

Department of Veterans Affairs

**Phase [select: I, II, III or IV] CLINICAL TRIAL
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA)**

This cover page identifies the Parties to this CRADA as follows:

The U.S. Department of Veterans Affairs, a Federal government agency, as represented by
VA Northern California Health Care System, having offices at 10535 Hospital Way,
Mather, CA 95655

hereinafter referred to as “**VA**”

and

[Collaborator's official name],

hereinafter referred to as “**Collaborator,**”
having offices at [Collaborator's address],

created and operating under the laws of [State or Country of Incorporation].

and

East Bay Institute for Research & Education,

hereinafter referred to as “**NPC,**”
having offices at 10535 Hospital Way, Bldg. 722, Room 121,
Mather, CA 95655

created and operating under the laws of California.

The title of the project to which this CRADA pertains is [Project Title].

Protocol Number: [Protocol Number]

VA Principal Investigator: [Name and Degree(s) of PI]

**VA PHASE [select: I, II, III or IV] CLINICAL TRIAL
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT**

Article 1. Introduction

This Phase [I, II, III, or IV] Clinical Trial Cooperative Research and Development Agreement (CRADA) is entered into under the authority of the Federal Technology Transfer Act of 1986, 15 U.S.C. § 3710a, *et seq.*, and shall be effective on the date of the last signature of the Parties.

Any inconsistency between the standard terms of Articles 1 through 13 of this CRADA and any appendices to this CRADA shall be resolved by giving precedence to Articles 1 through 13.

Article 2. Definitions

The terms listed in this Article shall carry the meanings indicated throughout the CRADA. Terms defined in applicable statutes or regulations, but not defined in this CRADA, shall carry the meaning of the statutory or regulatory definition.

“Background Invention” means an invention conceived and reduced to practice or made the subject of a patent application in accordance with patent law in the United States, or in any other country or region, before the effective date of this CRADA.

“Biological Specimens” mean human biologic specimens that the Protocol requires VA to collect and provide to the Collaborator.

“Case Report Form” means a printed or electronic document designed to record all of the Protocol-required information to be reported to the Collaborator on each study subject.

“Collaborator Confidential Information” means scientific, business and financial information, including the Protocol, disclosed by or on behalf of Collaborator in writing and marked or otherwise identified as confidential.

“Collaborator Materials” means any tangible material, provided by Collaborator, listed in Appendix A.

“Confidential Information” means Collaborator Confidential Information, VA Confidential Information, and other written documents marked or otherwise identified as confidential provided that the information is not:

- (a) Publicly known or available from public sources; or
- (b) Made available by its owner to others without a confidentiality obligation; or
- (c) Already known by the receiving Party, or independently created or compiled by the receiving Party without reference to or use of information provided under this CRADA.

“CRADA Data” means the data contained within the Case Report Form with any additional data described as a deliverable in the Protocol. CRADA Data does not include patient medical

records or Individually Identifiable Information, except for any that may be contained in the completed Case Report Form.

“CRADA Subject Invention” means any invention conceived or first actually reduced to practice in the performance of the Protocol. (15 U.S.C § 3703(8)).

“Individually Identifiable Information” means any information, including health information maintained by the Veterans Health Administration (VHA), pertaining to an individual that also identifies the individual or for which there is a reasonable basis to believe the information can be used to identify the individual.

“NPC” means the VA-affiliated non-profit research, or research and education, corporation created and operated under the laws of the state identified on the cover page. The NPC’s role and obligations are set forth in this CRADA pursuant to its statutory authority under 38 U.S.C. §§ 7361-66 and VHA Handbook 1200.17.

“Principal Investigator” means the VA Employee as identified on the cover page of this CRADA who conducts and, oversees the scientific and technical aspects of the study in accordance with the Protocol or, in the event of research conducted by a team of VA investigators, is the responsible leader.

“Protocol” means the formal, detailed written description of the study to be performed under this CRADA, approved amendments and associated documents such as an informed consent form. The Protocol is attached to this CRADA under Appendix B.

“Test Article” means, the drug [name or describe drug] that is the subject of the Protocol (21 U.S.C. § 301 *et seq.*).

“VA Confidential Information” means patient medical records, Individually Identifiable Information, and scientific information disclosed in written form by or on behalf of VA.

