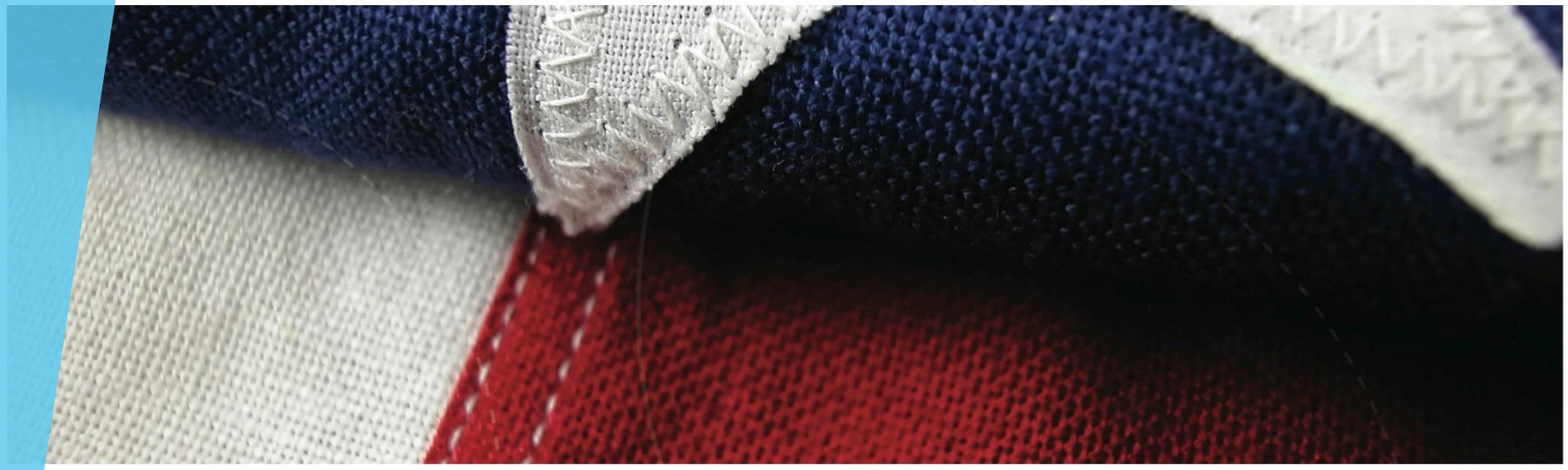

HSR&D Training:
JIT: “Show Me the Money!!!”

HSR&D and Finance Office Research and Development Staff

May 2, 2021

ChooseVA

VA HEALTH CARE Defining EXCELLENCE in the 21st Century

Scaling new heights

HSR&D
VA Health Services Research & Development Service

Overview of Presentation

- 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)
  - OMB Exemptions (Patients/Caregivers)
- Clinical Trials Registration
- Data & Safety Monitoring Board (DSMB)
- Intellectual Property
- Q&A

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VA Health Services Research & Development Service

Poll Question #1

What is your role?

(select one)

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

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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

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Time to Complete JIT

You have 180 days to complete JIT.

- If you have not cleared JIT at 150 days, you will be requested to submit a waiver.

What is the average time to complete each JIT section?

- If you have Central IRB, it may take 5-12 months.
- Union notification takes approximately 8 weeks.
- Budgets take about a month, if you are responsive.
- ACOS Assurance depends on your local R&D and IRB.

HSR&D Summary Budget Table
Do NOT use the colored worksheets!

SUMMA WORKSHEET - up to 20 Sites

Exper	Budget Period 1	Budget Period 2	Budget Period 3	Budget Period 4	Budget Period 5		
mary S	VA Maryland Healthcare System						
I ONLY (Section A, top line)						Yr 1 Effort (Cal Mo)	Degr
Salary	0		0	0	0	2.4	MD
Fringe	0		0	0	0		
her VA Personnel (include Sr/Key VA personnel, exclude IPAs)						Total Yr 1 Effort (Cal Mo)	# unique staff
d - Salary		0		0	0	1.2	1
- Fringe		0	0		0		
Salary		0	0		0		
ge		0	0		0		
To A Personnel Salary	0	0	0	0			
inge	0	0	0	0			
(Se							

HSR&D Summary Budget Table

HSR&D SUMMARY BUDGET TABLE

PI:	Duration (months):	Original Budget Request (from current personnel): $	Termination Date:
Project ID:	Project Title:		

Primary Site Personnel (section A-D)	Degree	Primary Site	Role	Clinical Responsibilities/Appointment	Grade	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	PI	N	13	8	30	29,535	29,535	29,535	29,535	118,14
Darwin, Charles	PhD	Gainesville, FL	Co-I	N	12	6	30	21,862	21,862	21,862	21,862	87,44
Blackwell,	MD	Gainesville, FL	Co-I	Y	15	5	10					
TBD		Gainesville, FL	RA	N	11	4	50	23,432	23,432	23,432	23,432	93,72
TBD		Gainesville, FL	RA	N	11	4	50	23,432	23,432	23,432	23,432	93,72
							Site Subtotal	98,261	98,261	98,261	98,261	393,044

