CVRE CENTER FOR VETERANS RESEARCH AND EDUCATION

CLINICAL TRIAL REVIEW FORM

Please complete all appliable fields and submit to admin@cvre.org

To be read in conjunction with instructions on **page 4**.

PI Name _____ Email _____

VA Title _____ Service Line _____

Have you previously serviced as a CVRE PI? No

Application Details:

Sponsor: _____

Protocol Title: _____

Short Title: _____ Project Period: _____

Has the trial opened to enrollment? No

Which IRB is the study utilizing?

Does the sponsor have a Master CRADA? No

If no, have they recently executed a CRADA with another VA? Yes, different protocol

Will CVRE serve as the lead site? No

Will the PI serve as the lead PI? No

Relevance to VA mission:

Clinical trial guidelines (provide link or click to attach):

Sponsor Contacts:

Type:	Name:	Email:
Sponsor Contact		

Patient Population:

Are there alternative treatments available for this population? No

Is there a clinical impact on patient treatment or need for therapy? No

Will you recruit from your own clinic? No

If no, specify where patients will be recruited:

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# of anticipated patient enrollment?

Are frequent and severe SAEs expected? No

Are vulnerable populations involved (prisoners, etc.) that may require additional IRB and recruitment protection? No
Will non-veterans be enrolled? No

If yes to either, provide details:

Protocol:

Can the protocol be adequately integrated with routine standard of care? No

Are non-study personnel required to conduct special procedures or efficacy measures? No

If yes, specify:

Does your study require biosafety review and approval (blood collection and processing, gene therapy, live vaccines, viruses, etc.)? No

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Staff & Supplies:

Does the PI have adequate time to devote to the protocol? No

Are visit schedules and times practical for study personnel? No

Is specialized equipment required? No

If yes, provide details:

Are source documents provided? No

Is the study being conducted in patient care areas? No

If yes, has PI met and discussed with leadership of affected units? No

Resources (non-personnel):

Check all that apply:

☐ Imaging ☐ Pharmacy ☐ Lab Services ☐ Data Team/Stats Support

☐ Human Subjects ☐ Animal Laboratory ☐ Other

Will Subcontracts be needed? No Will Consultants be used? No

Planned Study Personnel:

VA/CVRE:

Name:	Role:	VA/CVRE:	Effort %:
		CVRE	
		CVRE	
		CVRE	
		CVRE	
		CVRE	

I understand that submission of this form is not study approval and a thorough review will be conducted by CVRE per the **Study Evaluation Process** on page 4. I further acknowledge that *official study authorization* is required from CVRE prior to beginning any study tasks i.e. IRB/IACUC submission work, document preparation, hiring.

Principal Investigator Signature Date

CVRE OFFICE USE ONLY

Form received date: _____ CVRE Tracking ID _____

CVRE Clinical Trial Review Form Approval (per Step 1) Date

CVRE Comments:

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Instructions:

Please complete all applicable fields, sign (PI only) and submit to admin@cvre.org.

Study Evaluation Process:

- **Step 1**: The *Clinical Trials Review Form* is reviewed for errors and completeness. PI may be contacted for clarification and follow-up questions. A signed form will be returned to acknowledge receipt of the clinical trial review form.
- **Step 2:** CVRE will contact PI and sponsor and gather documents. A *CVRE Resources Review* will be performed.
- **Step 3**: If *CVRE Resources Review* is approved, CVRE will perform a *financial feasibility* and conduct *budget negotiations* with the sponsor.
- **Step 4**: If *budget negotiations* are successful, CVRE will commence *CRADA negotiations*.
- **Step 5**: *CRADA* will go through detailed administrative, fiscal, and legal review.
- **Step 6**: Upon final approval, *CRADA* will be fully executed.
- **Step 7**: CVRE will provide ***official study authorization*** to PI to commence study and pursue IRB/IACUC/RDC approval.

The PI will be notified of review/approval status after each step is completed.