“VA Employee” means any individual who is employed by VA, including one who is salaried by VA or is working under a VA Without-Compensation (WOC) Appointment (38 U.S.C. § 513 and § 7405) or under an Intergovernmental Personnel Act assignment (5 U.S.C. §§ 3371-3375). When used in this CRADA, the term “VA” includes VA Employees.

Article 3. Cooperative Research and Development

3.1 Performance of Research and Development. Each Party agrees to comply with, and to ensure that its contractors and agents comply with the Protocol, applicable Federal laws, regulations, and VA policies, Executive Orders, including but not limited to 38 C.F.R. Parts 16 and 17, 21 C.F.R. Parts 50, 56, and 312 as applicable to the research described in the Protocol. Such regulations include, but are not limited to, the Standards for Privacy of Individually Identifiable Health Information and the Security Standards for the Protection of Electronic Protected Health Information (45 C.F.R. Parts 160 and 164), as well as those set forth in VA’s security directives.

3.2 Use and Disposition of Collaborator Materials. VA agrees to use Collaborator Materials only in accordance with the Protocol. Upon completion, expiration or termination of this CRADA, VA agrees to dispose of these materials as directed by Collaborator.

- 3.3 **Principal Investigator Responsibilities.** The Principal Investigator shall be responsible for coordinating the scientific and technical conduct of this project on behalf of VA. Prior to beginning research under this CRADA, the Principal Investigator shall obtain VA Research and Development (R&D) Committee approval of the Protocol. Such approval entails Institutional Review Board (IRB) approval of the Protocol and all associated documents including informational documents, the informed consent form and advertisements used in the performance of this CRADA.
- 3.4 **Human Subjects Protection.** The Parties shall promptly notify each other upon identifying a serious unanticipated problem involving risks to subjects or others and/or an unanticipated Serious Adverse Event which may be related to the Protocol. VA shall promptly notify the Collaborator of Protocol deviation using the notification method and time frame described in the IRB-approved protocol; Collaborator shall promptly notify VA in writing upon identifying an interim data analysis result, or study result finding that may adversely affect the safety or well-being of subjects. If study result findings are provided to VA for conveyance to subjects, such communication to subjects shall be subject to Federal law and regulations and VA policy. VA always reserves the right to communicate and notify any safety concerns to the subjects.
- 3.5 **Test Article Information and Supply.** Collaborator agrees to provide VA, without charge and on a schedule that shall ensure timely performance of the Protocol, a sufficient quantity of formulated and acceptably labeled, clinical-grade Test Article and, if required by the Protocol, any placebo, comparator, or supplemental drug necessary to complete the Protocol. Collaborator shall provide to VA information regarding safety and efficacy data from clinical and non-clinical studies, recommended dosage or usage, storage and known risks or contraindications, if any.
- 3.6 **Test Article Delivery, Use and Disposition.**
- 3.6.1 Collaborator shall ship the Test Article, placebo, comparator and supplemental drug, if any, to the pharmacy at the participating VA facility, or as otherwise directed by VA, in containers marked in accordance with 21 C.F.R. § 312.6. Pharmacy contacts at VA shall be determined by VA and communicated to Collaborator.
- 3.6.2 VA agrees to use Test Article only in accordance with the Protocol.
- 3.6.3 Upon completion, termination, or expiration of this CRADA, any unused quantity of Test Article will be returned to Collaborator or disposed of as directed by Collaborator.
- 3.7 **Monitoring.**
- 3.7.1 In accordance with VA policies regarding site monitors and subject to the restrictions in this CRADA concerning Individually Identifiable Information, VA shall permit Collaborator or its designee(s) upon reasonable notice and during regular business hours to monitor, in accordance with the section on monitoring of the International Conference on Harmonization (ICH) E6: "Good Clinical Practice: Consolidated Guideline," 62 Fed. Reg. 25692 (1997) where and as adopted by the Food and Drug Administration (FDA), the conduct of the research, as well as to audit source documents:

- (a) For regulatory purposes; and
- (b) To the extent necessary to verify compliance with:
 - (i) Good Clinical Practice in accordance with the International Conference on Harmonisation (ICH) E6: "Good Clinical Practice: Consolidated Guideline," 62 Federal Register 25692 (1997) where and as adopted by the FDA; and
 - (ii) The Protocol.

