

HSR&D Training: JIT: The Final Frontier

HSR&D and Finance Central Office Staff







Overview of Presentation

- Project Budget Process and Updated Guidance
- Quad Chart
- IRB
- Union Notification Data Collection Involving VA Employees
- OASC Review Surveys of 1000+ VA Employees or 10+ Sites
- OMB Exemptions Data Collection Involving Patients/Caregivers
- Clinical Trials Registration
- DSMB
- Q&A



Poll Question #1

What is your role?

(select one)

- Principal Investigator
- Budget/Financial Analyst
- Administrative Officer
- Project Manager/Coordinator or Other Support

Poll Question #2

What is your level of experience working on HSR&D project funding requirements?

(select one)

- None
- Beginner/novice level
- Intermediate level
- Advanced level



Poll #3: Common Problems

When you have a question regarding your budget or JIT documents, who do you ask?

(select one)

- Colleague
- Director
- Administrative Officer
- Scientific Portfolio Manager



HSR&D

Summary

Budget

Table

				SUMMAR	Y BU	JDGI	ET TA	ABLE				
Expense												
Primary Site Personnel (section A+B)	Degre e	Primary Site	Role	Clinical Responsibiliti es/Appointme nt	Grad e	Ste P	ž Effo rt	Year 1 Salary+Frin ge	Year 2 Salary+Fria ge	Year 3 Salary •Fringe	Year 4 Sələry+Frin ge	Total Project Cost
Einstein, Albert	PhD	Gainesville,	PI	N	13	8	30	29,535	29,535	29,535	29,535	118,141
Darwin, Charles	PhD	Gainesville,	Co-l	N	12	6	30		21,862	21,862	21,862	87,446
Blackwell,	MD	Gainesville,	Co-I	Y	15	5	10					
TBD		Gainesville,	RA	N	11	4			23,432	23,432	23,432	93,728
TBD		Gainesville,	RA	N	11	4 CL	50 total	23,432 98,261	23,432 98,261	23,432 98,261	23,432	93,728
					JILE	Juu	totai	30,201	30,201	30,201	30,201	
Additional Site Personnel	Degre e	Site	Role	Ulmical Responsibiliti es/Appointme	Grad e	Ste P	ž Effo rt	Year 1 Sələry+Frin ge	Year 2 Salary+Frin ge	Year 3 Salary •Fringe	Year 4 Salary+Frin ge	Total Project Cost
Sinatra, Frank	PhD	Seattle, WA	Co-I	Ň	10	2	25	22,678	22,678	22,678	22,678	90,712
Cass, Mama	RN	Seattle, WA	Project Coord.	N	7	4	50	31,684	31,684	31,684	31,684	126,736
Stevens, Cat	MS	Seattle, WA	RA	N	7	4	50	31,684	31,684	31,684	31,684	126,736
							total	86,046	86,046	86,046	86,046	
				Project Tota	l for F	ersc	nnel	184,307	184,307	184,307	184,307	*****
Consultant (section F3)	Degre e	Site		Clinical Responsibiliti es/Appointme				Year 1	Year 2	Year 3	Year 4	Total Project Cost
Buck, Pearl	PhD	Gainesville,		Ň				2,400	2,400	2,400	2,400	9,600
Fitzgerald, F. Scott	MA	Seattle, WA		N				2,400	2,400	2,400		9,600
Twain, Mark	MS	Seattle, WA		N				2,400	2,400	2,400	2,400	9,600
Equipment (total per site-do not itemize)								Year 1	Year 2	Year 3	Year 4	Total Project Cost
Gainesville, FL								2,000	0	2,000	_	
Seattle, WA								2,000	0	2,000	0	.,
Supplies (total per site-do not itemize)								Year 1	Year 2	Year 3	Year 4	Total Project Cost
Gainesville, FL								1,000	500	250		1,875
Seattle, WA								1,000	500	250	125	1,875
Project Travel (total from Travel Table do not itemize)								Year 1	Year 2	Year 3	Year 4	Total Project Cost
Gainesville, FL								1,800	이	2,300	0	4,100
Seattle, WA								1,440	0	780	0	2,220
Other (Section F 8/9/10+) (Do not list IT expenses from Planned IT	Degree	Site	% Effort	Clinical Responsibiliti es/Appointme nt				Year 1	Year 2	Year 3	Year 4	Total Project Cost
IPA: Kennedu.	PhD	Gainesville,	10					5,509	5,509	5,509	5,509	22,036
T-4	PhD	Gairresville;	5	N				3,393	3,393	3,393	3,393	13,572
IPA: Lincoln, Abe	PhD	Seattle, WA	10	N				4,302	4,302	4,302	4,302	17,208
Subject Payments		Gainesville,						1,200	1,700	0	0	2,900
Service Contract (University of Oz)		Gainesville, FL						1,790	2,300	1,500		5,590
						TC	TAL	216,941	209,711	213,791	204,961	******

