

NPC Reimbursement to the Office of General Counsel (OGC) for Legal Services Attributable to Research and Education Agreements¹

Standard Operating Procedure (SOP)

I. Definitions of Agreement Types

a) Cooperative Research and Development Agreements (CRADAs)

<u>“Simple” CRADAs</u>	<u>“Moderate” CRADAs</u>	<u>“Complex” CRADAs</u>
Use of the Master Template CRADA		
Use of a model CRADA with non-substantive changes	Use of a model CRADA with extensive non-substantive changes and/or substantive changes that require moderate consultation and negotiation to resolve	Use of a model CRADA with extensive substantive changes and/or any changes that require extensive consultation and negotiation to resolve and/or require significant drafting of CRADA terms
Non-lead multi-site CRADA		Hybrid CRADAs (those requiring combining elements of two or more model CRADAs)
		Complex CRADA negotiations with Collaborator(s) and/or CRO(s)

b) Other Agreements. See Part II (c).

¹ Pursuant to 38 U.S.C. § 7364(a)(1)(D)(2010), as amended by S. 1963/PL 111-163, a VA NPC may reimburse the VA Office of General Counsel for any of its expenses in providing “legal services attributable to research and education agreements.”

II Rate Determination for CRADA and Non-CRADA Agreement Services²

a) Flat Fee Rate:³

“Simple” CRADAs = \$215

“Moderate” CRADAs = \$650

“Complex” CRADAs = \$1,225

b) Determination of CRADA Types: Upon receipt of a redlined CRADA from a collaborator, or after the NPC has completed discussions with the collaborator, NPC forwards the CRADA to OGC. NPC may include a recommendation as to CRADA type. OGC makes an initial determination as to the CRADA type—simple, moderate or complex--and notifies NPC. If OGC’s determination of CRADA type differs from an NPC’s recommendation, OGC includes the reason for the difference with its notification. Final decisions of OGC regarding type are and non-appealable.

1) The initial CRADA determination and notification to the NPC must be made in time to be captured by the NPC during the budget planning process.

2) After the initial determination, OGC may change the characterization of a CRADA based on facts that may emerge.

3) A CRADA characterization and billing may be adjusted as required up until the time that the CRADA legal review is complete.

4) Upon written request by NPC, OGC may waive or reduce fees for good cause such as, but not limited to, situations where a proposed CRADA is reviewed but does not result in an executed or final agreement by the parties.

5) Designated fields in GCLaws facilitate billing, collection, and accounting for the fees. Standard naming practices and uniform practices for use of these fields are determined by OGC for consistency in entering and reporting of data. Reports from this GCLaws functionality provide updated accounting of all funds collected and generate a uniform task report that is given to the NPC when legal review is complete. See III (2).

² Work covered by this SOP is performed primarily by VA attorneys at or near the GS 14 Step 5 level. Salary at this level and 30% for benefits are calculated to total \$72 an hour. This amount was converted into flat fees based on the estimated hours required for each CRADA type.

³ Fees are based on an approximate attorney effort for work performed as shown by GCLaws data from one Regional Counsel (RC) Office that is active in CRADAs. Simple CRADAs are calculated to require an average of three hours (\$215). Fees for Moderate CRADAs are calculated at an average of nine hours (\$650), and Complex CRADAs are calculated to take an average of seventeen hours (\$1225).

- c) Non-CRADA Research or Education Agreement Services: OGC may also review other research or education agreements (i.e., grants, subgrants, contracts, subcontracts and education agreements). Prior to formal review of such documents, OGC will provide NPC with an approximate cost based on estimated hours multiplied by an hourly rate of \$72 and will negotiate an agreed upon attorney's fee for the matter with the NPC.

III Collection of CRADA Funds

- a) The OGC attorney handling the matter is responsible for the invoicing of the fees based on the CRADA type or other non-CRADA research or education agreement on services.
- b) Upon completion of legal review, OGC provides the NPC with an invoice and a task report as produced from GCLaws.
- c) NPC reimburses the OGC Budget Office within 30 days of the NPC's receipt of the first milestone payment from the company or receipt of an invoice from OGC, whichever is later.
 - 1) Reimbursement is made by check payable to VA Office of General Counsel.
 - 2) Checks are sent to:
 - OGC Budget Office (026E)
 - Department of Veterans Affairs
 - 810 Vermont Ave, NW
 - Washington, DC 20420
 - 3) A subaccount for CRADA has been created by the OGC Budget Office.

IV Use of the CRADA Funds

- a) Authorized uses are detailed in 38 U.S.C. § 7364, which provides that amounts reimbursed to OGC under this subchapter for OGC expenses for providing legal services for research and education agreements ("CRADA Funds") shall be available for use by OGC only for:
 - 1) Staff;
 - 2) Training related to the provision of such legal services; and

- 3) Travel related to such training.⁴
- b) Expenses covered by the “staff” category include:
 - 1) Costs of dedicated attorneys or paralegals,
 - 2) Awards or bonuses to staff for achievements in this area, and
 - 3) Educational materials related to VA non-profits/research and education.
- c) CRADA Funds remain available to OGC for these purposes **without fiscal year limitation**.

V **Distribution of CRADA Funds**

- a) OGC Professional Staff Group (PSG) VI administers the CRADA Funds and records their receipt and disbursement.
- b) Although the best use of these funds is likely for an attorney(s) dedicated to CRADA work, such a use cannot be fully considered until practice under this SOP reveals necessary data regarding its effectiveness, and therefore cannot be implemented until it is clear that funds will be sufficient on an on-going basis.
- c) PSG VI may use any CRADA funds collected for purposes consistent with the law and in a manner that will enhance OGC’s ability to provide these services.

VI **One-Year Assessment of SOP**

- a) After one full year of experience, all aspects of this SOP will be reassessed by the OGC Research Specialty Panel with the assistance of PSG VI.
- b) Through surveys and other information collection methods, the assessment will cover, at a minimum -
 - 1) How much money was collected;
 - 2) How the money was spent;

⁴Congress intended OGC to use this money to help relieve the workload as well as to provide training related to CRADAs and related agreements. “This would enable OGC to accommodate the substantial workload associated with CRADAs and provide training to VA attorneys on CRADA requirements.” House Report to Accompany H.R. 2770, Veterans Nonprofit Research and Education Corporations Enhancement Act of 2009, 111–225, at 6.

- 3) Whether the correct type of CRADA was designated based on a review of the actual hours worked as shown by GCLaws;
 - 4) Whether it worked well to have three levels of CRADAs for billing purposes or whether just two- Simple and Complex – would work better;
 - 5) How well each aspect of the SOP worked;
 - 6) Best practices;
 - 7) Satisfaction of OGC and NPCs, and attorneys involved
- c) Need for improvement or change will be identified and suggestions for improvement will be made.
 - d) While this assessment is being conducted and reported, use of the SOP will continue.
 - e) A report of this assessment will be provided to the Assistant General Counsels for PSGs III and VI within six months of the date when the assessment is initiated.

Office of General Counsel
Department of Veterans Affairs

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