REHABILITATION RESEARCH AND DEVELOPMENT SERVICE INSTRUCTIONS FOR SUBMITTING A LETTER OF INTENT

- **1. PURPOSE:** This Rehabilitation Research and Development Service (RR&D) document contains requirements for preparing and submitting a Letter of Intent (LOI) to RR&D.
- 2. RATIONALE: The LOI process is designed to provide a systematic and defined approach to enhance the development of successful applications for RR&D funding, to allow investigators as much time as possible to develop and fine tune applications, and to permit adequate time for required reviews and approvals at the facility level.

RR&D uses the LOI process to achieve the following:

- a. Confirm that each application forwarded to RR&D is responsive to the Request for Application. *NOTE: The Associate Chief of Staff (ACOS) for Research should carefully review the mission of each Service within the Office of Research and Development (ORD) to ensure that applications are sent to the most appropriate Service for review.*
- b. Identify and resolve major problem areas such as investigator eligibility, off-site research, and/or budget issues prior to the submission of a full application.
- c. Plan for appropriate resources that allow for an efficient and effective review process.
- **3. POLICY:** Each application submission must be preceded by an LOI, including resubmissions.
 - a. <u>Request for Application (RFA)</u>. An RFA can be announced at any time and will contain special requirements and due dates. RFAs are posted on the ORD Intranet at <u>http://vaww.research.va.gov/funding/rfa.cfm</u>.
 - b. <u>Due Date</u>. Please refer to the ORD Submission Calendar at <u>http://vaww.research.va.gov/funding/process/submission-calendar.cfm</u> and the applicable RFA for submission deadlines.
 - c. <u>Review Process</u>. LOIs will be administratively reviewed for:
 - i. Relevance to the <u>purview</u> of RR&D;
 - ii. Responsiveness to the RFA noted;
 - iii. Applicant eligibility;
 - iv. Proposed project duration and budget; and,
 - v. Proposed research location(s).

Email notification of LOI receipt will be issued to the submitting VA facility within two weeks of the LOI submission deadline. If any issue(s) arise with the LOI, a Scientific Program Manager (SPM) will contact the station to attempt to resolve the issue(s). If the issue(s) cannot be resolved, then the LOI will be disapproved and an email to that effect will be sent. Notification to the station will be made at least two weeks prior to the application submission deadline. If the station is not contacted by an RR&D SPM, then the LOI has been accepted.

- d. <u>Eligibility</u>. All applicants (i.e., all persons assigned the PD/PI role) for VA research funds must hold a minimum 5/8 VA salaried position before a research project can be funded (see <u>Program Guide 1200.15</u>). There are additional eligibility requirements for Research Career Scientist (see <u>Program Guide 1200.20</u>) and Career Development Award nominees (see <u>Program Guide 1200.04</u>) as cited in the applicable RFA. Waiver requests should be submitted to the RR&D Director (<u>rrdreviews@va.gov</u>) at least 60 days prior to the due date for receipt of applications to allow sufficient time for processing. Name the file as follows: principal investigator's last name_station number_Eligibility Waiver (e.g., Jones_122_Eligibility Waiver). Refer to Table 2 in the applicable RFA for deadlines. Applications submitted without an approved eligibility waiver will be returned without review.
- e. <u>Duration and Budget.</u> Refer to the applicable RFA for details about project duration and budget caps. Waiver requests should be submitted to the RR&D Director (<u>rrdreviews@va.gov</u>) at least 60 days prior to the due date for receipt of applications to allow sufficient time for processing. Name the file as follows: principal investigator's last name_station number_Budget Waiver (e.g., Jones_122_Budget Waiver). Refer to Table 2 in the applicable RFA for deadlines. Applications submitted without an approved budget waiver will be returned without review.
- f. <u>Off-Site Research</u>. VHA policy mandates that VA-funded research be performed within VA medical centers or in VA leased space previously approved by the Office of Research and Development for research use (see <u>Program Guide 1200.16</u>). Any waiver request must indicate if there is a memorandum of agreement, memorandum of understanding, or any such arrangement with the owner of the off-site space.
 - i. Full off-site waiver requests should be submitted to the RR&D Director (<u>rrdreviews@va.gov</u>) at least 60 days prior to the due date for receipt of applications to allow sufficient time for processing. Name the file as follows: principal investigator's last name_station number_Off Site Waiver (e.g., Jones_122_Off Site Waiver). Refer to Table 2 in the applicable RFA for deadlines. Applications for full off-site research submitted without an approved waiver will be returned without review.
 - ii. Partial off-site waivers will be addressed during the Just in Time (JIT) process for applications selected with an intent-to-fund. Partial off-site research occurs when some, but not all, of the research will be conducted at the VA medical center or approved VA leased space.