Additional Site Personnel	Degree	Additional Site	Role	Clinical Responsibilities/Appointment	Grade	Step	% Effort	Year 1 Salary+Fringe	Year 2 Salary+Fringe	Year 3 Salary+Fringe	Year 4 Salary+Fringe	Total Project Cost
Sinatra, Frank	PhD	Seattle, WA	Co-I	N	10	2	25	22,678	22,678	22,678	22,678	90,71
Carr, Mama	RN	Seattle, WA	Project Coord.	N	7	4	50	31,684	31,684	31,684	31,684	126,73
Stevens, Cat	MS	Seattle, WA	RA	N	7	4	50	31,684	31,684	31,684	31,684	126,73
							Site Subtotal	$6,046	$6,046	$6,046	$6,046	$44,184
							Project Total for Personnel	184,307	184,307	184,307	184,307	737,228

Consultant (section E)	Degree	Site		Clinical Responsibilities/Appointment				Year 1	Year 2	Year 3	Year 4	Total Project Cost
Buck, Pearl	PhD	Gainesville, FL		N				2,400	2,400	2,400	2,400	9,60
Fitzgerald, F. Scott	MA	Seattle, WA		N				2,400	2,400	2,400	2,400	9,60
Twain, Mark	MS	Seattle, WA		N				2,400	2,400	2,400	2,400	9,60

Equipment (total per site-detail tracker)								Year 1	Year 2	Year 3	Year 4	Total Project Cost
Gainesville, FL								2,000	0	2,000	0	4,00
Seattle, WA								2,000	0	2,000	0	4,00

Supplies (total per site-detail tracker)								Year 1	Year 2	Year 3	Year 4	Total Project Cost
Gainesville, FL								1,000	500	250	125	1,87
Seattle, WA								1,000	500	250	125	1,87

Project Travel (total from Travel Table; detail tracker)								Year 1	Year 2	Year 3	Year 4	Total Project Cost
Gainesville, FL								1,800	0	2,300	0	4,10
Seattle, WA								1,440	0	780	0	2,22

Other (Section F 8/3/18-) (Do not list IT expenses from	Degree	Site	% Effort	Clinical Responsibilities/Appointment				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	22,03
IPA: Roosevelt, Ted	PhD	Gainesville, FL	5	N				3,393	3,393	3,393	3,393	13,57
IPA: Lincoln, Abe	PhD	Seattle, WA	10	N				4,302	4,302	4,302	4,302	17,20
Subject Payments		Gainesville, FL						1,200	1,700	0	0	2,90
Service Contract (University of Oz)		Gainesville, FL						1,790	2,300	1,500	0	5,59
							TOTAL	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Project Budget Summary Table

SUMMARY BUDGET TABLE												
Expense Category												
Primary Site Personnel (section A+B)	Degree	Primary Site	Role	Clinical Responsibilities/ Appointment	Grade	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	PI	N	13	8	30	29,535	29,535	29,535	29,535	118,141
Darwin, Charles	PhD	Gainesville, FL	Co-I	N	12	6	30	21,862	21,862	21,862	21,862	87,446
Blackwell, Elizabeth	MD	Gainesville, FL	Co-I	Y	15	5	10					
TBD		Gainesville, FL	RA	N	11	4	50	23,432	23,432	23,432	23,432	93,728
TBD		Gainesville, FL	RA	N	11	4	50	23,432	23,432	23,432	23,432	93,728
							Site Subtotal	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) at the bottom of the summary budget table.

Personnel

SUMMARY BUDGET TABLE

Expense Category

Primary Site Personnel (section A+B)	Degree	Primary Site	Role	Clinical Responsibilities Appointment	Grade	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	PI	N	13	8	30	29,535	29,535	29,535	29,535	118,141
Darwin, Charles	PhD	Gainesville, FL	Co-I	N	12	6	30	21,862	21,862	21,862	21,862	87,446
Blackwell, Elizabeth	MD	Gainesville, FL	Co-I	Y	15	5	10					
TBD		Gainesville, FL	RA	N	11	4	50	23,432	23,432	23,432	23,432	93,728
TBD		Gainesville, FL	RA	N	11	4	50	23,432	23,432	23,432	23,432	93,728
							Site Subtotal	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 <u>must</u> 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¶

