

# CRADA Guidelines

## **I. Purpose of the CRADA:**

The Army and Navy require that HJF establish a Co-operative Research Agreement (CRADA) between the Army or Navy site and the Henry M. Jackson Foundation for the Advancement of Military Medicine (HJF) when work is conducted at these sites, even if the sites do not have to be reimbursed for the expenses incurred at those sites. A CRADA should be developed at the request of the PI or the Clinical Investigation Department at the Army or the Navy site.

## **II. Types of CRADA:**

- (1) Army CRADA
- (2) Navy CRADA
- (3) Other CRADAs

## **III. Parties to the CRADA:**

- (1) Walter Reed CRADA - HJF and Walter Reed (WRAMC)
- (2) Navy CRADAs –
  - a. Parties can be the Navy, HJF and other non-navy-collaborators
  - b. Parties can be Navy and other non-navy collaborators with HJF as the ‘Third-Party’.

## **IV. CRADA Approvals:**

A CRADA can be established under USAMRAA grants even if the site does not have to be reimbursed for the work conducted at that site. However, if the site has to be reimbursed for the research conducted at that site, before establishing a CRADA, the Grants Specialist (GS) should work with USAMRAA Contracting Officer to obtain prior written approval from them indicating that the CRADA can be established under the specific grant or have them provide funding directly to the site via Funding Authorization Document (FAD) to conduct the research. The GS should obtain further guidance from their Manager or Sr. Manager in this regard, if need be.

## **V. CRADA Procedure:**

### **(1) Army CRADA:**

#### **Background:**

A master CRADA has already been established between HJF and the Army. When a principal investigator (PI) at the Army site agrees to conduct the research under the auspices of HJF, HJF will amend the master CRADA through a study specific statement of work (SOW) and the budget. The SOW will provide information on the research involved, the roles and responsibilities of both the Army site and HJF employees (and any additional parties), and the amount of funding provided by each party.

**(A) Walter Reed Army Medical Center (WRAMC) CRADA:**

Only the SOW and the budget need to be completed, since a Master CRADA has already been established. The following procedure should be followed when the WRAMC CRADA needs to be prepared:

1. When a request for the CRADA is received, the Grants Specialist (GS) in OSP should resolve any grant related issues related to the CRADA.
2. The GS should enter the ticket for the CRADA in the web help-desk and should update through out the process.
3. The GS should obtain/complete the following information and forward it by e-mail to the CRADA Specialist (CS) in Clinical Trials Department:
  - a. CRADA Checklist - to be completed by the GS (see template on page 6)
  - b. Protocol – to be obtained from the PI
  - c. Protocol Specific budget as per the template on page 8 and 9
    - i. GS can check with the PI as to what % of the total budget will be expended at the site and complete the budget.  
OR
    - ii. With USU grants, GS should check 3208/3209 USU forms to determine what % of the work is being done at the site and confirm with the PI that % can be used and complete the budget.  
OR
    - iii. The PI can complete the budget template with accurate budget costs to be incurred at the site for specific protocol.
  - d. Impact Statement, if available – to be obtain from the PI - Impact statement is normally requested by the IRB for Pharmacy, DPALS, Radiology costs, etc incurred at the site.
4. The CS should complete the Budget and SOW (as a part of the CRADA) from the protocol and should work with the GS to resolve any issues. If the issues are not resolved, the GS and the CS should have a conference call with the PI to resolve the issues.

Notes:

(a) An IRB fee of \$ 1,000 for exempt protocols, \$ 2,000 for standard non-exempt protocols and \$ 4,000 for complicated protocols (such as developing MOUs, etc.) will be a part of the budget and should be charged to the grant.

(b) Tri-Service Nursing Research Program grants do not allow IRB fee.

(c) For grants which do not allow IRB fees, the PI should contact Department of Clinical Investigation (DCI – Daisy Ward - Daisy.Word@us.army.mil) at Walter Reed to obtain waiver for this fee, if possible.

