

JIT Guidance for Investigators

Biomedical Laboratory Research and Development (BLR&D)

and Clinical Science Research and Development (CSR&D)

After a BLR&D or CSR&D project has been reviewed and an Intent to Fund notice has been generated, various documents will need to be submitted to ORD by your local research office using the Just-in-Time (JIT) website. Your local research office staff will tell you the JIT requirements for your project and their procedures for submission. This document provides guidance on all JIT items; some may not be required for your research. Please note that all VA policies regarding research apply to every funded project.

The following guidelines are designed to assist you as you prepare the various document types for submission. Your research office staff can retrieve and provide blank forms, more detailed instructions, and sample documents, which are available for download within the JIT website, for your reference. Since researchers do not have access to the JIT website, the forms and templates are also posted on the [BLR&D/CSR&D JIT Forms and Templates web page](#).¹

The title of your project, as indicated on your submitted documents, must be consistent with the title used in your application approved for funding.

The JIT document submission and review process is critical to timely release of project funds. Maintaining regular communication with your research office will help ensure any outstanding concerns are addressed in a timely manner. If you need to contact CSR&D regarding JIT requirements, email VHABLRD-CSR&D@va.gov.

¹http://www.research.va.gov/services/shared_docs/jit-files.cfm

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1. Quad Chart

BLR&D and CSR&D Services require a Quad Chart for all funded projects. The Quad Chart is designed to briefly inform a non-technical audience about the design and merits of your work. Your research office will provide the Quad Chart template as well as a document containing frequently asked questions and expected content. You can also obtain them from the [BLR&D/CSR&D JIT Forms and Templates website](#).²

Quadrant 1: Project Description

Quadrant 2: Project Benefits and Innovations

Please provide a succinct, bulleted summary of project aims, scientific innovations, and benefits to Veterans. Please use **font Arial, font size 11**. The information should be written for members of the public rather than researchers or professionals. Your responses must be suitable for a senior high school student to understand and should be written in clear, plain English. Avoid the use of jargon and abbreviations, and explain any technical terms that have been included.

Quadrant 3: Graphic Representation of the Most Significant Scientific Problem or Approach

The graphic representation can be an illustration of the problem, your approach, pathways, graphics, video or any relevant data. *Do not include any Personally Identifiable Information or an image such as the face of a human subject, unless you have permission to do so in accordance with VHA Handbook 1605.01 (e.g. a completed VA Form 10-5345).*

- To insert an image from a file, click on the “Insert” ribbon (PowerPoint 2010), then click “Picture”, then navigate to the file, click it, then click “Insert.” Make the image fit within this quadrant by dragging the handles at each corner. Hold down “Shift” when dragging to maintain the original shape while resizing, if needed.
- To use an image from another program, either a) export the image as a JPEG and use the directions above, b) copy and paste the image (e.g. from a browser), or c) do a screen capture and crop the image as needed (for PowerPoint 2010 click on Picture Tools “Format”, “Crop”, then use the handles to remove unwanted portions of the image, then click anywhere off the image to see and use the resizing handles at the any of the four corners).
- To embed a movie file (no larger than about 23 Mb for a total file size of no more than 25 Mb), you must use PowerPoint 2010 or a later version and use the 2010 or later file format (“Save as type”= “PowerPoint presentation”). Have a copy of the movie file on your hard drive (mp4, mov, qt, swf, asf, avi, mpg, mpeg, or wmv formats), then click on the “Insert” ribbon, then chose “Video”, then “Video From file”, then navigate to the folder with the movie file, then click on the file, then click on “Insert.” Move the image representing the movie to Quadrant 3 and use the corner handles to resize as needed to fit. To make sure the movie will play, click the “Slide Show” ribbon, then click “From Beginning”; when the movie box is clicked, the movie should play, including audio.

Quadrant 4: Timelines

When filling out the Timeline table, please identify timelines for the aims described in the first quadrant. Type "XXXX" in the table cells or use the rectangle shape to illustrate each aim duration (Ctrl-D to duplicate the rectangle after clicking on it; use corner handles to resize).