Project Budget Summary Table

	SUMMARY BUDGET TABLE															
Expense Category				1												
Primary Site Personnel (section A+B)	Degre	e	Primary Site		Role		Clinical Responsibilities/ Appointment	G	rade	Step	% Effort	Year 1 Salary+Fringe	Year 2 Salary+Fringe	Year 3 Salary +Fringe	Year 4 Salary+Fringe	Total Project Cost
Einstein, Albert	PhD		Gainesville, FL	Ы			N		13	8	30	29,535	29,535	29,535	29,535	118,141
Darwin, Charles	PhD		Gainesville, FL	C	-		N		12	6	30	21,862	21,862	21,862	21,862	87,446
Blackwell, Elizabeth	MD		Gainesville, FL	C)-l	1	Y		15	5	10					
TBD		1	Gainesville, FL	K/	١	1	N		11	4	50	23,432	23,432	23,432	23,432	93,728
TBD			Gainesville, FL	R/	١		N		11	4	50	23,432	23,432	23,432	23,432	93,728
									S	ite Su	btotal	98,261	98,261	98,261	98,261	393,044

- Under Primary Site, list City, state not VHA. If Central Office, list VACO.
- Clinical Responsibilities/Appointment
- Divide the budget into project years, not fiscal years. (For QUERI only, use FY)
- The final budget is expected to closely reflect the original proposal budget and not exceed the original total. If there are any required changes, they must be identified and justified; any increases to the proposal budget amount are not allowed without the permission of HSR&D.
- Include the budget total (sum of all project years) in summary budget table.

Personnel

						SUMMAR	łΥ	BU	DG	E'	T T	ABLE				
Primary Site Personnel (section A+B)	7	Degree	P	rimary Site	Role	Clinical Responsibilities Appointment	" I	Grade	Step	E	% ffort	Year 1 Salary+Fringe	Year 2 Salary+Fringe	Year 3 Salary +Fringe	Year 4 Salary+Fringe	Total Project Cost
Einstein, Albert		PhD	Ga	inesville, FL	PI	N		13	8	3	30	29,535	29,535	29,535	29,535	118,141
Darwin, Charles		PhD	Ga	inesville, FL	Co-l	N		12	(6	30	21,862	21,862	21,862	21,862	87,446
Blackwell, Elizabe	h	MD	G	inesville, FL	Co-l	Υ		15	5	5	10					
TBD			G	ainesville, FL	RA	N		11	4	ŀ	50	23,432	23,432	23,432	23,432	93,728
TBD			G a	ainesville, FL	RA	N	V	11	4	1	50	23,432	23,432	23,432	23,432	93,728
	1						1	S	ite S	ub	total	98,261	98,261	98,261	98,261	393,044

- List all degrees of the personnel (MD, PhD, RN, MS etc.).
- List grade and step of all personnel. Salaries may include anticipated personnel actions (e.g., within grade increases), but may not exceed Office of Personnel Management approved salary rates.
- Maximum 2% per year cost-of-living adjustment (COLA)
- PIs and each site PI need to have an ePromise account in order for money to be transferred and must be 5/8th, unless there is an approved waiver from HSR&D.
- The text, including title and degrees, in the justification and the proposal must match the summary budget table.

HSR&D Budgetary Guidelines - Services Rendered By Individuals

Table · Summarizing · HSR&D · Budgetary · Guidelines · · · Services · Rendered · By · Individuals ¶

1						,	
Ħ		VAX			No	n-VA¤	
Ø		Clini	cians¤			Clinicians¤	
¤	Non-clinicians¤	Licensed-Medical- Professionals¤	MD#	Non-clinicians¤	Licensed-Medical- Professionals¤	MDs-and-Dentists- <u>NOT-</u> licensed-in- the-US-and- providing-NON- CLINICAL-servicesX	MD-licensed-inside- US-(including- residents)¤
Personnel¶ Section¤	ОКЯ	OK-if-GS- employee-or-if- Title-38-Waiver- granted-by- Director-for- services-beyond- usual-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.¤	Not-allowed#	Not-allowed∺	Not-alloweds:	Not-alloweds:
IPA¶ Section¤	Not-alloweds:	Not-allowed#	Not-alloweds:	OKX	OK-if-budget- justification-states- no-clinical- responsibilities¤	Ok-if-not-licensed- in-US-and-has-no- clinical- responsibilities¤	Not-alloweds:
Contract¶ Section¤	Not-alloweds:	Not∙allowed≈	Not-alloweds:		tracts-should-be-with-th n-their-employeesCor		
Consultant¶ Section¤	Not-allowed;- Should-be-listed- under-personnel¤	OK-if-no-salary- compensation⊭	Ok-if-no-salary- compensation.⊭	ОКЯ	OK-only-if-stated-as- performing-non- clinical-services#	OK,-can-be-paid- consultant-fee¤	OK-if-no-consultant- fee.¤