5. Once the SOW and the budget are finalized, the CS should forward the documents to the GS.
6. The GS should verify the documents for accuracy and obtain Grants Manager's approval and forward the final SOW and budget to the PI, indicating if DCI has any questions they should contact the CS.
7. The PI should then submit the SOW and the budget to DCI at Walter Reed through IRBnet. If the PI requires assistance in IRBnet they should contact the DCI Office.
8. When the CRADA is submitted by the PI on IRBnet, it is forwarded to CRADA Committee at WRAMC and then routed to Clinical Investigation Regulatory Office (CIRO - Mary Klote) for approval. If there are any questions regarding the CRADA, CIRO will contact the PI or the CA. The CA will coordinate with the GS, if need be, and revise the CRADA and resubmit it to CIRO.
9. CIRO signs the CRADA and forwards it to CS, who should obtain the approval of the HJF/President and CEO.
10. CS should keep a copy and forward the one fully executed original to the GS in OSP for filing.

**(B) Other Army CRADAs:**

When an Army sites other than WRAMC requests their CRADA template to be used, the Grants Specialist should check with the HJF/Clinical Investigation Department (Norman Gardner/Beth Johnson) if such template can be used to develop the CRADA.

If the funds need to be provided to the Army site, the GS should encumber the funds for the CRADA in HJF Financial System (Oracle).

**(2) (A) NAVY CRADA:**

The following procedure should be followed when the Navy CRADA (other than Naval Medical Center and Naval Medical Center-Detachment sites – see section 2B instructions below for these CRADAs) needs to be prepared:

1. When a request for the CRADA is received, the Grants Specialist (GS) in OSP should resolve any grant related issues related to the CRADA.
2. The Grants Specialist (GS) in OSP should obtain/complete the following information and forward them to CRADA Specialist (CS) in Clinical Trials Department:
  - a. CRADA Checklist – to be completed by the GS (see template on page 6)
  - b. Protocol – obtain from the PI

- c. Protocol Specific budget provided by the PI (There is no specific budget format)
  - d. Payment terms & Reporting Requirements - GS should work with Grants manager to develop this section (only if payments are made to the Navy collaborator)
3. The CS should complete the CRADA and work with the GS to resolve any issues. If the issues are not resolved, the GS and the CS should have a conference call with the PI to resolve the issues.
  4. If the funds are provided to the Navy site, the GS should encumber the funds in HJF Financial System (Oracle).
  5. Once the CRADA is finalized, the CS should forward the documents to HJF/Legal and obtain their approval.
  6. The CS should then forward the CRADA to the GS. The GS should obtain their manager's approval and forward it to CS.
  7. The CS then should forward the CRADA to the Office of Research and Technology Applications (ORTA) at the Navy (Roxanne Charle). The CS should work with the Navy to resolve any issues related to the CRADA and should revise the CRADA, if need be.
  8. ORTA will obtain necessary signatures on the CRADA from the non-navy collaborators (other than HJF) and forwards it to the Navy Site Commander for approval.
  9. Navy forwards the signed final CRADA to CS, who will then obtain the approval of the HJF/President and CEO.
  10. CS should retain a copy and forward one fully executed original CRADA to the GS in OSP for filing and one fully executed original CRADA to ORTA.

**(B) Naval Medical Research Center (NMRC) and Naval Medical Research Center – Detachment (NMRC-D) CRADAs:**

Under the NMRC and NMRC-D CRADAs, HJF can be a non-navy collaborator or a third-party to the CRADA. In both cases ORTA at NMRC (Roxanne Charles) initiates the CRADA.

1. Working with the NRMRC Principal Investigator (PI), ORTA at NMRC (Roxanne Charles) initiates and completes the CRADA including the SOW and the budget for the work supported by the HJF managed grant. NMRC ORTA then forwards the completed draft CRADA to the CS with a copy to the GS for review and approval.

Note: Since the CRADA is initiated and completed by ORTA, NMRC, the GS need not have to complete the CRADA checklist and the budget template

2. While the CS starts reviewing the CRADA, the GS should take the following action:
  - a. In case where the HJF is a non-navy Collaborator (i.e. party to the CRADA), the GS should verify that the SOW is related to the project; and the PI information, budget and the period of performance in the CRADA are accurate.
  - b. In case where HJF is a Third-party to the CRADA, the GS should verify as above and provide the funding source information to the CS via e-mail. The CS should then update the Third party agreement in the CRADA with funding source information.
  - c. Encumber the funds in HJF Financial System (Oracle), if funds are provided by HJF to NMRC or NMRC(D).
3. The CS should forward the CRADA to HJF/Legal and obtain their approval.
4. The CS should then forward the CRADA to GS. The GS should obtain their manager's approval and forward it to the CS.
5. The CS should then forward the CRADA to the ORTA at the NMRC (Roxanne Charles). The CS should then work with the ORTA, NMRC to resolve any issues related to the CRADA and should modify the CRADA, if need be.
6. ORTA will obtain necessary signatures on the CRADA from the non-navy collaborators (other than HJF) and forwards it to the NMRC Commander for approval.
7. Navy forwards the signed final CRADA to CS, who will then obtain the approval of the HJF President and CEO.
8. CS should retain a copy and forward one original fully executed CRADA to the GS in OSP for filing and one original fully executed CRADA to ORTA.