4. FORMAT

- a. Type all pages single-spaced, with at least one-half inch margins (top, bottom, left, and right). Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger. Type density, including characters and spaces, must be no more than 15 characters per horizontal inch and 6 lines per vertical inch.
- b. Number all pages consecutively, in the bottom right-hand margin, starting with the first page following the LOI Cover Page (<u>VA Form 10-1313-13</u>) and ending with the last page. Include the applicant's name and page number (e.g., Jones-1).

5. CONTENT

a. LOI Cover Page (VA Form 10-1313-13). Check applicable categories in each box and

type in all requested information.

- i. In Box 2 mark: "new" if this is the first submission of the ensuing application; "resubmission" if the ensuing application is a resubmission of a previously reviewed application; "revision" if the LOI has been modified from the initial LOI submission in the current review cycle. Use the previous application number (e.g., RX001234) in Box 2 for resubmissions.
- ii. Check the appropriate program and level in Box 3. Provide the RFA number under *Response to Specific Announcement*.

b. Text Pages.

- i. <u>Merit Review Award (I01) and Small Projects in Rehabilitation Research</u> <u>Award (SPiRE) (I21)</u>. Sections (a) through (g) not to exceed three pages total. Note: This information (5.b.i.) is not required for resubmission applications; only the cover page (5.a.) is required. In the following order, state:
 - (a) Purpose. List the goals and specific objectives of the proposed research; clearly state the question to be addressed, hypothesis to be tested, methods, concepts, systems, or devices to be developed or evaluated.
 - (b) Background. State the scientific rationale for the proposed research and its relationship to other major research findings. Explain how this research will advance knowledge in rehabilitation research. Describe the significance of the research and how it relates to RR&D priority areas. Indicate how this research directly benefits Veterans and how it contributes to the quality of services provided by VA.
 - (c) Methods and Research Plan. Outline the proposed study design and methods. Identify Veteran subject population, sample size, and rationale for inclusion or exclusion of population served; (it is required that women and members of diverse ethnic and racial groups be recruited, unless contraindicated due to the study's aims). Identify key issues that may have an impact on the success of the proposed project, such as: subject recruitment, participation of specialized personnel, orphan companies, space, and budget. Specify if the proposed research will involve animals and, if so, the time frame to clinical application. Indicate implications for technology transfer and potential for replication.
 - (d) Key Personnel. Identify PI(s), co-investigators, collaborators, and consultants, and state their areas of expertise in a table format. Also include writers of support letters.

Name	Institution (if university, also include any VA affiliation (i.e., IPA, WOC))	Role and Percent Effort	Expertise