Personnel

- Do not request salary (VA or non-VA) for any licensed medical professional with clinical responsibilities (Hybrid Title 38 occupations with clinical appointments).
- If a licensed medical professional is a General Schedule (GS) employee and does not have clinical responsibilities, his/her salary may be included in the budget, but the budget table and justification must indicate that he/she does not have any clinical responsibilities.
- Licensed Nurses in clinical positions may be listed in the budget as research personnel
 only if they have a Title 38 Waiver granted by the HSR&D Director for services beyond
 usual care.
- Ph.D. level nurse scientists in General Schedule (GS) positions may be listed in the budget to receive salary support as study PIs.
- Physicians cannot be paid unless they were credentialed outside the U.S. or are not licensed.
- VA personnel hired using the 2210 job series should be paid using IT funds.
 - If performing tasks related to IT, confirm in the justification narrative that the person listed has not been hired using the 2210 job series, can say "this is a non-2210 IT employee".
- Only VA employees should be listed under personnel. All non-VA project staff should be identified in the justification as non-VA.

Personnel Budget Justification

Budget Justification

Primary Site: Gainesville, FL

Personnel

Albert Einstein, Ph.D., Project Director/Principal Investigator, (2.4 cal mos, GS 14/3, 5/8th VA, salary \$21,874/yr, fringe \$9,374/yr, years 1-4.) Dr. Einstein will oversee all aspects of the project. He will hire, train, and supervise all study personnel at the Gainesville 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.

Charles Darwin, Ph.D., Co-Investigator (0.4 cal mos, GS 14/4, 5/8th VA, no salary requested in years 1-4.) Dr. Darwin is a licensed Clinical Research Psychologist based at the MIRECC affiliated with the Veterans Affairs Medical Center in Gainesville, where he specializes in research on family interventions. He will assist Dr. Einstein 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

				SUIVIIVIAN	I DU	פטו	E I 1	MDLE
Expense Category								
Primary Site Personnel (section A+B)	Degree	Primary Site	Role	Clinical Responsibilitie s/Appointment	Grad e	Step	% Effort	Year 1 Salary+Frin ge
Einstein, Albert	PhD	Gainesville,	PI	N	13	8	30	29,535
Darwin, Charles	PhD	Gainesville,	Co-I	N	12	6	30	21,862
Blackwell, Elizabeth	MD	Gainesville,	Co-I	Y	15		10	
TBD		Gainesville,	RA	N	11	4	50	23,432
TBD		Gainesville,	RA	N	11	4	50	23,432
			•		5	ite Su	ibtotal	98,261
Additional Site Personnel	Degree	Additional Site	Role		Grad e	Step	% Effort	Year 1 Salary+Erin ge
Sinatra, Frank	PID	Seattle, WA	Co-I	N	10	2	25	22,678
Cass, Mama	RN	Seattle, WA	t Coold	N	7	4	50	31,684
Stevens, Cat	MS	Seattle, WA	RA	N	7	4	50	31,684
					5	ite Su	ibtotal	86,046
				Project T	otal fo	r Pers	onnel	184,307
Consultant (section F3)	Degree	Site						Year 1
Buck, Pearl	PhD	Gainesville,		N				2,400
Fitzgerald, F. Scott	MA	Seattle, WA		N				2,400
Twain, Mark	MS	Seattle, WA		N				2,400
Equipment total per site-do	haata /	Cl *2 /\$7						Year 1

Personnel should be grouped by site where there are multiple study sites. List Site PI first.

VA employees cannot be paid as consultants.

Physicians may not be paid as consultants.