3.7.2 Monitors will be subject to applicable Federal laws, regulations and VA policies on access to Federal facilities, data, and data systems. VA shall disclose Individually Identifiable Information to monitors only to the extent permitted by the subjects' prior signed informed consent and authorization document(s), and this CRADA. Collaborator shall ensure study monitors comply with Article 3.7.

3.8 **Registration of Protocol.** VA encourages Collaborator to register the Protocol with www.clinicaltrials.gov, and any other registry with requirements consistent with the registration and publication guidelines of the International Committee of Medical Journal Editors.

Article 4. Financial and Capital Equipment Contributions

4.1 **VA and Collaborator Contributions.** The financial contributions of the Collaborator are set forth in the Appendix A. All payments by Collaborator shall be made to NPC and shall be in U.S. dollars by check or bank draft, sent in accordance with Article 13.16.4, or shall be made by electronic transfer. Collaborator's failure to make any scheduled payment shall be deemed a material breach. If Collaborator fails to cure such breach within thirty (30) days, VA and NPC shall not be obligated to perform their responsibilities under this CRADA and may terminate this CRADA in accordance with the procedures set forth in Article 9.3. All remedies for such non-payment remain available to VA and NPC under Federal and state law.

4.2 **Capital Equipment.** Collaborator's commitment, if any, to provide VA with capital equipment appears in the Protocol. If Collaborator transfers capital equipment to VA or provides funds to VA or NPC for purchase of capital equipment, VA or NPC shall own the equipment. If Collaborator loans capital equipment to VA for use pursuant to this CRADA, Collaborator shall be responsible for paying costs associated with the transport, installation, maintenance, repair, removal, or disposal of the equipment, and VA shall not be liable for damages to the equipment, except due to the negligence of VA.

Article 5. Inventions and Intellectual Property

5.1 **Background Inventions.** Nothing in this CRADA shall be construed to grant a Party any rights in another Party's Background Invention other than to use the Background Invention to fulfill the requirements of the Protocol.

5.2 **Reporting.** VA and Collaborator shall promptly report to each other in writing each CRADA Subject Invention disclosed by its respective personnel.

- 5.3 **Ownership of CRADA Subject Inventions.** With respect to VA rights in any CRADA Subject Invention made solely by a VA employee(s) or jointly made by a VA Employee and a Collaborator employee(s), VA hereby assigns to Collaborator its ownership interest to any CRADA Subject Invention, subject to the requirements of 15 U.S.C. § 3710a(b)(1).
- 5.4 Collaborator shall place the following statement in any patent application it files on a CRADA Subject Invention: “This invention was created in the performance of a Cooperative Research and Development Agreement with the Department of Veterans Affairs, an agency of the U.S. Government, which has certain rights in this invention.”
- 5.5 The Government shall have a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced any CRADA Subject Invention throughout the world by or on behalf of the Government subject to 15 USC § 3710a.

Article 6. Ownership, Access and Use of Data and Materials

6.1 Case Report Forms and Records.

Collaborator shall own the original, completed Case Report Forms and the CRADA Data; VA must retain copies. Collaborator acknowledges that the CRADA Data may be replicated in VA-owned patient medical records. Collaborator ownership of CRADA Data in no way limits VA's ownership and use of data in its medical records. Except data contained in the Case Report Forms and the CRADA Data, patient medical records, Individually Identifiable Information, original notes, documents, and records created by VA in the course of performing the Protocol shall be the property of VA. Collaborator shall have access to such materials solely for auditing and compliance purposes as described in Article 3.7.

6.2 Use of CRADA Data, Biological Specimens and Individually Identifiable Information

- 6.2.1 VA may use CRADA Data and Biological Specimens for educational, research and health care purposes, and to comply with any applicable Federal state and local government laws and regulations, and only to the extent permitted by the subjects' informed consent and HIPAA authorization.
- 6.2.2 Collaborator may use CRADA Data, for any lawful purpose including research purposes, the creation and maintenance of a research database or repository, and regulatory filings, consistent with its obligations under this CRADA only to the extent allowed in the informed consent and authorization document(s) signed by the research subject. Biological Specimens will be handled in accordance with the Protocol and informed consent. Collaborator shall destroy, Biological Specimens at the completion of the Protocol, and certify destruction to VA, unless otherwise directed in writing by VA.
- 6.2.3 Collaborator may use Individually Identifiable Information and Biological Specimens only to the extent allowed in the informed consent and authorization document(s) signed by the research subject.
- 6.2.4 Collaborator shall (1) comply with all laws, regulations and provisions of this CRADA relating to Information privacy and data security in regard to Individually

Identifiable Information; (2) take appropriate measures to protect the confidentiality and security of all such Individually Identifiable Information; and (3) use and disclose such information only as authorized by the subject's prior signed informed consent and authorization document(s) and in accordance with this CRADA. If Collaborator discloses Individually Identifiable Information to a recipient who is not a Party to the CRADA the Collaborator shall ensure the recipient complies with (1) through (3) above.

