

VA



U.S. Department
of Veterans Affairs

HSR Training

**Just-in-Time:
Your research project is approved;
what are the next steps?**

HSR and Finance Office Research and Development Staff

May 8, 2024

VA

OFFICE OF RESEARCH & DEVELOPMENT

HEALTH SYSTEMS RESEARCH



Light at the end
of the tunnel



Overview of Presentation

- **JIT in eRA process**
- **Project Budget Process and Updated Guidance**
- **Quad Chart**
- **IRB**
- **Data Collection – Surveys & Interviews**
 - **Union Notifications (VA Employees)**
 - **OASC Review (VA Employees, surveys >10,000 participants or >20 sites)**
- **Clinical Trials Registration**
- **Data & Safety Monitoring Board (DSMB)**
- **Intellectual Property**
- **Q&A**



eRA Just-in-Time

- JIT for VA Applicants now accessed through eRA
[https://era.nih.gov/erahelp/Commons/default.htm#Commons/status/jit_VA.htm?TocPath=Status%2520Module%257CJust%2520in%2520Time%2520\(JIT\)%2520Search%2520for%2520SOs%257C_2](https://era.nih.gov/erahelp/Commons/default.htm#Commons/status/jit_VA.htm?TocPath=Status%20Module%257CJust%2520in%2520Time%2520(JIT)%2520Search%2520for%2520SOs%257C_2)
- Corresponding PI and the site's designated Signing Official are responsible for the upload of all JIT documents from all sites. The Signing Official is the only one that can submit documents.
- eRA help: <https://www.research.va.gov/funding/jit.cfm>



Time to Complete JIT

You have 180 days to complete JIT.

- If you have not cleared JIT at 150 days (October 5), you will be asked to submit a waiver.
- **IRB** is a long process that may take the entire time period in JIT. **START NOW!**
- **Don't Wait--Upload JIT documents** as completed to show progress.
- Union notification takes approximately 8 weeks.
- Revised Budgets are due June 7th.
- ACOS Assurance depends on your local R&D Committee and IRB.
- DAPs are due June 22nd (45 days).





JIT Budget Requirements

SUMMARY BUDGET WORKSHEET - up to 20 Sites

Expenditure	Budget Period 1	Budget Period 2	Budget Period 3	Budget Period 4	Budget Period 5		
Primary	VA Maryland Healthcare System						
PI ONLY (Section A, top line)						Yr 1 Effort (Cal Mo)	De
Salary	0	0	0	0	0	2.4	ML
PI Fringe	0	0	0	0	0		
Other VA Personnel (include Sr/Key VA personnel, exclude IPAs)						Total Yr 1 Effort (Cal Mo)	# unique staff
Hired - Salary		0		0	0	1.2	1
Hired - Fringe		0		0	0		
Salary		0	0		0		
Fringe		0	0		0		
VA Personnel Salary	0	0	0	0	0		1
VA Personnel Fringe	0	0	0	0	0		



Summary Budget Table

Primary Site: <i>Tatooine VAMC, Mos Eisley, Tatooine</i>												
VA Personnel (include transcription staff if done in-house)	Degree	Project Role	Duties/ Appointments	VAFTE (Number of eight)	Grade	Step	% Error for each project year	Year 1 Salary+Fringe	Year 2 Salary+Fringe	Year 3 Salary +Fringe	Year 4 Salary+Fringe	Total Cost
Luke Skywalker	PhD	PI	n	8	15	4	20,20,20,25	\$30,000	\$30,600	\$31,212	\$36,836	\$128,648
Anakin Skywalker	MD	Co-I	y	8	14	8	10,10,10,10	\$0	\$0	\$0	\$0	\$0
Boba Fett	PhD	Co-I	n	5	13	9	10,10,10,10	\$10,000	\$10,200	\$10,404	\$10,612	\$41,216
Jabba the Hutt	PhD	Co-I	n	5	13	6	10,10,10,10	\$10,000	\$10,200	\$10,404	\$10,612	\$41,216
Rey Skywalker	PhD	Co-I	y	8	13	1	10,10,10,10	\$0	\$0	\$0	\$0	\$0
C-3PO	MS	Proj Coord	n	8	12	1	50,50,50,50	\$35,000	\$35,700	\$36,414	\$37,142	\$144,256
R2D2	MS	Programmer	n	8	12	1	50,50,50,50	\$35,000	\$35,700	\$36,414	\$37,142	\$144,256
Assistant Droid 3YA	BA	Res Asst	n	8	11	3	50,50,50,50	\$20,000	\$20,400	\$20,808	\$21,224	\$82,432
Statistics Droid 112	MS	Biostatistician	n	8	11	3	50,50,50,50	\$20,000	\$20,400	\$20,808	\$21,224	\$82,432
Transcription Droid 202	BA	Transcription	n	8	9	1	0,30,30,10	\$0	\$3,000	\$3,060	\$1,121	\$7,181
Transcription Droid 203	BA	Transcription	n	8	9	1	0,30,30,10	\$0	\$3,000	\$3,060	\$1,121	\$7,181
Personnel Subtotals:								\$160,000	\$169,200	\$172,584	\$177,036	\$678,820
Primary Site Non-personnel costs												
Equipment (Enter Total from Justification)								Year 1	Year 2	Year 3	Year 4	Total Cost

- The final budget should closely reflect the original budget and **not exceed the original total**. All changes must be identified and explained in the justification. **Budget increases must be approved by HSR leadership but this year, no increases are anticipated to receive approval.**
- For each site, list VAMC name, city, and state. If Central Office, list VACO.
- The PI or Site PI responsible for project activities should be listed first on the Summary Budget Table and Justification for each site.
- Clinical Duties/Appointment (yes/no)
- Include the budget total (sum of all sites and project years) at the bottom of the Summary Budget Table.



Personnel

VA Personnel (include transcription staff done in-house)	Degree	Project Role	Clinical Duties/ Appointments	VA FTE (Number of eights)	Grade	Step	% Effort for each project year	Year 1 Salary+Fringe	Year 2 Salary+Fringe	Year 3 Salary +Fringe	Year 4 Salary+Fringe	Total Cost
Luke Skywalker	PhD	R	n	8	15	4	0,20,20,25	\$30,000	\$30,600	\$31,212	\$36,836	\$128,648
Anakin Skywalker	MD	Co-I	y	8	14	8	0,10,10,10,	\$0	\$0	\$0	\$0	\$0
Boba Fett	PhD	Co-I	n	5	13	9	0,10,10,10,	\$10,000	\$10,200	\$10,404	\$10,612	\$41,216
Jabba the Hutt	PhD	Co-I	n	5	13	6	0,10,10,10,	\$10,000	\$10,200	\$10,404	\$10,612	\$41,216
Rey Skywalker	PhD	Co-I	y	8	13	1	0,10,10,10,	\$0	\$0	\$0	\$0	\$0
C-3PO	MS	Proj Coord	n	8	12	1	0,50,50,50,	\$35,000	\$35,700	\$36,414	\$37,142	\$144,256
R2D2	MS	Programmer	n	8	12	1	0,50,50,50,	\$35,000	\$35,700	\$36,414	\$37,142	\$144,256
Assistant Droid 3YA	BA	Res Asst	n	8	11	3	0,50,50,50,	\$20,000	\$20,400	\$20,808	\$21,224	\$82,432
Statistics Droid 112	MS	Postausiua	n	8	11	3	0,50,50,50,	\$20,000	\$20,400	\$20,808	\$21,224	\$82,432
Transcription Droid 202	BA	Transcription	n	8	9	1	0,30,30,10	\$0	\$3,000	\$3,060	\$1,121	\$7,181
Transcription Droid 203	BA	Transcription	n	8	9	1	0,30,30,10	\$0	\$3,000	\$3,060	\$1,121	\$7,181
Personnel Subtotals:								\$160,000	\$169,200	\$172,584	\$177,036	\$678,820

