards and Technology (formerly through the National Institutes of Health) (https://www.iEdison.gov) within the times specified for reporting. A final DD Form 882 is required and must be submitted electronically with the final technical report. The DD Form 882 can be accessed on the Funding Opportunities & Forms page at https://ebrap.org/eBRAP/public/Program.htm. List all inventions made during the award POP, or state "none," as applicable. The award will not be closed until the PI/institution has met all reporting requirements. Refer to Appendix C for additional information about completing the DD Form 882 Report of Inventions

Data Sharing of Research Results

It is the intent of the CDMRP that data and research resources generated through CDMRP-funded research (basic research, clinical studies, surveys, etc.) be made available to the research community and to the public at large. It is critically important to share unique data and research resources that

cannot be readily replicated, such as: 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; or studies of rare phenomena, such as rare diseases. For additional information on CDMRP expectations for data sharing, refer to the "Policy on Sharing Data and Research Resources," available on the eBRAP website (https://ebrap.org/eBRAP/public/Program.htm) under Reference Material.

CHAPTER 7: AWARD CLOSE-OUT

Final Reporting Requirements

Final Technical Report

A final technical report prepared in accordance with the RPPR format and summarizing the entire research effort shall be submitted no later than 120 calendar days after the award POP end date. Final reports should be submitted via eBRAP (https://ebrap.org). A "Technical Report Instructional Guide" is available under the Funding Opportunities & Forms tab on eBRAP and provides step-by-step instructions for uploading a technical report to the site. Note that concurrent submission of the Final DD882 Invention and Patent Report (see below) is required in order to upload a final technical report to eBRAP. Refer to Chapter 4 for additional details regarding technical reporting requirements.

Final DD Form 882 Patent and Invention Disclosure

A Report of Inventions and Subcontracts (DD Form 882) is due no later than 120 calendar days after the award POP end date. All patent applications that were submitted during the award POP and include data that was acquired using funds from the CDMRP-funded project, should be listed on the DD Form 822. A blank form with instructions can be downloaded from the Funding Opportunities & Forms page of eBRAP, https://ebrap.org/eBRAP/public/Program.htm. Refer to Appendix C for additional information about completing the DD Form 882 Report of Inventions. The completed, final DD Form 882 must be uploaded via eBRAP (https://ebrap.org) concurrently with the final technical report, even if there are no patents or inventions to disclose for the award.

OHARO Protocol Closures

Once USAMRDC support for a project has ended, no further review of the protocol will be conducted, and the OHARO protocol file(s) will be closed. The ACURO requires notification from the PI that the DOD-funded animal work has been closed. If a human subject protocol has been completed at the institution, the OHRO will require a copy of the IRB closure documents. If the human subject protocol is ongoing after USAMRDC support has ended, OHRO will request a statement about the current study status from the PI, prior to closing their record of the protocol.

Financial Reporting

The Business Official should submit a final SF425 Federal Financial Report via eBRAP within 120 days of the end of the award POP. Refer to Chapter 4 for additional information and resources regarding financial reporting.

Outcome/Output Follow-up

PIs are strongly encouraged to provide any follow-up information about pending outcomes and/or outputs to the SO if there are any updates after the final technical report has been approved (e.g., a publication that had been under review at the time of final technical report submission has been accepted and is available online or a patent was issued after the final technical report was approved).

CDMRP and/or contract support staff may contact award recipients post-award for the purpose of research outcome follow-up. Please ensure that the PI's eBRAP account contains the most current contact information for the PI and that the SO is provided with any new contact information.

Appendix A: Useful Websites

CDMRP website: https://cdmrp.health.mil/

- Can navigate to program-specific pages, search CDMRP-funded projects, find information about various CDMRP positions and policies (e.g., CDMRP's position on research duplication and procedures to avoid duplication), etc.

CDMRP Electronic Receipt Portal: https://ebrap.org/

- Can navigate to the CDMRP Funding Opportunities & Forms page from the main eBRAP page.

USAMRAA Home Page: https://usamraa.health.mil

- Can navigate to the Resources page, which includes the USAMRAA General Terms and Conditions Addendum to the DOD R&D Terms and Conditions and links to the DD Form 882 and SF425.

