U.S. Department of Veterans Affairs
Office of Research and Development
(VA-ORD)

VA-ORD Research Performance Progress Report (RPPR) or Final Report (Final RPPR)

Part 2: Completing a Report

For use by VA intramural investigators for progress report submissions to:

Biomedical Laboratory Research & Development Service (BLR&D)
Clinical Science Research & Development Service (CSR&D)
Health Services Research & Development Service (HSR&D)
Quality Enhancement Research Initiative (QUERI)
Rehabilitation Research & Development Service (RR&D)

Revised: October 25, 2018

DISCLAIMER STATEMENT

No data shown in illustrations/figures (screen shots) represent any real account, project, or individual. Any resemblance to actual accounts, projects, or individuals is purely coincidental.

Because the illustrations/figures (screen shots) throughout this document are those that will be viewed by investigators when completing their progress report, VA-ORD has maintained use of those figures presented by the National Institutes of Health (NIH) in its guidance. Thus, any references to PHS (Public Health Service) or NIH in such screen shots should be attributed to VA-ORD (Department of Veterans Affairs-Office of Research and Development). References found throughout the document that should also be attributed to VA-ORD, include:

IC = one of the four Research and Development (R&D) Services within VA-ORD (Biomedical Laboratory [BLR&D], Clinical Science [CSR&D], Health Services [HSR&D], and Rehabilitation [RR&D]). The Quality Enhancement Research Initiative (QUERI) is under the purview of HSR&D.

Grant = Award

Grantee organization or Grantee institution = Awardee's VA Medical Center (VAMC)

Submit to Agency = Submit to VA-ORD

In addition, other references to specific NIH documents reflected in the illustrations/figures, such as the NIH Public Access Policy, have been changed within this guidance to reference appropriate VA-ORD documents and hyperlinks.

RPPR ACRONYMS

ACOS/R	Associate Chief of Staff/Research
AO	Administrative Official
CDA	Career Development Award (CDA-1/IK1, CDA-2/IK2)
COIN	Center of Innovation (I50)
CREATE	Collaborative Research to Enhance and Advance Transformation and Excellence Initiative (I01)
DUA	Data Use Agreement
eRA Commons	Electronic Research Administration
eRA Commons ID	eRA User Identification for log-in to system
Final RPPR	Final Research Performance Progress Report
FOA/RFA	Funding Opportunity Announcement/Request for Application
FRAM	Final Report Additional Materials
HSS	Human Subjects System
IC	NIH term for Institutes and Centers; for VA-ORD the awarding research and development service (Biomedical Laboratory [BLR&D], Clinical Science [CSR&D], Health Services [HSR&D], Rehabilitation [RR&D])
iEdison	Interagency Edison, helps government grantees and contractors comply with a Federal law, the Bayh-Dole Act. Bayh-Dole regulations require that government funded inventions be reported to the Federal agency who made the award.
IDRs	Inclusion Data Records
MB	Megabytes
MPI	Multiple Program Directors/Principal Investigators
MTA	Material Transfer Agreement
My NCBI	My National Center for Biotechnology Information - retains user information and database preferences to provide customized services for many NCBI databases.
NIH	National Institutes of Health
NLM	National Library of Medicine
NRI	Nursing Research Initiative (IK3)
OMB	Office of Management and Budget
OGC	Office of General Counsel
OSC	Other Significant Contributor
PDF	Portable Document Format
PD/PI	Program Director/Principal Investigator

RPPR ACRONYMS (CONTINUED)

PO	Program Official
PHS	Public Health Service
PPED	Project Period End Date
PRAM	Progress Report Additional Materials
PubMed	Comprises more than 24 million citations for biomedical literature from MEDLINE, life science journals, and online books. Citations may include links to full-text content from PubMed Central and publisher Web sites.
PubMed Central® (PMC)	A free archive of biomedical and life sciences journal literature at the U.S. National Institutes of Health's National Library of Medicine (NIH/NLM).
RCS	Research Career Scientist Award (IK6)
REAP	Research Enhancement Award Program (I50)
RePORT	NIH's Research Portfolio Online Reporting Tool
RPPR	Research Performance Progress Report
SNAP	Streamlined Noncompeting Award Process
SO	Signing Official
SPM	Scientific Portfolio Manager
TTP	Technology Transfer Program
TTS	Technology Transfer Specialist
URL	Uniform Resource Locator (Internet Web site addresses)
VA	Department of Veterans Affairs
VAMC	VA Medical Center
VA-ORD	Department of Veterans Affairs-Office of Research and Development
VHA	Veterans Health Administration
WIP	Work in Progress

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LIST OF FIGURES

1 Purpose

The purpose of Part 2 is to provide those preparing a Research Performance Progress Report (RPPR) or Final Report (Final RPPR) in Electronic Research Administration (eRA) Commons with guidance on completing the report content specific to VA-ORD award reporting requirements. *Not all NIH questions within the report template may be relevant to VA-ORD - within each section,* and VA-ORD may direct awardees to complete only specific questions or provide other content. In Part 1, VA-ORD provides the steps for accessing and completing the report in eRA Commons, as well as navigating, validating, routing, and submitting the RPPR or Final RPPR, and submitting any additional materials requested (via PRAM or FRAM) to VA-ORD for review and approval.

Progress reports are required to continue support of a VA-ORD award for each budget year within a competitive segment. Final reports are required for any funded award that has ended and will not be extended through a renewal or other award. PD/PIs (program director/principal investigators) must be current with all requirements related to submission of RPPRs, final reports, clinical trials registration and results reporting (i.e., ART/clinicaltrials.gov) for existing and previous awards for continued future application submission acceptance and consideration of funding.

2 RPPR Differences and Due Dates

The RPPR and Final RPPR are nearly identical in process, format and information required. Differences between the annual RPPR and Final RPPR are few – for the Final report, only Section D.1 is required in the Participants section; Section F. Changes is not available; and Section I. Outcomes is now required (see special instructions under this section). In addition, there is the difference for when and where the reports are made available to initiate and submit.