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

Equipment/Supplies

Equipment (total per site-do not itemize)				Year 1	Year 2	Year 3	Year 4	Total Project Cost
Gainesville, FL				2,000	0	2,000	0	4,000
Seattle, WA				2,000	0	2,000	0	4,000
Supplies (total per site-do not itemize)				Year 1	Year 2	Year 3	Year 4	Total Project Cost
Gainesville, FL				1,000	500	250	125	1,875
Seattle, WA				1,000	500	250	125	1,875

- Itemize each category separately in budget justification.
- If equipment sounds like it might be IT, please note in justification that you have already consulted with IRM (local IT) and confirmed that item is non-IT.
- For equipment purchases, note in justification the post project disposition.
- Funds are no longer allowed for general office supplies; these should come from your medical center. If supplies requested are not standard office supplies and/or not available from the medical center, please note this in the justification.
- Audio voice recorders should be categorized as supplies. Need ISO approval.

Travel Summary Budget Table

Total travel budget must be included in the summary budget table located in the budget justification section of your application.

Project Travel (total from Travel Table do not itemize)					Year 1	Year 2	Year 3	Year 4	Total Project Cost
Gainesville, FL	ſ				1,800	0	2,300	0	4,100
Seattle, WA					1,440	0	780	0	2,220

Travel Budget Justification

- HSR&D will consider <u>one</u> request <u>per project</u> for the <u>PI only</u> to present <u>FINAL</u> research results. Funds will not be disbursed until a meeting is identified and funds are requested from Central Office.
- Travel costs should be itemized per trip for hotel and transportation in a table in the justification. In the project budget, include travel that is directly related to the conduct of the research. These funds will be disbursed along with the "other" project funding.

Project 7	Travel Tab	ole				
Traveler	Status (VA or non VA)	Destination	Number of Trips	Year of Trip	Estimated Cost	Purpose: 1)Conduct Research 2)Dissemination 3)Final research Results
Total						

Travel Budget Justification

- Not authorized for non-VA employee; travel should be rolled into the contract or IPA mechanism with instructions to follow GSA and the VA's travel policies.
- Project meetings can be included in project budget, however,
 - Funds for meeting will be held until
 - Specific meeting/travel budget is submitted along with meeting approval (local or higher level depending on size).
 - See Meeting Approval Guidance:

https://myees.lrn.va.gov/Conferences/default.aspx

Travel Budget Justification

- Professional Development Travel
 - PI unaffiliated with COIN
 - HSR&D will consider requests from funded PIs, not affiliated with a COIN, to allow participation of the PI or their project team designee in scientific meeting/professional development.
 - PI affiliated with COIN
 - PI/project team designee affiliated with COIN should not submit request to Central Office, and instead submit their request locally for use of professional development funds distributed directly to the COIN.
 - Amount of travel funds allocated for professional development is at the discretion of the COIN.

Other Direct Costs

Other (Section F 8/9/10+) (Do not list IT expenses from Planned IT Expenses	Degree	Site	Eff	% fort			Year 1	Year 2	Year 3	Year 4	Total Project Cost
Table)											
IPA: Kennedy, John	PhD	Gainesville, FL		10	N		5,509	5,509	5,509	5,509	22,036
IPA: Roosevelt, Ted	PhD	Gainesville, FL		5	N		3,393	3,393	3,393	3,393	13,572
IPA: Lincoln, Abe	PhD	Seattle, WA		10	N		4,302	4,302	4,302	4,302	17,208
Subject Payments		Gainesville, FL					1,200	1,700	0	0	2,900
Service Contract		Grinesville, FL					1.790	2.300	1.500	0	5,590
(University of Oz)		Galliesville, I L					1,730	2,300	1,500	U	5,550
						TOTAL	216,941	209,711	213,791	204,961	845,404

- HSR&D is an intramural program; it is expected that VA staff will be hired to perform the research and provide needed expertise.
- It is expected that any contracted services and/or IPAs will not EXCEED 30% (COIN) of the proposed total budget (40% for non-COIN), unless approved via waiver during 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 an individual.
- VA employees cannot be paid as 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 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 where the funds are to be sent, not the location of the IPA/contract.

19

Other Direct Costs Participant Payment

Other (Section F 8/9/10+) (Do not list IT expenses from Planned IT Expenses Table)	Degree	Site	% Effort				Year 1	Year 2	Year 3	Year 4	Total Project Cost
IPA: Kennedy, John	PhD	Gainesville, FL	10	N			5,509	5,509	5,509	5,509	22,036
IPA: Roosevelt, Ted	PhD	Gainesville, FL	5	N			3,393	3,393	3,393	3,393	13,572
IPA: Lincoln, Abe	PhD	Seattle, WA	10	N			4,302	4,302	4,302	4,302	17,208
Subject Payments		Gainesville, FL					1,200	1,700	0	0	2,900
Service Contract (University of Oz)		Gainesville, FL					1,790	2,300	1,500	0	5,590
				·	1	OTAL	216,941	209,711	213,791	204,961	845,404

- Note that any references to "participant incentives" or "participant reimbursements" must be changed to "participant payments".
- If the project plans to compensate non-physician VA employees for participation in research, the research team needs to contact their local OGC STAR (Specialty Team Advising Research). It is recommended that this is done prior to IRB submission.
- Payments to physicians for serving as research participants are not authorized.
- The compensation for participant payments should be presented in a table that clearly shows how the total amount was calculated. In addition, note how the payment will be made to the study participants (e.g., canteen gift card, Visa gift card, check, etc.)
- Note that any unused participant payments must be returned to HSR&D.