- List all terminal degrees of all VA personnel (MD, PhD, RN, MS, etc.).
- List grade and step of all personnel, including MDs.
- Salaries may not exceed Office of Personnel Management locality salary rates.
- Salaries may include routine anticipated personnel actions (e.g., within grade increases) but may not include planned promotions or other non-routine HR actions.
- A maximum 2% cost-of-living adjustment (COLA) per year is allowable.
- PIs and Site PIs must have a local ePromise account to receive funds.
- PIs and Site PIs must be $\geq 5/8^{\text{th}}$ VA, unless there is an approved waiver.
- Ensure that personnel names, degrees, roles, grade/step, effort levels/ calendar months, salary and fringe are consistent in the Summary Budget Table and Budget Justification, or the budget will be returned for revision.



HSR Budgetary Guidelines

Services Rendered By Individuals

	VA Employees			Non-VA Employees			
	Non-clinicians	Clinicians		Non-clinicians	Clinicians		
		Licensed Medical Professionals	MD		Licensed Medical Professionals	MDs and Dentists <u>NOT</u> licensed in the US and providing NON-CLINICAL services	MD licensed inside US (including residents)
Personnel Section	OK	OK if GS employee or if Title 38 Waiver granted by CRADO for services beyond clinical care	OK, if time is contributed; Physicians and Dentists who are not licensed to practice in the US may request salary, but they must be clearly identified as such in the budget justification section.	<i>Not allowed</i>	<i>Not allowed</i>	<i>Not allowed</i>	<i>Not allowed</i>
IPA Section	<i>Not allowed</i>	<i>Not allowed</i>	<i>Not allowed</i>	OK	OK if budget justification states no clinical responsibilities	Ok if not licensed in US and has no clinical responsibilities	<i>Not allowed</i>
Contract Section	<i>Not allowed</i>	<i>Not allowed</i>	<i>Not allowed</i>	<i>Not Allowed. Contracts should be with the entity/agency providing the service who will then assign their employees. Contracts are for services, not individuals.</i>			
Consultant Section	<i>OK if no salary compensation</i>	<i>OK if no salary compensation</i>	<i>Ok if no salary compensation</i>	OK	OK only if stated as performing non-clinical services	OK, can be paid consultant fee	OK if no consultant fee.



Personnel

- **Only VA employees** should be listed under personnel. All non-VA project staff should be identified in the justification as non-VA.
- Do not request salary (VA or non-VA) for any licensed medical professional with clinical responsibilities (Hybrid Title 38 occupations with clinical appointments).
- Salary support for licensed medical professionals (e.g., psychologist, nurse) who are General Schedule (GS) employees and do not have clinical responsibilities may be requested, but the Summary Budget Table and justification must indicate that they do not have any clinical responsibilities.
- Salary support for licensed medical professionals in clinical positions **may not** be requested, unless they have a Title 38 Waiver approved by the HSR Director. Refer to RFA for waiver instructions.
- Physicians may not be paid unless they were credentialed outside the U.S. or are not licensed.
- VA personnel hired using the 2210 job series cannot be paid using HSR funds. If performing tasks related to IT, confirm in the justification that the person identified (or TBH) “is a non-2210 IT employee.”
- Waivers may be approved for special circumstances. Please contact your SPM.



Personnel Budget Justification

Primary Site: Tatooine VAMC, Mos Eisley, Tatooine

Personnel

Luke Skywalker, Ph.D., Principal Investigator, (GS 14/3; 5/8th VA; 2.4 calendar months; Year 1 salary \$21,874, fringe \$6,562; Year 2 salary \$22,968, fringe \$6,890; Year 3 salary \$23,427, fringe \$7,028). Dr. Skywalker will oversee all aspects of the project. He will hire, train, and supervise all study personnel at the Mos Eisley site and organize and lead the initial training for personnel at both study sites in Year 1. He will provide oversight of all aspects of participant recruitment, enrollment and retention, intervention delivery, data collection, analysis and dissemination. **In Year 2, there is a step increase to 14/4.**

Jabba the Hutt, Ph.D., Co-Investigator (GS 14/4; 5/8 VA; 1.2 calendar months Year 1, 0.6 calendar months Years 2-3; Year 1 salary \$10,443, fringe \$3,133; Year 2 salary \$5,326, fringe \$1,598; Year 3 salary \$5,432, fringe \$1,630). Dr. Hutt is a licensed Clinical Research Psychologist based at the MIRECC affiliated with the Veterans Affairs Medical Center in Mos Eisley, where he specializes in research on family interventions. **He will assist Dr. Skywalker and his team in the creation and implementation of treatment strategies for adapting standard family communication training to accommodate emotion processing deficits.**



Additional Sites and Consultants

Site 2: <i>Mandalore VAMC, Sundari, Mandalore</i>								
VA Personnel (include transcription staff if done in-house)	Degree	Project Role	Clinical Duties/ Appointments	VA FTE	Grade	Step	% Effort for each project year	Year 1 Salary+Fringe
Din Djarin	PhD	Co-I	y	8	14	3	10,10,10,10	\$10,000
Bo Katan Kryze	PhD	Co-I	n	6	13	3	5,5,5,5	\$5,000
Satine Kryze	MS	Statistician	n	8	12	2	5,10,20,20	\$4,000
BB8	MS	Proj Coord/ Programmer	n	8	12	5	50,50,50,50,	\$30,000
Personnel Subtotals:								\$49,000
Site 2 Non-personnel costs								
Equipment (Enter Total from Justification)								Year 1
Equipment Subtotals:								\$0
Site Travel (Enter Total from Travel Table in Justification)								Year 1
								\$1,000
Travel Subtotals:								\$1,000
All Other: Consultants, IPAs, Supplies, Contracts, Participant Payments, Services (e.g., transcriptions), etc. (Itemize) (No IT expenses)			Degree (if consultant)	VA or non-VA (if consultant)				% Effort for each project year (if IPA)
Consult - Fennec Shand			PhD	non-VA				\$2,500
Participant Payments								\$800
IPA - Grogu					5,5,5,5			\$8,000
All Other Subtotals:								\$11,300
Site 2 Totals:								\$61,300
Site 3: <i>Alderaan VAMC, Aldera, Alderaan</i>								
VA Personnel (include transcription staff if done in-house)	Degree	Project Role	Clinical Duties/ Appointments	VA FTE	Grade	Step	% Effort for each project year	Year 1 Salary+Fringe
Princess Leia Organa	MD	Co-I	Y	6	15	2	5,5,5,5	\$0
Bail Organa	MS	Res Asst	N	8	12	1	20,20,20,20	\$15,000

All site information should be grouped. List Site PI first.