	VA			Non-VA			
		Clinicians			Clinicians		
	Non-clinicians	Licensed·Medical·Professionals	MD	Non-clinicians	Licensed·Medical·Professionals	MDs·and·Dentists·NOT·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·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·allowed*	*Not·allowed*
IPA Section	*Not·allowed*	*Not·allowed*	*Not·allowed*	OK	OK·if·budget·justification·states·no·clinical·responsibilities	Ok·if·not·licensed·in·US·and·has·no·clinical·responsibilities	*Not·allowed*
Contract Section	*Not·allowed*	*Not·allowed*	*Not·allowed*	*Not·Allowed.·Contracts·should·be·with·the·entity/agency·providing·the·service·who·will·then·assign·their·employees.·–Contracts·are·for·services,·not·individuals.*			
Consultant Section	*Not·allowed;·should·be·listed·under·personnel*	*OK·if·no·salary·compensation*	*Ok·if·no·salary·compensation.*	OK	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, their salary may be included in the budget, but the budget table and justification must indicate that they **do 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; it 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

SUMMARY BUDGET TABLE

Expense Category								
Primary Site Personnel (section A+B)	Degree	Primary Site	Role	Clinical Responsibilities/Appointment	Grade	Step	% Effort	Year 1 Salary+Fringe
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
							Site Subtotal	98,261
Additional Site Personnel	Degree	Additional Site	Role		Grade	Step	% Effort	Year 1 Salary+Fringe
Sinatra, Frank	PhD	Seattle, WA	Co-I	N	10	2	25	22,678
Cass, Mama	RN	Seattle, WA	Project Coord	N	7	4	50	31,684
Stevens, Cat	MS	Seattle, WA	RA	N	7	4	50	31,684
							Site Subtotal	86,046
							Project Total for Personnel	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								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** (VA approved) 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								1,800	0	2,300	0	4,100
Seattle, WA								1,440	0	780	0	2,220

Travel Budget Justification

- HSR&D will consider **one** request **per IIR project** for the **PI only** to present **FINAL** research results in the budget. 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 Travel Table						
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 are 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 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
							TOTAL	216,941	209,711	213,791	204,961	845,404

- **HSR&D manages an intramural research 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 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 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 be where the funds are to be sent, not the location of the IPA/contract.**

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
							TOTAL	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 or VA employees for serving as research participants are not authorized unless participating outside of tour of duty.
- 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 in the justification that any unused participant payments must be returned to HSR&D.

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.

If using CTSP and the CTSP quote is more than 6 months old, you are required to obtain a **new quote**. CTSP quotes need to be appended to the budget justification.

Centralized Transcription Services Program (CTSP)

When listing in the budget:

- If Salt Lake City (SLC) is <u>not</u> 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." See August 2020 RFA and Budget Guidance for correct justification.
  - 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 or 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.
- 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 (DATE OF THIS SUBMISSION)** in the header of document when submitting to JIT.

HSR&D SUMMARY BUDGET TABLE			
PI:	Duration (months):	Original Budget Request (from approved proposal): $	Version Date:
Project ID:	Project Title:		

- At the top of the summary budget table, please note the duration of the study (e.g., 48 months).
- 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 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.

Poll #3: Start Date

I indicated my start date on my application. Is that when I will be allowed to start my project?

(select one)

- Yes
- Yes, but only if my project documentation is approved in JIT before that date.
- No

HSR&D
VA Health Services Research & Development Service

Start Dates

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

- **Starts are only on the 1st of the month.**
- **Continuing Resolutions limit new project starts.**
- **Project should CLEAR JIT prior to requesting a start date. If a continuing resolution is in place, we cannot guarantee start dates.**

Start Dates

If you want to start your project this fiscal year or October 1, the project has to clear JIT prior to August. The Financial databases are closed in September.

ORD Budget Tips and Reminders

- When contacting the ORD Budget Analyst:
  - Ensure you include Project ID in the email subject
  - Include the SPM on all emails to the Budget Analyst
  - Have one person designated as POC for communication.
- Review station funding monthly to ensure funds have been distributed appropriately. (August & September are close out months).

Poll #4: Common Problems

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

(select one)