Centralized Transcription Services Program (CTSP)

- If Salt Lake City (SLC) is not already a research site, it will not be added as a research site in JIT for CTSP services only.
- If SLC is already a research site, JIT requirements will remain unchanged.
- It will not require additional research related regulatory documents (e.g. ACOS/R Assurance and PI Assurance documents). CTSP services are an exception because they are not considered research.

Centralized Transcription Services Program (CTSP)

Use of these services is not mandatory, but we require you to contact CTSP for a comparison quote as part of application process.

Listing in BUDGET

If you decide **not** to utilize their services, please provide HSR&D with a brief summary of the reason(s) for not utilizing the CTSP in your final revised budget justification in JIT.

When listing in the 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, who is responsible for the funds sent to and the work performed at SLC.
 - For Dr. Zickmund's percent effort, please list "N/A" and list her salary as "contributed."
 - In addition, list "CTSP Transcription Services (SLC)" along with associated funds under "Other" on the budget.
- If SLC is already a research site,
 - Do not list Susan Zickmund as PI nor co-I.
 - Please <u>only</u> list "CTSP Transcription Services (SLC)" along with associated funds under "Other" on the budget.

IT Budget

- Research funds are not used to pay for IT. VA has a separate IT appropriation, which is not controlled by research.
- If devices such as laptops or tablets are to be used by patients only, they can
 be considered patient medical devices and thus a non-IT purchase (can be
 purchased with research funds). If the devices are to be used by both patient
 and personnel, then they are considered an IT purchase and must be included
 on the IT budget. IT approved voice recorders can be purchased with
 research funds.
- If you are requesting IT funds, 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.
- Purchase of GoToMeeting must be approved by local CIO before funds will be provided. If approved, list under Other Direct Costs in budget.
- Atlas software may be purchased using research funds as it is considered "scientific computing." It should be listed under Other Direct Costs in budget.
- SAS and SPSS may be used in VINCI platform, so they are not approved for purchase.
- Please see memo from ORD for guidance on obtaining SAS, SPSS, and Stata at http://vaww.research.va.gov/funding/docs/FY18-IT-Funds.pdf

When submitting a revised budget

- Always include a version date in the header of document when submitting to JIT.
- At the top of the summary budget table, please note the duration of the study (e.g., 48 months).
- Please indicate responses to each of the budget items uploaded in JIT, in a section labeled 'Budget Updates' at the beginning of the budget justification narrative. Also include in this narrative justification for any other changes from the original budget in the proposal. The total budget should not exceed the total amount requested in the proposal.

Required Project Approvals

- PI/Local Site Assurance Forms
- PI/Local Site ACOS/R Assurance Forms
- Quad Chart
- Budget Table & Justification
- Union Notification (for data collection among VA employees)
- OASC Review (for large surveys of staff)
- OMB Exemption Brief
- IRB determination (for research protocols)
- DSMB
- Clinical Trial Registration

Assurance Forms

- PI/Local Investigator Assurance Forms attests to the PI's agreement to comply with VA policies. The PI must agree to comply with VA regulations and policies concerning intellectual property, complete and submit progress reports and cite the VA support of the work in all publications, in accordance with VA Handbook 1200.19.
- ACOS/R Assurance Forms attests to the completion of review by the R&D Committee and relevant research subcommittees, as well as the investigator's eligibility to receive VA funding based on VA employment status.

Central IRB versus Local IRB

For HSR&D-funded studies with four or more performance sites engaged in human subject research, it is required that IRB oversight be provided by the VA-CIRB

Contact Central IRB with Questions and Clarifications.

vacentralirb@va.gov;
https://www.research.va.gov/vacentralirb/

ACOS

- An ACOS assurance form needs to be submitted if research is being conducted at the site and/or the site is receiving funds.
- In general, a VA facility is considered to be "engaged" in human subject research when someone with an appointment (an agent of) at that facility obtains for the purposes of the research study one of the following:
 - Data about the subjects of the research through intervention or interaction with them
 - Identifiable private information about the subjects of the research
 - The informed consent of human subjects for the research
- If IRB oversight is not required (non-applicable) then the R&D Committee approval only needs to be submitted with the ACOS form.