VA employees cannot be paid as consultants.

Limited to \$500 per consultation and \$2,500 per project year. Clearly explain the involvement of each consultant with regard to the proposed research, and the nature of the service to be provided.



Equipment and Supplies

Primary Site Non-personnel costs											
Equipment (Enter Total from Justification)				Year 1	Year 2	Year 3	Year 4	Total Cost			
Equipment				\$5,000	\$0	\$0	\$0	\$5,000			
Equipment Subtotals:				\$5,000	\$0	\$0	\$0	\$5,000			
Site Travel (Enter Total from Travel Table in Justification)											
Travel				\$5,000	\$2,000	\$2,000	\$2,000	\$11,000			
Primary Site Travel Subtotals:				\$5,000	\$2,000	\$2,000	\$2,000	\$11,000			
All Other: Consultants, IPAs, Supplies, Contracts, Participant Payments, Services (e.g., transcriptions), etc. (Itemize) (No IT expenses)		Degree (if consultant)	VA or non-VA (if consultant)			% Effort for each project year (if IPA)				-	
Consult - Yoda		PhD	non-VA				\$2,500	\$2,500	\$2,500	\$2,500	\$10,000
Contract - Tuscan Raiders							\$0	\$25,000	\$25,000	\$12,000	\$10,000
Participant Payments							\$1,200	\$3,600	\$3,600	\$0	\$62,000
Recorders							1,000				\$1,000
											\$0
											\$0

- Itemize each category (personnel, equipment, travel, all other) separately in budget justification.
- Audio voice recorders (VA approved) should be categorized as supplies and need ISO approval. **NOTE: VA TEAMS and Webex can be used to record but Zoom is not approved for recording.**
- For equipment and supplies, note in justification the post project disposition.
- General office supplies should be provided by your VAMC. If supplies requested are not standard office supplies and/or not available from the medical center, please note this in the justification.
- Do not include computers or other IT equipment in your budget request. If an item sounds like it might be IT-related, note in justification that you have already consulted with local OI&T and confirmed that item is non-IT.



IT Budget

- Research funds may not be used to pay for IT purchases, with one exception: Atlas, Nvivo, and other scientific software may be purchased using research funds as it is considered “scientific computing.” It should be listed under All Other in the Summary Budget Table and justification.
- SAS and SPSS may be used in VINCI platform so they are not approved for purchase.
- There is currently no approved process to issue VA-owned laptops, tablets or other mobile devices to research subjects.
- IT approved voice recorders can be purchased with research funds.
- If you are requesting IT funds from your facility, please ask your local CIO to sign-off on the request indicating ability to provide funds and include this in the budget materials you upload to JIT.
- For more information about Research Information Technology, refer to the ORD 2022 Research IT FAQs and Guidance document (updated March 2022), located here: [Human Research \(va.gov\)](#)



Travel

- Well justified travel for essential project meetings may be included in the project budget
- Travel support is not authorized for non-VA employees but may be included in the contract or IPA mechanism for such staff with instructions to follow GSA and VA travel policies.
- Merit awards (not pilots) may request up to \$1,500 in travel funds for presentation of final results. This is a one-time opportunity that must occur before the project ends and be included in your budget.
- Professional Development Travel (not final presentation)
 - PIs who are not affiliated with a COIN may request support (up to \$1,200 per year) for PI or designee participation in a scientific meeting or other professional development activity.
 - **COIN-based PIs** may not request Professional Development funds as all COINs receive Professional Development funds in their annual budgets for allocation at the discretion of the COIN leadership.



Travel Summary Budget Table

Enter total travel budget for each year and site as a line item in the Summary Budget Table and provide details in the Budget Justification.

Site Travel						
Enter total from (Travel Table in Justification)						
Travel					\$3,080	

Budget Justification

- Itemize travel costs for each required trip in a table in the justification. Include travel that is directly related to the conduct of the research.

Traveler	Role	Travel Period	Purpose	Destination	Days/Date	Lodging	Per Diem	Transportation X-wing fighter	Miscellaneous (tips, etc.)	Estimated Cost
Luke Skywalker	PI	Year 1	Train staff on Implementation	Mandalore VAMC Sundari, Mandalore	2 days	\$295	\$110	\$1,200	\$20	\$1,625
Jabba the Hutt	CO-INV	Year 1	Train staff on Implementation	Alderaan VAMC, Adera, Alderaan	2 days	\$325	\$120	\$1,000	\$10	\$1,455

- Round trip transportation (e.g., air, train, POV), hotel, and per diem rates must align with approved government rates. Travel estimates may be calculated by your local Travel Office or by using this resource: [GSA Travel Guidance](#). The standard estimate for Ground Transportation approved by HSRD Finance is \$150 per traveler.



Other Direct Costs

All Other: Consultants, IPAs, Supplies, Contracts, Participant Payments, Services (e.g., transcriptions), etc. (Itemize) (No IT expenses)	Degree (if consultant)	VA or non-VA (if consultant)	Travel Subtotals:		% Effort for each project year (if IPA)	\$1,000	\$0
Consult - Fennec Shand	PhD	non-VA				\$2,500	\$2,500
Participant Payments						\$800	\$240
IPA - Grogu					5.5.5.5	\$8,000	\$5,000
All Other Subtotals:						\$11,300	\$7,740

- HSR is an intramural research program; it is expected that VA staff will be hired to perform the research and provide needed expertise.
- Contracted services and/or IPAs may not EXCEED 30% (COIN) of the proposed total budget (40% for non-COIN) unless approved via waiver during the proposal submission process.
- Justify the use of IPA agreements. An IPA is not a contract. It is an OPM registered agreement with a University or Federal Agency. An IPA must name both the individual (in the Summary Budget Table and Justification) and the University or Agency (in the Justification).
- VA employees cannot be paid by IPAs.
- Clinicians (e.g., MDs, RNP, PA, etc.) cannot be paid via IPAs unless they are not licensed in U.S. and then they may be paid for non-clinical work.
- Contracts are for services, not people and must go through local contracting. Describe the service; do not identify the individual(s) who will provide the service.
- You may not contract for clinical services.
- The site should be where the funds are to be sent, not the location of the IPA/contract.