- Administrative Officer
- Colleague
- Director
- Scientific Portfolio Manager

HSR&D
VA Health Services Research & Development Service

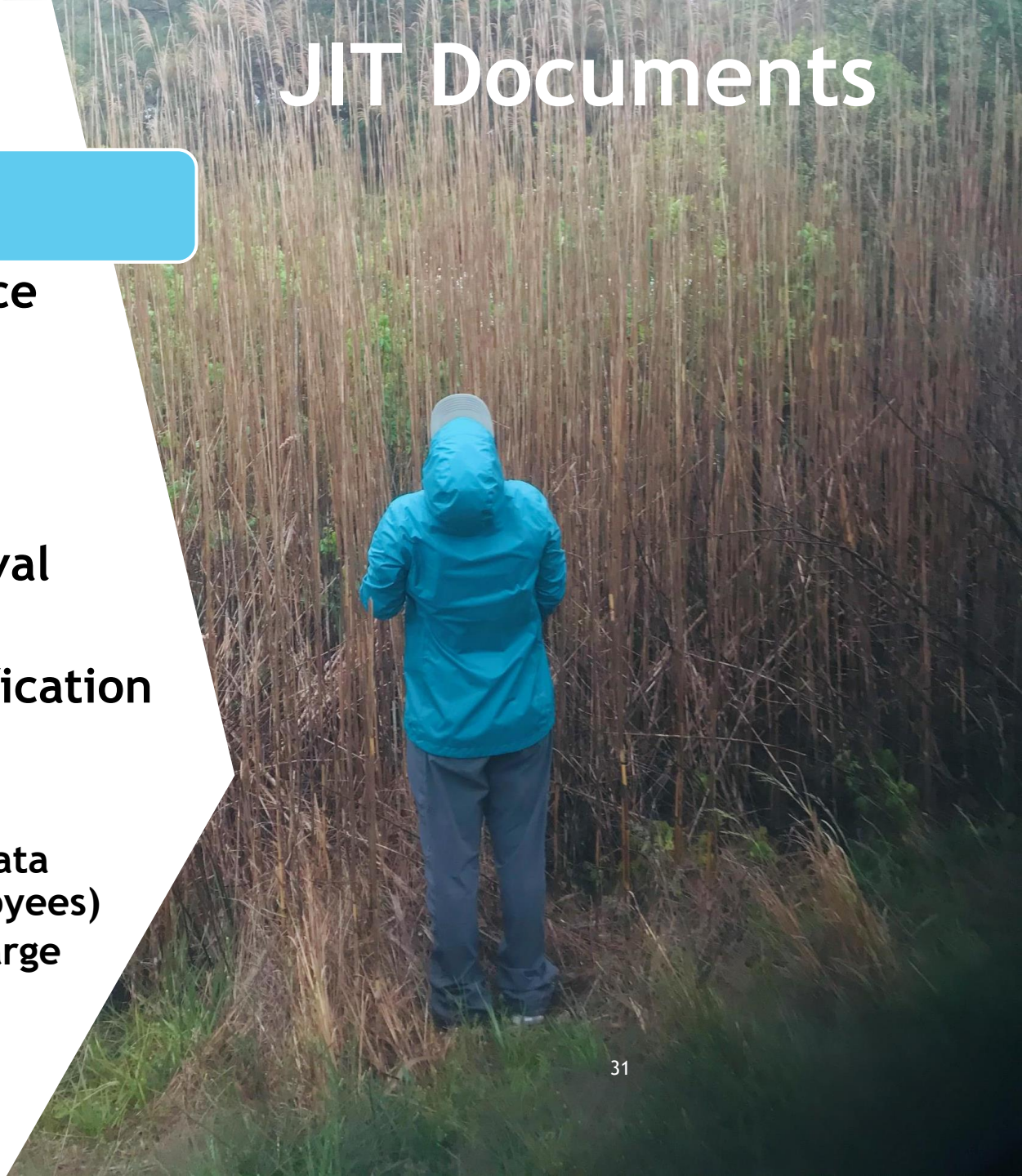
JIT Documents

For all studies:

- PI/Local Site Assurance Forms
- PI/Local Site ACOS/R Assurance Forms
  - IRB determination and R&D approval
- Quad Chart
- Budget Table & Justification

As appropriate:

- Non-Veteran Waiver
- Union Notification (for data collection from VA employees)
- OASC Review (for very large surveys of staff)
- OMB Exemption Brief
- DSMB plan approval
- Clinical Trial Registration



Assurance Forms

- **PI/Local Investigator Assurance Forms** attest 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.
  - **Please note that all site PIs must be registered in ePromise.**
- **ACOS/R Assurance Forms** attests to the **completion of review** by the R&D Committee and relevant research subcommittees, including IRB review, as well as the **investigator's eligibility** to receive VA funding based on VA employment status.

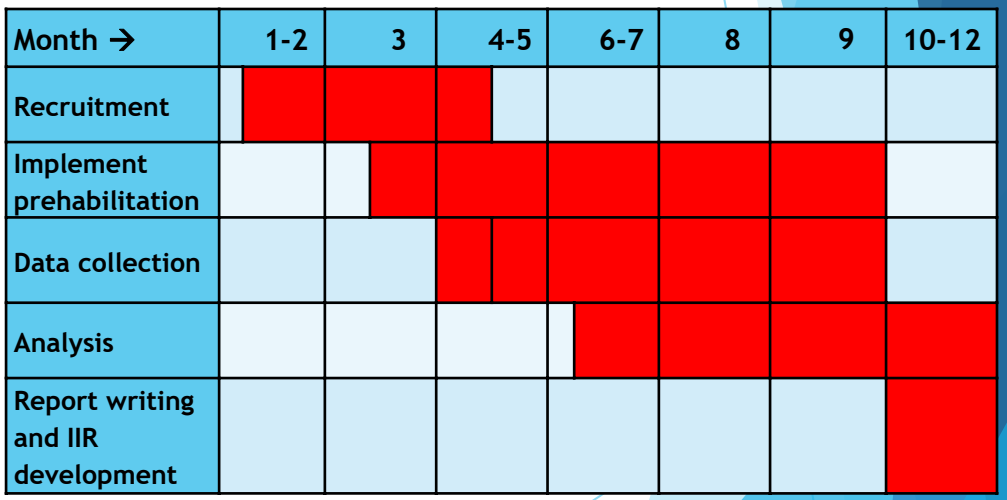
ACOS

- 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 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.