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 HSRD website 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 measureable
 Milestones. If a one-year project, by
 months or quarters.

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

Activities should be specified and not just identified as Aims

Union Notification Data Collection Involving VA Employees

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

Facility Level Only

Contact Local HR for Local Union Approval

Notify HSRD when complete

VISN Level Only

Contact VISN HR for VISN Level Union Approval

Notify HSRD when complete

Across Multiple VISNs

Submit National
Union
Notification
Packet to ORD via
JIT and/or email

ORD will contact Study PI when notification is final

Union Notification Data Collection Involving VA Employees

For national union notification, please provide the following information compiled into one PDF file in the Miscellaneous JIT area. HSR&D and LMR will work to have national unions notified.

- A copy of the survey or interview questions
- A list of the selected sites or of sites that are being considered to receive the survey or interview
- A brief description of the study (including what is being studied and what types of VA personnel will be studied)
- What participation entails (e.g., interview and/or survey, how much time is required for subjects to participate, how much time is required for subjects to participate)
 - Please note that the survey/interview must be voluntary, anonymous, and confidential.
 These terms should be stated explicitly.
- Types of data being collected (e.g., survey, interview guide)
- Study team contact information, including email address, phone number, and VA facility name/location

31

OASC Review Large Multi-Site Surveys of VA Employees

- Organizational Assessment Sub-Committee (OASC) Review is needed for all research and operations surveys that involve VA employees <u>and</u> that also meet at least one of the following two criteria:
 - -Surveys 1000 or more VA employees
 - -Surveys VA employees across 10 or more sites
- OASC review is needed so that the survey does not overlap with other National VA surveys.
- OASC has no jurisdiction over surveys to Veterans.
- OASC only has authority to review surveys (paper and pencil or web based) and not interviews.
- Please see the web page at https://www.research.va.gov/resources/oasc.cfm for clarification of the criteria that pertain to data collection involving VA employees. The website includes an attachment that describes the general rules.

OASC Review Large Multi-Site Surveys of VA Employees

Research surveys of 1,000+ VA employees or 10+ sites that have received IRB approval should be sent to David Mohr (<u>David.Mohr2@va.gov</u>), and surveys that do not have IRB approval should be sent to a mailbox at <u>VHAOASC@va.gov</u>. The sub-committee typically provides a response within a few weeks. Submit your project abstract, a description of the survey, a sampling plan, and the following items:

- 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

OMB Exemption Overview: Data Collection Involving Patients

- If the project involves collection of information or data from 10 or more individuals that are not VA employees (e.g., Veterans, caregivers), OMB review and approval, or exemption from OMB review, is required prior to conducting the surveys/interviews.
- The OMB exemption brief submitted to HSRD/QUERI needs to explain how this data collection benefits clinical care and how the survey/interview is not duplicative.

OMB Exemption Brief: Data Collection Involving Patients

An OMB exemption can be based on one or more of the following criteria:

Justification for Exemption of this Study under 5 CFR Part 1320.3:

Prevent clinical disorders by:

	3 - 1
	☐ Clinical trial
	☐ Clinical examination
	☐ Direct treatment
	☐ Prevention of a clinical disorder
	☐ Interpretation of biological analyses
•	One criterion is sufficient for an exemption.
	(Sample Text) This research study, and the survey/focus group of a cohort of male and female veterans, is exempt from 5 CFR Part 1320.3 because the research will prevent clinical disorders related to
	This research will:

o [Use bullets to list the various ways you expect this study to prevent clinical disorders and identify the disorder and means of prevention.] There needs to be specificity regarding the condition or disorder (e.g., depression, anxiety associated with....)

OMB Exemption Brief: Data Collection Involving Patients

Project Overview

- This summary should provide a brief and focused overview of the study and emphasize the importance of the research with regard to the applicable **exemption criteria**. The summary should also include a brief discussion of the data collection effort (e.g., phone survey of 100 Veterans, collected at time intervals and number of times e.g., twice at 6 and 12 months) and its importance to the overall research objectives.
- Follow the template closely.
- (Sample Overview) This research study will examine the effects of This study represents a unique opportunity to.... The study includes (number, brief description of subjects).... (Describe exactly what will be done) The findings from this study will inform....