- 6.3 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.
- 6.3.1 Review.** Principal Investigator shall submit to Collaborator for review a draft 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 draft. The draft 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. VA shall give reasonable consideration to all requested edits received from Collaborator.
- 6.3.2 Single Site Data.** After pooled dataset is published by Collaborator or one hundred eighty (180) calendar days after data lock, whichever is earlier, Principal Investigator may freely publish and/or present the results derived from the data collected solely by VA. VA shall 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 6.3 Presentations and Publications.
- 6.3.3 Excise of Confidential Information.** VA shall excise Confidential Information, other than the results of the research, identified by Collaborator in the draft presentation or publication.
- 6.3.4 Extension of Time for Patentable Inventions.** If Collaborator determines that any draft presentation or publication 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 draft presentation or publication.

Article 7. Confidentiality

- 7.1 Non-disclosure and Non-use.** Neither VA nor NPC may disclose or use any Collaborator Confidential Information, and neither Collaborator nor NPC may disclose or use any VA Confidential Information, except as expressly permitted in this CRADA or as required by law.

7.2 Disclosure and Use of Confidential Information

- 7.2.1 Each Party may use and disclose Confidential Information as needed to accomplish the Protocol.
- 7.2.2 A Party may disclose the other Party's Confidential Information:
- (a) As required by a court, administrative or regulatory body of competent jurisdiction, or by law, regulation or other applicable legal authority, or for patent filings and/or prosecution; or
 - (b) When requested by the chairman of a congressional oversight committee of jurisdiction acting in its oversight capacity; or
 - (c) When needed to provide medical care to a research subject when, in the opinion of the research subject's health care providers, such treatment is reasonable and necessary; or
 - (d) With the prior written consent of the providing Party.
- 7.2.3 A Party shall provide notice to the other Parties of an intended disclosure under (a), (b), (c), of Article 7.2.2 as soon as possible and shall limit any such disclosure to the extent possible. Disclosure in accordance with Article 7.2.2 will not otherwise affect the confidential nature of the information.

7.3 Duration of Confidentiality Obligation.

- 7.3.1 Confidential Information that is a trade secret, commercial or financial information under the meaning of section 552(b)(4) of title 5 of United States Code, obtained either in the conduct of this CRADA or as a result of activities related to this CRADA, and is from the Collaborator, shall not be disclosed by VA. (15 U.S.C. § 3710a(c)(7)(A)).
- 7.3.2 Confidential Information that results from research and development activities under this CRADA (that would be a trade secret or commercial or financial information if the information had been obtained from Collaborator under Article 7.3.1) shall be maintained as confidential by a Party for five (5) years after development of such information. (15 U.S.C. § 3710a(c)(7)(B)).
- 7.3.3 The obligation to maintain the confidentiality of Individually Identifiable Information shall last as long as the Party or any successor-in-interest maintains the Individually Identifiable Information.

Article 8. Warranties

8.1 Party Warranties. The Parties warrant:

- (a) Each has authority to enter into this CRADA;
- (b) The signatories have authority to sign on behalf of their organization;

- (c) Neither they nor any of their personnel involved in this CRADA are debarred or suspended by any agency of Government, or are excluded from any Federal health care program, or have received notice of intent to seek such action; and
- (d) No person or organization that becomes debarred or suspended during the performance of this CRADA shall be allowed to provide services or to participate in research under this CRADA.

8.2 Additional Collaborator Warranties. Collaborator also warrants:

- (a) Collaborator is financially able to satisfy the funding obligations described herein; and
- (b) Collaborator maintains insurance or self-insurance at levels sufficient to support the indemnification obligations assumed herein. Upon request, Collaborator shall provide evidence of such insurance, and
- (c) Collaborator's study monitors understand and will respect the confidential nature of VA patient's health records.