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



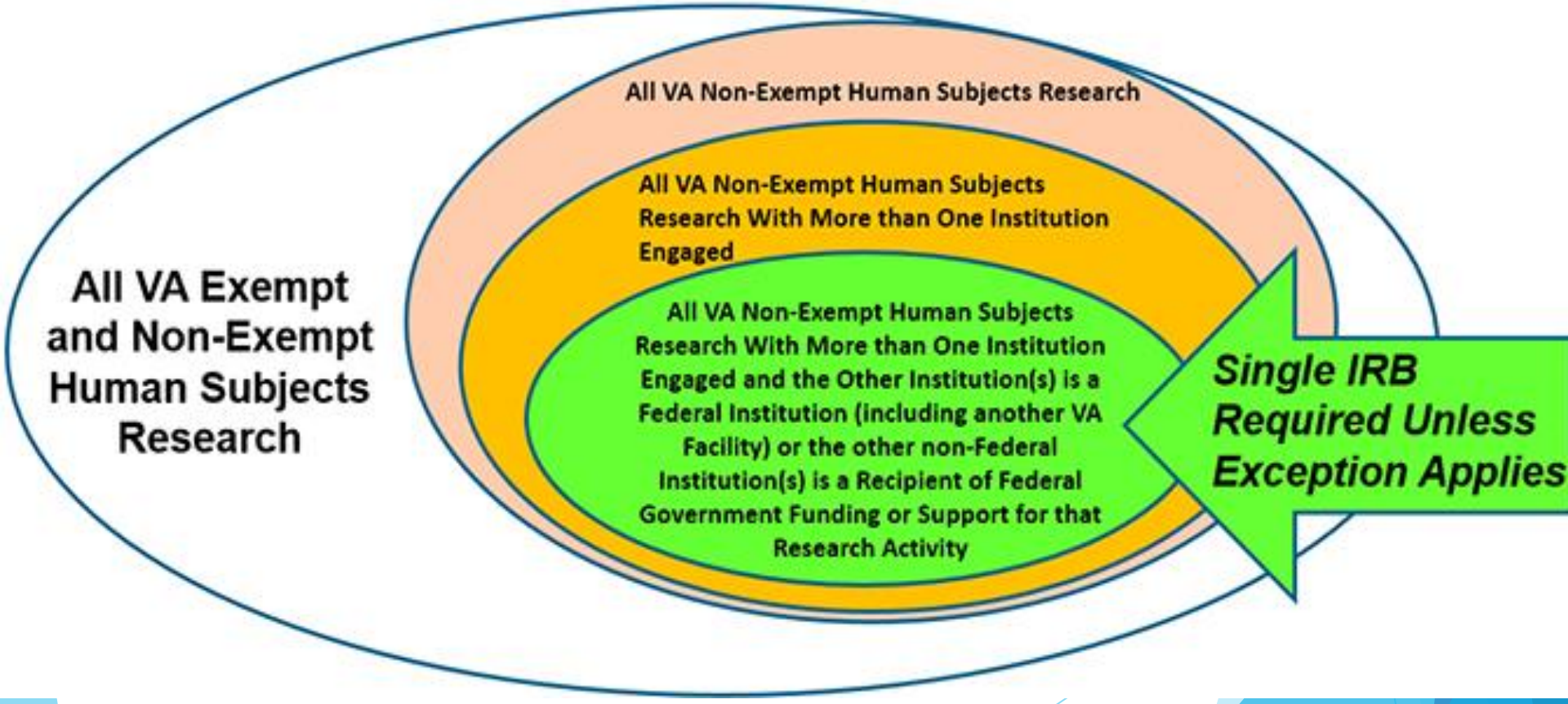
- Quadrant 4: Timelines

  This should reflect the timeline in Gantt Chart format with measureable Milestones. If a one-year project, by months or quarters.