Other Direct Costs: Participant Payments

All Other: Consultants, IPAs, Supplies, Contracts, Participant Payments, Services (e.g., transcriptions), etc. (Itemize) (No IT expenses)	Degree (if consultant)	VA or non-VA (if consultant)	Travel Subtotals:		% Effort for each project year (if IPA)	\$1,000	\$0
Consult - Fenner Shand	PhD	non-VA				\$2,500	\$2,500
Participant Payments						\$800	\$240
IPA - Grogan					5,5,5,5	\$8,000	\$5,000
All Other Subtotals:						\$11,300	\$7,740

- References to “participant incentives” or “participant reimbursements” must be changed to “participant payments.”
- Do not specify that participant payments will be made by gift cards; rather, specify that participant payments will be processed in accordance with locally approved procedures.
- If the project plans to pay non-physician VA employees for participation in research, the research team needs to contact their local OGC STAR (Specialty Team Advising Research) for guidance. It is recommended that this is done prior to IRB submission.
- Payments to physicians or VA employees for serving as research participants are not authorized unless they are participating outside of tour of duty.
- Planned participant payments should be presented in a table that clearly shows how the total amount was calculated.



Centralized Transcription Services Program (CTSP)

Use of CTSP services is not mandatory.

If using CTSP and the CTSP quote is >6 months old, you are required to obtain a new quote and append it to the budget justification.

Budget:

- If Salt Lake City (SLC) is not already a research site:
 - SLC should be added as an additional site to the budget with Susan Zickmund listed as the site PI responsible for the funds sent to and the work performed by CTSP.
 - For Dr. Zickmund's percent effort, please list "N/A" and list her salary as "contributed." See Budget Guidance for correct justification language.
 - In addition, list "CTSP Transcription Services" along with associated funds under "Other" on the budget.
- If SLC is already a research site:
 - Do not list Susan Zickmund as PI or Co-I.
 - Please only list "CTSP Transcription Services" along with associated funds under "Other" on the budget.



When submitting a revised budget

- Always update the **version date (DATE OF THIS SUBMISSION)** in the header of the Summary Budget Table when submitting to JIT.

HSR SUMMARY BUDGET TABLE (version date: 10/2023)			
PI Name & Degree:	HSR Project ID:	eRA ID:	Current Version Date:
Project Title:			IMPI Name & Degree:
Original Budget Amount (from approved proposal): \$	Current Budget Request (from below): \$	Project Duration (months):	PI site: ** Save file as: [PI last name&project id] Budget Table [date]

- At the top of the summary budget table, please note the duration of the study (e.g., 48 months).
- Include both the HSR Project ID (e.g., IIR xx-xxx) and the eRA ID.
- Always include both the Summary Budget Table AND Budget Justification.
- Budget Justifications: Please include 'Budget Updates' at the beginning of the budget justification. You should summarize your responses by item to all budget action points. Also describe in the narrative justification any other changes from the original proposal budget. **The total budget should not exceed the total amount requested in the original proposal.**



CDA Budget Note

Current CDA awardees and those submitting revised applications are **not eligible** for the increased supplemental research support (\$75,000 per year x 5 years) in the currently posted RFA.

Supplemental research support for CDA-2 budgets for new awardees, current awardees, and resubmissions is capped at \$40,000 per year for the first 3 years for awardees based at COINs and \$50,000 per year for the first 3 years for all other awardees.

Start Dates

Once you **complete** JIT requirements, you can select a date to start.

- Due to budget constraints, the earliest start dates for projects from this round will be October 1
- Requests for earlier start dates will be considered on a case-by-case basis depending on the availability of funds
- Start dates are only on the 1st of the month
- Continuing Resolutions (temporary spending bills) may impact start dates.





ORD Budget Tips and Reminders


- Request monthly budget reports from the Research Office to ensure your budget is being executed as intended.
- If project delays or other circumstances impede your ability to spend allocated funds in a given year, return the funds to HSR so they can be used elsewhere. If the funds will be needed later in the project, submit a project modification as early as possible to request and justify redistribution of funds to later fiscal years.
- Be aware that Finance will sweep surplus funds in excess of 2% at the end of each fiscal year; they will be lost to your project and our program.