Article 9. Expiration and Termination

- 9.1 **Expiration.** This CRADA shall expire after the pooled dataset is published by Collaborator or one hundred eighty (180) calendar days after data lock whichever is earlier. The term of this CRADA may be extended by mutual written consent of the Parties in accordance with Article 13.6.
- 9.2 **Termination by Mutual Consent.** VA and Collaborator may terminate this CRADA at any time by mutual written consent given in accordance with Article 13.6.
- 9.3 **Unilateral Termination.** Either VA or Collaborator may unilaterally terminate this CRADA (1) at any time by providing written notice in accordance with Article 13.6 at least sixty (60) days before the desired termination date; or (2) immediately upon a material breach, for good cause, for subject safety, or upon termination of the study by the FDA.
- 9.4 **Payments.** If this CRADA is terminated, Collaborator shall pay any funds due through the date of termination and for work accomplished through the date of termination, as well as for reasonable termination costs and non-cancelable obligations; i.e., costs which cannot be prevented or mitigated and which arise directly as a result of this CRADA, including the cost of returning Collaborator property or removal of abandoned Collaborator property. If the total payments made by Collaborator exceed the final calculation of the payments owed, NPC shall promptly reimburse such excess to Collaborator.
- 9.5 **New Commitments.** No Party shall incur new expenses related to this CRADA after expiration, mutual termination, or unilateral termination and shall, to the extent feasible, cancel all outstanding commitments and contracts by the termination date.

Article 10. Disputes

- 10.1 **Settlement.** Disputes shall be submitted jointly to VA and Collaborator in accordance with Article 13.6. If VA and Collaborator are unable to jointly resolve the dispute within thirty (30) days after notification thereof, the VHA Office of the Under Secretary for Health shall propose a resolution. Nothing in this Article prevents VA or Collaborator from pursuing any additional administrative remedies that may be available and, after exhaustion of such administrative remedies, pursuing judicial remedies. When imposed by the IRB, requirements and modifications pertaining to the conduct of the Protocol are not disputes subject to settlement under this Article. In the event that a joint decision cannot be reached, VA policy is to encourage the use of Alternative Dispute Resolution (ADR) procedures.
- 10.2 **Continuation of Work.** Pending the resolution of any dispute pursuant to this Article, the Parties agree to diligently pursue performance of all obligations to the extent possible.

Article 11. Contract Research Organizations (CROs) **[optional if there is a CRO; if not this Article will remain blank]**

- 11.1 Pursuant to 21 CFR Part 312.52, Collaborator may retain one or more contract research organizations (“CROs”) to assist Collaborator in managing and monitoring the study. VA acknowledges Collaborator’s right to transfer, in whole or in part, without the consent of VA, any of Collaborator’s obligations under this Agreement to any such CROs. The Parties acknowledge that the CROs are independent contractors of Collaborator, and when assuming any obligation of Collaborator, must comply with 21 CFR Part 312.
- 11.2 Collaborator agrees that responsibility for the quality and integrity of the data, including VA Confidential Information remains with Collaborator after the data is received by the Collaborator. Collaborator represents and warrants that: 1.) Collaborator and CRO have entered into a separate contract whereby the CRO has assumed obligations and liability for any obligations that CRO undertakes pursuant to this CRADA; 2.) Collaborator’s use of CRO in managing and monitoring the study will not impact Collaborator’s indemnification and liability responsibilities as set forth in Article 12 and 3.) CRO will abide by the terms and conditions of this CRADA as applicable.
- 11.3 Liability between the CRO and VA: Collaborator represents and warrants that in its separate contract with CRO, the CRO has or will acknowledge that it shall be liable for any monetary or property loss, injury or death caused by its negligence in performance of its responsibilities under this CRADA, and any breach of this Agreement caused by the CRO. Notwithstanding the foregoing, the Collaborator agrees that it may not escape any liability or indemnification it may have toward VA in the course of this CRADA by using a CRO.

Article 12. Indemnification and Liability

12.1 Collaborator’s Indemnification and Liability

- 12.1.1 Collaborator shall defend, indemnify and hold harmless VA, VA Employees, the responsible IRB, the NPC and any of their agents (collectively the “Indemnitees”) from all liabilities, claims, actions and suits for personal injury, property damage

or death arising from the performance of this CRADA except to the extent that such injury, damage or death arises from the negligence or wrongful act of any Indemnitee.

