

DEPARTMENT OF THE ARMY

US ARMY MEDICAL RESEARCH ACQUISITION ACTIVITY
820 CHANDLER STREET
FORT DETRICK MD 21702-5014

MCMR-AAP-D

JAN 2 9 2018

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Assistance/Procurement Advisory Notice 15-01 (rev), Supporting Military Facilities' Costs when Performing Collaborative Research with Extramural Awardees

1. PURPOSE. This notice:

- a. Revises APAN 15-01 "Supporting Military Facilities' Costs when Performing Collaborative Research with Extramural Awardees," dated 10 November 2014.
- b. Establishes procedures to be followed to support research-related costs incurred by the Department of Defense (DoD) in Military Facilities when performing collaborative research with Extramural Awardees.
- c. Rescinds Procurement Advisory Notice 09-02, "Appropriated funds provided to recipients under procurement contracts and assistance agreements and sent to U.S. Government entities via cooperative research and development agreements (CPADAs)", 01 May 2009.

2. APPLICABILITY.

- a. This policy applies to all U.S. Army Medical Research and Materiel Command (USAMRMC) funded Extramural Research contracts and assistance agreements when Military Facilities collaborate with Extramural Awardees.
 - b. This policy is not applicable to collaboration with non-DoD federal agencies.

REFERENCES.

- a. DoD Instruction 6000.08, "Defense Health Program Research and Clinical Investigation Programs," January 22, 2014
 - b. DoD Financial Management Regulation 7000.14-R
 - c. 15 USC §3710a, "Cooperative Research and Development Agreements"

4. DEFINITIONS.

- a. Military Facility. Military health system facility, military research laboratory, military treatment facility, military dental treatment facility, or a DoD activity embedded within a civilian medical center.
 - b. Extramural Organization. A non-federal entity.
- c. Awardee. A non-federal entity awarded a research contract or assistance agreement (grant or cooperative agreement).
 - d. Intramural Research. Research conducted by the DoD in a Military Facility.
- e. Extramural Research. Research other than Intramural Research which is conducted by an Extramural Awardee.
- f. Technology Transfer. The use of legal instruments such as Cooperative Research and Development Agreements (CPADAs), Material Transfer Agreements, and Interagency Agreements to exchange knowledge, technologies, samples, etc. among federal and non-federal entities in support of research.
- g. Direct Fund. When the Resource Management (RM) office provides funds directly to the Military Facility via a Funding Authorization Document (FAD), Military Interdepartmental Purchase Request (MIPR), or other authorized method.
 - h. Out Years. Future years of a multi-year project.

5. GENERAL.

- a. The USAMRMC supports Intramural and Extramural Research and Technology Transfer to accomplish its mission to create, develop, deliver, and sustain medical capabilities for the Warfighter.
- b. The USAMRMC receives proposals and applications from Extramural Organizations to perform research. When an Extramural Organization's proposal or application is selected for funding, the U.S. Army Medical Research Acquisition Activity (USAMRAA) awards a contract or assistance agreement (hereinafter, award) as the legal instrument to authorize support and provide funding.

- c. When Military Facilities collaborate with Awardees, they may need additional resources or incur costs (direct and indirect) associated with performance of their Intramural Research portions of the Extramural Research projects.
- d. The Awardee may provide resources to the Military Facility, such as personnel, supplies, or equipment, procured using award funds. The resources to be provided should be identified in the proposal or application.
- e. In those rare cases where the Awardee plans to provide award funds to the Military Facility, the funding methods and procedures described in this notice must be followed to support the costs incurred by the Military Facility.

PROPOSAL/APPLICATION REQUIREMENTS.

- a. Military Facilities which perform collaborative research with Awardees will receive support for their direct and indirect costs incurred in performance of their Intramural portions of the Extramural research projects in accordance with the requirements and procedures described herein.
- b. The Military Facility's direct and indirect costs must meet the requirements of the DoD Financial Management Regulation (FMR) 7000.14-R and be substantiated by the USAMRMC's or Military Facility's RM office, comptroller office, or equivalent.
- c. USAMRMC Funding Opportunity Announcements (FOAs) (solicitations, Broad Agency Announcement or Program Announcements), as appropriate, will state the Military Facility's submission requirements to be included in the Extramural proposal or application. At a minimum:
- (1) The DoD Intramural Researcher must obtain a letter from his/her commanding officer or Military Facility director authorizing his/her participation in the Extramural Research project. This letter must be provided to the Extramural Organization for inclusion in the proposal or application.
- (2) The DoD Intramural Researcher must also coordinate with his/her local RM office (or equivalent) to prepare a sound budget and justification for the estimated costs. Where there are no DoD-established reimbursement rates [e.g., institution review board (IRB) fees, indirect cost rates, etc.], the Military Facility's RM office (or equivalent) must provide details of how the proposed rates were determined. The DoD Intramural Researcher must use the enclosed budget and justification form when developing the estimated costs and provide it to the Extramural Organization for inclusion in the proposal or application. Instructions for completing this form will be included in the FOA.
- (3) The Extramural Research proposal or application must include a proposed financial plan for how the Military Facility's Intramural Research costs will be supported

[i.e., directly funded by DoD, resources (other than award funds) provided by the Awardee to the Military Facility, or award funds provided by the Awardee to the Military Facility (in accordance with the requirements below)].

