**CRADA Processing**

**(Cooperative Research and Development Agreement)**

**Standard Operating Procedure**

**Background:** The use of CRADAs is governed by the VA’s Office of Research and Development VHA Directives 1206 and 1200.18, found at the following links:

* [VHA Directive 1206: Use of a Cooperative Research and Development Agreement (CRADA)](https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=7452)
* [VHA Directive 1200.18: Determination of Rights for Inventions and Discoveries](http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=4307) - VA Technology Transfer Directive (Revised May 5, 2017)

**Purpose:** It is VHA policy that a CRADA must be used to establish the terms of new research collaborations with a non-Federal or Federal partner in which VA provides the non-Federal partner with any of the following: personnel (VA employees as defined under VHA Directive 1200, Research and Development Program, dated May 13, 2016), services, facilities, equipment, intellectual property or other resources, excluding funds. Most commonly, although not always, a **CRADA** is used when a VAMC Principal Investigator (PI) is interested in participating in a study for which a commercial company (Sponsor):

1) owns the investigational new drug (IND) or device;

2) designs the protocol; and

3) funds the project.

These are typically pharmaceutical companies or medical device companies.

**Procedures:**

**NDA/CDA**

1. Sponsor emails its template CDA/NDA in an editable Word format to DRI’s Executive Director (ED). If the Sponsor sends the CDA/NDA directly to the PI, the PI or his/her study coordinator must forward the CDA/NDA to DRI’s ED upon receipt. The ED will then email the CDA/NDA to the designated Specialty Team Advising Research (STAR) counsel (VA Legal). DRI’s current STAR attorney is Brian Barrett (brian.barrett@va.gov).

**Note:** As a best practice, the ED should ask the designated STAR attorney if s/he is aware of a master CDA/NDA with the particular Sponsor or the specific trial, and/or if it appears that there may be multiple VA sites submitting the same CDA/NDA for review. If so, STAR review of the CDA/NDA may be consolidated to a single STAR point-of-contact who may or may not be DRI’s designated attorney. If there is not a master CDA/NDA and it does not appear to be a multi-site trial, DRI’s ED will function as the intermediary between STAR and Sponsor to resolve any issues/discrepancies.

1. Once the STAR attorney has concurred, DRI’s ED will route the document for authorized signature by the ACOS-Research. The Rocky Mountain Regional VA’s current ACOS-Research is Robert ‘Bob’ Keith (Robert.Keith@va.gov). Upon return by the ACOS-Research, DRI’s ED will route to the PI for signature. While not an authorized signatory, the PI must acknowledge the following statement contained within the CDA, “I have read and acknowledge this Agreement made and entered into by [Sponsor] and VA, and I agree to abide by the terms therein.”

**Note:** If the above statement is not already included in the Sponsor’s template CDA, the ED will insert prior to sending to STAR attorney for review.

Once these two signatures are obtained, DRI’s ED will route to Sponsor for execution.

**Site Selection**

1. Once the CDA is fully executed, Sponsor will release any combination of a site feasibility questionnaire, study protocol, draft participant budget and draft informed consent form (ICF) to the PI and research coordinator (RC) for their review and feasibility determination.

**Budget and CRADA Negotiation**

1. After PI reviews the protocol and decides to pursue opening the study, and is selected as a site by the Sponsor, the ED will transition the project to DRI’s G&CA. The PI and research coordinator will work with DRI staff to negotiate the budget with the Sponsor. DRI’s *Guide to Completing a CRADA Budget* (Appendix B) is used to document standard study fees and assist the PI and/or RC to identify study-specific fees that should be considered, depending upon the nature of the study. The budget will be agreed upon by DRI, PI and Sponsor. By reason of ethics, VA employees should not be involved in budget communications/negotiations directly with the Sponsor.
2. Once a budget has been agreed upon between DRI, PI and Sponsor, the study coordinator submits the evaluation package to COMIRB/VA CIRB and the VAMC R&D committee for regulatory approvals. Brandi Lippman (Brandi.Lippmann@va.gov) is currently the coordinator at the VAMC for this process.
3. Concurrently, DRI’s G&CA will review the protocol and utilize STAR’s *Guidance on Selection of the Appropriate CRADA Model* to determine the appropriate CRADA template. Model CRADA templates are accessible at <https://www.research.va.gov/programs/tech_transfer/model_agreements/default.cfm>

Again, as a best practice, the G&CA should ask the designated STAR attorney if s/he is aware of a master CRADA with the particular sponsor or the specific trial, and/or if it appears that there may be multiple VA sites submitting the same CRADA for review. If so, STAR review of the CRADA may be consolidated to a single STAR point-of-contact who may or may not be DRI’s designated attorney. If there is not a master CRADA and it does not appear to be a multi-site trial, DRI’s G&CA will function as the intermediary between STAR and Sponsor to resolve any issues/discrepancies, with the DRI ED’s assistance.