OMB Exemption Brief: Data Collection Involving Patients

Justification that the Survey is not Duplicative:

- The standard language should be followed closely.
- (Standard Language) The VA Office of Research and Development has funded this research study based on its originality in addressing the health care needs of veterans who have experienced..... This decision was based upon merit review and the portfolio manager's examination of other research supported by VA and other organizations. This research is unique in its study of... The survey/focus group is not duplicative of any other survey with this population.

OMB exemption briefs are typically about 1-page in length.

Clinical Trials Registration

- The VA-ORD definition of a clinical trial is below
- "Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
 - Please consult with the assigned Scientific Program Manager to determine whether a specific study should be considered a clinical trial when this is not clear.
- Registration of trials helps ensure that a trial can be published when complete and may be required by federal law.
- After all other JIT requirements have been met, the Clinical Trials Registration JIT area will be activated and the primary PI will receive an email from ART about how to register with clinicaltrials.gov.
- Do not register VA-ORD funded studies with clinicaltrials.gov before you are contacted by ART. You will be contacted through your VA email address, so please check your VA email account.

Recruitment

Site 1	Location:					PI:				
		Scree	ened	Enro	lled	Partici	pating	Comp	leted	Withdra wn/Lost
Year 1	Date	Projected	Actual	Projected	Actual	Projected	Actual	Projected	Actual	Actual
Q1	10/1/2018	1	1							
Q2		1	1							
Q3		1	1							
Q4		1	1							
W 3	ъ.	B : . II		B 1 . I		B 1 . I		n : . I		
Year 2	Date	Projected	Actual	Projected	Actual	Projected	Actual	Projected	Actual	Actual
Q1 Q2										
Q3										
Q4										
7.										
Year 3	Date	Projected	Actual	Projected	Actual	Projected	Actual	Projected	Actual	Actual
Q1										
Q2										
Q3										
Q4										
	_						- 1	1		
Year 4	Date	Projected	Actual	Projected	Actual	Projected	Actual	Projected	Actual	Actual
Q1										
Q2 Q3										
Q3 Q4										
Á.										
	TOTAL	4	4	0	0	0	0	0	0	0
	# Non- Veterans									

When is Data and Safety Monitoring Board (DSMB) Oversight Required?

- HSR&D DSMB oversight is required for multisite (2 or more sites) intervention trials that include human subject research participants. DSMB approval is accomplished by an independent review board charted by HSR&D that meets at specified intervals and requires routine reporting from the PI.
- All HSR&D studies that require DSMB oversight must submit a Data Analysis Plan (DAP) for review by the DSMB as part of the JIT compliance process. Studies are generally not allowed to begin until DSMB approval of the DAP has been provided.
- For certain studies involving particularly vulnerable study participants (e.g., children or persons with impaired ability to consent) that do not include interventions, it might be beneficial to obtain DSMB oversight as an additional measure of human subject protection. The advisability of DSMB oversight in these situations should be reviewed with the SPM and IRB of record who can assist the PI with making a determination about whether or not to submit the study to a DSMB.

When is DSMB Oversight Required?

HSR&D DSMB oversight is required for the following types of studies:

- Clinical trials intended to provide definitive information about effectiveness and/or safety of a medical or bio-behavioral intervention.
- Studies in which prior data suggest that the intervention being studied has the
 potential to induce potentially unacceptable toxicity.
- Clinical trials evaluating mortality or another major endpoint, such that inferiority of one treatment arm has safety as well as effectiveness implications.
- Clinical trials of diseases with high mortality or morbidity, involving high risks, and for large multicenter clinical trials.
- Phase III studies, with the exception of low-risk behavioral and nutritional studies.
 - For this discussion, "low-risk" refers to trials where subjects are expected to experience only minor side effects, and interim analyses are not crucial for the protection of the subjects
 - The involvement of a DSMB may still be requested for low-risk studies if the studies are exceptionally large, long term, and/or involve vulnerable subjects
- Phase II studies which are "high risk".
 - For this discussion, "high-risk" refers to trials of interventions associated with substantial side effects to subjects (e.g., side effects that could result in serious morbidity or death, or are irreversible), trials of diseases associated with high mortality or morbidity, and trials of highly experimental therapies (e.g., gene therapy)

When is DSMB Oversight Not Required?

DSMB oversight is not required in the situation below.

 Single-center open-label Phase I and II clinical trials since the local investigator will have access to all data. In these types of trials, the investigator could appoint an independent medical monitor to evaluate adverse events and make recommendations for continuing or stopping a trial.

DSMB oversight may not be required in the situations below. The DSMB, not the PI, makes the determination of study exemption in these scenarios.