- 12.1.2 VA shall promptly notify Collaborator of any liability, claim, action, suit, complaint and/or injury relating to its obligations under this Article.
- 12.1.3 Collaborator shall have the right to select defense counsel and to direct the defense or settlement of any such liability, claim, action and/or suit except to the extent that the Department of Justice is defending an indemnitee.
- 12.1.4 Material deviations from the terms of the Protocol that arise out of necessity do not constitute negligence, wrongful act or willful malfeasance, and do not constitute a waiver of indemnification. VA shall promptly notify Collaborator of any such deviations.
- 12.2 **VA's Liability.** The liability, if any, of the United States for damage to or loss of property, or personal injury or death shall be governed exclusively by the provisions of the Federal Tort Claims Act.
- 12.3 **Costs of Subject Injury.** Collaborator shall be responsible for reasonable and customary costs incurred for treatment of injury related to the subject's participation in the study described in the Protocol except to the extent that:
- (a) The injury is determined to be attributable to the negligence or willful misconduct of an Indemnitee; or
 - (b) The injury is attributable to Indemnitee's failure to administer Test Article as required in the Protocol or to otherwise substantially follow the Protocol.
- 12.4 **Force Majeure.** If a *force majeure* event occurs, the Party unable to perform shall promptly notify the other Party in accordance with Article 13.6. It shall use reasonable efforts to resume performance as quickly as possible and shall suspend performance only for such period of time as is necessary as a result of the *force majeure* event.

Article 13. Miscellaneous

- 13.1 **Governing Law.** This CRADA shall be governed by U.S. Federal law, as applied by the Federal courts in the District of Columbia. If any provision in this CRADA conflicts with or is inconsistent with any U.S. Federal law or regulation, the applicable U.S. Federal law or regulation shall preempt that provision.
- 13.2 **Waivers.** None of the provisions of this CRADA shall be considered waived by any Party unless a waiver is given in writing to the other Parties. The failure of a Party to insist upon strict performance of any of the terms and conditions hereof, or failure or delay to exercise any rights provided herein or by law, shall not be deemed a waiver of any rights of any Party.
- 13.3 **Severability.** The illegality or invalidity of any provisions of this CRADA shall not impair, affect, or invalidate the other provisions of this CRADA. If any provision is found illegal or invalid, the Parties shall promptly negotiate a substitute provision.

- 13.4 **Amendments.** This CRADA may be modified only by written instrument executed by an authorized signatory for each Party. The Protocol may be modified by mutual written consent of Collaborator and the Principal Investigator only for changes in clinical activities, subject to approval, if required, by the IRB and R&D Committee. VA may deviate from the Protocol for subject safety with appropriate notification to the IRB and Collaborator.
- 13.5 **Assignment.** Neither this CRADA nor any rights or obligations of any Party hereunder may be assigned or otherwise transferred by any Party without the prior notification and approval of the other party, in accordance with Article 13.6. Such approval shall not be unreasonably withheld. This CRADA shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assignees.
- 13.6 **Notices.** All notices shall be in writing and signed by an authorized representative of the notifying Party. Parties shall send notices by registered or certified mail by U.S. Postal Service with return receipt, or by an express/overnight commercial delivery service, with delivery prepaid. Notices shall be properly addressed to the other Parties at the addresses provided below or to any other address designated in writing by the other Parties.
- 13.7 **Party Relationships.** All Parties are independent from one another. This CRADA does not establish a contract between any VA entity and NPC.
- 13.8 **Use of Name; Press Releases.** By entering into this CRADA, VA does not endorse any product or service. Collaborator shall not state or imply that the Government or any of its organizational units or employees endorses any product or service. The Parties shall provide proposed press releases related to this CRADA to each other for review and comment at least five (5) business days before publication. Any Party may disclose the title of this CRADA to the public without the approval of the other Parties.
- 13.9 **Reasonable Consent.** Whenever a Party's consent or permission is required under this CRADA, its consent or permission shall not be unreasonably withheld.
- 13.10 **Export Controls.** Collaborator agrees to comply with U.S. export law and regulations.
- 13.11 **Record Retention.**
- 13.11.1 **Study Records.** Study records are managed in accordance with VA Privacy Act System of Records Notice, currently identified as "Veteran, Patient, Employee and Volunteer Research and Development Project Records-VA" (34VA12). VA will retain study records for this clinical trial in accordance with applicable regulations and VA policy. Study records may be destroyed thereafter in accordance with federal Privacy Act guidelines and VA Records Control Schedule 10-1.
- 13.11.2 **Storage.** The expense of storage of research records in excess of six (6) years due to clinical trial activities shall be paid by Collaborator. The costs for this additional retention will be negotiated in good faith at the time Collaborator undertakes this expense. Ownership of the records remains with VA. The records must remain in the possession of VA until they are destroyed.