(4) The DoD Intramural Researcher should also coordinate with his/her technology transfer office.

7. DIRECT FUND.

- a. Whenever possible, the USAMRMC's RM Office will Direct Fund the collaborating Military Facility to support its total costs to be incurred in performance of the Intramural Research portion of the project awarded to the Extramural Organization.
- b. When the Military Facility is Direct Funded for a project's year-one costs only, the USAMRMC execution management agent (EMA) will be responsible for budgeting for any estimated out year Intramural costs of the project, including associated DoD civilian and military travel costs. When applicable, the EMA will coordinate with the associated Program Area Directorate (PAD) and/or Joint Program Committee (JPC) for planning of "out year" funding. The EMA, PAD, and/or JPC, as appropriate, will then coordinate with the USAMRMC Plans, Programs, Analysis & Evaluation (PPA&E) office for Direct Funding of Intramural "out year" costs. During the year of execution, these plans will be part of the spend plan executed by each PAD and/or JPC by the EMA and coordinated with the USAMRMC RM office.

8. FUNDS OBLIGATED ON EXTRAMURAL AWARD.

- a. Circumstances may exist whereby USAMRMC is not able to Direct Fund the Military Facility. When direct funding is not possible, funds may be included in the Extramural award to enable the Extramural Awardee to provide funds to the Military Facility. This funding method can be employed with prior approval when it is determined to be necessary due to extraordinary circumstances and is in the best interest of the Government. The specific process to request approval under this funding method is described in paragraph 9 below.
- b. Examples of circumstances which may be considered for approval include (not all inclusive and would not apply if core funding is utilized):
- (1) When the research protocol involves radiological studies, CT scans, or other procedures or treatments which must be performed and analyzed at the Military Facility and that would not otherwise be performed as part of standard medical care;
- (2) When the research requires the purchase and use by the Military Facility of chemical or biological materials, controlled substances, or research animals that cannot legally be purchased or used by the Extramural Awardee;

- (3) When costs associated with research protocols can only be conducted at the Military Facility due to the nature of the research;
- (4) When clinical care costs are incurred by the Military Facility, e.g., for research-related outpatient care visits at the Military Facility. The costs must be in accordance with DoD established reimbursement practices and rates for equivalent or essentially similar clinical care visits, as established by the DoD comptroller (or equivalent).
- (5) When other clinical trial related costs are incurred by the Military Facility (e.g., research nurse time, animal caretaker time, study-related drugs, regulatory oversight personnel time, quality assurance personnel time, information technology infrastructure, equipment maintenance, etc.).
- (6) When the nature of the project makes the Military Facility's need for the funds highly dependent upon activities outside of its control (e.g., multi-site IRB reviews and approvals, patient enrollment, Food and Drug Administration approval of a study device, etc.).
- (7) When the Military Facility's research activities are dependent on the work first being completed by the Extramural Awardee, thereby altering the timing of the Military Facility's funding needs.
- (8) Under multi-year awards, incremental funding of the project may not be possible if future receipt of funds for the same purpose are uncertain. This occurs when an appropriation is unplanned or unprogrammed (e.g., Congressional Special Interest appropriations). Therefore, funds would not be available to Direct Fund the Military Facility in out years. In this case, funds for all years of the project must be obligated on an award at the time of initial award.
- c. DoD military labor costs cannot be paid. **In rare cases,** when DoD civilian employee labor costs are aligned with reimbursable funding on the Military Facility's Table of Distribution and Allowances, these costs may be paid by Direct Funding from the appropriation funding the research. The EMA, PAD, and/or JPC, as appropriate, should coordinate with the USAMRMC RM office for Direct Funding of DoD civilian employee labor costs each year. If program funds are not available to support these costs, the Military Facilities should consider the use of other authorized funds.
- d. DoD civilian employee and military travel costs cannot be paid through an award, i.e., by the Extramural Awardee with award funds. The EMA, PAD, and/or JPC, as appropriate, should coordinate with the USAMRMC RM office for Direct Funding of DoD civilian employee and military travel costs each year. If program funds are not available to support these costs, the Military Facilities should consider the use of other authorized funds.

