

VA-ORD Just-In-Time (JIT) Guidelines

For assistance with any of the JIT areas outlined in the following guidance, please contact the service that is funding the project:

BL/CSR&D JIT Manager: vhacoblcsrdjit@va.gov

HSR&D JIT Manager: vhacohsrdjit@va.gov

RR&D JIT Manager: rrdreviews@va.gov

Animal Subjects Research Review

A secondary veterinary review is required for VA-funded research that involves research with animals. This review is handled outside of eRA Commons. At the present time, all documents needed for the secondary veterinary review are to be submitted by the station as email attachments to Dr. Alice Huang (alice.huang@va.gov). These documents include:

1. The final version of the protocol(s) covering all work with animals that is part of the project to be funded, approved by the local IACUC.
2. Each applicable appendix to the protocol, approved by the IACUC.
3. Each applicable certification statement for the protocol and appendices, with valid dated signatures entered.
4. Each local standard procedure document that is referenced in the protocol.

The secondary review is conducted by the office of the CVMO and may involve further email correspondence between the station and the office of the CVMO to address concerns noted in the secondary review. Please send the documents for review as soon as they are available, to allow time for this process. Additionally, research with canines, felines, or non-human primates may only be conducted with the written approval of the VA Secretary; the office of the CVMO will assist in securing that approval.

When the secondary review processes are completed, and all required approvals have been secured, the office of the CVMO will approve this JIT area. There is no requirement for the station to upload or submit anything into eRA.

If you have any questions about the secondary veterinary review process, please send an email to Dr. Huang at Alice.Huang@va.gov.

Associate Chief of Staff for Research (ACOS/R) Assurance

The ACOS/R Assurance Form attests to the completion of review by the R&D Committee and relevant research subcommittees, as well as the PI's eligibility to receive VA funding based on VA employment status. A template of the ACOS Assurance form is available and should be downloaded from the ORD website at <https://www.research.va.gov/funding/jit.cfm> and completed. *An ACOS assurance form must be completed for each multiple PI.*

Complete the ACOS/R assurance as follows:

A. Committee Reviews

- Enter the date of R&D Committee approval – and –

- For the IRB and IACUC subcommittee reviews, please check that the review has been completed - or- that review does not apply to this project (“N/A”).

NOTE: The Central IRB (CIRB) must be used for all multi-site VA research. If the first aim is single site research, the local site IRB may be used initially and then the CIRB for the aim(s) that involve multiple sites. The benefit of using the CIRB from the beginning however is that they will already be familiar with the research, and any issues related to central oversight (PO and ISSO) may have already been resolved.

- For the SRS and/or IBC review(s), please check that the review has been completed – or – that a determination was made that the project did not involve safety hazards.

B. Verification that the PI is eligible to receive research funding based on VA employment status. Please check the option that applies:

- The PI has a 5/8th or greater VA appointment – or –
- The PI has a waiver from the 5/8ths requirement - or –
- There are hiring or promotion actions currently underway to hire the PI with a VA paid appointment that will make the PI eligible to receive funding. **NOTE:** the start date will not be set until the hiring or promotion is complete.

Signature: By signing the ACOS/R JIT Assurance Document, the ACOS/R attests that all VA requirements for the study regarding the conduct of research in VA will be met, that required training has been completed, and that records will be maintained in accordance with VA requirements for research. **NOTE:** Handwritten and electronic signatures are acceptable, but typed names in the signature box and pasted images of signatures will not be approved. Be sure to complete the date field when handwritten signatures are used.

Associate Chief of Staff for Research (ACOS/R) Assurance for Secondary Sites

If the study involves more than one site, the ACOS/R at each site must attest to the completion of review by the R&D Committee and relevant research subcommittees at their respective site, as well as the site PI’s eligibility to receive VA funding based on VA employment status. A template of the ACOS Assurance form for secondary sites is available and should be downloaded from the ORD website at <https://www.research.va.gov/funding/jit.cfm> and completed.

NOTE: *All of the guidelines for completion of the ACOS/R Assurance outlined above apply to the secondary site. All relevant committee and subcommittee approvals must be conducted in accordance with VHA Handbooks 1200.05, 1200.06, 1200.07, and 1200.08. Documentation of all review and approval actions and completion of required training must be maintained in the local protocol files, but do **not** need to be uploaded in JIT.*

Clinical Trial Registration

The VA-ORD definition of a clinical trial is "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes."