²http://www.research.va.gov/services/shared_docs/jit-files.cfm

2. VA Research Support Agreement Regarding Completion of JIT Requirements

Depending on the type of award you are selected for, you may be required to submit an agreement regarding the amount of time permitted to satisfy all JIT requirements. If this is the case for your project, an agreement (with project details already included) will be made available for download from JIT. The agreement needs to be completed, signed and dated, and uploaded by your research office. The template for the BLR&D VA Research Support Agreement can also be obtained from the [BLR&D/CSR&D JIT Forms and Templates website](#).³

³http://www.research.va.gov/services/shared_docs/jit-files.cfm

3. R&D Committee Approval

Following review and approval by all required committees, subcommittees, or other entities, the R&D committee must give final approval to the project.

Documentation of R&D Committee approval must be the formal notification from the Associate Chief of Staff for Research to the investigator that the project may be initiated.

Do not include any minutes documenting the approvals.

4. VA Research Support Agreement Regarding Intellectual Property

Intellectual property is any art, machine, manufacture, design, or composition of matter, or any variety of plant, which is or may be patentable under the patent laws of the United States. The Department of Veterans Affairs has the right to assert a right, title, and interest in and to all inventions made by any VA salaried employee under certain circumstances. For more details, see [VHA Handbook 1200.18 "Intellectual Property."](#)⁴

If your project is identified as having potential issues regarding ownership of intellectual property, an intellectual property agreement will be uploaded to JIT by central office staff. You can also obtain a copy of the from the [BLR&D/CSR&D JIT Forms and Templates website](#)⁵. This agreement must be signed by the principal investigator, Associate Chief of Staff for Research, and Chief of Staff before being returned.

⁴http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=403

⁵http://www.research.va.gov/services/shared_docs/jit-files.cfm

5. Human Subjects Research

Section A. Institutional Review Board Approval

An IRB is a board, committee, or other group formally designated by an institution to review, approve, require modification in, disapprove, and conduct continuing oversight of human research in accordance with 38 CFR Part 16 and other applicable VA and Federal requirements. If your project involves human subject research activities, an IRB must document its approval of the project unless the project involves activities which are exempt from IRB review and approval. IRB approval of the project must be documented in a signed IRB approval letter. If the IRB determines that a project is exempt from IRB review and approval, you must obtain IRB documentation in a signed IRB exempt determination letter. The IRB's documentation of exempt status must be signed by the IRB voting member who reviewed the research and made the exempt determination. If the IRB approves the protocol at a convened IRB

meeting or by expedited review, the IRB approval letter must be signed by the Chair or a voting member who reviewed the research. The title of the project referenced in the IRB approval letter or documentation of exempt status must in any case match that of the project for which it is submitted.

Section B. Informed Consent Form, VA Form 10-1086

(1) For non-exempt human subjects research activities, written informed consent must be obtained from VA subjects using [VA Form 10-1086 "Research Consent Form"](#)⁶ unless the IRB approved (a) a waiver of informed consent or (b) a waiver of documentation of informed consent.

(2) The title of the study listed on the VA Form 10-1086 must be the same as the title of the project. If multiple informed consents are needed, the consent form title may be the project title with a sub-project title appended to it (example – Exact Name of VA Project; Tissue Banking Informed Consent).

(3) The IRB approval date must be documented by the use of a stamp or preprinted box on each page of the informed consent form. This stamp or preprinted box must indicate the most recent date of IRB approval of the informed consent form.

Section C. Documentation of Current Human Subjects Protection Training:

(1) The Ethical Principles of Human Subjects Protection

(2) Good Clinical Practice

All individuals involved in conducting VA human subjects research are required to successfully complete training in ethical principles on which human research is to be conducted and accepted good clinical practices (GCP). The training documentation must not have expired at the time of submission to JIT.

Documentation may be in the form of a certificate from any [ORD approved training course](#)⁷ [e.g., Collaborative Institutional Training Initiative ([CITI Program](#))⁸]. One document detailing the training for multiple investigators is acceptable, provided it includes completion dates for all individuals

⁶http://www.va.gov/vaforms/form_detail.asp?FormNo=1086

⁷<http://www.research.va.gov/pride/training/options.cfm>

⁸<https://www.citiprogram.org/>

6. Animal Subjects Research

A secondary veterinary review is required for research that involves animals. The station must submit the following:

(1) ACORP (Animal Component of Research Protocol)

This form can be obtained from your research office or from the [BLR&D/CSR&D JIT Forms and Templates website](#).⁹ Make sure that all signatures are present in section Z, and that all appendices are included with the ACORP. The signature of the R&D Chair is no longer required, and signatures may now be more than a year old.

