NPC TOWN HALL meeting FAQ August 2014
Specialty Team Advising Research (STAR)
August 19, 2014

A. Nondisclosure Agreements (NDA)/Confidential Disclosure Agreements (CDA)

1. Do NDA/CDAs require STAR review?

There is no specific requirement, but STAR encourages NPCs to send documents for legal review. Virtually all sponsor and Contract Research Organizations' CDAs have provisions that require modification in order to be in compliance with law and VA policy.

2. What are the VA key required elements of a CDA? How detailed do they need to be?

- VA's authority to enter into the CDA - Federal Technology Transfer Act (FTTA) of 1986, as amended (15 U.S.C. §§ 3710a et seq.), and 38 U.S.C. §7303.
- VA, ***not*** *the PI*, is the party.
- Identification/description of information to be disclosed.
- VA's obligation of nondisclosure and nonuse lasts 5 years.
- Types of information excluded from VA's obligation of nondisclosure and nonuse.
- VA ideally requires Disclosing Party to label/mark all information it considers confidential prior to disclosure to VA.
- VA ideally requires oral disclosures to be reduced to writing within 30 days.
- Governing law is U.S. Federal law.
- Venue is U.S. Federal Courts in the District of Columbia.
- The Medical Center Director (MCD) or his/her designee by appropriate written delegation (usually the Associate Chief of Staff/Research (ACOS/R) signs for VA).
- VA Principal Investigator should acknowledge the CDA in the signature section.

3. What makes a CDA problematic?

When the Disclosing Party:

- Refuses to mark the information as "Confidential information."
- Wants to give third-party beneficiaries the right to enforce the Agreement.
- Asks for intellectual property rights.

- Seeks to own VA's notes made during its review of the confidential information.
- Wants VA to agree to injunctive relief and other remedies.
- Requires VA to destroy or return Disclosing Party's information.
- Asks VA to agree to execute individual confidentiality agreements with each employee who will have access to the confidential information.

4. Do each of the Collaborators with Master template agreements also have Master CDAs?

No, but STAR is trying diligently to obtain Master CDAs from each Collaborator when they start Master negotiation. However, we have had no success thus far. NPCs play a vital role in communicating the need for various Masters with our Collaborators since having any type of Master in place will facilitate and reduce negotiation time.

B. CRADA Process/SOP

1. Will TTP be open to committing to timeframes on their review as the STAR attorneys have done in this SOP?

No. TTP has stated it will provide its reviews as quickly as possible; however, because of the unique and complicated nature of these modifications and limited resources, TTP is not able to commit to a specific timeframe for its review at this time.

2. Can the ACOS-R sign any of the CRADAs or must it always be the director of the health system or hospital?

The ACOS-R may sign CDAs and Material Transfer Agreements so long as the appropriate written delegation of authority has been put in place. Should you need assistance with the delegation letter, please contact your STAR attorney. The VAMC Director has to sign all other agreements such as subawards and CRADAs.

3. Is there a process for getting the negotiated CRADA to other VA sites? Should it come from the lead site or STAR attorney or the Collaborator?

A multi-site CRADA is defined as a CRADA that is being conducted at more than one VA Medical Center for the identical protocol.

Each STAR attorney is only responsible for his/her jurisdiction and generally the attorneys are not aware that an agreement is multi-site in nature. When an NPC is

informed of the multi-site nature of an agreement, the NPC can contact its designated STAR attorney to find out if another attorney on STAR has worked on that agreement, and use the same negotiated template. NPCs should let their colleagues at other NPC sites know when they are aware of a multi-site study.

Once a multi-site CRADA is negotiated at one site, the lead NPC should inform other sites of the availability of this document. The agreed CRADA template can be shared with the NPC at the non-lead sites. The non-lead site STAR attorney will work with his/her NPC to make sure no changes were made to the document and to generate a concurrence memo.

4. **Can you please highlight specific required elements as well as problematic areas of the CRADA? (What are the "deal breakers"?)**

   Here are a few:

   - Lack of availability of indemnification in clinical trials especially high risk studies.
   - Deletion of the Government Use License, and
   - Suggesting VA adhere to State law.

   The most important factors in our CRADAs are subject safety, confidentiality, and privacy. There are many factors that can be deal breakers. They depend on the agreement.

5. **Does the request to review a CRADA come from the MCD or Executive Director?**

   The request for a CRADA generally comes from the NPC since the NPC is coordinating review. However, there is no requirement that CRADA review be sent to STAR from a specific person/group. We do, however, suggest the NPCs coordinate the process in-house to avoid duplication of effort at the VAMC.

