

## **CT CRADA LEGAL REVIEW PROCESS**

This legal review process applies to all CT CRADAs. After TTP has released its policy decisions following the March 31, 2007 General Counsel Decision Memo, this process will be reviewed and revised if necessary.

### **I. PROCESS**

1. CRADAs will be negotiated in the field by VHA and NPC personnel, with assistance from the local office of Regional Counsel (RC), as appropriate. Negotiations will be based on the current model CT CRADA posted on the Technology Transfer Program (TTP) Intranet website [http://vaww.research.va.gov/programs/tech\\_transfer/model\\_agreements/default.cfm](http://vaww.research.va.gov/programs/tech_transfer/model_agreements/default.cfm).
2. No CT CRADA involving an investigator who is a dually-appointed personnel (DAP) holding both a VA and an academic affiliate position may be entered into unless either 1) the applicable Cooperative Technology Administration Agreement provides that VA will take the lead on patenting, marketing, and licensing any invention made under a CT CRADA; or 2) VA and the university agree on a case-by-case basis to VA taking the lead on managing CRADA subject inventions. NPC personnel will confirm any necessary university approvals prior to entering into a CT CRADA involving a DAP.
3. Under the TTP Standard Operating Procedure (SOP) that has been distributed to VAMCs and NPCs, the entity handling negotiations (NPC or VAMC) will provide the RC with an electronic tracked-changes version of the proposed CRADA showing all changes from the model, for RC review and approval. In addition to the proposed CRADA, NPC or VAMC will provide RC with the requisite conflict-of-interest survey and a draft memo from the Regional Counsel to the Director of the VAMC or local equivalent (the "justification memo") that:
  - a. states that there are no changes that are believed to be "significant," that the RC concurs in the proposed CRADA and recommends that the Director sign it, or
  - b. identifies changes that are believed to be "significant" and contains justification for the approval of the significant changes identified, including an explanation of the factors deemed to be important in the particular case, or
  - c. identifies changes that are believed to be significant and contains a statement that the proposed CRADA represents a best

effort, although it contains significant variation for which there is not available justification. See Guidance below.

4. Regional Counsel then:
  - a. forwards the proposed CRADA found by the RC not to contain significant changes to the VAMC Director for signature, together with a final of the justification memo, concurring in the CRADA; or
  - b. forwards a tracked-changes electronic version of a proposed CRADA found by the RC to contain significant changes from the model, together with the justification memo, to the Director, TTP (12TT), for review, with a copy to OGC (023) and the NPC. TTP will coordinate with OGC (023) for legal review and comments.
5. In any case in which the proper documents are provided, the RC will complete its review in 10 working days or less. Where the CRADA is particularly complicated or the documentation requires additional work, the RC will complete its review and move the CRADA on in no more than 20 working days.
6. TTP will respond to the RC with the comments of Central Office (023 and TTP combined), with a copy to 023 and the NPC, within 15 working days of TTP's receipt of the proposed CRADA, indicating approval, disapproval or recommended changes, and suggesting next steps.
7. For purposes of tracking CRADAs and creating an educational resource, NPCs are required to register CT CRADAs through the TTP website at [http://www.research.va.gov/programs/tech\\_transfer/crada/resources.cfm](http://www.research.va.gov/programs/tech_transfer/crada/resources.cfm)

## **II. GUIDANCE:**

1. **Justification for Significant Changes:** The factors that should be weighed in a particular case include, but are not limited to:
  - The VAMC's view of the importance to veterans and VA of the research based on its subject matter;
  - The ownership of substantial background inventions by the Collaborator;
  - The extent to which the research involves substantial VA resources (personnel, equipment, etc.) or a substantial intellectual contribution to the research by VA.
  - The relevance of the research to a PI's other or ongoing research;
  - Availability of alternative treatments for veterans;

- The VAMC's view of the likelihood that new IP may arise in the course of the research (the "IP risk").
  - RC's view that the changes, although numerous, do not make a significant change in the import of the provision.
2. **Significant Changes:** Changes to any one of the following subject areas within the Model CT CRADA that are beyond stylistic are likely to be significant, because of the sensitivity of their substance. They should be carefully considered to determine their nature as significant or not.
- **Definitions** (Article 2)
  - **Data rights and ownership** (see § 3.2 Use and disposition of Collaborator Materials, §7.1 Case Report Forms and Records, § 7.2 CRADA Data and CRADA Materials)
  - **Pre-commitment of IP rights in CRADA Subject Inventions** (see §5.2 Ownership of CRADA subject inventions)
  - **Licensing** (see Article 6)
  - **Privacy rights of veterans** (see §§7.1 and 7.2 )
  - **Indemnification by VA and costs of subject injury** (see §§12.2 and 12.3)

Other changes when viewed *in toto* may rise to the level of significant changes. RCs should use their discretion in identifying these instances.

3. **Minor Additions** – Additions that clarify details or improve the administration of the CRADA may be added as desired by the parties. Such additions will not be considered substantial variations. They include the following:
- A requirement to report or list Background Inventions in an attachment or elsewhere
  - A requirement to identify Collaborator or VA materials or Collaborator Capital Equipment under the CRADA;
  - A prompt for addition of NPC's Tax ID number or a payment schedule, or attachment of a budget spreadsheet.
4. Suggestions of changes that may be significant or minor are also provided in the "Annotations to Model CT CRADAs, Phase I-II and Phase III-IV, June 2007 Version." The list provided in "Significant Changes" will shrink and the one in "Minor Additions" will grow as experience is gained, comfort levels increase, and additional guidance is provided by TTP on acceptable changes under the March 31, 2007 memo from OGC.
5. Of course, discussion between RCs and TTP and 023 on general issues or particular CRADAs is encouraged at any time.