- 13.11.3 **Patient Medical Records.** Patient medical records of clinical treatment of VA patients in the course of the Protocol are covered by VA Privacy Act System of Records currently entitled “Patient Medical Records-VA” (24VA19). VA shall retain and dispose of these records in accordance with the published Federal Register notice for these records and the applicable VA Records Control Schedule.
- 13.12 Collaborator will notify VA when it receives approval from FDA of its marketing application related to the Test Article identified in this CRADA. If the Collaborator is not submitting a marketing application to FDA, VA must be notified within 60 days of this decision.
- 13.13 **Entire Agreement.** This CRADA constitutes the entire agreement of the Parties concerning the subject matter of this CRADA and supersedes any prior understanding or written or oral agreement.
- 13.14 **Survivability.** The provisions of Articles 3.1, 3.2, 4.0, 5.1- 5.5, 6.2, 6.3, 7, 9.4, 11, 12.1, 12.2, 12.3, 13.5, 13.6, 13.8, 13.10, 13.11, 13.13 – 13.15 shall survive the expiration or early termination of this CRADA.
- 13.15 **Interpretation.** Any reference in this CRADA to an article of this CRADA includes all sub-articles thereof.
- 13.16 **Contacts.**

13.16.1 **CRADA Notices.**

For VA:

Dawn Schwenke, PhD, Associate Chief of Staff, Research
10535 Hospital Way, Bldg. 650, Room 2B004
Mather, CA 95655

and

Principal Investigator

For Collaborator:

Name & Address

For NPC:

John C. Johnson, PsyD, MSW, President and Executive Director
P.O. Box 1908
Rancho Cordova, CA 95741

13.16.2 Patenting and Licensing.

For VA:

Department of Veterans Affairs
Director, Technology Transfer (10P9TT)
810 Vermont Av NW
Washington, DC 20420
Email: VHACOTTC@va.gov

For Collaborator:

Name & Address

13.16.3 Delivery of Materials (if any).

For VA:

Name & Address

For Collaborator:

Name & Address

For NPC:

n/a

13.16.4 Payments.

For NPC:

EBIRE
P.O. Box 1908
Rancho Cordova, CA 95741

SIGNATURES ARE FOUND ON THE NEXT PAGE.

**DEPARTMENT OF VETERANS AFFAIRS
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT**

SIGNATURE PAGE

ACCEPTED AND AGREED:

By executing this agreement, each Party represents that all statements made herein are true, complete, and accurate to the best of its knowledge; that each has read and understood this CRADA prior to signing; and that each enters into it freely and voluntarily.

FOR COLLABORATOR:

Signature

Date

Typed Name, Title

FOR VA:

VAMC Director Signature

Date

David Stockwell

FOR NPC:

Signature

Date

John C. Johnson, President and Executive Director

Principal Investigator Acknowledgement

While not a Party, I understand and agree to the Principal Investigator obligations stated in this Agreement. Further, I certify that I am not debarred under subsections 306(a) or (b) of the Federal Food, Drug, and Cosmetic Act and shall not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Agreement. I also certify that I am not excluded from any Federal health care program, including but not limited to Medicare and Medicaid.

Principal Investigator Signature

Date

Principal Investigator Name

**DEPARTMENT OF VETERANS AFFAIRS
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT**

APPENDIX A

[Describe Collaborator Materials if any, to be provided by Collaborator, for use in study]:

[Describe Capital Equipment, if any, to be provided by Collaborator]:

[In accordance with Section 4.1, provide Financial Details (budget)]:

**DEPARTMENT OF VETERANS AFFAIRS
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT**

APPENDIX B

Protocol