

VA Model Clinical Trial Cooperative Research and Development Agreement (CT CRADA)

AAHRPP Requirement	CT CRADA Section that Meets the AAHRP Requirement
<p>Element IV.1.A: The Organization has a written agreement with the sponsor that the Organization will use procedures that protect research participants.</p>	<p>3.4 Human Subjects Protection. The research to be conducted under this CRADA involves human subjects or human tissues as described in 38 C.F.R. Part 16. All research to be performed under this CRADA shall conform to laws, regulations and VA policies and procedures pertaining to protections for human subjects. Collaborator and VA shall immediately notify each other, and VA shall promptly notify the IRB, upon identifying any aspect of the Protocol, including unanticipated problems involving risk and information discovered during site monitoring visits, or in the study results that may adversely affect the safety, well-being, or medical care of subjects, or that may affect the willingness of subjects to continue participation in the research, may influence the conduct of the study, or may alter the IRB's approval to continue the study. When subject safety or medical care could be directly affected by study results, VA shall send study subjects a written communication the content of which is subject to IRB approval.</p>
<p>Element IV.1.B. The organization has a written agreement with the sponsor that addresses medical care for research participants with a research-related injury.</p>	<p>12.3 Costs of Subject Injury. Collaborator shall be responsible for reasonable and customary costs incurred for treatment of injury reasonably related to the subject's participation in the study described in the SOW unless:</p> <ul style="list-style-type: none"> (a) the injury is solely attributable to VA Employees' negligence or willful misconduct; or (b) the injury is solely attributable to an underlying illness, whether previously diagnosed or not; or (c) the injury is solely attributable to failure to administer Test Article as required in the SOW or to otherwise substantially follow the SOW.
<p>Element IV.2.A: In studies where sponsors bear responsibility for monitoring of the research, the Organization has a written plan with the sponsor that the sponsor promptly reports to the Organization findings that could affect the safety of participants or their willingness to continue participation, influence the conduct of the study, or alter the IRB's approval to continue the study.</p>	<p>3.4 Human Subjects Protection. The research to be conducted under this CRADA involves human subjects or human tissues as described in 38 C.F.R. Part 16. All research to be performed under this CRADA shall conform to laws, regulations and VA policies and procedures pertaining to protections for human subjects. Collaborator and VA shall immediately notify each other, and VA shall promptly notify the IRB, upon identifying any aspect of the Protocol, including unanticipated problems involving risk and information discovered during site monitoring visits, or in the study results that may adversely affect the safety, well-being, or medical care of subjects, or that may affect the willingness of subjects to continue participation in the research, may influence the conduct of the study, or may alter the IRB's approval to continue the study. When subject safety or medical care could be directly affected by study results, VA shall send study subjects a written communication the content of which is subject to IRB approval.</p>
<p>Element IV.3.A: Before initiating research, the Organization has a written agreement with the sponsor about plans for disseminating findings from the research and the roles that investigators and sponsors will play in publication or disclosure of results.</p>	<p>7.3 Presentations and Publications. VA and Collaborator have the right to make publicly available the results of their research and are encouraged to do so. Authorship shall be determined by mutual agreement of Collaborator, VA and Principal Investigator in accordance with customary scientific practices.</p> <p>7.3.1 Review. Principal Investigator shall submit to Collaborator for review a manuscript of each proposed presentation or publication of the results of the research performed under this CRADA. Collaborator shall have a review period of thirty (30) days. Collaborator may comment upon, but may not make editorial changes to the results and conclusions set forth in the manuscript or presentation. The manuscript may be submitted for publication or presentation upon receipt of Collaborator's written comments or upon expiration of the review period with no comments received from Collaborator. Reasonable consideration shall be given to all edits requested by Collaborator.</p> <p>7.3.2 Single Site Data. After pooled dataset is published by collaborator or 180 days after data lock, Principal Investigator may freely publish and/or present the results derived from the data collected solely by VA. VA shall</p>

	<p>determine the authorship and contents (including scientific conclusions and professional judgments) of any publication or presentation. VA shall provide collaborator with a copy for review in accordance with Articles 7.3.1, 7.3.3 and 7.3.4.</p> <p>7.3.3 Excise of Confidential Information. Confidential Information, other than the results of the research, contained in the manuscript or presentation shall be excised from the manuscript or presentation.</p> <p>7.3.4 Extension of Time for Patentable Inventions. If Collaborator determines that any manuscript of a publication or presentation submitted for review in accordance with this Article describes one or more potentially patentable CRADA Subject Inventions, Collaborator shall provide notice to VA of this determination prior to expiration of the review period. Collaborator shall have ninety (90) days from the date of such notice to file patent application(s) for such inventions in accordance with Article 5, during which time VA shall refrain from publication of the manuscript or presentation.</p>
<p>Element IV.3.B: When participant safety or medical care could be directly affect by study results, the Organization addresses in the written agreement with the Sponsor how results will be communicated to study participants.</p>	<p>3.4 Human Subject Protection. Last sentence: When subject safety or medical care could be directly affected by study results, VA shall send study subjects a written communication the content of which is subject to IRB approval.</p>