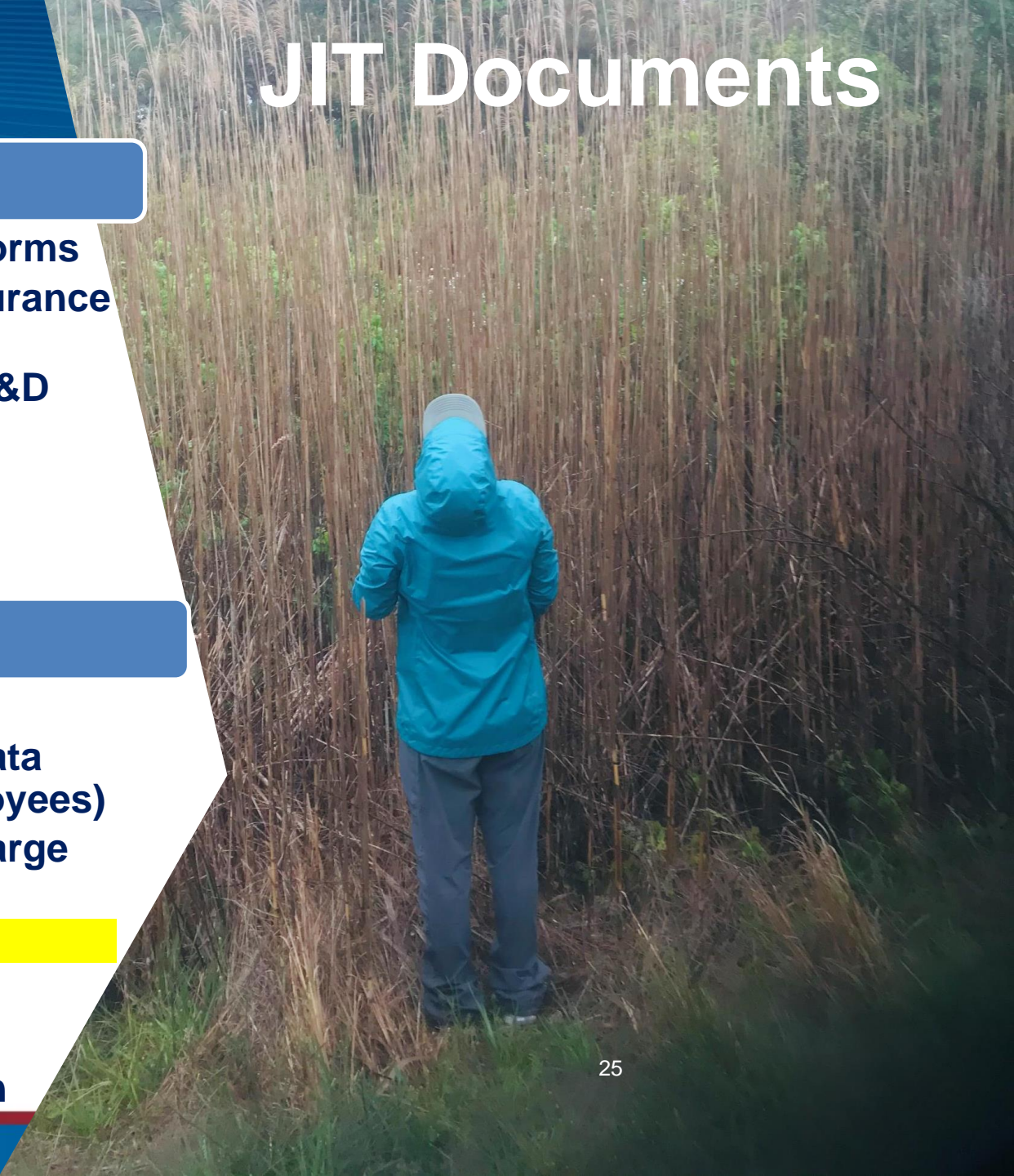




JIT Documents

For all studies:

- PI/Local Site Assurance Forms
 - PI/Local Site ACOS/R Assurance Forms
 - IRB determination and R&D approval
 - Quad Chart
 - Budget Summary Table & Justification
-
- Non-Veteran Waiver
 - Union Notification (for data collection from VA employees)
 - OASC Review (for very large surveys of staff)
 - 
needed
 - DSMB plan approval
 - Clinical Trial Registration





PI, MPI, Local Site PI Assurance Forms

- **Required for all PIs, MPIs, and Site PIs, even if no study funds are received by that site**
- **Attest to the PI's (or MPI or Site PI) agreement to comply with VA regulations policies, including those concerning intellectual property, progress report requirements, and acknowledgement of VA support in all publications, in accordance with VA Handbook 1200.19**
- **All PIs, MPIs, and Site PIs must be registered in ePromise at their local VAMC**



ACOS/R&D Assurance Forms

- **Attest to local R&D Committee approval, including all relevant research subcommittees (e.g., IRB) as well as the investigator's eligibility to receive VA funding based on VA employment status**
- **Required from each site that is engaged in the research and/or receiving funds**



Engagement in Research

- An institution is “engaged” in human subjects research when its employees or agents obtain for the purposes of a research project:
 - Data about the subjects of the research through intervention or interaction with them;
 - Identifiable private information about the subjects of the research; or
 - The informed consent of human subjects for the research
- See [Engagement of Institutions in Human Subjects Research \(2008\) | HHS.gov](#) for more detail.
- A site is engaged if a co-investigator is located at that site or if funds are going to that site.
- If IRB oversight is not required (non-applicable), then only the R&D Committee approval needs to be submitted with the ACOS form. Please upload the IRB’s determination that IRB oversight is not required.



IRB: Local or Central?

**1 site = Local IRB or
Determination
Committee**

**2 or more sites = VA
CIRB**





VA Central IRB

All CIRB applications must be submitted through IRBNet

https://www.research.va.gov/programs/orppe/vacentralirb/irb_submissions.cfm

Website address: gov.irbnet.org

- PIV Login
- Accessible from outside the VA network

Information on how to register for IRBNet (VAIRRS University for research teams):

<https://dvagov.sharepoint.com/sites/VHAORPPE/VAIRRS/SitePages/New-User-Registration.aspx>



Welcome to IRBNet

Not registered yet? [Register Now](#) to get started!

If you are already registered on govCloud you can log in

or log in with your PIV card? (If you have not yet been logged in to your network.)

Forgot your Username or Password? Click here for help.

Username:

Password:










Notice: This system processes U.S. Government information and is for the sole use of authorized personnel for official business only. This system and any related equipment, network, data and usage are subject to monitoring, recording and audit. Unauthorized use of this system is prohibited and may be subject to criminal and civil penalties. By accessing this system, you consent to monitoring and recording of your use of this system and to the terms set forth in this notice.












ePROS Resource SharePoint

[ePROS Communication Page for VHA Researchers \(sharepoint.com\)](#)







Tools

-  [FIND Pro](#)
-  [ORD RISE- Coming Soon!](#)
-  [Research Law Explorer](#)
-  [SOPHIA Knowledge Management System](#)
-  [VA Innovation and Research Review System...](#)
-  [VA Electronic Determination Aid \(VAEDA\)](#)
-  [REDCap- Electronic Data Capture by VIREC](#)
-  [VAIRRS Dashboards \(or scroll down this page\)](#)
-  [Webinars- Upcoming and Recorded](#)



ePROS Webpages

-  [Education](#)
-  [OSIRES \(EHRM and Research Team\)](#)
-  [Policy](#)
-  [Training Requirements- Animal Research](#)
-  [Training Requirements- Human Subjects Protection](#)
-  [VA Information Resource Center \(VIREC\)](#)
-  [VA Animal Research Program](#)
-  [VA Central Institutional Review Board \(IRB\)](#)
-  [VA Informatics and Computing Infrastructure \(VINCI\)](#)
-  [VA Technology Transfer Program \(TTP\)](#)

Submit a Request

-  [DocuSign](#)
-  [VA Box.com](#)
-  [Qualtrics](#)
-  [Field Enterprise Research Support Services \(FERSS\)](#)
-  [Proactive Calling](#)
-  [Single IRB Exceptions](#)

Local Research Office Contact Updates

-  [Instructions and Update Form](#)
-  [Forms and Templates for change in VA CIRB Signatory Official](#)



VA Central IRB in IRBNet

USER PROFILE LOGOUT



Welcome to IRBNet
Don Workman

Forms and Templates

These libraries have been made available to you by your Boards so that you can easily download blank forms, document templates and reference materials to assist you in your work.