ORD requires PIs of trials that it funds to register, and report results to ClinicalTrials.gov. In addition, [federal regulations](#) require mandatory registration and results reporting for certain clinical trials of drugs, biologics, and devices.

If the Clinical Trials Registration JIT area is assigned to a project in the eRA Commons JIT, the ORD funding service will notify the Assessment and Research Reporting Tool (ART) Program that the project requires clinical trial registration. ART will then send the PI an email with instructions for accessing the ART website and entering the registration information. Note: one must have VA network permissions to access the ART website. If the PI does not have VA network permissions, the station R&D AO or ACOS may be granted access to the trial record instead.

Do not register ORD-funded studies directly with ClinicalTrials.gov. Do not attempt to register a clinical trial prior to receiving instructions from ART. The PI must follow the instructions provided by the ART Program and enter trial information on the ART Website. The ART Program processes the registration with ClinicalTrials.gov and provides a PDF copy of the proof of registration.

The station must submit the PDF copy of the proof of clinical trial registration received from ART in eRA JIT.

Once registered, clinical trial information must be updated not less than once every 12 months. Regulations further require that some data elements be updated more rapidly.

Data Monitoring Committee (DMC)/Data and Safety Monitoring Board (DSMB)

The funding research service may require that a VA Data Monitoring Committee (DMC) or Data and Safety Monitoring Board (DSMB) oversee clinical trials that meet specific criteria such as, but not limited to, a risk assessment of greater than minimal risk. The assignment to a DMC (CSR&D) or DSMB (HSR&D) will be indicated in JIT to inform the local station research office of the assignment.

For CSR&D clinical trials, the assignment to a DMC will be indicated in JIT, but no station action is required. The DMC will communicate directly with the PI and their research office to convey procedures and requirements.

For HSR&D projects, the assignment of the DSMB JIT area requires the submission of a Data Analysis Plan (DAP) 45 days from the date on which the project was released to the station in JIT. The DAP details (1) the study design and analysis plan with respect to the research questions and (2) the plan to monitor and track serious adverse events.

The DAP should include the following elements, as applicable: 1) sample size rationale; 2) specific description of data collection process(es); 3) randomization approach (e.g., stratification or blocking); 4) plans and justification of any interim analyses (e.g., stopping rules for superiority, futility, or sample size re-estimation); 5) methods for prevention and handling of handling missing data (including loss to follow-up); 6) list and

definitions of covariates to be included in models (including potential confounders); 7) methods for dealing with data transformations; 8) definitions of the analytical cohorts (i.e. intent-to-treat, per protocol, etc.); and 9) list and definition of adverse and serious adverse events to be monitored and plans for prospectively tracking.

The DAP must be 3-7 pages, using appendices if necessary. It must include a table of contents and footer on each page that includes page number, PI name, and date. Name the document as follows: PI Last name_XXX ##-###_DAP.pdf (e.g., Doe_IIR 00-000_DAP.pdf).

Memorandum of Understanding (MOU)

For an investigator with joint appointments at the VA and an affiliate university, an MOU defining the distribution of the investigator's time and effort at the two sites may be required. A template is available on the ORD website at <https://www.research.va.gov/funding/jit.cfm>.

Miscellaneous

Miscellaneous issues not covered by other JIT areas must sometimes be addressed as part of the JIT review process. Examples of the issues that will be addressed in the Miscellaneous JIT area and guidance on providing a response to address the request in JIT are detailed below. If specific instructions to guide your response are required, additional information will be uploaded by ORD.