Office of Naval Research: https://www.nre.navy.mil/work-with-us/manage-your-award/manage-grant-award/grants-terms-conditions

- Location of DOD R&D General Terms and Conditions

USAMRDC Researcher Resources: https://mrdc.health.mil/index.cfm/resources/researcher_resources

- Can navigate to the Technical Reporting Requirements page from the main USAMRDC page.

Office of Human and Animal Research Oversight (OHARO): https://mrdc.health.mil/index.cfm/collaborate/research_protections

- Can navigate to the ACURO and OHRO pages from the main OHARO page.

Defense Technical Information Center (DTIC): https://discover.dtic.mil/

Interagency Edison (iEdison) System: https://www.nist.gov/iedison

Appendix B: Abbreviations

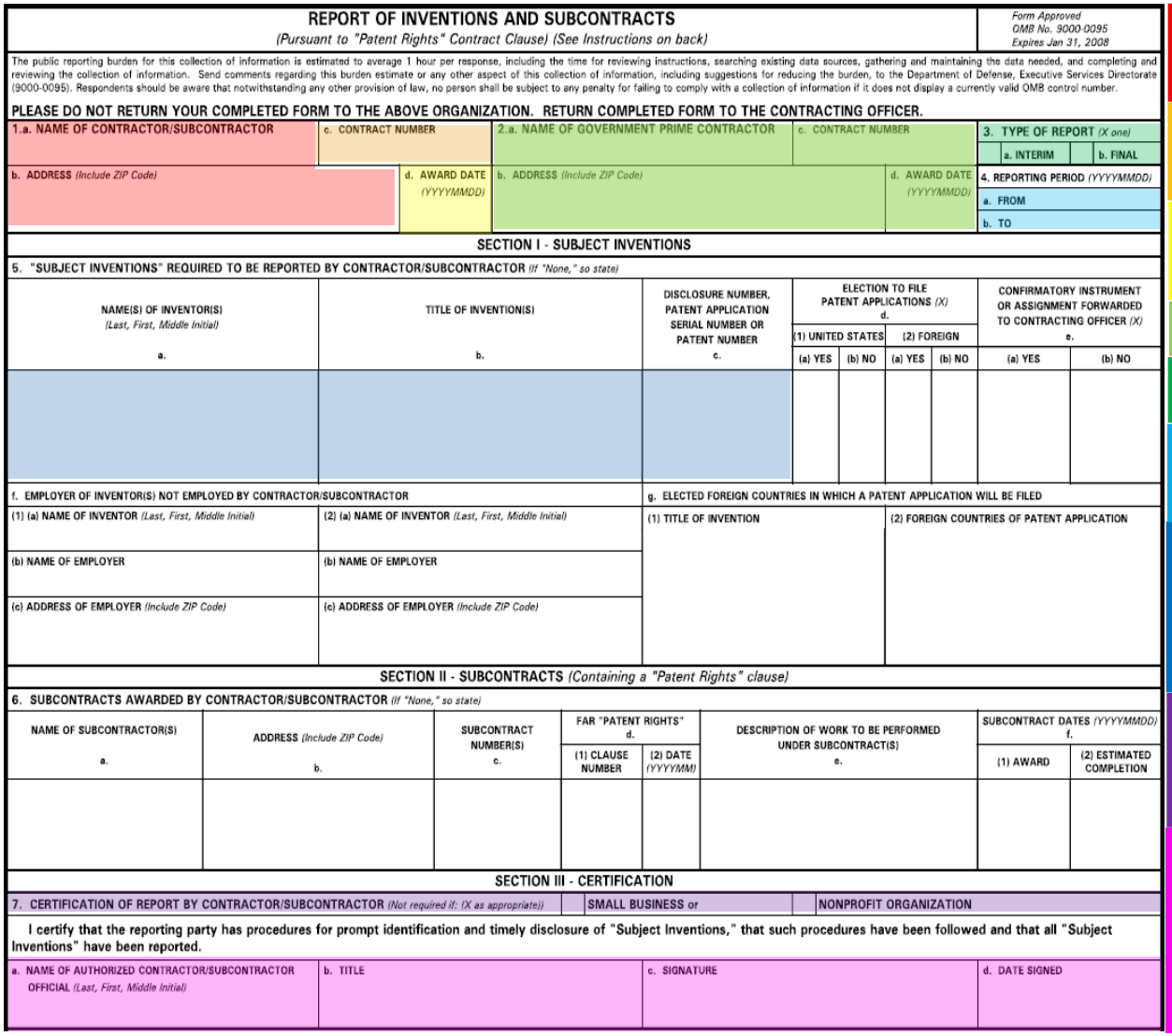
ABBREVIATION	FULL FORM	DEFINITION
ACURO	Animal Care and Use Review Office	Part of the Office of Human and Animal Research Oversight; Regulatory office that ensures that all research projects and investigations involving animals are conducted in accordance with Federal, State, DOD, Army, USAMRDC, and international laws and regulatory requirements
BAA	Broad Agency Announcement	A type of funding opportunity; a competitive solicitation procedure used to obtain proposals for basic and applied research and the part of development not related to the development of a specific system or hardware procurement
CDMRP	Congressionally Directed Medical Research Programs	The program office that manages and executes the program cycle from investment strategy to award execution
CFR	Code of Federal Regulations	Codification of the general and permanent rules published in the Federal Register by the departments and agencies of the U.S. Federal Government
DOD	U.S. Department of Defense	An executive branch department of the U.S. federal government charged with coordinating and supervising all agencies and functions of the government directly related to national security and the U.S. Armed Forces
DODGAR	Department of Defense Grant and Agreement Regulation	Governing DOD regulatory document for awards
DTIC	Defense Technical Information Center	The repository for research and engineering information for the U.S. Department of Defense
EBRAP	Electronic Biomedical Research Application Portal	CDMRP electronic application receipt portal and source for funding opportunity listings and forms (https://ebrap.org)
FDA	U.S. Food and Drug Administration	U.S. federal agency responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation
FITBIR	Federal Interagency Traumatic Brain Injury Research	Database of records from traumatic brain injury (TBI) studies funded by the DOD and NIH
GO	Grants Officer	Federal government employee within USAMRAA who is the only person with authority to commit funds, enter into agreements, approve award modifications, and/or make official decisions affecting the cost and/or the terms and conditions of awards
GOR	Grants Officer's Representative	Federal government employee appointed by USAMRAA for his/her technical knowledge and subject matter expertise in order to assist the GO in administering awards
GS	Grants Specialist	Federal government employee within USAMRAA who is assigned to assist the Grants Officer with award-related issues. The GS is the primary point of contact for business and/or non-scientific award related issues. **Note:** You may