For RPPRs, three automatic email notifications are sent from eRA to the PD/PI prior to the report due date – at 60 days, 30 days and about 4 days after the due date.

As an awardee, you can determine which **progress reports** are due (4 months out from due date) through the website located at: https://public.era.nih.gov/chl/public/search/progressReportByIpf.era, by entering your organization's IPF number. You should periodically check the site, which is updated on/around the 30th of each month. Progress report due dates are also available in the eRA Commons Status system.

A Final RPPR template becomes available after the project period end date (PPED) as part of the Closeout process with the link appearing only on the Closeout Status screen. Three Closeout emails are sent from eRA to the PD/PI and Signing Official (SO) at 10, 120 and 150 days after the PPED.

VA-ORD awards are considered SNAP (Streamlined Noncompeting Award Process), therefore, a progress report is due the 15th of the month preceding the month in which the budget

period ends (e.g., if the budget period ends 11/30, the due date is 10/15). Final reports are due within 120 calendar days of the PPED (e.g., if the PPED is 6/30, the report must be submitted by 11/1). If the due date falls on a weekend or Federal holiday, the due date is automatically extended to the next business day.

3 Completing a RPPR or Final RPPR - Sections A–I

These instructions apply to the following VA-ORD awards: I01 (Merit and Collaborative Research to Enhance and Advance Transformation and Excellence Initiative/CREATE, I21 (pilot/SPiRE), and K-Series awards (IK1 and IK2 Career Development Awards/CDA, IK3 Nursing Research Initiative/NRI, and IK6 Research Career Scientist/RCS). The RPPR and Final RPPR are currently not available in eRA Commons for I50 awards (Centers, Research Enhancement Award Programs/REAPs, and Centers of Innovation/COIN).

Although the RPPR template is NIH based, there are exceptions throughout (items that are not applicable, replace, or are in addition to) that are specific to VA-ORD. There are also Supplemental Instructions for Specific Grant (Award) Types and Special Instructions for Section I. Outcomes (for Final RPPRs) that must be followed in addition to the standard instructions. While the electronic RPPR display is dynamic and shows the appropriate questions and instructions based on the activity code and SNAP status of the award, the template is still specific to NIH grants – which is why it is important to review all guidance in this document when completing a VA-ORD report. NOT APPLICABLE next to a particular question/item indicates that item does not apply to the particular VA-ORD award, and it can be ignored.

See the VA-ORD Application Guide SF424 (R&R), for application submission instructions.

Whenever there are significant changes in the project or its direction, you (as the PD/PI) are required to obtain prior written approval from the appropriate R&D Service within VA-ORD. *The RPPR is not an appropriate vehicle to request significant changes.* See ORD Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification.

Section A – Cover Page

Section A. Cover Page includes information about the award, PD/PI, organization, and project/reporting/budget periods. Much of this information is pre-populated from data in eRA systems, but certain fields are editable.

The addresses, emails and phone numbers are pre-populated from the Commons Profile. To update contact information as displayed, go to the Commons Profile and save the changes there.

To select a Signing Official (SO) and Administrative Official (AO), choose a name from the associated drop-down box. The SO and AO may be the same individual. The SO need not be the SO that submits the report.

If there has been an approved change to the Contact PD/PI (Multiple PD/PI awards only), select the **YES** radio button and enter the Commons ID (user identification) of the new Contact PD/PI in the associated field. The change in Contact PD/PI does not take effect in the RPPR system

until VA-ORD accepts the report. The Contact PD/PI must have a PD/PI role in eRA Commons and must be associated with a VAMC.

The RPPR is not an appropriate vehicle for a request to change, add, or delete PD/PIs. All such requests for significant change must follow guidance appropriate for the specific R&D Service within VA-ORD. See ORD Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification.

The **Recipient ID** field allows the awardee to record an internal tracking number or identifier for its own use. It is not a mandatory field and the awarding R&D Service within VA-ORD will disregard the information.