Approvals from the IACUC after February 1, 2014, must be on version 4 of the ACORP. Approvals obtained before this date may be on either version 3 or version 4.

⁹http://www.research.va.gov/services/shared_docs/jit-files.cfm

(2) Training Certificates for each individual listed in ACORP (E.4)

Please provide the latest official training certificates documenting that VA training requirements for each individual listed in Item E.4 of the ACORP are satisfied (see [VHA Handbook 1200.7, Section 8.m](#)¹⁰).

Please upload documentation for each of the courses required for each individual. Each certificate should show:

- Title of the course taken
- Date of completion,
- Certificate number, and
- Contact information for the entity issuing the certificate.

Up to three weeks after the required documents have been submitted, a comment form generated by the ORD secondary veterinary reviewer will be made available to the research office in JIT. If a reviewer concern is given a score of:

- **0 on the reviewer form:** no further station action is needed.
- **1 on the reviewer form:** the IACUC must review the comments to determine whether any *local* action is needed.
- **2 or 3 on the reviewer form:** the JIT area cannot be cleared until a station response to the concerns is uploaded for ORD review and approval.

¹⁰http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2464

7. Biosafety and Laboratory Safety

VA Form 10-0398 “Research Protocol Safety Survey” is required to be submitted. The form can be obtained from your research office or from the [BLR&D/CSR&D JIT Forms and Templates website](#).¹¹

Important notes:

- Alternate forms of VA Form 10-0398 are not acceptable.
- It is not necessary to include the chemical inventory of the laboratory.
- Certain proposals involve no biosafety issues. If this is the case, a signed form or letter verifying this circumstance is needed from the biosafety/safety committee chair (Subcommittee for Research Safety [SRS], or Institutional Biosafety Committee [IBC]).

¹¹http://www.research.va.gov/services/shared_docs/jit-files.cfm

8. Verification of Employment

Investigators must have at least a 5/8ths (25 hours) VA appointment in order to be recipients of funding. Documentation, in the form of a memo from the Medical Center Director, is required stating that the awardee satisfies this requirement. Please include a statement that includes the following:

- The awardee has a VA-paid appointment which will extend continuously through the duration of the award
- The appointment is not a contract position
- The fractional effort (8ths) for the awardee

For appointments less than 5/8ths, include a copy of the eligibility waiver. If the principal investigator is a CADE clinician awardee, see below.

9. Verification of Employment for CADE Clinicians

A memo from the Medical Center Director is required that the awardee has a VA-paid appointment shared between Medical Care and Research, which will extend continuously through the duration of the Merit Review award. Please state the fractional effort (8ths) for this awardee, and include a breakdown of the effort (8ths) for Medical Care and the effort (8ths) for Research.

10. Memorandum of Understanding Regarding Distribution of Time and Effort

For an investigator with joint appointments at the VA and an affiliate university, the MOU defining the distribution of the investigator's time and effort at the two sites must be uploaded. Your research office can provide detailed guidance on the issues that must be addressed in the MOU. A sample template can also be found on the [BLR&D/CSR&D Forms and Templates website](#).¹²

¹²http://www.research.va.gov/services/shared_docs/jit-files.cfm

11. Other Support

Complete and up-to-date information on Other Support is required for all applications prior to receiving funding. Although the applicant provided this information with your application, several months have passed, and current information is required.

Compile this information by updating Other Support for each of the Key Personnel. The research office will then upload a single combined file for all of the Key Personnel to JIT. Statements regarding the presence or absence of overlap must be included for each funded project listed.

Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Prizes and gifts should not be included, but training awards including Career Development should be included.

Information on Other Support assists VA-ORD staff in the identification and resolution of potential overlap of support. Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. The goals in identifying and eliminating overlap are to ensure that sufficient and appropriate levels of effort are committed to the project; that there is no duplication of funding for scientific aims, specific budgetary items, or an individual's level of effort; and that only funds necessary to the conduct of the approved project are included in the award.

Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salary) are requested in an application but are already provided for by another source.

Commitment overlap occurs when a person's time commitment exceeds 100 percent, whether or not salary support is requested in the application. While information on other support is only requested for Key Personnel (excluding consultants), no individuals on the project may have commitments in excess of 100 percent.

Scientific overlap occurs when: (1) substantially the same research is proposed in more than one application or is submitted to two or more different funding sources for review and funding consideration, or (2) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more applications or awards, regardless of the funding source.

Your research office can provide a sample document and guidance, which can also be found on the [BLR&D/CSR&D JIT Forms and Templates website](#).¹³

¹³http://www.research.va.gov/services/shared_docs/jit-files.cfm

12. Overlap Concerns

Budgetary, scientific, and other overlap issues must sometimes be addressed as part of the JIT review process. If overlap concerns were identified in your application for funding, you will be required to provide additional information. Your research office will provide specific instructions.

13. Off-site Research

VA-funded research must be performed in laboratory, clinical, or office space within a VA facility or VA-leased space. If any of the proposed work will be conducted in non-VA space, a waiver to perform the research off-site must be obtained prior to the research being funded. Approved off-site waivers are good for the lifecycle of a proposal and the duration of the research project if funded. If you need to request an off-site waiver, you will be given instructions and a template to guide your response, which can also be found on the [BLR&D/CSR&D JIT Forms and Templates website](#).¹⁴ Additional information is available in [VHA Handbook 1200.16](#).¹⁵

¹⁴http://www.research.va.gov/services/shared_docs/jit-files.cfm

¹⁵http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2955

14. Conflict of Interest

If conflict of interest concerns were not clearly and completely addressed in your application for funding, you may be required to satisfy this JIT area, and will be given instructions to guide your response.

15. Clinical Trial Registration

The Food and Drug Administration Amendments Act of 2007 (FDAAA or US Public Law 110-85) was passed on September 27, 2007. The law requires mandatory registration and results reporting for certain clinical trials of drugs, biologics, and devices.

As of May 17, 2010 the requirements for www.clinicaltrials.gov were changed in the Annual Reports (ART) system, and the ART system was set up to interact directly with JIT to register projects that are being processed in JIT. When the Clinical Trials Registration JIT area is added to a project in JIT, the ORD Administrator enters the principal investigator's contact email address and VA login. The ART system is then notified that Clinical Trials Registration is required for the project and sends the principal investigator an e-mail with the instructions on how to access the ART system. **Please note:** a VA email address must be used in ART.

When the project is ready to be registered (It is generally best to wait until after all other JIT requirements have been met), the principal investigator must enter the information required for this trial on the ART Website. The ART system processes the registration, and will then notify the JIT system directly (by uploading a confirmation into the Clinical Trials Registration JIT area, and posting a link to the ClinicalTrials.gov registration) when the registration is complete. ORD will receive an email alert that this has been done. A PDF copy of the proof of registration will also be sent to the principal investigator, but there is no need for the station to upload it, as the ART system will have already done so.

ORD then checks the registration and approves the JIT area.

ORD personnel are available to work with investigators and assist them with registering their clinical trials using the ART System. Please note that once entered in www.clinicaltrials.gov, there is a requirement for six-month updates. Delinquency notices generated by the ClinicalTrials.gov website will be sent to ART and forwarded to the investigator's VA email address.

16. Contract Issues

If contract issues were not clearly and completely addressed in your application for funding, you may be required to satisfy this JIT area, and will be given instructions to guide your response.

17. Miscellaneous

Miscellaneous issues not covered by other JIT areas must sometimes be addressed as part of the JIT review process. If such issues pertain to this your project, you will be given instructions to guide your response.

18. Career Development Award Agreement

To complete this JIT area, please upload the signed single-page document. This form can be obtained from your research office or the [BLR&D/CSR&D JIT Forms and Templates website](#),¹⁶ and requires signatures from the principal investigator and the associate chief of staff for research.

¹⁶http://www.research.va.gov/services/shared_docs/jit-files.cfm