- [Approval by the Organizational Assessment Sub-Committee of the Human Resources Committee of the National Leadership Board](#)

Surveys of VA employees must be approved by the Organizational Assessment Sub-Committee (OASC) if the survey will be administered to 10,000 or more VA employees, or in 20 or more VA medical centers. To obtain OASC review, e-mail your project abstract, a description of the survey, and a sampling plan to VHAOASC@va.gov for review by the sub-committee. If the survey has IRB approval, the packet may be sent to David Mohr (David.Mohr2@va.gov) Please ensure that the following items are provided in your documents:

- Purpose of survey
- Intended audience and number invited to participate
- Modality of survey administration
- Proposed administration dates
- Copy of survey
- Plan to disseminate survey to your target respondent group
- Anticipated use of results
- Have you piloted the survey with the potential respondent group? (Y/N)
- Would you like assistance developing your survey? (Y/N)
- Contact person
- Project director

To address this JIT area, please upload the response that you receive, documenting approval by the Organizational Assessment Sub-Committee (OASC).

- **Correspondence addressing budgetary, scientific, or other overlap issues**

Budgetary, scientific, and other overlap issues must sometimes be addressed as part of the JIT review process. If concerns of overlap were identified during the review of the application, additional information will be requested in JIT.

To address specific overlap concerns, the specific aims of the specified award must be uploaded in JIT. As well, verification that there is no scientific, budgetary, or compensated time overlap must also be provided in a separate memorandum that must be signed by both the Principal Investigator and Associate Chief of Staff for Research.

- **Correspondence addressing a conflict of interest issue**

If conflict of interest concerns were identified during the review of an application, the identified concerns will need to be addressed in JIT. Specific instructions will be provided to help guide the response if conflicts of interest are identified during review because conflicts of interest will be different with each application.

- **Correspondence addressing a contract issue**

If contract issues were identified during the review of an application, the identified concerns will need to be addressed in JIT. Specific instructions will be provided to help guide the response if concerns are identified, because contract issues will be different with each application.

- **Correspondence involving an issue not covered by other JIT areas**

Specific instructions will be provided to help guide the response

- **JIT Extension**

If you will not complete JIT within 180 days, or the date specified by the funding service, you must submit [a](#) request for an extension. Be sure to provide a justification for the extension and a remediation plan; include a detailed timeline of attempts to obtain regulatory approval and anticipated date(s) for submission of remaining JIT documents. Requests without this information will not be considered.

- **Prefunding Modification**

A change from the original application in Key Personnel, Aims and Methods, Sites, or PI 8ths, requires a prefunding modification to document the change and receive approval.

The prefunding modification JIT area will be set, if the SPM is aware that a modification is needed prior to the release of JIT. If the PI becomes aware of a project change after JIT is set, contact the SPM to explain why a change is needed and to request a prefunding modification via email.

▪ Union Notification

Prior union notification is required for all research and operational projects involving VA personnel (e.g., interviews, surveys, or other data collection methods) when asking about conditions of employment of bargaining unit employees. It is important to note that some clinicians, including physicians, are bargaining unit employees.

- **Local Union Notification**. If your study will administer surveys or interviews involving VA personnel **entirely at the primary facility's level**, please contact your local HR department and arrange with them to have all necessary unions notified of the surveys/interviews. Please add a note to this JIT area when this has occurred confirming that necessary unions have been notified.
- **VISN Union Notification**. If your study will administer surveys or interviews involving VA personnel **beyond the primary facility's level but still within a single VISN**, please contact your VISN HR department and arrange with them to have all necessary unions notified of the surveys/interviews. Please add a note to this JIT area when this has occurred confirming that necessary unions have been notified.
- **National Union Notification** If your study will administer surveys or interviews involving VA personnel **across more than one VISN**, please send vhacohtsdjit@va.gov the following information in a single pdf file (please no Adobe "Portfolios"):
 1. **Overview**. Brief description of the study and objectives.
 2. **Data Collection**. Describe the intended data collection (survey, interview); number and type of VA personnel from whom data will be collected; and anticipated timeline for data collection (start and end dates). *Note: Do not send in requests for national union notification more than 3 months prior to the intended start date of the data collection. If surveys or interviews will occur later in the study period, please work with your SPM to clear JIT in the interim.*
 3. **Finalized list of sites from which VA personnel will be recruited**
 4. **Study Team Contact Information**
 5. **Final version of the survey/interview guide**. The unions require an explicit statement at the top of each survey/interview guide regarding the voluntary, anonymous, and confidential nature of the data collection. If anonymity is not possible, include a statement that (1) explains why participation cannot be anonymous; (2) explains what steps will be taken to protect the identity of the respondents; and (3) follow-up is voluntary. For example, "Anonymity will be protected in that the identity of the respondents

will be kept confidential by the research team and identifiers will be kept separate from the coded data. Results will be reported in aggregate and will therefore be anonymous in such reports.”