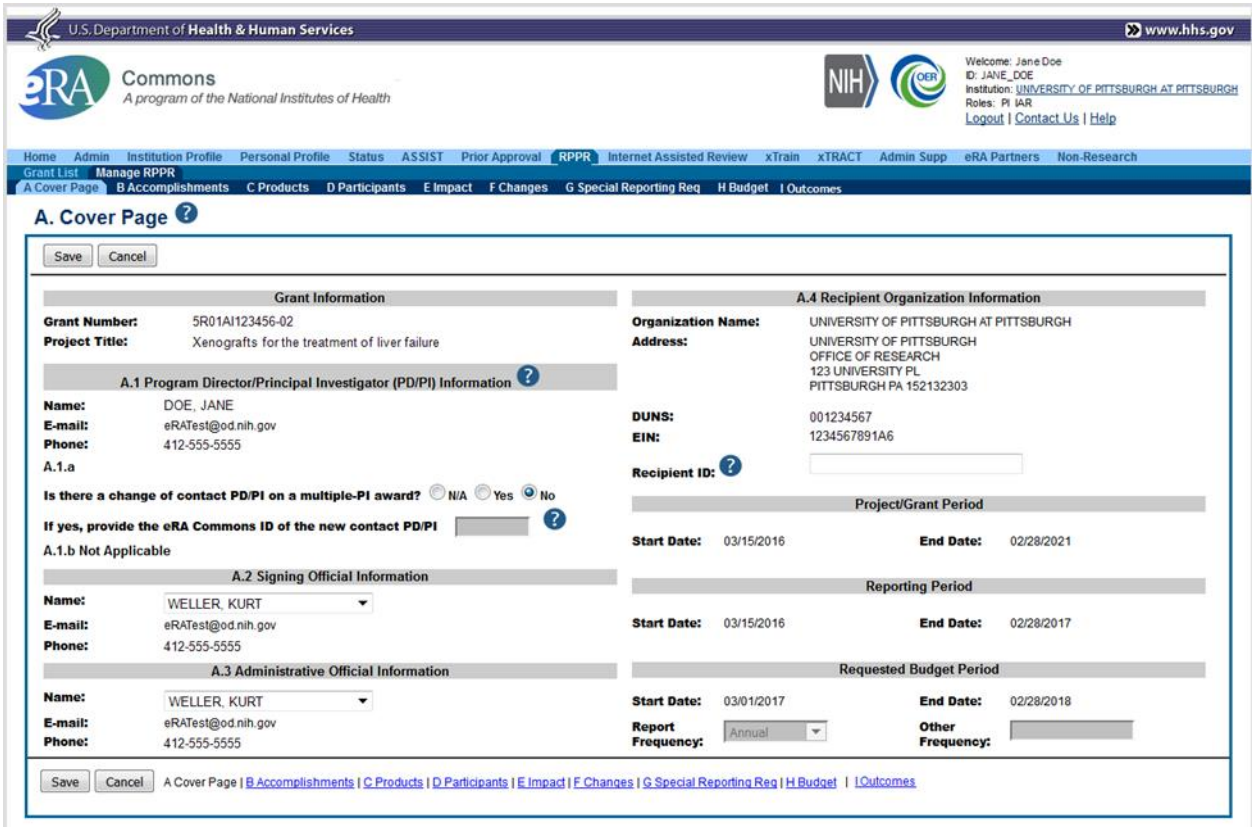


Figure 1: RPPR Section A. Cover Page

NOTE: It is important to click the SAVE button in the navigation bar before leaving a screen (section) in order to retain data entered on that screen.

Section B – Accomplishments

Section B. Accomplishments allows VA-ORD to assess whether satisfactory progress has been made during the reporting period.

Whenever there are significant changes in the project or its direction, you (as the PD/PI) are required to obtain prior written approval from the appropriate R&D Service within VA-ORD. ***The RPPR is not an appropriate vehicle to request significant changes.*** See ORD

Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification.

B.1. What are the major goals of the project?

Goals are equivalent to *specific aims*. List the specific aims of the project as stated in the approved application or as approved by VA-ORD through a project modification. If the application lists milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Generally, the specific aims will not change from one reporting period to the next. However, if VA-ORD approved changes to the specific aims during the reporting period, list the revised aims. Also explain any significant changes in approach or methods from the VA-ORD approved application or plan.

Significant changes in specific aims ***require prior written approval*** (through a project modification request) by the awarding R&D Service within VA-ORD. ***The RPPR is not an appropriate vehicle to request such a change.*** See ORD Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification.

The specific aims must be provided in the initial RPPR. In subsequent RPPRs this section will pre-populate with the aims previously entered, and may be amended by answering **YES** to question B.1.a.

B.1.a. Have the major goals changed since the initial competing award or previous report?

Select **YES** if the specific aims have changed since the initial competing award or previous report, and provide a revised description.

Significant changes in specific aims ***require prior written approval*** (through a project modification request) by the awarding R&D Service within VA-ORD. ***The RPPR is not an appropriate vehicle to request such a change.*** See ORD Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification.

The first year that a RPPR is submitted, any revised specific aims should be entered into the text box for B.1. In subsequent years, if you select **YES** the text box under B.1.a., will be provided for entering revised specific aims.

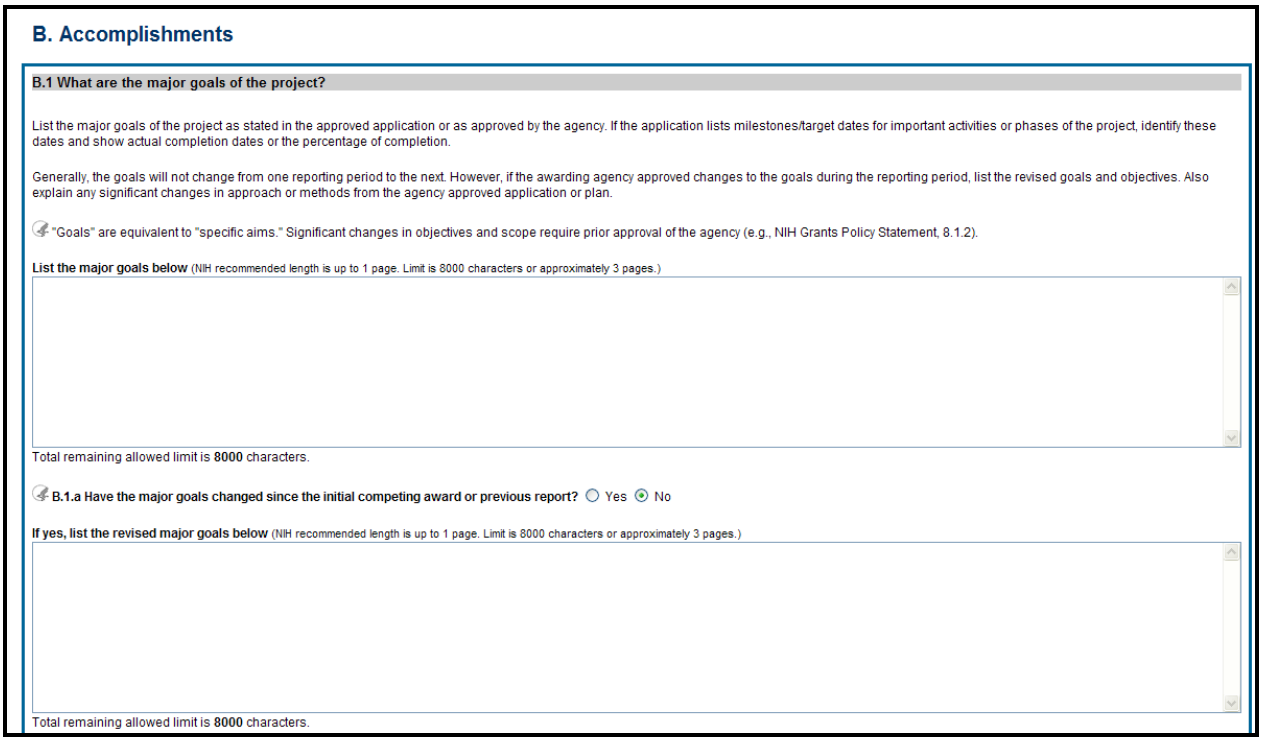


Figure 2: RPPR Section B. Accomplishments - Question B1

B.2. What was accomplished under these goals?