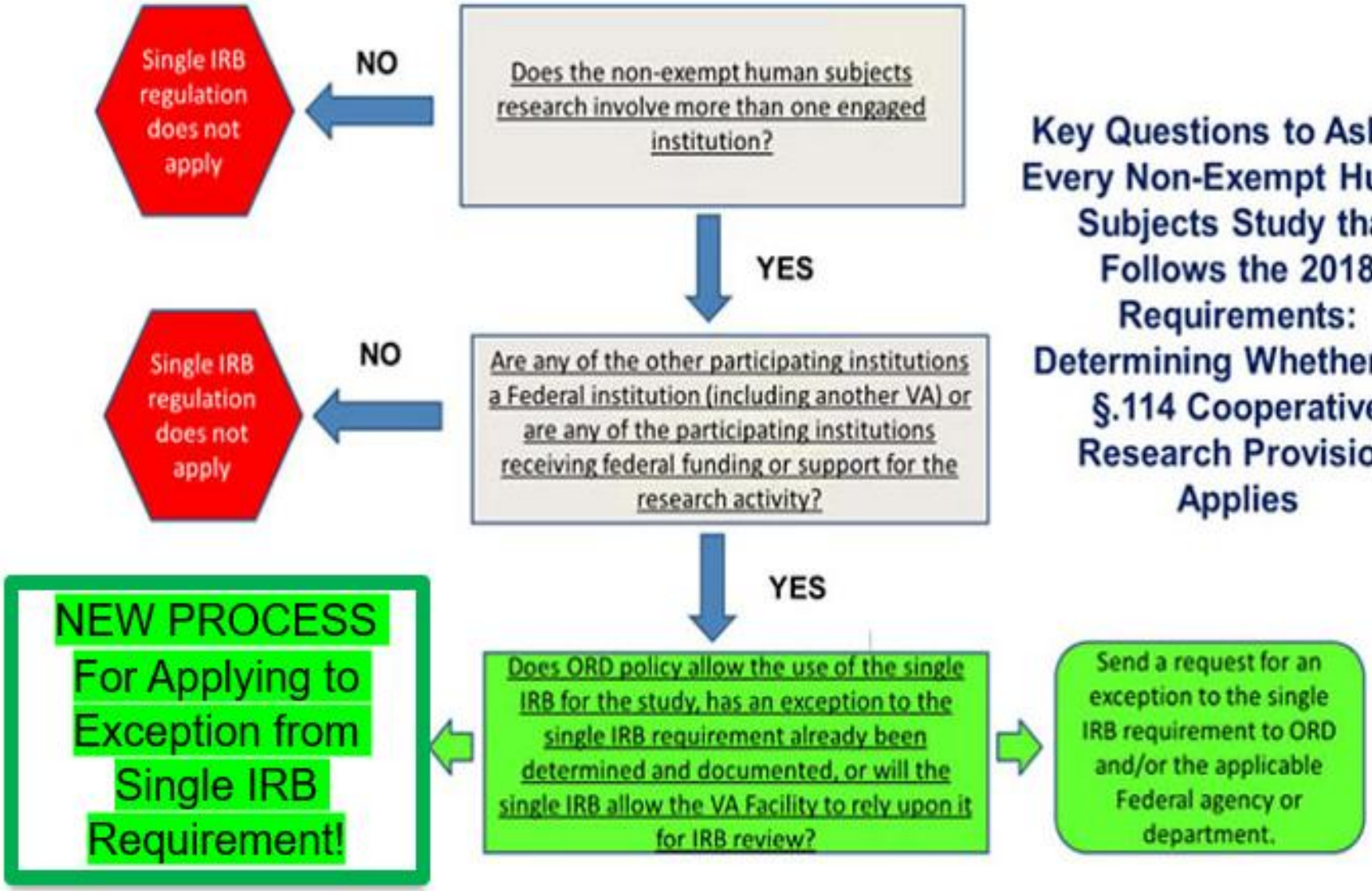
  Activities should be specified and not just identified as Aims

IRB: Local, Single, or Central?

Requesting an Exception from Single IRB Requirement



Single IRB



Key Questions to Ask for Every Non-Exempt Human Subjects Study that Follows the 2018 Requirements: Determining Whether the §.114 Cooperative Research Provision Applies

Requesting an Exception from Single IRB Requirement

ORD supports use of a **single IRB** when possible, but ORD also

provision also recognizes that use of a single IRB is not always

New

VHA Facilities wishing to **request an exception** from the single requirement for an applicable study must use the

https://dvagov.sharepoint.com/sites/VHAORPPE/IRBRelianceRequests/Home/SitePages/Exemption%20Requests.aspxequests

- Requests will be reviewed by ORD with an expected response time no later than 10 business days.
- Questions: IRBRelianceandSIRBExceptions@va.gov

Access handouts for webinar on the VA Single IRB SharePoint site: https://dvagov.sharepoint.com/sites/VHAORPPE/Education/WebExDownloads/Forms/AllItems.aspx

Central IRB (cIRB)

New

The VA Central IRB now accepts all IRB submissions through IRBNet (effective March 12, 2021).