Select a Library:

VA Central IRB Administration, Washington, DC - Documents for Researchers



- Submission Manager
- Agendas and Minutes
- My Projects
- Create New Project
- My COI
- My Reminders (5407)

- Other Tools
- Track Training
- Forms and Templates
- Library Manager

Documents in this Library:

Document Description	Last Updated	
-Guidance 000 CIRB Table of Reporting Requirements V1	06/28/2023 09:55 AM	
-Guidance 001 Flowchart: PI and LSI New Project Submission Process	11/02/2023 04:27 PM	
-Guidance 001 Instructions: PI and LSI New Project Submission Process	01/08/2024 06:49 PM	
-Guidance 002 Flowchart: PI and LSI Exempt Project Submission Process	11/02/2023 04:28 PM	
-Guidance 002 Instructions: PI and LSI Exempt New Project Submission Process	01/08/2024 06:49 PM	
-Guidance 003 Instructions: Creating a New Project in IRBNet	09/30/2021 12:47 PM	
-Guidance 004 Instructions: Creating a New Package in IRBNet	09/30/2021 12:50 PM	
-Guidance 005 Instructions: Multi-Site Projects in IRBNet	10/17/2023 10:54 AM	
-Guidance 006 Instructions: ERDSP Guide V 2.2	03/01/2022 12:19 PM	
-Guidance 007 Flowchart: Co-PIs at Different VA Facilities	11/02/2023 04:29 PM	
-Guidance 007 Instructions: Co-PIs at Different VA Facilities	01/08/2024 06:49 PM	
ERDSP Template V2.7 Amendment 2	04/27/2022 01:30 PM	
Form 100 Protocol Template V1.1	01/22/2024 05:24 PM	
Form 101 Protocol Template - Data Specimen Only V1.1	01/22/2024 05:24 PM	
Form 102 Local ACOS Review V1	06/28/2023 01:44 PM	
Form 103 Waiver of HIPAA Authorization V1	06/28/2023 01:44 PM	



VA Central IRB in IRBNet

Documents in this Library:

Document Description

- Guidance 000 CiRB Table of Reporting Requirements V1
- Guidance 001 Flowchart: PI and LSI New Project Submission Process
- Guidance 001 Instructions: PI and LSI New Project Submission Process
- Guidance 002 Flowchart: PI and LSI Exempt Project Submission Process
- Guidance 002 Instructions: PI and LSI Exempt New Project Submission Process
- Guidance 003 Instructions: Creating a New Project in IRBNet
- Guidance 004 Instructions: Creating a New Package in IRBNet
- Guidance 005 Instructions: Multi-Site Projects in IRBNet
- Guidance 006 Instructions: ERDSP Guide V 2.2
- Guidance 007 Flowchart: Co-PIs at Different VA Facilities
- Guidance 007 Instructions: Co-PIs at Different VA Facilities
- ERDSP Template V2.7 Amendment 2

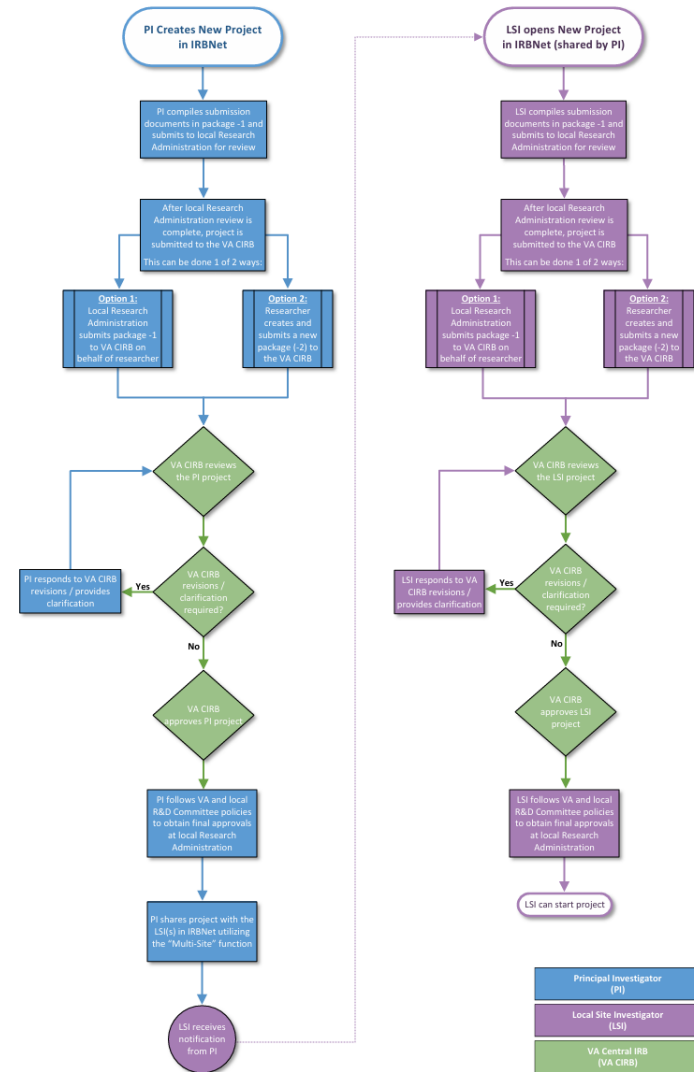




VA CIRB Steps

1. PI creates new project in IRBNet, and assigns access for study team and local research office (read/write, or write)
2. PI/Coordinator compile submission documents in package and submits to local Research Administration for review
3. After local Research Administration review is complete, project is submitted to the VA CIRB

VA Central IRB PI and LSI New Project Submission Process

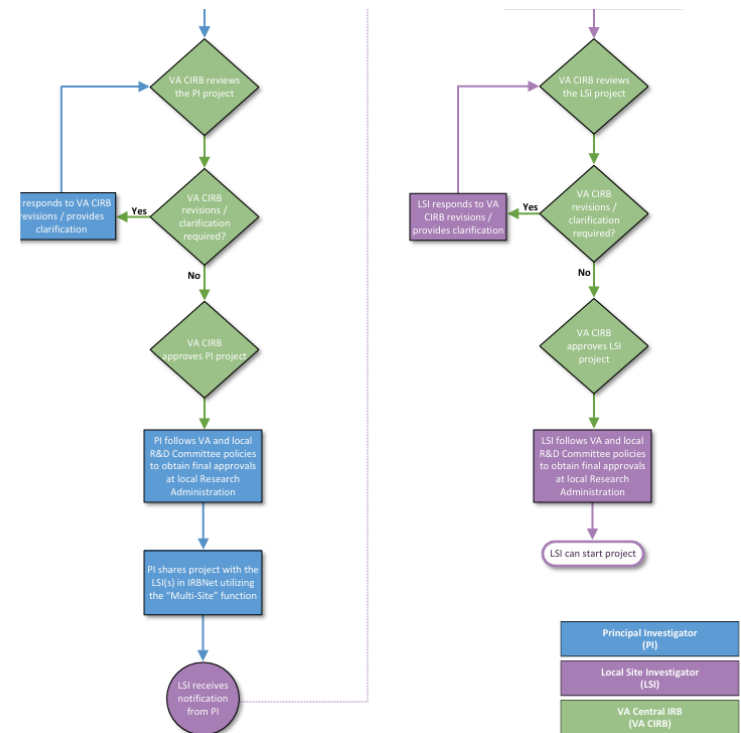


NOTE: Local accountability occurs throughout the VA CIRB review process.



VA CIRB Steps

4. VA CIRB reviews PI Application
 - a) CIRB revisions / clarification required?
 - b) PI submits revisions as applicable
 - c) CIRB reviews the PI/SC project
 - d) CIRB approves PI/SC project and LSI
5. CIRB makes final approval decision on application
6. PI may now share the project with the LSI's in IRBNet utilizing the "Multi-Site" function.