1. Alternatively, the G&CA may request that the VAMC’s clinical trials coordinator, currently Kim Owens (Kimberly.Owens9@va.gov), verify if the VA has a master CRADA with the Sponsor here: <http://vaww.research.va.gov/programs/tech_transfer/crada/master_crada/default.cfm>

If a master CRADA is not in play and upon selecting the appropriate CRADA template, DRI’s G&CA will complete the initial draft based on the known information, and forward to the STAR attorney in an editable Word format.

**Note:** Along with the draft CRADA, the CRADA packet sent for legal review must also include the following:

* Statement of Work (Appendix A; often already incorporated into the CRADA document)
* Budget (Appendix B) – a draft is acceptable if it has not yet been finalized
* Study protocol
* Financial Conflict of Interest (FCOI/Form 450) signed by the PI

If revisions are required, once the STAR attorney has made any required revisions to the CRADA, DRI’s G&CA will forward the revised document to the Sponsor and function as intermediary to gain concurrence (this can go back and forth several times between the Sponsor and VA legal). DRI’s designated STAR attorney will send a concurrence memo once the CRADA is finalized.

1. DRI’s G&CA notifies the PI/RC once CRADA concurrence is obtained. The PI/RC will then email copies of the regulatory approvals to DRI’s G&CA.

**Execution/Signatures**

1. Upon receipt of the IRB and R&D Committee approvals and OGC legal concurrence, the G&CA will route the CRADA for signatures first to the PI in pdf format with electronic signature, then to the NPC ED, moving forward to the Associate Chief of Staff (ACOS) signature, and finally routed to the VA Medical Center Director along with the full contents of the CRADA file for signature.

**Notes:** The CRADA routing request email should include:

* Summary Sheet with study title, PI, brief synopsis of the study and checklist of file contents
* CRADA with DRI ED and PI signatures
* CRADA OGC concurrence memo
* IRB approval letter
* R&D Committee approval letter
1. The G&CA then emails the CRADA version with signatures to the Sponsor for full execution. Once the Sponsor returns the fully executed CRADA, be sure to send a copy to the PI/RC if they were not already copied.

**Final Actions & Record Keeping**

1. The G&CA will relay CRADA details to Staff Accountant for project setup in Blackbaud. To do this, upload a copy of the fully executed CRADA to the Project Setup MS Teams thread, along with the following details:
	* Agreement term (dates)
	* Total budget
	* Payment frequency
	* Invoicing
	* Sponsor
	* PI
	* Study nickname
	* COMIRB #

##  **The G&CA will email a copy of the CRADA only to VAMC’s clinical trials coordinator, currently Kim Owens (****Kimberly.Owens9@va.gov****). The VAMC must upload every active CRADA to an internal VA website.**

## **The G&CA will complete the details of the study in the Agreement Tracking spreadsheet.**

1. The G&CA will maintain a file for each study (filed by PI, then by study title) to include:
* Word version of fully executed CDA
* PDF version of fully executed CDA
* FCOI/Form 450 executed by PI
* Statement of Work
* Protocol
* Budget
* Word version finalized CRADA
* PDF version of fully executed CRADA
* CRADA concurrence letter from STAR attorney
* IRB approval letter
* R&D Committee approval letter
* Study Activation letter from Sponsor

## **If, during the course of a study, if an amendment is submitted to DRI by the Sponsor, DRI’s G&CA should refer to the following guidance:** [**Submitting Cooperative Research And Development Agreement (CRADA) Amendments to OGC Specialty Team Advising Research (STAR)**](https://www.research.va.gov/programs/tech_transfer/policies/CRADA-Amendment-SOP.pdf)