For this reporting period, for each specific aim describe in detail (using the space allowed - up to 2 pages): 1) major activities; 2) specific objectives; 3) significant results, including major findings, developments, or conclusions (both positive and negative); and 4) key outcomes or other achievements. Include a discussion of stated aims not met. Emphasize the significance of the findings to the scientific field. As the project progresses, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Projects that involve the recruitment of human subjects must include one of the following statements regarding recruitment:

a. not yet recruiting;

b. recruiting;

c. no longer recruiting (i.e., recruitment goal has not been met); or

d. recruitment completed (i.e., recruitment goal has been met).

In addition, include the projected enrollment to date and actual enrollment to date.

NOTE: For Final RPPRs, include only the actual enrollment completed for the project.

Significant changes in specific aims ***require prior written approval*** (through a project modification request) by the awarding R&D Service within VA-ORD. ***The RPPR is not an appropriate vehicle to request such a change.*** See ORD Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification.

B.3. Competitive Revisions/Administrative Supplements

For this reporting period, are there one or more Revisions/Supplements associated with this award for which reporting is required?

Answer NO to this question, and click "OK" – this will remove any text entered inadvertently in B.3., text boxes. VA-ORD does not accept submission of competing supplemental applications ("Revision" applications), which would request additional support for expansion of an existing project's scope or research protocol.

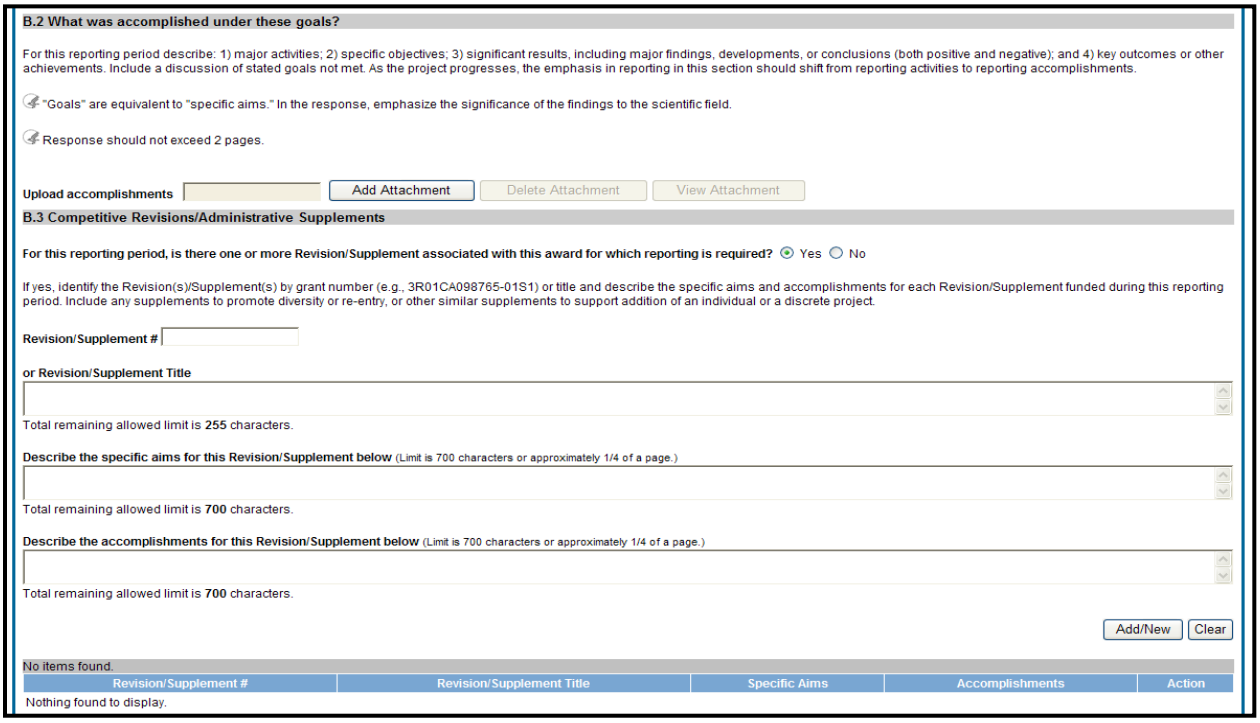


Figure 3: RPPR Section B. Accomplishments - Questions B2 & B3

B.4. What opportunities for training and professional development has the project provided?

If the research is not intended to provide training and professional development opportunities or there is nothing significant to report during the reporting period, select: **Nothing to Report**.

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project.

Training activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor.

Professional development activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

For K-Series awards - IK1 and IK2 (CDAs), IK3 (NRI), and IK6 (RCS) designed to provide training and professional development opportunities, a response is REQUIRED. Do not reiterate what is reported under Accomplishments. Limit the response to this reporting period (except for Final RPPRs which require a response covering the entire award period), and upload a PDF attachment. See Supplemental Instructions for Specific Grant (Award) Types for additional information.

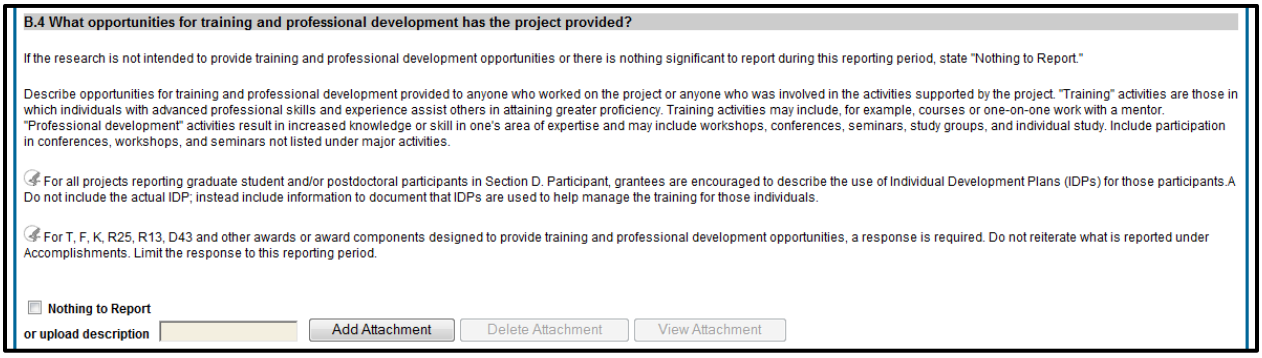


Figure 4: RPPR Section B. Accomplishments – Question B4

B.5. How have results been disseminated to communities of interest?