Tips for Success with VA CIRB

- **Start Now, not in the last weeks before JIT deadline.**
- **Thoroughly review documents prior to submission**
- **If you are a first-time user of the CIRB, reach out to us for an initial planning meeting.**
- **Respond timely to CIRB questions and requests**
 - **Process works best when we both respond quickly**
- **Avoid consecutive amendments – they slow the process**
 - **Group your changes when possible – try to limit to 2/year (not a requirement, just a request)**
 - **Downstream effects of changes is hard on LSIs and CIRB staff and IRB reviewers**



CIRB

For clarification about whether a particular HSR funded study requires VA CIRB review, please consult with the HSR Scientific Program Manager assigned to the study.

Contact CIRB with Questions and Clarifications.

- **Email:** vacentralirb@va.gov
- **Visit:** [VA Central Institutional Review Board \(IRB\)](#)



Quad Chart

Project Quad Chart presents a brief snapshot of the study across four quadrants of a single PowerPoint slide. They are shared with ORD leaders for review and discussion as well as at cross-agency reviews. Please refer to the [JIT instructions](#) for the Quad Chart template and instructions.

- **Quadrant 3: Graphic Representation of the Most Significant Scientific Problem or Approach**
- **Quadrant 4: Timelines**
This should reflect the timeline in Gantt Chart format with measurable milestones. If a 1-2 Year project, time may be by months or quarters. Activities should be specified and not just identified as aims.

Month →	1-2	3	4-5	6-7	8	9	10-12
Recruitment							
Implement prehabilitation							
Data collection							
Analysis							
Report writing and IIR development							



Non-Veteran Waiver

Any ORD study that enrolls Non-Veterans is required to submit a Non-Veteran waiver. Non-Veteran includes employees and caregivers.

Follow directions closely. If you have questions, contact SPM.

Department of Veterans Affairs

Memorandum


Date:

From: Enter PI Name:
Thru: ACOS for Research and Development (151)
Enter VAMC Station/Location:

Subj: Waiver for non-Veteran Enrollment in VA Sponsored Research Director,

To: Health Services Research and Development (HSRD) (14RDH)

1. I am the principal investigator on the proposed HSRD study entitled:
2. I am requesting authorization to enroll non-Veterans in this research study.
3. I understand that research funded by HSRD must be focused on improving the quality of healthcare/well-being of Veterans and/or ailments specifically affecting the Veteran population served by VHA. For greater than minimal risk studies, I understand that you require a written risk assessment from the Principal Investigator (i.e., for purposes of this waiver, risk pertains to non-Veterans). My justification for enrolling non-Veterans in this protocol are described below. The justification clearly describes the nature of the risk, and my plan to mitigate risk. The mitigation plan includes (1) a description of how non-Veteran data will be protected, (2) where non-Veteran data will be stored, and (3) who will have access to non-Veteran data.


4. I understand that if the Director, HSRD approves this request I must obtain approval from my facility R&D Committee to enroll the proposed non-Veteran research subjects.
5. Thank you for your consideration in approval of this request.



Data Collection: Requirements for Surveys & Interviews

Requirement	Participants	Modality	Criteria
Union Notification	VA Employees	Surveys & Interviews	Local, VISN, or National (see next slide)
OASC Review	VA Employees	Surveys	>10.000 participants or >20 sites

<https://www.research.va.gov/resources/oasc.cfm>



Union Notification: Surveys & Interviews Involving VA Employees

Prior union notification is required for all data collection (e.g., interviews, surveys) involving VA personnel when asking bargaining unit employees about conditions of employment.

Note: Some clinicians, including physicians, are bargaining unit employees.

- **Facility Level**
 - Contact local HR for approval. Upload document acknowledgement to JIT when received from HR.
- **VISN Level**
 - Contact VISN HR for approval. Upload document acknowledgement to JIT when received from HR.
- **National (across more than one VISN)**
 - Submit National Union Notification Packet to ORD via JIT and vhacohsrdjit@va.gov
 - HSR will work with the Office of Labor Management Relations (LMR) to contact relevant national unions. ORD will notify PI when LMR concurrence is received.



National Union Notification

Please compile the following information into a single PDF file; upload the PDF file in the Miscellaneous JIT area and submit it to vhacohsrdjit@va.gov

- **Overview**

- Brief description of the study

- **Data Collection**

- Details re: type of data collection (surveys and interviews), including time required for participation
- Number and type of VA personnel from whom data will be collected
- Anticipated timeline for data collection (start and end dates)
- List of the sites from which VA personnel will be recruited
- Study team contact information

- **Final*** Versions of all Data Collection Instruments

- Each data collection instrument must include an explicit statement that participation is voluntary, anonymous, and confidential.
 - 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.

****If surveys/interviews will not be conducted until later in the study, please work with your SPM to clear JIT in the interim and submit union notification request at a later date.***



OASC Review

Large Multi-Site Surveys of VA Employees

Organizational Assessment Sub-Committee (OASC) Review is required for all research and operations surveys that involve VA employees and meet at least one of the following two criteria:

- Administered to $\geq 10,000$ VA employees
- Administered to VA employees across 20 or more sites

Note

- OASC has no jurisdiction over surveys to Veterans.
- OASC only has authority to review surveys (paper-and-pencil or web-based) and not interviews.



OASC Review: Submission Instructions

- **Send surveys that have received IRB approval to David Mohr (David.Mohr2@va.gov)**
- **Send surveys that do not have IRB approval to VHAOASC@va.gov for review by the sub-committee. *A response is typically provided within a few weeks.***
- **Submit project abstract, a description of the survey, a sampling plan, and the following information:**
 - 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 by the organization
 - Plan for feedback to the target audience
 - 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



Clinical Trials Registration

ORD is committed to informing Veterans and the public about its research and maximizing the impact of the studies it supports, including requiring public registration and reporting of results for clinical trials.

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.”

Registration and reporting also help ensure that studies meet journal requirements for publication and may be required by federal law.



Clinical Trials Registration

Registration Process ([ClinicalTrials.gov](https://clinicaltrials.gov))

1. Consult with assigned SPM to determine whether the study meets the definition and should be registered.
2. **WAIT** until all other JIT requirements have been met.
3. Once the Clinical Trials Registration area is activated, the Contact PI will receive an email sent to their VA email account from ART about how to register with clinicaltrials.gov.