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:
https://www.research.va.gov/programs/orppe/education/webinars/orppe-030221.cfm

Central IRB (cIRB)

6 CIRB steps – Multi-site review

- Step 1 - PI completes and submits PI Application
- Step 2 – VA Central IRB reviews PI Application
- Step 3 - Local Site Review and Submission of Local Site Investigator Applications
  - 3a – Local Site Review (Admin 15 days to comment on PI application)
  - 3b – Submission of LSI applications
- Step 4 – Review of Local Site Comments and Local Site Investigator Applications
  - 4a – review and adjudicate comments from sites on LSI
  - 4b – review LSI applications with revisions from 4a if applicable
- Step 5 – PI and LSI Submit Revisions as applicable
- Step 6 – VA Central IRB Makes Final Approval Decision on LSI Application

How to succeed with the cIRB

- Thorough review of documents prior to submission
- Encourage PIs to meet with their cIRB Manager/IRB reviewer
- When the PI gets questions/changes from cIRB, the PI and/or study team should address them immediately
  - The longer the PI waits to respond, the harder for the cIRB manger or IRB reviewer to remember
- Consecutive amendments do not help the cIRB – it slows reviewers down
  - Group changes when possible – try to limit to 2/year
  - Downstream effects of changes is hard on LSIs and cIRB staff and IRB reviewers

Central IRB

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

Contact Central IRB with Questions and Clarifications.

- **Email: vacentralirb@va.gov**
- **Visit: https://www.research.va.gov/programs/orppe/vacentralirb/default.cfm**
- **Single IRB: https://www.research.va.gov/programs/orppe/single_irb.cfm**

Non-Veteran Waiver

New

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

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 (HSR&D) (14RDH)

1. I am the principal investigator on the proposed HSR&D study entitled:

2. I am requesting authorization to enroll non-Veterans in this research study.

3. I understand that research funded by HSR&D 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 (and risk assessment as applicable) for enrolling non-Veterans in this protocol is described below.

4. I understand that if the Director, HSR&D 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
OMB Exemption	Patients/ Caregivers	Surveys & Interviews	>9 patients/caregivers

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. Notify HSRD when complete.
- **VISN Level**
  - Contact VISN HR for approval. Notify HSRD when complete.
- **National (across more than one VISN)**
  - Submit National Union Notification Packet to ORD via JIT and vhacohsrdjit@va.gov
  - HSR&D 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 that meet at least one of the following two criteria:

- Administered to **10,000** or more 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 your 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

OMB Exemption: Data Collection Involving Non-VA Employees (e.g., Veterans & Caregivers)

- OMB review and approval -- or exemption from OMB review -- is required prior to conducting surveys/interviews for all projects involving data collection from **more than 9 individuals who are not VA employees.**

- **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 of other data collection efforts
  - Project Overview, including details re: the number, type, content, and frequency of data collection
  - Justification for Exemption
  - Justification that the study is not duplicative

Follow the template provided in JIT closely
Be specific and concise in providing the requested information.

OMB Exemption Brief:

Justification for Exemption of this Study under 5 CFR Part 1320.3

Research needs to meet only one of the following criteria:

- **Clinical Trial.** Study should meet the following definition of a clinical trial: *"…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."*

- **Clinical Examination.** Criterion should only be used when the surveys/interviews are administered in conjunction with clinical examination (rather than the study just involving clinical examination)

- **Direct Treatment.** Criterion should only be used when the surveys/interviews are administered as part of direct treatment (rather than the research results impacting direct treatment)

- **Prevention of a Clinical Disorder.** Criterion under which most of our non-randomized studies are exempted

- **Interpretation of biological analyses.** Criterion should only be used when the surveys/interviews are administered in conjunction with interpretation of biological analyses

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

Registration Process (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 until SPM confirms the study is ready to start and you have received an email from ART. Please check your VA email.

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

HSR&D Data and Safety Monitoring Board (DSMB)

- Provides ongoing evaluation of studies' progress, including patient accrual and retention, monitoring of 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 charted by HSR&D that meets at specified intervals and requires routine reporting from the PI.

DSMB Referral & Requirements

- Decision for referral to review by the HSR&D DSMB is determined by the SPM at the time of funding decisions.

- General criteria for referral
  - Multi-site clinical trial
  - Studies recruiting from multiple locations (even within a single VAMC) and/or have potentially complicated analytical plans
  - Low-risk studies if the studies are exceptionally large, long term, and/or involve vulnerable subjects

- Studies referred to the HSR&D DSMB are required to submit a Data Analysis Plan (DAP) for review by the DSMB within 45 days of JIT opening.

- 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.

- 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 8ths, 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):

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

Primary VAMC Location (City, State):

Proposed Project Start Date: 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.

Poll #5: Intellectual Property

Who must disclose intellectual property to the VA?

(Select one)

- Salaried Employees
- IPA
- WOC Appointees with Research Responsibilities
- Dual Appointment Personnel
- All of the above

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, **regardless of whether or not the invention is patentable, require that a disclosure be made**. Even if an invention is found not to be patentable, the 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?