		occasionally see this person referred to as the Contract Specialist, or CS
HAS	Human Anatomical Specimens	Samples collected from human subjects (e.g., saliva, blood, tissue, cells, etc.); research involving HAS must be reviewed and approved by OHRO
HES	Human Embryonic Stem cell line	Established cell lines that have been derived from human embryonic stem cells
HSPS	Human Subjects Protection Scientist	Staff member of the OHRO who is responsible for reviewing human data/anatomical specimen and/or human subjects protocols to ensure that all DOD-funded human studies meet DOD-specific regulations
OHRO	Office of Human Research Oversight	Part of the Office of Human and Animal Research Oversight; Regulatory office that ensures that all research projects and investigations involving human subjects, human cadavers, and/or human anatomical substances (including human cell lines and analysis of human data) are conducted in accordance with Federal, State, DOD, Army, USAMRDC, and international laws and regulatory requirements. Formerly known as the Human Research Protection Office (HRPO)
IACUC	Institutional Animal Care and Use Committee	Local ethics committee that oversees animal research at an institution; institutions may use different names for this committee, particularly those outside the U.S.
IDE	Investigational Device Exemption	Allows an investigational device (i.e., not FDA-approved) to be used in a clinical study in order to collect safety and effectiveness data
IEDISON	Interagency Edison	System through which awardees are able report an inventions and patent funded by U.S. government agencies
IND	Investigational New Drug Application	A request from a clinical study sponsor to obtain authorization from the FDA to administer an investigational drug or biological product to humans
IRB	Institutional Review Board	Local ethics committee that oversees human research at an institution; institutions may use different names for this committee, particularly those outside the U.S.
IRBO	Institutional Review Board Office	The IRBO is one of three OHARO offices. The IRBO provides services for scientists and researchers assigned to the USAMRDC Headquarters, and serves as the primary IRB for USAMRDC subordinate institutes and laboratories
NCE	No-Cost Extension	Modification to award to extend the period of performance without additional funding. **Note:** You may occasionally see an NCE referred to as an extension without funds (EWOF)
NIH	National Institutes of Health	U.S. federal agency that is part of the U.S. Department of Health and Human Services and is the nation's largest medical research agency
OHARO	Office of Human and Animal Research Oversight	Regulatory office that ensures that all USAMRDC research projects and investigations involving animals, human subjects, human cadavers, and/or human anatomical substances (including human cell lines and analysis of human data) are conducted in accordance with Federal,