Describe how the results have been disseminated to stakeholders within VA and the broader community (See VHA Handbook 1200.19 Presentation of Research Results). Include any outreach activities that have been undertaken for the purpose of enhancing understanding and increasing interest in learning and careers in science, technology, and health care delivery. Ensure that public access has been accomplished within the required timeframe as outlined in your Notice of Award.

In this section, you should include any presentation(s) at scientific meetings (oral and/or poster) and briefings for VA offices relevant to the award. In addition, all presentations must be communicated to the VHA Research Communications Office (http://vaww.pubtracker.research.va.gov), and must cite the PI's VA affiliation and the award (grant) number. Note that scientific publications and the sharing of research resources will be reported under Section C. Products.

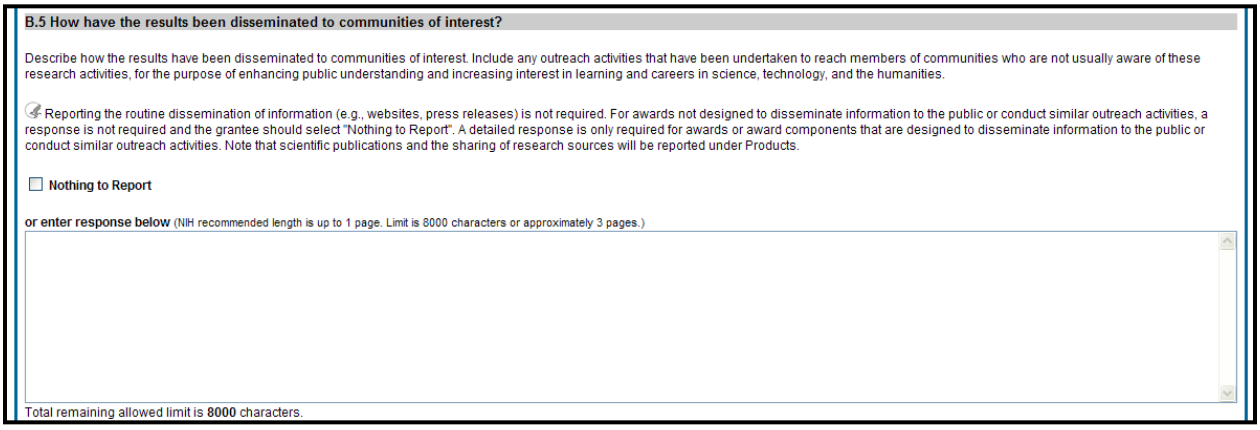


Figure 5: RPPR Section B. Accomplishments – Question B5

B.6. What do you plan to do for the next reporting period to accomplish the goals?

(Not Required for Final RPPR)

Describe in detail what you plan to do during the next reporting period to accomplish each specific aim using the full space allowed – up to 8000 characters/approximately 3 pages. **NOTE:** A one to two word/short response is not considered acceptable for reporting on this section.

Significant changes in specific aims ***require prior written approval*** (through a project modification request) by the awarding R&D Service within VA-ORD. ***The RPPR is not an appropriate vehicle to request such a change.*** See ORD Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification.

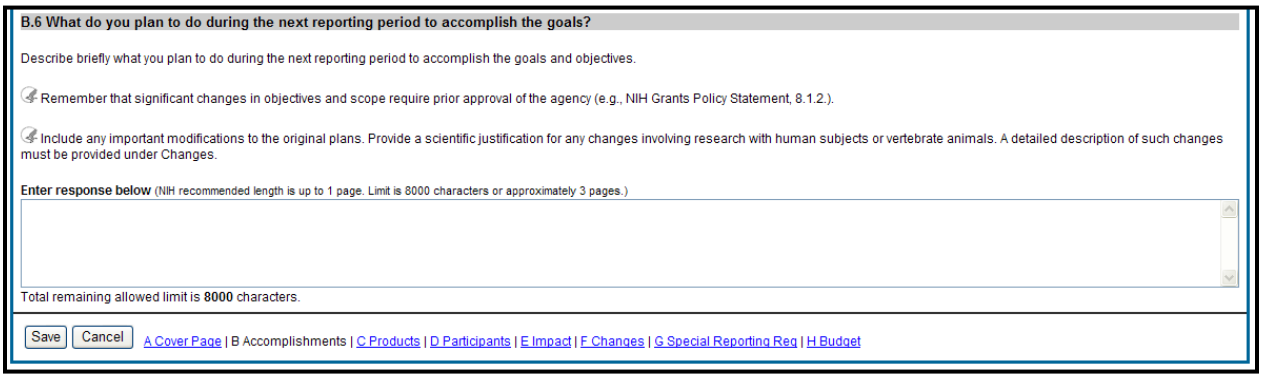


Figure 6: RPPR Section B. Accomplishments – Question B6

NOTE: It is important to click the SAVE button in the navigation bar before leaving a screen (section) in order to retain data entered on that screen.

Section C – Products

Section C. Products allows VA-ORD to assess and report both publications and other products to Congress, communities of interest, and the public.

C.1. Publications

Are there relevant publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, monograph) during the reporting period resulting directly from this award?

You are REQUIRED to report all publications that result from your VA-ORD award within the reporting period in this section. All publications in My NCBI must cite the PD/PI's VA affiliation and the award (grant) number for the award.

