Standard Operating Procedure (SOP) For Submitting Cooperative Research And Development Agreement (CRADA) Amendments to OGC Specialty Team Advising Research (STAR)

Nonprofit Corporations (NPCs) or VA Medical Centers (VAMCs) will forward a draft CRADA amendment to their assigned STAR attorney whenever an NPC or VAMC receives a request from a collaborator to amend a CRADA or when the NPC or VAMC wishes to amend a CRADA, along with the documents and information noted below.

- 1. The NPC or VAMC will forward STAR:
 - A copy of the fully executed CRADA and STAR GCL case number;
 - A copy of the collaborator's (or NPC's/VAMC's) unprotected, Word document CRADA amendment; and
 - A copy of the applicable STAR CRADA amendment template with all fill-in information completed (NPC or VAMC to complete). See applicable attached STAR amendment templates. If necessary, a STAR CRADA template may be modified to address the particular details of a CRADA amendment.
- 2. Referral of a CRADA amendment to STAR is mandatory *except* for a CRADA amendment that involves:
 - "Budget only" changes; and/or
 - Extensions of time for a study.

However, the above changes may be referred to STAR if the NPC or VAMC wishes legal review.

- 3. For a change in VA Principal Investigator, referral to STAR requires a copy of VAPI(s)' completed conflict of interest form (OGE FORM 450 Alternative-VA).
- 4. If you have any questions regarding this SOP, please contact your site's assigned STAR attorney.