ORD staff will forward these documents to VA’s Office of Labor Management Relations (LMR) to notify the national unions. This process may take several weeks beyond the 30 days that the unions have for their review. An LMR representative may contact the study team and request additional information. The LMR representative will notify all applicable unions, and ORD staff will notify the study team after the process is completed.

Non-Veteran Waiver

Any ORD study that enrolls non-Veterans is required to submit a non-Veteran waiver. Non-Veterans includes employees and caregivers. Non-Veterans may only be entered into VA studies when there are insufficient Veteran patients suitable for the study (see 38 CFR 17.45, 17.92), or for studies that will generally benefit Veterans and their well-being but would not include Veterans as subjects. If this JIT area has been assigned, the funding service has noticed the investigator’s plan to enroll non-Veterans and a non-Veteran enrollment waiver request with sufficient justification for inclusion of non-Veterans is required.

Off-site Research

See [Off-site Research \(va.gov\)](#)

VA-funded research must be performed in laboratory, clinical, or office space within a VA facility or VA-leased space. If any portion of the proposed work will be conducted in non-VA space, including recruitment of research subjects, a waiver to perform the research off-site must be obtained prior to the research being funded.

If the Off-site Research JIT area has been selected, the intended conduct of off-site research was identified during the review of the proposal, but there is no record of an off-site waiver request for the proposal.

An off-site waiver request must be completed and submitted through JIT. Templates are available at the link above. If an off-site waiver was obtained prior to submission of the application, the approved off-site waiver must be uploaded into JIT.

Approved off-site waivers are valid for the duration of the funded research project, unless otherwise stated in the approval memo (e.g., approvals for interim use of off-site facilities during construction). Additional information is available in [ORD Program Guide 1200-16](#).

OMB Approval for Surveys Conducted Under Paperwork Reduction Act

If the project involves collection of information or data from 9 or more individuals who are not VA employees (e.g., Veterans, caregivers), OMB review and approval – or

exemption from OMB review – is required. [Click here](#) for a description of this process (OMB Approval Process Enclosure). To address this JIT area:

If the project meets the criteria for an OMB Exemption, the "Background Information for OMB Exemption Brief" must be uploaded. Please refer to the OMB Approval Process Enclosure document for required content and format guidance.

If the project requires OMB approval, documentation showing OMB approval must be uploaded. ORD staff will assist the PI in coordinating with the VHA OMB Liaison to submit all necessary forms. The VHA OMB Liaison will contact the PI when full OMB Approval is granted.

Other Support

Other Support includes all resources made available to researchers or senior key personnel in support of and/or related to all their research endeavors, regardless of whether they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current award. This includes resources and/or financial support from all foreign and domestic entities that are available to the researcher. This includes, but is not limited to, financial support for laboratory personnel, and provision of high-value materials that are not freely available (e.g., biologics, chemicals, model systems, technology, etc.). Institutional resources, such as core facilities or shared equipment that are made broadly available, should not be included in Other Support, but rather listed under Facilities and Other Resources. Other Support also includes in-kind contributions (such as office/laboratory space, equipment, supplies, or employees or students supported by an outside source).

- If in-kind contributions **are intended for use on the project being proposed to VA-ORD** in this application, the information must be included as part of the Facilities and Other Resources or Equipment section of the application and need not be replicated on this form.
- In-kind contributions not intended for use on the project/proposal being proposed in this application must be reported below. If the time commitment or dollar value is not readily ascertainable, reasonable estimates should be provided.

Institutions are required to submit copies of contracts specific to senior/key-personnel foreign appointments and/or employment with a foreign institution for all foreign activities and resources that are reported in Other Support. If they are not in English, recipients must provide translated copies. This does not include personal service contracts, or employment contracts for fellows supported by foreign entities.

NOTE: Other support does not include training awards, prizes, gifts, or start-up support provided to the individual by the applicant organization.

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 salary support is requested in the application. While information on other support is only requested for Senior/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.

