DEPARTMENT OF THE ARMY



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

MCMR-AAP-D

NUV 10 7014

MEMORANDUM FOR SEE DISTRIBUTION

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

1. PURPOSE. This policy:

- 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.
- b. 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 (CRADAs)", 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.

3. 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. Extramural 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 (CRADAs), 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 Research Management office provides funds directly to the Military Facility via a Funding Authorization Document, Military Interdepartmental Purchase Request, or other authorized method.
- 5. POLICY. Military Facilities which perform collaborative research with Extramural Awardees will receive support for their direct and indirect costs incurred in performance of their Intramural portions of the research projects in accordance with the requirements and procedures described below.

6. 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. When Military Facilities collaborate with Extramural Awardees, they may incur costs (direct and indirect) associated with their Intramural portions of the Extramural Research projects. In those cases, the funding methods and procedures described in this policy will be followed to support the costs incurred by the Military Facilities.

7. PROCEDURES.

- a. The Military Facilities' direct and indirect costs to be supported when performing collaborative research with Extramural Awardees 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 Resource Management (RM) office, comptroller office, or equivalent.
- b. Each USAMRMC Funding Opportunity Announcement (FOA) (Broad Agency Announcement or Program Announcement) 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. The DoD Intramural Researcher should also coordinate with his/her technology transfer office, when applicable. 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 proposal or application must include a financial plan for how the Military Facility's Intramural costs will be supported [i.e., directly funded by DoD, resources (other than award funds) provided by the Extramural Awardee to the Military Facility, award funds provided by the Extramural Awardee to the Military Facility (in accordance with the requirements in paragraphs 7.h. and i. below), etc.].
- c. Whenever possible, the USAMRMC's RM Office will Direct Fund the collaborating Military Facility to support its costs to be incurred in performance of the Intramural portion of the research project awarded to the Extramural Organization.

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" (future years of a multi-year project) Intramural costs of the project, including associated DoD civilian and military travel costs. When applicable, the EMA will coordinate with the associated Research Area Directorate (RAD) and/or Joint Program Committee (JPC) for planning of "out year" funding, including associated DoD civilian and military travel costs. The EMA, RAD, 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 RAD and/or JPC by the EMA and coordinated with the USAMRMC RM office.

- a. The Extramural Awardee may provide resources to the Military Facility, such as personnel, supplies, or equipment, paid for/purchased using award funds. The resources to be provided should be identified in the proposal or application.
- b. The Extramural Awardee may also provide to the Military Facility resources or funds that originated from non-DoD sources. The resources or funds to be provided should be identified in the proposal or application.
- c. Certain circumstances may exist whereby USAMRMC is not able to Direct Fund the Military Facility. This may occur under multi-year awards. Due to an appropriation that is unplanned and unprogrammed (e.g., Congressional Special Interest appropriations), future receipt of funds for the same purpose are uncertain. In this case, incremental funding of the project may not be possible and all funds for all years of the project must be obligated on an award at the time of initial award. Therefore, funds would not be available to Direct Fund the Military Facility in "out years."
- d. When the USAMRMC cannot Direct Fund the Military Facility due to the situation described in paragraph 7.c. above, funds may be included in the award so that the Extramural Awardee can provide funds directly to the Military Facility, but only when unusual and extraordinary circumstances exist. This funding method must be done in accordance with the procedures below and be based on unusual and extraordinary circumstances. Examples of unusual and extraordinary circumstances include (not all inclusive):
- (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) Costs associated with research protocols that can only be conducted at the Military Facility due to the nature of the research;
- (4) Clinical care costs, 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) DoD civilian employee labor costs, in accordance with the DoD FMR 7000.14-R. (Military labor costs cannot be supported through an award.)

- (6) Clinical trial related costs incurred by the Medical 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.).
- (7) When the nature of the project makes the Medical 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.).
- (8) 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.
- (9) Note that DoD civilian and military travel costs cannot be paid through an award, i.e., by the Extramural Awardee with award funds. The EMA, RAD, and/or JPC, as appropriate, should coordinate with the USAMRMC RM office for Direct Funding of DoD civilian and military travel costs. If program funds are not available to support these costs, the Military Facilities should consider the use of other authorized funds.
- e. Before the Extramural Awardee can provide award funds to the Military Facility, prior approval must be obtained using the following procedure:
- (1) The Military Facility, in conjunction with the Extramural Awardee, must provide a written justification for the funding method. Suggested areas to address are the research-related activities that will take place at the Military Facility, the associated costs, when the activities will take place, why Direct Funding is not possible, why the Extramural Awardee cannot provide the necessary resources and/or services, the Comptroller's (or equivalent) ability to accept and process award funds appropriately, etc.
- (2) If the Contracting or Grants Officer has concerns with the request, (s)he will confer with USAMRAA acquisition and policy staff, USAMRMC Office of the Staff Judge Advocate, and USAMRMC RM Office, as appropriate, prior to making a final decision. If the Contracting or Grants Officer determines the request to be adequately justified, (s)he will prepare a memorandum for the USAMRMC Principal Assistant Responsible for Contracting (PARC), incorporating the justification and requesting approval of the funding method.
- (3) The memorandum will be sent for concurrence through the USAMRAA Chief of Operations, USAMRMC RM Office, and USAMRMC Office of the Staff Judge Advocate, to the PARC.
 - (4) The PARC will be the approving official.
- (5) The Contracting or Grants Officer will include the above approval in the award file.

- (6) Approval described above is not required if statutory authority exists (other than CRADA authority) to provide funds to the Military Facility.
- (7) A CRADA or other instrument (as authorized by law or regulation) must be utilized for the Extramural 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 award.
- (8) 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.
- 8. PROPONENT. USAMRAA Procurement Policy Branch and Assistance Agreement Policy Branch.

Encl Budget Form BRIAN E. MARTIN

Principal Assistant Responsible

for Contracting

DISTRIBUTION:

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COLLABORATING DoD MILITARY FACILITY BUDGET FORM

Military Facility:		

Detailed Cost Estimate Form (Submit 1 form for EACH year)

Name of Principal Investigator (last, first, middle)

DETAILED BUDGET	From	THROUGH							
PERSONNEL			ANNUAL BASE SALARY	% Effort ON Project	DOLLAR AMOUNT REQUESTED (OMIT CE		(OMIT CENTS)		
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Detailed Cost Estimate Form (Year 2)

Name of Principal Investigator (last, first, middle)

DETAILED BUDGET						FROM	THROUGH	
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TOTAL DIRECT AND INDIRECT COSTS FOR THIS BUDGET PERIOD						\$		

Detailed Cost Estimate Form (Year 3)

Name of Principal Investigator (last, first, middle)

DETAILED BUDGET	FROM	THROUGH						
PERSONNEL				%	DOLLAR AMOUNT REQUESTED (OMIT CENTS			
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Name of Principal Investigator (last, first, middle)

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Consultant (Costs						
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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.

Personnel Costs: Military labor costs cannot be supported through the extramural award.

Travel Costs: Military and DoD civilian employee travel costs cannot be supported through the extramural award.

¹ Itemize all budget categories on the Justification page that follows.

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