**(C) Other Navy CRADAs:**

When a Navy site requests their CRADA template (other than the standard template) to be used, the Grants Specialist should work with their manager and the Clinical Investigation Department (Norman Gardner/Beth Johnson) if such template can be used to develop the Navy CRADA.

**CRADA CHECKLIST**  
 (Grants Specialist should complete this checklist for all types of CRADAs)

1. PI Name & Department: \_\_\_\_\_
2. PI's Phone number & e-mail address: \_\_\_\_\_
3. Performance Site: \_\_\_\_\_
4. Project Title:  
 \_\_\_\_\_  
 \_\_\_\_\_
5. HJF Cost Code number: \_\_\_\_\_
6. Grants Specialist Name: \_\_\_\_\_
7. Project Period: \_\_\_\_\_
8. CRADA Period (if different from the project period) \_\_\_\_\_
9. Background information for developing the CRADA:
10. Attachments - Following documents must be provided with the checklist:
11. Parties to the CRADA:

Name & Address of the Party to the CRADA (Other than HJF)	Point of Contact (POC) Name	POC Phone number	POC e-mail address

**Army CRADA:**

1. Protocol Attached  Yes
2. Budget  Yes
3. Impact Statement (if available)  Yes  N/A

**Navy CRADA:**

- |  |                              |                              |
|--|------------------------------|------------------------------|
| 1. Protocol Attached   | <input type="checkbox"/> Yes |                              |
| 2. Budget  | <input type="checkbox"/> Yes |                              |
| 3. Payment Terms<br>(Required if payments are made to the Navy Collaborator<br>Grants Specialist to work with the Manager/PI)          | <input type="checkbox"/> Yes | <input type="checkbox"/> N/A |
| 4. Reporting Requirements<br>(Required if payments are made to the Navy Collaborator<br>Grants Specialist to work with the Manager/PI) | <input type="checkbox"/> Yes | <input type="checkbox"/> N/A |

## WRAMC CRADA BUDGET TEMPLATE

PI Name, Rank: \_\_\_\_\_

Protocol Title:

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**List below only the Protocol related Costs: (if you have more than one protocol attach a budget for each protocol :**

**Personnel:**

Position Title	% effort	Total Salary Paid for the Entire project period
TOTAL COST		

**Consumable Supplies:** (This category is for office and/or lab supplies).

Consumable Supply Item	Supply cost
	\$
	\$
	\$
TOTAL COST	\$

**Equipment:** (List the items that are not consumable supplies)

Equipment Item	Amount
	\$
	\$
	\$
TOTAL COST	\$

**Travel:**

Travel Details	Amount
	\$
	\$
	\$
TOTAL COST	\$



**Departmental Impacts**

If IRB has requested an impact statement, for Pharmacy, DPALs, Radiology, costs, complete the following table from the Impact Statement. If there are no such costs, mark N/A.

<b>Department</b>	<b>Amount</b>
Pharmacy	
DPALs	
Radiology	

**IRB Fee: Army charges a fee for IRB administrative services. If it is a WRAMC CRADA, check (a) or (b) to identify which category the protocol falls under. Check (c), if the Army directly funds WRAMC. Mark (d), if none of the above.**

**(a) 1,000 (for Exempt Protocols) (b) \$ 2,000 (non-exempt protocols)**  
**(c) Funds directly transferred to WRAMC (d) N/A**

**Other**

List any other expenses such as Patient stipends/incentives, etc. not indicated above:

<b>Other Expenses</b>	<b>Amount</b>

**NAVY & OTHER TYPES OF CRADA BUDGET:**

There are no specific format for all types of CRADAs except WRAMC. The budget for the all CRADAs except WRAMC (use the format above for the WRAMC CRADA) is provided by the PI/Program Manager. If additional budget information is required CRADA Specialist will contact the Grants Specialists.