6. **Is there a specific format preferred when bringing questionable CRADA language to the attention of the STAR attorney?**

   There's no specific format so long as the STAR attorney can distinguish the person who made the changes (NPC or Collaborator), and identify any proposed modifications, and questions as *track-changes*. Questions can be asked in the body of the message or as comment notes to the document. In the instance that comment notes are inserted, and in scenarios where the document becomes too complex due to the number of changes, please communicate to the STAR attorney

that you have provided some comments to the document and the applicable sections.

7. Is it wrong to start negotiations with a VA CRADA template provided by the Collaborator?

No, but it is not wise. Because most Collaborators do not know that VA has several CRADA templates, or that VA policies have changed, the old CRADA template that the Collaborator has from a previous study years ago is no longer legally sufficient for VA purposes. It is best to start with a CRADA Model template that you received from *within* VA (TTP's website).

8. During CRADA negotiations, if a Collaborator alludes to language VA agreed to in another CRADA approved by VA in the past, how should I try to verify the Collaborator's assertion?

Whenever a Collaborator alludes to a past VA CRADA, ask the Collaborator to provide the following items: (1) VAMC involved, (2) Study Title, (3) Protocol Number, and (4) Name of VA POC. You can always provide the information to your STAR attorney and have him/her check OGC's database.

9. If I have already consulted with TTP on the appropriate CRADA model to use prior to forwarding the redlined CRADA draft to my STAR attorney, should I inform my STAR attorney of TTP's approval when I send my CRADA package?

Yes, it will save your STAR attorney time and facilitate approval.

C. Master CRADAs

1. Where can I find a list of all of VA Master CRADAs?

TTP has posted on its website a listing of the names of the companies for which VA has finalized a Master CRADA. To see an updated list, click here.

2. STAR alluded to the fact on one town hall meeting that there has not been a "new" Master negotiated in the last three years. Are there currently any negotiations in the works? And if so, which companies? If not, what is the plan forward?

We recently completed a Master CRADA with Forest which is in the process of going through concurrence. We have begun negotiation on several new Masters for Clinical Trials and Devices, but nothing has been finalized yet. TTP is in the process of modifying the Model Clinical CRADA template (Phase I-IV). The new forthcoming Model will represent a significant departure from the existing Model and we believe that companies will welcome these changes. Consequently, we have temporarily halted negotiations on Master clinical and device CRADAs pending the review and approval of the proposed new language for the Models. At this time, VA will not enter into any Master CRADAs for Basic, PI Initiated or Data Use.

D. CRADA Registry

1. When do I first enter a CRADA into the e-registry?

For clinical CRADAs, you should enter the agreement into the e-registry when your VAMC site has been selected to participate in the study. For all other CRADAs, you should enter the data into the registry when you have sent the Collaborator a copy of the CRADA to review.

Entry of the CRADA into the registry when your site has been selected to participate in the clinical trial allows other sites to determine whether a CRADA may already be in negotiation. For multi-sites, the first negotiated CRADA is a "model" for subsequent CRADAs at other sites so long as it is for the same protocol. Using the registry and checking it for other studies saves time and effort for everyone. If you are still unsure if other sites have executed a similar CRADA for the same study, you can contact your STAR attorney, provide the protocol # and title, and ask him/her to search for the same protocol in OGC's database.

E. Billing

1. Does STAR need to review amendments?

Not in most instances. STAR is working on crafting a la cart templates for amendments in order to address NPCs' needs (e.g. change in budget, SOW, etc). We encourage NPCs to work with their STAR attorney to make sure accurate language is crafted and negotiated for every amendment.

2. Does STAR bill for review of amendments?

STAR does not bill for any review of amendments. For further information on STAR billing, please see STAR CRADA Fee SOP.

3. Can I get a copy of the billing SOP for the NPCs?

A SOP dated September 2012 was put together by OGC and NAVREF to assist with the details of STAR billing.

F. Ethics

1. What procedures are followed for processing Conflict of Interest (COI) forms?

Follow your local procedures until the VHA COI Handbook is issued.

2. How can I reach out to a member of OGC Ethics Specialty Team?

Depending on your jurisdiction, the enclosed PDF provides guidance on whom to contact for ethics advice. All completed COI forms for CRADAs should be sent to STAR for review and referral to EST as necessary. For any other Government ethics advice, NPCs should contact EST directly.