		State, DOD, Army, USAMRDC, and international laws and regulatory requirements. ACURO and OHRO are subordinate offices of OHARO. Formerly known as the Office of Research Protections (ORP)
PAIR	Pre-award Information Request	Request for information sent by the USAMRAA grants specialist to the recipient institution's sponsored programs office as part of pre-award negotiations
PCPS	Previous, Current, and Pending Support	Document detailing all funding that has ended in the past 5 years, active/current funding, and all pending support for the PI and key personnel
PI	Principal Investigator	Named investigator on research proposals
POP	Period of Performance	Time between the official start and end dates for an award during which work is completed
PSR	Program Sponsor Representative	Government representative designated by a program office outside of CDMRP, such as a Joint Program Committee/Program Area Directorate, who serves as a technical resource in support of award management for a given award
RDT&E	Research, Development, Test, and Evaluation	The category of Congressional appropriations used to support CDMRP-funded research
RPPR	Research Performance Progress Report	The uniform format for reporting performance progress on federally funded research projects and research-related activities
SF	Standard Form	U.S. government form
SO	Science Officer	CDMRP staff member selected for his/her technical knowledge and scientific expertise to manage awards recommended for funding. The SO is the primary point of contact for the PI on all matters related to the CDMRP-funded project's execution and general award management questions for the lifetime of the award
SOW	Statement of Work	A detailed document that clearly defines the project strategy to include general methodology and an appropriate timeline. Progress is evaluated against the SOW during the review of technical progress reports
SPO	Sponsored Programs Office	Business office at the recipient institution that handles grants/awards administration; the individual representing the SPO is referred to as the Business Official in this guide
USAMRAA	U.S. Army Medical Research Acquisition Activity	The contracting and assistance agreement element of USAMRDC; the office that executes awards and approves changes to awards
USAMRDC	U.S. Army Medical Research and Development Command	U.S. Army's medical materiel developer, with responsibility for medical research, development, and acquisition
VA	U.S. Department of Veterans Affairs	U.S. federal agency that is part of the U.S. Department of Health and Human Services and provides assistance to people who have served in the U.S. Armed Forces

Appendix C: How to Complete a DD Form 882 for CDMRP

Please note: The information provided below is for informational purposes. PIs and Business Officials should consult the official instructions provided with the DD Form 882, which can be downloaded from eBRAP.



REPORT OF INVENTIONS AND SUBCONTRACTS
(Pursuant to "Patent Rights" Contract Clause) (See Instructions on back)

Form Approved OMB No. 9000-0095 Expires Jan 31, 2008

The public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (9000-0095). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.

PLEASE DO NOT RETURN YOUR COMPLETED FORM TO THE ABOVE ORGANIZATION. RETURN COMPLETED FORM TO THE CONTRACTING OFFICER.