Publications listed in other parts of the RPPR will not be tracked as award products. If there are publications to report select **YES** and ensure that the '**Associate with this RPPR'** box is checked as appropriate. **For those publications that are not accessible through PubMed, please provide the VA-ORD Program Official (PO) with a copy of the award-relevant publications.**

If there are no publications to report select, **No**. The tables draw information from the PD/PI's My NCBI account. You can log in to your My NCBI account via the **My NCBI** link at the top of the C.1 screen. For guidance on linking eRA Commons, University or other account to your NCBI account go to Sign in to NCBI, under Account Troubleshooting FAQ, click on Link eRA Commons, University, or other account to your NCBI account.

My NCBI Management

Log into your My NCBI account. If you do not have a My NCBI account, you can create one by simply logging in to My NCBI with your eRA Commons credentials, which will automatically create a My NCBI account. Note that the publication data in these tables is dynamic until the report is submitted to the VA-ORD. Any change to data occurring in PubMed, PubMed Central and your My Bibliography account, will be reflected in the report once the screen is refreshed (i.e., by clicking the **Save** button) or opening the RPPR in another session. When the report is submitted to VA-ORD, the publication data is frozen in the report. NOTE: The first time a RPPR is submitted, all award-paper associations you have made in My Bibliography are reported as a part of a one-time transitional measure to ensure that the required systems can store all appropriate associations (Reporting Publications in Research Performance Progress Report (RPPR) NOT-OD-15-090). For more information, go to My NCBI.

Table 1: All Publications Associated with this Project in My NCBI

The ***first table***, '**All Publications Associated with this Project in My NCBI'**, lists all publications that are in your My Bibliography collection, are associated with this award, and have not been reported in previous reports for this award.

The ***first column*** '**Associate with this RPPR'** is automatically checked. Leaving the box checked upon submission does the following: (1) associates the publication with this report; (2) results in the publication being displayed in RePORT (Research Portfolio Online Reporting Tool); and (3) makes the award-publication association in My NCBI permanent and the association will be reported in PubMed. Unchecking the box does the following: (1) disassociates the publication with this report, and (2) upon submission of the RPPR to VA-ORD, removes the award-publication association in My NCBI. NOTE: When selecting/deselecting publications for RPPR submission, you will see a gold lock next to those publications that cannot be removed from the RPPR. To remove an award affiliation from a publication with a gold lock, you will need to contact the NIH Manuscript Submissions (NIHMS) Help Desk through its web form.

The ***second column***, 'NIH Public Access Compliance', is NOT APPLICABLE for VA-ORD awards and therefore, the status displayed will be "**N/A: Not NIH Funded**".

Table 2: Publications Not Associated with this Project in My NCBI

The ***second table***, '**Publications not associated with this project in MyNCBI'**, lists all other publications that are in your My Bibliography collection but do not have an association to this award. Checking **Associate with this RPPR** box will associate a publication with the award both in the report and in My NCBI. **Only publications associated with your VA-ORD award will be evaluated as products resulting from the project. Do NOT include any other publications.**

Refreshing this screen (i.e., clicking the Save button) will also remove the newly associated publications from this table to the first table. Similarly, publications disassociated in the first table will appear in this table when the screen is refreshed.

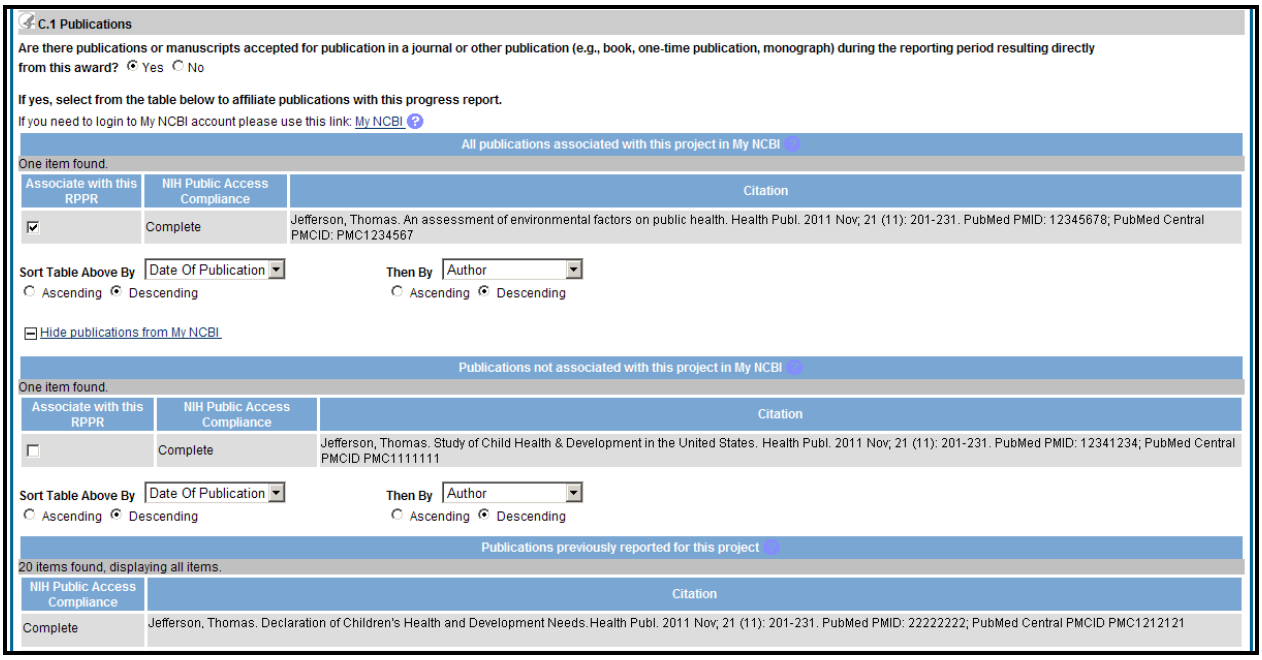
Table 3: Publications Previously Reported for this Project

The ***final table***, '**Publications previously reported for this project'**, lists publications reported in a previous electronic progress report for this award. **You are responsible for ensuring that these publications comply with the VA Public Access policy** (see VHA Handbook 1200.19 and ORD Public Access, NIH Manuscript Submission for VA Investigators) **even if they were provisionally compliant (listed as *in Progress*) when previously reported.** In addition, you must notify the VHA Research Communications Office of the publications (Go to the ORD PubTracker at http://vaww.pubtracker.research.va.gov/PubTracker/default.cfm).