- A multicenter, high-risk Phase I clinical trial if there are very clear rules for stopping the trial. For example, DSMB oversight may not required for a classic open-label dose escalation trial with clear and objective criteria for halting the dose escalation when unacceptable side effects are observed.
 - DSMB oversight is likely to be requested if the Data Safety Monitoring Plan (DSMP) lacks objective criteria for continuing or halting the trial.
- DSMB oversight may not be feasible for clinical trials that are expected to accrue too quickly to allow for a DSMB to be constituted and to complete data and safety monitoring.

DSMB DAP Requirements

For HSR&D projects, the assignment of the DSMB JIT area requires the **submission** of a Data Analysis Plan (DAP) **60 days** from the date of the Intent to Fund letter. The DAP describes the plan to monitor and track serious adverse events and summarizes the statistical analyses for the primary and important secondary data proposed by the research questions. DAPs and associated documents are to be uploaded directly into the DSMB portal in the Clinical Trials Module of ART.

Data Analysis Plan (DAP)

- 1. Rationale for the study sample size
- 2. Specific description of how the data will be collected
- 3. Method of randomization (describing any stratification and blocking techniques)
- 4. Plans for and specification of the purpose of any interim analysis of the data (with regard to stopping rules for superiority, futility, or sample size re-estimation)
- 5. Methods for handling missing data points and subject dropouts
- 6. Definitions of covariates to be included in adjustment models
- 7. Methods for dealing with data transformations
- 8. Definitions of the analytical sets (i.e. intent-to-treat, per protocol, and any other analytical subsets)
- 9. List of adverse and serious adverse events to be monitored, how they will be defined, and a plan for prospectively tracking them.

Pre-funding Project Modifications

While in JIT if you have a change 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
- The Pre-funding Project Modification form will be uploaded to JIT.
- Once complete (PI signature only no ACOS needed), please upload the document into the Miscellaneous section.
- Once approved changes will occur in JIT as required.

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):

Proposed Project Start Date:

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

Primary VAMC Location (City, State):

Proposed Project End Date:

Request Categories	Instructions		
Change in PI	Complete sections 1, 2, and 7 below.		
	Section 5 must clearly explain why a change in PI is being requested.		



Road Blocks: Project Modifications

Project modification for change in Aims, Methods, or Key Personnel/Effort, and/or Budget.

https://www.hsrd.research.va. gov/funding/projectmodification-notification.cfm

RPPR is NOT a project modification mechanism.

Q&A

If you have administrative/business questions, please have you or your Administrative Officer contact:

Expertise	Name	Phone No.	Email
ORD & HSR&D Finance	Mary Jones	(202) 443-5628	Mary.Jones@va.gov
CDA	Rob Small	(202)443-5743	Robert.Small@va.gov
QUERI	Melissa Braganza	(202) 443-5818	Melissa.Braganza@va.gov
OMB Exemptions	Linda Lipson	(202) 443-5747	Linda.Lipson@va.gov
Union Notification	Faith Booker	(202) 443-5714	Faith.Booker@va.gov
HSR&D Overall Budget & Waivers	Liza Catucci	(202) 443-5797	Liza.Catucci@va.gov
JIT Management & DSMB	Shannon Jordan	(202) 443-5744	Shannon.Jordam2@va.gov

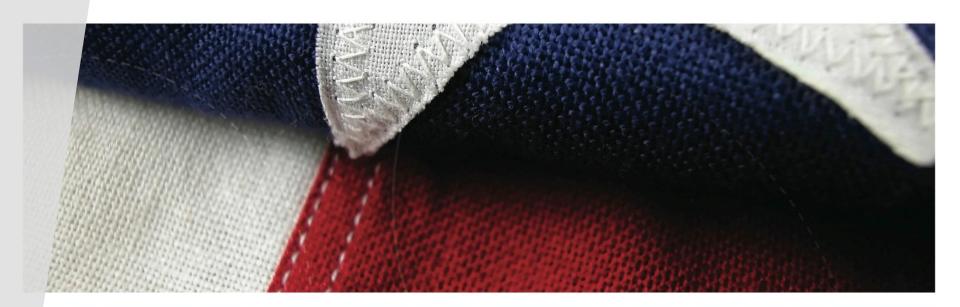
Q&A

If you have project-specific questions, please directly contact the appropriate Scientific Program Manager.

Expertise	Name	Phone No.	Email
Project- Specific			George.Fitzelle@va.gov
Questions			Cathie.Plouzek@va.gov
			Linda.Lipson@va.gov
			Robert.O'Brien2@va.gov
			Stephen.Marcus@va.gov
			Miho.Tanaka@va.gov

Questions?

Please use the chat feature to submit questions.



Thank you for attending

HSR&D Training:

JIT: The Final Frontier