Do NOT register VA-ORD funded studies with [ClinicalTrials.gov](https://clinicaltrials.gov) until you received an email from ART with the instructions. Please check your VA email.

https://www.research.va.gov/resources/ord_admin/clinical_trials/default.cfm



HSR Data and Safety Monitoring Board (DSMB)

- **Provides ongoing evaluation of study progress, including participant accrual and retention, adverse events, and the adequacy and efficiency of the analysis plan to discern outcomes that might require study modifications or result in early cessation of the study due to its benefits or harms.**
- **Oversight is accomplished by an independent review board chartered by HSR that meets at specified intervals and requires routine reporting from the PI.**



DSMB Referral & Requirements

- Referral for review by the HSR DSMB is determined by the SPM at the time of funding decisions.
- General criteria for referral
 - Multi-site clinical trials
 - Studies recruiting from multiple locations (even within a single VAMC)
 - Studies with potentially complicated analytical plans
 - Low-risk studies that are exceptionally large, long term, and/or involve vulnerable subjects
- Studies referred to the HSR DSMB must submit a Data Analysis Plan (DAP) for review by the DSMB **within 45 days of JIT opening (December 14)**
- On rare occasions after review of the DAP, the DSMB may determine that a study does not require DSMB monitoring.



DSMB Data Analysis Plan (DAP) Requirements

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

Required DAP Elements

1. Sample size rationale
2. Detailed description of data collection process(es)
3. Randomization approach (e.g., stratification and blocking techniques), as appropriate
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.)
9. List and definition of adverse and serious adverse events to be monitored and plans for prospectively tracking.

DAPs should be uploaded into JIT within 45 days of JIT opening. (Dec 21)

- Include a statement of assurance with DAP documents indicating agreement to refrain from recruitment activity (as distinct from initiating the study itself) until DSMB DAP approval has been received.



Pre-funding Project Modifications

While in JIT, if you have a change from the original proposal in key personnel, site, aims and methods, or PI 8^{ths}, you need to submit a pre-funding project modification.

- Contact your SPM to explain why a change is needed and to request the Pre-funding Project Modification form**
- Once completed (PI signature only – no ACOS needed), please upload the Pre-funding Project Modification form in the Miscellaneous section of JIT.**

**Health Services Research and Development (HSR&D)
Pre-Funding Project Modification Form**

Instructions: Please review the “Pre-Funding Project Modification Form - Criteria and Instructions” document. The VA principal investigator (PI) should complete this form, sign it electronically, and email it to the local Research Office. The local Research Office should then upload the form and supporting documents to Just-in-Time (JIT) for the project. Check appropriate box (es) on left and follow instructions on right for all requested modifications.

Project Information

Project Title:

Project ID (e.g. IIR 12-345):

eRA Grant Number (e.g. I01HX1234-01):

Primary VAMC Location (City, State):



Intellectual Property

- ▶ Under VA regulations and policies all inventions must be disclosed to VA even if disclosed to your university affiliate.
- ▶ My invention is not patentable. Am I still required to submit a VA disclosure?

Federal law and regulations concerning inventions made by VA employees require disclosure, whether or not the invention is patentable.

Even if an invention is found not to be patentable, VA can pursue other opportunities with a commercial partner to further develop the invention.

Specifically, a Cooperative Research and Development Agreement (CRADA) provides management of any new discovery or intellectual property that may result from the collaboration.





Intellectual Property

The VA did not make any contribution to my invention. Am I still required to submit a VA disclosure?

Even if VA made no contribution towards an invention, i.e., the invention was made entirely outside official working hours, unrelated to VA employment, and with no use of VA facilities, equipment, etc., a VA disclosure is still required by Federal law.

Following disclosure, the Technology Transfer Program will review the file and make a recommendation regarding ownership to the Office of General Counsel (OGC).

OGC will review the facts presented in the disclosure and issue a legal determination of rights.



Intellectual Property

Should inventors refrain from publishing papers or making oral disclosures before a patent application is filed?

Inventors must **take extreme care not to disclose information** that would enable someone skilled in the **sale of the invention**.

Disclosure of any information prior to technology to which the invention pertains to make and/or use the invention. **Public disclosure could include talks, lectures, poster presentations, newspaper or newsletter interviews, all publications, public use, sale, or offer to filing appropriate paperwork with the Patent and Trademark Office (PTO) voids all international patent rights.** Domestic US patent rights are voided if appropriate paperwork is not filed with the PTO within one year of disclosure of pertinent invention information.

- **VA Technology Transfer Program (TTP)**
- **Email: vattid@va.gov**
- **https://www.research.va.gov/programs/tech_transfer/default.cfm**
- **Specialty Team Advising Research (STAR)** is a legal team dedicated to research issues.
<https://vaww.ogc.vaco.portal.va.gov/law/research/SitePages/Home.aspx>



Project Modifications

Once an Award starts:

- An approved Project Modification is needed for any changes in study budget, duration, distribution of funds across fiscal years or sites, aims, methods, key personnel (e.g., PI, MPI, Site PI, Co-I, or eighth changes)
- See guidance and required documents at: <https://www.hsrd.research.va.gov/funding/project-modification-notification.cfm>
- **RPPR is NOT a project modification mechanism.**





Best Practices for Fiscal Management

Maintain regular communications with your local ACOS and Research Administration.

Review status/budget reports monthly to identify and remediate problems early.

If there are issues with your study, contact your Scientific Portfolio Manager.



JIT Timeline

1. Start IRB immediately
2. June 7: Revised Budget due (4 weeks)
3. June 22: DAP due if required (6 weeks)
4. October 5 (150 days): JIT waiver if not going to clear in 180 days (November 4)
5. JIT progress must be demonstrated for a 180-day waiver to be approved



Q&A

For project-specific **JIT** questions, please contact the appropriate **JIT** Scientific Program Manager.

Expertise	Name	Email	Panel
JIT Scientific Portfolio Manager	Cathie Plouzek	Cathie.Plouzek@va.gov	HSR1
	Crystal Henderson	Crystal.Henderson@va.gov	HSR2
	Cathie Plouzek	Cathie.Plouzek@va.gov	HSR3
	Bob O'Brien	Robert.O'Brien2@va.gov	HSR4
	Amanda Borsky	Amanda.Borsky@va.gov	HSR5
	Bob O'Brien	Robert.O'Brien2@va.gov	HSR6
	Bob O'Brien	Robert.O'Brien2@va.gov	HSR7
	Kara Beck	Kara.Beck@va.gov	MRA0



Q&A

For general administrative questions, please contact:

Expertise	Name	Email
CDA		
QUERI	Kara Beck	<u>Kara.Beck@va.gov</u>
JIT Management	Jillian Holmes	<u>vhacohsrdjit@va.gov</u>
DSMB	Christine Nguyen	<u>Christine.Nguyen@va.gov</u>
CIRB	Don Workman	<u>Don.Workman@va.gov</u>
Intellectual Property	John Kaplan	<u>John.Kaplan@va.gov</u>
<u>http://www.research.va.gov/programs/tech-transfer/contacts.cfm</u>		



Please use the Q&A feature to submit questions.

Scaling new heights

VA



U.S. Department
of Veterans Affairs

VA OFFICE OF RESEARCH & DEVELOPMENT
HEALTH SYSTEMS RESEARCH

Thank you for attending

**Just-in-Time:
Your research project is
approved;
what are the next steps?**

May 8, 2024