Submitting a RPPR with Noncompliant Publications

The report may be submitted with noncompliant publications; however the Scientific Portfolio Manager (SPM) will be reviewing the RPPR for compliance with VA Public Access policy, and will send an email to you (with copy (cc) to your VAMC Administrative Official and Signing Official) requesting that the you provide evidence of compliance or an explanation (e.g., the sole author has passed away before s/he was able to process the manuscript for posting to PubMed Central) by a specified due date. You must respond either via an email to the appropriate SPM, or respond via the Progress Report Additional Materials (**PRAM**) or Final Report Additional Materials (**FRAM**) link found on the eRA Commons Status page, if PRAM or FRAM has been initiated. The **PRAM** and **FRAM** links provide a text box in which you may respond through eRA Commons. You will be able to view the PRAM/FRAM in the award folder.

Publications listed in other parts of a report are not captured electronically. They will not be included in this table, and may not be listed as resulting from this award in RePORT.


C.1 Publications

Are there publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, monograph) during the reporting period resulting directly from this award? Yes No

If yes, select from the table below to affiliate publications with this progress report.

If you need to login to My NCBI account please use this link: My NCBI

All publications associated with this project in My NCBI

One item found.

Associate with this RPPR	NIH Public Access Compliance	Citation
☑	Complete	Jefferson, Thomas. An assessment of environmental factors on public health. Health Publ. 2011 Nov; 21 (11): 201-231. PubMed PMID: 12345678; PubMed Central PMCID: PMC1234567

Sort Table Above By: Date Of Publication — Ascending / Descending

Then By: Author — Ascending / Descending

Hide publications from My NCBI

Publications not associated with this project in My NCBI

One item found.

Associate with this RPPR	NIH Public Access Compliance	Citation
☐	Complete	Jefferson, Thomas. Study of Child Health & Development in the United States. Health Publ. 2011 Nov; 21 (11): 201-231. PubMed PMID: 12341234; PubMed Central PMCID PMC1111111

Sort Table Above By: Date Of Publication — Ascending / Descending

Then By: Author — Ascending / Descending

Publications previously reported for this project

20 items found, displaying all items.

NIH Public Access Compliance	Citation
Complete	Jefferson, Thomas. Declaration of Children's Health and Development Needs.Health Publ. 2011 Nov; 21 (11): 201-231. PubMed PMID: 22222222; PubMed Central PMCID PMC1212121

Figure 7: RPPR Section C. Products – Question C1

C.2. Web site(s) or other Internet site(s)

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above.

Most VA-ORD awards are not designed to create or maintain Web sites, in which case, a response is not required and you should select **Nothing to Report**. However, if the award is designed to create or maintain one or more Web site(s) to disseminate a product that falls into one or more of the other product categories, please select the appropriate category(ies) from the pull-down menu (select multiple categories, if appropriate, by holding down the *Ctrl* button while selecting the categories). If the Web site(s) is designed to disseminate information to communities of interest, then a description is also required.

C.3. Technologies or techniques

Identify technologies or techniques that have resulted from the research activities related to this award for this reporting period. Describe the technologies or techniques developed and how they would best be shared if available, include a file/case number for inventions and/or patents to the text box (see C.4. instructions below). Examples include, but are not limited to improved compositions or processes, tool kits, clinical decision aids, computer programs, mobile applications, inventions and patents.

In the Text Box, provide a paragraph describing the technology, and if available, a file/case number for any inventions and/or patents if filed/issued.

If the technology or technique falls into one or more of the product categories, please select the appropriate category(ies) from the pull-down menu (select multiple categories, if applicable, by holding down the *Ctrl* button while selecting the categories). If there are no technologies or techniques to report select **Nothing to Report**.

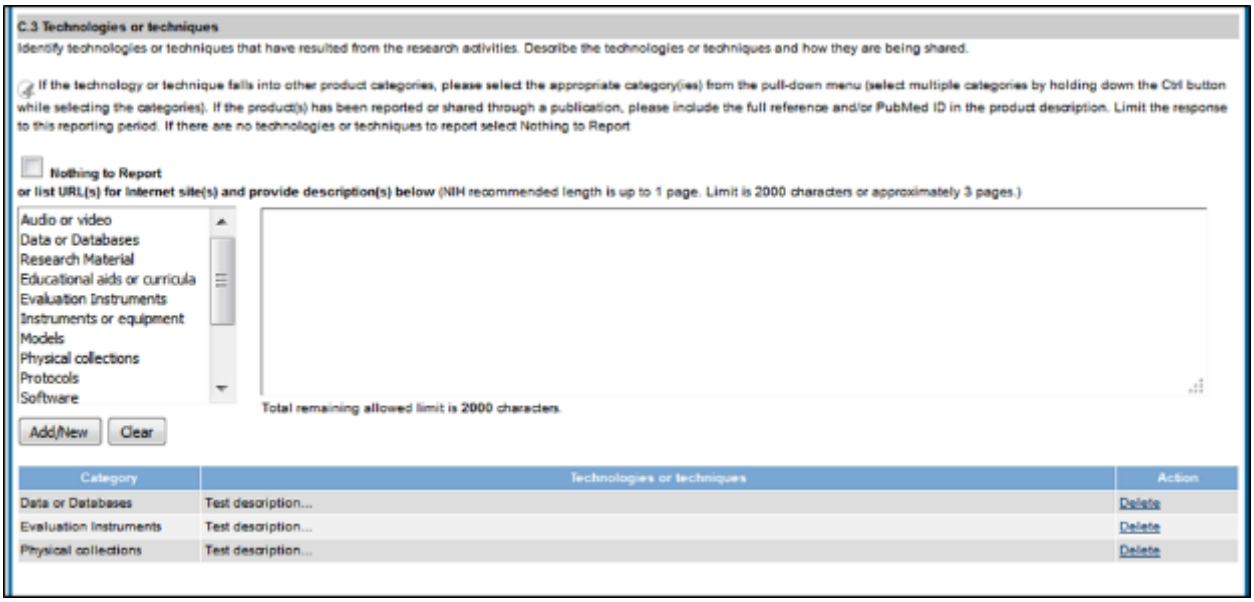


Figure 8: RPPR Section C. Products – Question C3

C.4. Inventions, patent applications and/or licenses

Have inventions, patent applications and/or licenses resulted from the award during this reporting period?