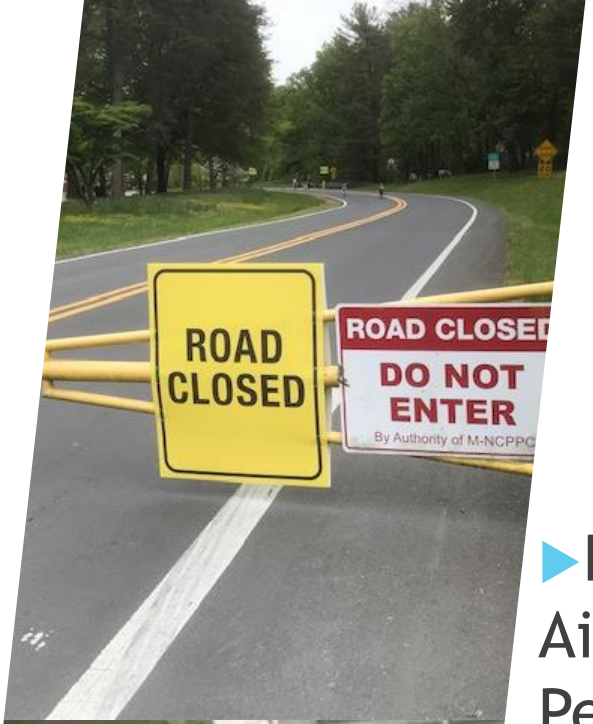
Even if VA made no contribution towards an invention, i.e., the invention was made entirely outside official working hours, unrelated to VA employment, and with no use of VA facilities, equipment, etc., a **VA disclosure is still required by Federal law.** Following receipt of a disclosure, the Technology Transfer office will review the file and make a recommendation regarding ownership and submit it 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 Prefunding and Award

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

- **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 the 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.

Q&A

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

Expertise	Name	Email
		Stephen.Marcus@va.gov
		Robert.O'Brien2@va.gov
		Cathie.Plouzek@va.gov
		Robert.Small@va.gov
		Nsini.Umoh@va.gov

Q&A

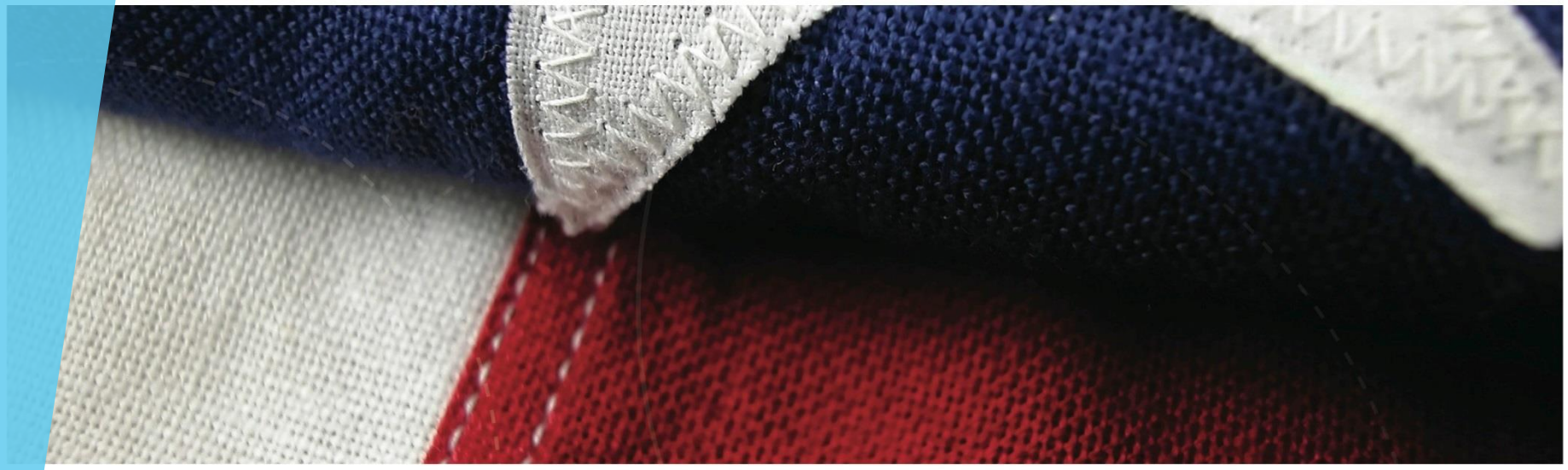
If you have administrative/business questions, please have either you or your Administrative Officer contact:

Expertise	Name	Email
CDA	Rob Small	Robert.Small@va.gov
QUERI	Melissa Braganza	Melissa.Braganza@va.gov
JIT Management	**Tiffin Ross-Shepard**	**Tiffin Ross-Shepard@va.gov**
ORD & HSR&D Finance	Danna Bastien	Danna.Bastien@va.gov
HSR&D Overall Budget & Waivers	Liza Catucci	Liza.Catucci@va.gov
OMB Exemptions	Emily Evans	Emily.Evans1@va.gov
Union Notification	Emily Evans	Emily.Evans1@va.gov
Intellectual Property https://www.research.va.gov/programs/tech_transfer/contacts.cfm	**John Kaplan**	**vattid@va.gov**

Questions?

Please use the chat feature

to submit questions.



Thank you for attending

HSR&D Training:
JIT: “Show Me the Money!!!”

May 2, 2021

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