To address this requirement, the information on 'Current and Other Support' that was provided **for the Principal Investigator AND each of the Key Personnel** within the application at the time of submission must be updated and uploaded as a single PDF file into the Just-in-Time (JIT) Document Manager. The updated Other Support should be in the same format used in the application submission. **NOTE:** Statements regarding the presence or absence of overlap must be included for each funded project listed.

PI's Response to Board Conditions

A document detailing the principal investigator's response to the scientific conditions listed in the Summary Statement or imposed by the funding service must be submitted.

Principal Investigator (PI) Assurance

The PI Assurance Form attests to the PI's agreement to comply with VA research policies. Co-located Multiple PIs must both complete the PI assurance form. A template of the PI Assurance form is available and should be downloaded from the ORD website at <https://www.research.va.gov/funding/jit.cfm> and completed.

Please fill out the information at the top of the form accurately, endorse the boxes with "X" to attest to adherence to all VA research policies and fill out the citation statement at the bottom. NOTE: The citation statement "This work was supported (or supported in part) by..." refers to the type of award (e.g., merit or career development), the Award Number refers to the eRA number, and "from the United States (U.S.) Department of Veterans Affairs.....Service" refers to the specific funding service within the ORD (e.g., Biomedical Laboratory, Clinical Sciences, Health Services, or Rehabilitation).

Sign the PI Assurance form before uploading. **NOTE:** Handwritten and electronic signatures are acceptable, but typed names in the signature box and pasted images of signatures will not be approved. Be sure to complete the date field when handwritten signatures are used.

Principal Investigator (PI) Assurance Form for Secondary Sites

If the study involves more than one site, the PI at each site must attest to his/her agreement to comply with VA research policies. A template of the secondary site PI Assurance form is available and should be downloaded from the ORD website at <https://www.research.va.gov/funding/jit.cfm> and completed.

Please fill out the information for the primary site and local site at the top of the form accurately and endorse the boxes with "X" to attest to adherence to all VA research policies. Sign the PI Assurance form before uploading. **NOTE:** Handwritten and electronic signatures are acceptable, but typed names in the signature box will not be approved. Be sure to complete the date field when handwritten signatures are used.

Quad Chart

The Quad Chart must be provided using the template available on the ORD website at <https://www.research.va.gov/funding/jit.cfm>, and is expected to inform a non-technical audience about the design and merit of the work as follows:

- Project Title: Same as submitted application
- PI: Include PI first and last name with degrees, if MPI, include all MPIs
- Station Code: List VAMC name and location of PD.
- Award #: Use eRA Commons and Project ID (found in RAFT (e.g: MHBC-003-21F))

Quadrants 1 & 2: Project Description and Project Benefits and Innovations

- Enter award amount
- Enter start and end date for award

Please provide a succinct, bulleted summary of the project aims, scientific innovations, and benefits to Veterans. Please use **Arial 11 point font**. Reduce the amount of text, not the size of the font, if you do not have enough space. Please ensure that the language is suitable for members of the general public, rather than for researchers or other professionals; it should be in clear, plain English that a typical senior high school student can understand. The use of jargon and abbreviations should be avoided, and any technical terms that are included must be explained.

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

The graphic representation can be a chart, graph, or other image that illustrates the problem, approach, pathways, or relevant data. *Please make sure that no Personal*

Identifiable Information or image (such as the face of a human subject) is included, unless permission to do so has been secured in accordance with VHA Handbook 1605.10 (and a completed Form 10-5345 has been obtained).

Quadrant 4: Timelines

Please ensure that the timelines and the tasks provided address the aims described in the first quadrant. List specific tasks/activities (not Aim 1, Aim 2...) in each Project year – this is similar to your Gantt Chart in your application. If the project is 1 year, please list by quarter.

A Word file with detailed instructions and FAQs for preparing the Quad Chart is available on the ORD website at <https://www.research.va.gov/funding/jit.cfm>.

Revised Budget

A revised Summary Budget Worksheet and justification must be submitted to address the concerns of the review board and/or funding service, and to reflect any budget-related changes to the study or study team. Budgets exceeding the amount approved in the proposal may only be submitted with approval of the funding service.