- (e) **Resources needed for the study with associated costs.** Refer to the applicable RFA for details about project duration and budget caps.
- (f) Project History. Indicate whether this study is new, a continuation of an existing project (include years funded) or related to a previously unfunded project. Indicate the project number, title, and date of the previous related submission.
- (g) **Research Site**. State the name of the lead facility where the research (subject and laboratory work) will take place. If a portion of the project will be performed at any other site(s), identify the site location(s).
- (h) Cited References (should be limited to one page).
- (i) **Biographical Sketch.** Include a biosketch for all personnel assigned the PD/PI role using the OMB approved <u>Biographical Sketch form</u>.
- (j) Review Assignment.
 - Indicate preference for assignment to a specific scientific review group and the SPM(s) with whom there have been discussions regarding this application. Resubmission applications are automatically assigned to the original review panel unless specifically requested otherwise. RR&D will make the final determination for best placement. See <u>Purview of RR&D</u> <u>Scientific Review Groups</u>.
 - 2. Indicate any review concerns (e.g., expertise needed to review your application, potential conflicts/reviewers that may have bias). Requests/ suggestions for specific reviewers will not be accepted. Requests to exclude reviewers that are not fully justified will not be considered.
- ii. <u>Career Development Award (CDA) (IK1 and IK2).</u> Sections (a) and (b) not to exceed two total pages. *Note: Only the cover page (5.a.) and a current biographical sketch (5.b.ii.e.) is required for resubmission applications.*
 - (a) Research Plan. Describe the scientific basis (rationale) for the proposed research and its relationship to other major research findings. Include the significance of the research, emphasizing its particular importance to Veterans or how it represents a unique opportunity within the VA healthcare system.
 - (b) Key Personnel. Identify mentor(s), co-investigators, collaborators, and consultants, and state their areas of expertise in a table format. Also include writers of support letters.

Name	Institution (if university, also include any VA affiliation (i.e., IPA, WOC))	Role and Percent Effort	Expertise

- (c) **Cited References.** Up to five reference citations relevant to the proposed study may be attached on a separate page.
- (d) Appointment Eligibility Documentation. Attach a letter from the local VA Human Resource Management office indicating that the nominee is eligible for the respective appointment (i.e., U.S. Citizen and can be hired by the VA medical center (VAMC) with at least 5/8ths time), if the CDA is funded. Indicate whether the nominee is currently employed by the VAMC or not.
- (e) **Biographical Sketch.** Include a biosketch for the nominee and primary mentor using the OMB approved <u>Biographical Sketch form</u>.
- (f) Review Assignment. Indicate any review concerns (e.g., expertise needed to review your application, potential conflicts/reviewers that may have bias). Requests/ suggestions for specific reviewers will not be accepted. Requests to exclude reviewers that are not fully justified will not be considered.
- iii. <u>Research Career Scientist Award (IK6).</u> Note: The cover page (5.a.) and a current biographical sketch (5.b.iii.a.) is required for all applications.
 - (a) **Biographical Sketch.** Include a biosketch for the nominee using the OMB approved <u>Biographical Sketch form</u>.

6. SUBMITTING THE LOI

The LOI must be saved as a single PDF file. Name the file as follows: principal investigator's last name_station number_LOI (e.g., Jones_122_LOI). Do not include waiver requests in the LOI. Waiver requests must be submitted separately. Submit the LOI to <u>rrdreviews@va.gov</u>. Use the following text in the email "Subject:" line: [insert PI last name] LOI for [insert review cycle] Merit Review (e.g., Jones LOI for Spring 2016 SPiRE Review).

- a. <u>Signatures.</u> The LOI must be signed by the ACOS or R&D Coordinator, or the appropriate designee, with a current date. LOIs will not be accepted without being processed through the appropriate research office.
- b. <u>Deadlines.</u> The signed LOI must be received by 11:59 p.m. ET on the submission due date to receive consideration. Please refer to the ORD Submission Calendar at <u>http://vaww.research.va.gov/funding/process/submission-calendar.cfm</u> and the applicable RFA for submission deadlines.

7. INQUIRIES AND ADDITIONAL INFORMATION

Inquiries may be directed to RR&D, Program Analysis and Review Section (PARS) at <u>rrdreviews@va.gov</u> or (202) 443-5757. Please refer also to the RR&D website at <u>http://www.rehab.research.va.gov/</u>.