Department of Veterans Affairs
Clinical Science Research & Development Service
Guidance for Submitting Letter of Intent:
Point of Care-Research (POC-R)

I. Overview

A Point of Care Research (POC-R) study begins with the submission of a Letter of Intent (LOI) by an eligible VA investigator to the Director, Clinical Science Research & Development Service (CSRD). The purpose of the LOI is to assure that the most relevant, veteran-focused trial applications are approved for submission and peer review, and to assess feasibility for this methodology to be applied to the proposed study question. The LOI provides an opportunity for CSRD to determine if the proposed trial will address a critically important clinical question aimed at improving Veteran healthcare, and whether the proposed idea meets the intent of the POC-R program. LOIs also provide an opportunity for the investigator to obtain feedback prior to planning regarding the trial question, design, feasibility of enrolling proposed population, etc.

POC-R will make use of the VA electronic medical record (EMR) for the purposes of obtaining data to answer comparative effectiveness questions. Subjects are randomized at decision points in clinical care where two or more alternative treatments or strategies are considered to be **equivalent**, and there is no clear option which is better.

In general:

- Recruitment occurs in the course of usual clinical care, optimally integrated with the EMR, with minimal perturbation of clinical work flow.
- Outcomes are assessed by automated extraction of data from the medical record of participants.
- Trial infrastructure and anticipated costs in comparison to a randomized controlled study are reduced. (As such, budget and infrastructure will be discussed collaboratively should the LOI be approved for planning the proposed study; no budget detail is required for this LOI.)

CSRD will review submitted LOIs at any time. PIs should understand that administrative and peer review may require a minimum of 60 days prior to a response.

II. Instructions

LOIs must be prepared using only letter-quality print, and all text must be prepared with at least 11-point font, with no more than 15 characters per inch and no more than 6 lines per inch. Page margins must be a minimum of 1 inch at each edge. LOIs should be no more than 10 pages in length. Each LOI must contain the following:

1. VA Form 10-1313-13, VHA Research & Development Letter of Intent Cover Page (available at http://www.research.va.gov/funding/process/forms.cfm). In Box 3, Select "OTHER" and specify "Point of Care Research"

2. Text describing the following:

    a. Objectives of the proposed research

    b. Importance of the study topic to the VA and its patients

    c. Justification of the need for a study of the size and scope justified by POC-R and how POC-R is a feasible methodology

    d. The feasibility of conducting the study within the VA

    e. Summary statement that the necessary preliminary research has been accomplished with data to support a large-scale evaluation and rationalize equipoise

    f. Description of the proposed study design, including how POC-R is suitable to answer the question. Include the following items in the description as appropriate:

        i. Interventions, treatments, and/or services to be compared

        ii. Any challenges the comparators may have on equipoise (e.g., costs, side effects, availability, etc.)

        iii. Population to be studied; note that only Veterans will be enrolled in POC-R studies

        iv. Unit(s) of analysis

        v. Sampling strategy

        vi. Data collection methods

        vii. Research strategy describing how POC-R is most appropriate

        viii. Description of the primary endpoint

        ix. Logical links between study questions, data, and endpoint

        x. Duration of the study

        xi. Number of patients and participating medical centers

    g. Are there any competing trials locally or nationally on this topic in this subject population? If so, describe and indicate distinction; if none,

indicate NONE. See www.clinicaltrials.gov as one source for this information.

3. Other documents that should accompany the LOI but are not included in the 10-page limit include:

    a. Statement of disclosure. A formal statement is required indicating that no financial or contractual relationship exists between the Principal Proponent(s) and any organization involved in the trial that may constitute a real or apparent conflict of interest. If such a relationship or contract does exist, or appears to exist, the Principal Proponent(s) must provide full disclosure.

    b. Statement of eligibility. To be eligible for planning support, a Principal Proponent must either have at least a 5/8th's VA appointment or have applied for and received approval to submit for funding from VA CSRD. In the latter case, a copy of the letter establishing eligibility to receive funds should be attached to the request.

    c. Biosketch of the Principal Proponent(s) with address, telephone and fax number(s) (not to exceed 4 pages) and highlighting clinical trial experience. Attach a list of on-going/submitted proposals that are directly related (e.g., pilot study, single-site/smaller clinical trial) to the study proposed in the LOI and the funding source.

    d. Potential Planning Committee Members. Names, addresses and telephone numbers of five to seven experts that would be appropriate for the study Planning Committee should the LOI be approved.

    e. Acknowledgment of the VA policy to include women and minorities in research (if applicable).

    f. Acknowledgment that the PI is ready and willing to work closely with POC-R program in planning and implementing this research, including the data collection managed through the VA electronic medical record

    g. References: Up to ten reference citations relevant to the proposed study.

III. Submission of an LOI

POC-R LOIs may be e-mailed to CLIN-Review@va.gov from the PI's local VA facility research office. Questions regarding POC-R may be directed to Eric Schwinder at eric.schwinder@va.gov or 202-443-5806.

If an LOI for a POC-R trial is approved, the POC-R program will schedule an initial planning meeting with the PI via telephone, to be followed by in person planning meeting with study team.

IV. Program Office Contacts

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