- 9. APPROVAL PROCESS. Before the Awardee can provide award funds to the Military Facility, prior approval from the Principal Assistant Responsible for Contracting (PARC) must be obtained using the following procedure:
- a. The Military Facility, in conjunction with the Awardee, must provide a written justification for the funding method. Suggested areas to be addressed are: research-related activities that will take place at the Military Facility and associated costs; when the activities will take place; why Direct Funding is not possible; why the Awardee cannot provide the necessary resources and/or services; the Comptroller's (or equivalent) ability to accept and process award funds; etc. This information should be included in the proposal/application. If not included, the Contracting or Grants Officer will request this from the Extramural Organization.
- b. Upon receipt of the request, the Contracting or Grants Officer, along with the program office, will hold a discussion with the USAMRMC RM Office as to the acceptability of the request. If there are concerns, they will consult with additional staff as appropriate, such as the USAMRAA policy staff, USAMRAA Assistance Agreement Group Chief, USAMRAA Services Group Chief, USAMRAA Chief of Operations, USAMRMC Office of the Staff Judge Advocate, and others. They may also request additional information from the Awardee and Military Facility. If not recommended for approval at this stage, the request will not be considered further.

c. Routing Process:

- (1) If recommended for approval by the USAMRMC RM Office, program office, and the Contracting or Grants Officer, the Contracting or Grants Officer will prepare a memorandum for the PARC's approval or disapproval. The memorandum will incorporate the Extramural Organization's and Military Facility's request and justification.
- (2) The memorandum will be signed by the Contracting or Grants Officer and sent for concurrence through the USAMRAA Chief of Operations, through the USAMRMC RM Office (for official signoff), through the USAMRMC Office of the Staff Judge Advocate, to the PARC.
 - (3) The PARC will make the final decision.
- d. Approval described above is not required if statutory authority exists (other than CRADA authority) to provide funds to the Military Facility (i.e. Henry M. Jackson Foundation and Uniformed Services University of Health Sciences).

10. AWARD RELATED DOCUMENTATION

- a. The Contracting or Grants Officer will include the above approval or disapproval in the award file.
- b. A Technology Transfer agreement, i.e., CRADA or other instrument as authorized by law or regulation must be utilized for the Awardee to provide award funds to the Military Facility. If the CRADA or other instrument is not executed by both the Extramural Organization and the Military Facility prior to issuance of the Extramural award, appropriate contract clauses or assistance agreement terms and conditions will be entered into the award document to establish execution timelines and any other related requirements. The Extramural Organization and the Military Facility should take all reasonable steps in advance of an award to prepare to enter into such agreement as soon as possible after notification of pending award.
- c. A contract clause or assistance agreement term and condition will be entered into the award document requiring Contracting or Grants Officer prior approval to make any changes to the approved Intramural costs and/or funding method. Changes may require processing the request through the above procedures, especially consulting with the RM Office. Prior approval of any changes will be via a modification to the award document.

11. PROPONENT. USAMRAA Assistance Policy Branch and Procurement Policy Branch.

Encl Budget Form BRIAN E. MARTIN

Principal Assistant Responsible

for Contracting

COLLABORATING DoD MILITARY FACILITY BUDGET FORM Military Facility:

Detailed Cost Estimate - Year 1

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COLLABORATING DOD MILITARY FACILITY BUDGET FO

Military Facility:

Detailed Cost Estimate Form Submit 1 Form for Each Year (Year 2)

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COLLABORATING DOD MILITARY FACILITY BUDGET FORM

Military Facility:

Detailed Cost Estimate Form Submit 1 Form for Each Year (Year 3)

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COLLABORATING DoD MILITARY FACILITY BUDGET FORM

Military Facility:

Detailed Cost Estimate Form Submit 1 Form for Each Year (Year 4)

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COLLABORATING Dod MILITARY FACILITY BUDGET FORM

Military Facility:

Detailed Cost Estimate Form

Submit 1 Form for Each Year (Year 5)

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COLLABORATING DOD MILITARY FACILITY BUDGET FORM

Military Facility:

Detailed Cost Estimate Form Roll-Up Years 1-5

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NOTES:

Additional Forms: Add yearly forms as needed, up to 5 years. Separate sets of forms are required for each Military Facility, if applicable.

Costs: All Military Facility costs will be direct funded (MIPR, FAD, etc.), if possible. Military personnel costs and DoD civilian and military travel costs <u>cannot</u> be paid through the extramural award and will be direct funded, if possible. If direct funding (other than for military personnel and travel costs) is not possible, funds will be included in the awarded budget and the awardee must provide the resources to the Military Facility. If the nature of the costs require the awardee to send funds to the Military Facility, special approvals are required. See Assistance/Procurment Advisiory Notice (APAN) 15-01 (http://www.usamraa.army.mil/pages/pdf/APAN 15-01-

JUSTIFICATION: ITEMIZE ALL BUDGET CATAGORIES FOR EACH YEAR. FOLLOW THE BUDGET JUSTIFICATION INSTRUCTIONS EXACTLY. USE CONTINUATION PAGES AS NEEDED.

I Itemize all budget categories for each year on the Justification page that follows.