1.a. NAME OF CONTRACTOR/SUBCONTRACTOR	c. CONTRACT NUMBER	2.a. NAME OF GOVERNMENT PRIME CONTRACTOR	c. CONTRACT NUMBER	3. TYPE OF REPORT *(X one)*
				a. INTERIM ☐ b. FINAL ☐
b. ADDRESS *(Include ZIP Code)*	d. AWARD DATE *(YYYYMMDD)*	b. ADDRESS *(Include ZIP Code)*	d. AWARD DATE *(YYYYMMDD)*	4. REPORTING PERIOD *(YYYYMMDD)*
				a. FROM
				b. TO

SECTION I - SUBJECT INVENTIONS

5. "SUBJECT INVENTIONS" REQUIRED TO BE REPORTED BY CONTRACTOR/SUBCONTRACTOR *(If "None," so state)*

NAME(S) OF INVENTOR(S) *(Last, First, Middle Initial)* a.	TITLE OF INVENTION(S) b.	DISCLOSURE NUMBER, PATENT APPLICATION SERIAL NUMBER OR PATENT NUMBER c.	ELECTION TO FILE PATENT APPLICATIONS *(X)* d.				CONFIRMATORY INSTRUMENT OR ASSIGNMENT FORWARDED TO CONTRACTING OFFICER *(X)* e.	
			(1) UNITED STATES		(2) FOREIGN			
			(a) YES	(b) NO	(a) YES	(b) NO	(a) YES	(b) NO

f. EMPLOYER OF INVENTOR(S) NOT EMPLOYED BY CONTRACTOR/SUBCONTRACTOR		g. ELECTED FOREIGN COUNTRIES IN WHICH A PATENT APPLICATION WILL BE FILED	
(1) (a) NAME OF INVENTOR *(Last, First, Middle Initial)*	(2) (a) NAME OF INVENTOR *(Last, First, Middle Initial)*	(1) TITLE OF INVENTION	(2) FOREIGN COUNTRIES OF PATENT APPLICATION
(b) NAME OF EMPLOYER	(b) NAME OF EMPLOYER		
(c) ADDRESS OF EMPLOYER *(Include ZIP Code)*	(c) ADDRESS OF EMPLOYER *(Include ZIP Code)*		

SECTION II - SUBCONTRACTS *(Containing a "Patent Rights" clause)*

6. SUBCONTRACTS AWARDED BY CONTRACTOR/SUBCONTRACTOR *(If "None," so state)*

NAME OF SUBCONTRACTOR(S) a.	ADDRESS *(Include ZIP Code)* b.	SUBCONTRACT NUMBER(S) c.	FAR "PATENT RIGHTS" d.		DESCRIPTION OF WORK TO BE PERFORMED UNDER SUBCONTRACT(S) e.	SUBCONTRACT DATES *(YYYYMMDD)* f.	
			(1) CLAUSE NUMBER	(2) DATE *(YYYYMM)*		(1) AWARD	(2) ESTIMATED COMPLETION

SECTION III - CERTIFICATION

7. CERTIFICATION OF REPORT BY CONTRACTOR/SUBCONTRACTOR *(Not required if: (X as appropriate))* ☐ SMALL BUSINESS or ☐ NONPROFIT ORGANIZATION

I certify that the reporting party has procedures for prompt identification and timely disclosure of "Subject Inventions," that such procedures have been followed and that all "Subject Inventions" have been reported.

a. NAME OF AUTHORIZED CONTRACTOR/SUBCONTRACTOR OFFICIAL *(Last, First, Middle Initial)*	b. TITLE	c. SIGNATURE	d. DATE SIGNED

This box should list the name and address of the recipient institution to which the award was made, NOT the PI

Contract Number: this box should list the Award Number for Assistance Agreements (HT9425-XX-X-XXXX)

Award Date: the award date is indicated on the front page of the Assistance Agreement

Leave blank

Type of Report needs to be marked as "Final"

Reporting Period: Period of Performance dates should be entered here

Name of Inventors/Title of Inventions: These sections should be filled in if applicable. If there are no relevant inventions/patents, make sure at least one of these boxes indicates "None" or "N/A"

Certification of Report: Recipients who are designated as either a Small Business or a Nonprofit should check the relevant box in section 7.

Certification is not required for Small Business or Nonprofit recipients, so if either box is checked in section 7, this portion of the form does not need to be signed. If neither box is checked, the form needs to be signed by an Authorized Representative.