If YES, has this information been previously provided to the PHS [VA-ORD] or to the official responsible for patent matters at the grantee organization?

If YES to the first question, provide a paragraph describing the technology, and if available, a file/case number for inventions and/or patents to the C.3. Technologies or Techniques text box (Figure 8 above). All inventions must be reported to the VA-ORD Technology Transfer Program (TTP) using the invention disclosure and certification forms available at Forms, Templates and Model Agreements. Questions about inventions, patent applications or licenses can be directed to your regional Technology Transfer Specialist (TTS). TTSs and their contact information can be found on the Technology Transfer Program Contacts web page.

NOTE: VA-ORD does not use iEdison, therefore reporting of inventions through this system is not required.

C.5. Other products and resources

C.5.a. Other products

Identify any other significant products that were developed under this project during this reporting period. Upload a PDF attachment describing such products.

Describe the product(s) and how it is or will be made available to be shared with the research community and/or Veterans. Products may be data or material. Do not repeat information provided above.

Examples of other products are: audio or video products; data and research material (e.g., imaging agents, pro-drug, cell lines, DNA probes, animal models, model organisms, survey instruments); databases; educational aids or curricula; instruments; devices; computational models; protocols; and software or netware. For sharing of animal models and/or model organisms, include information on the number of requests received and number of requests fulfilled during this reporting period.

Please note that all requests for sharing data or material must be evaluated by the appropriate individuals within your VA Facility to determine whether it is appropriate to share the materials or data, including whether or not a Material Transfer Agreement (MTA) or Data Use Agreement (DUA) is needed or required. For example, if biospecimens are to be shared with a non-VA institution, the appropriate authority must be present to allow the sharing of the biospecimens. The authority to share research materials such as biospecimens should be described in the VA-ORD and Office of General Counsel (OGC) approved MTA between your VA Facility and the recipient institution. A MTA is only for use with non-profit or academic institutions. If the research material will be utilized for screening, production, or sale, please contact the VA-ORD funding Service for guidance. If the research materials are to be shared with a for-profit organization or company, a license is used instead of a MTA. Please contact the VA Technology Transfer Program.

If the request for sharing data requires use of a DUA as required by VA-ORD policies, the VA-ORD and OGC approved DUA template must be used or an equivalent document as approved by OGC. The DUA is located on the ORD Policies and Guidance webpage. If the data is to be shared with a for-profit organization or company, please contact the VA Technology Transfer Program.

More information about the VA Technology Transfer Program can be found at https://www.research.va.gov/programs/tech_transfer/default.cfm.

If no products were developed under this project, select **Nothing to Report**.

C.5.b. Resource Sharing

Describe the progress in implementing the sharing of final research data, Genome Wide Association Studies data, or other such project-specific data, based on the Data Management and Access Plan (DMAP) included in the project e-application. If the sharing plan is fully implemented, provide a final statement on data sharing.

If nothing has been shared for the reporting period, select **Nothing to Report**.

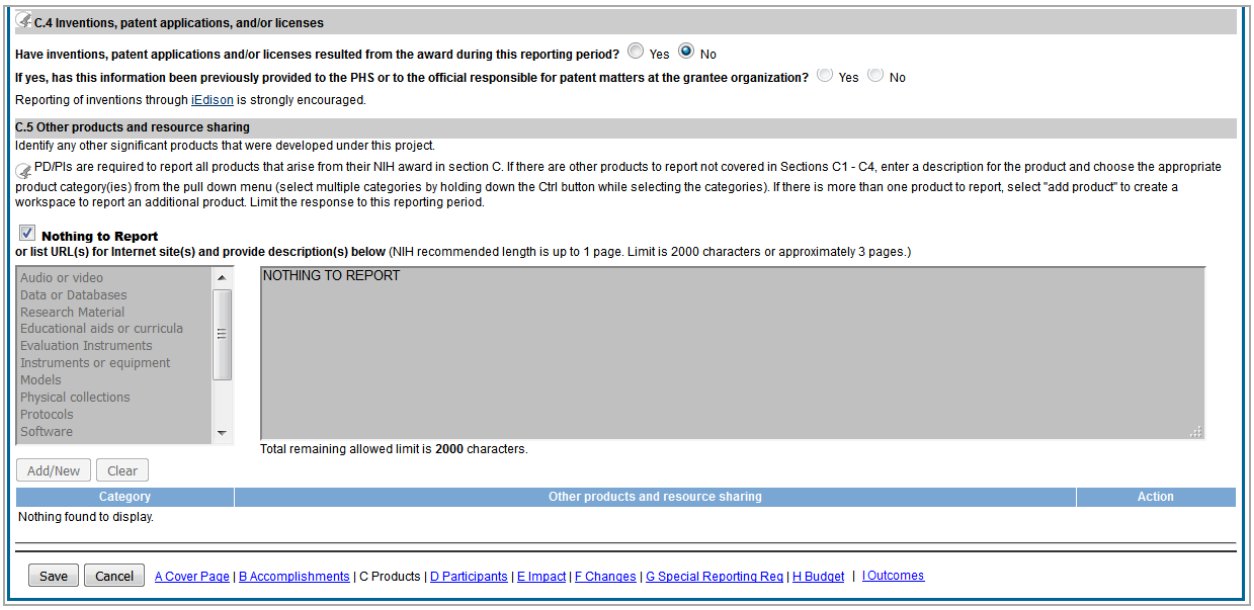


Figure 9: RPPR Section C. Products – Questions C4 & C5

NOTE: It is important to click the SAVE button in the navigation bar before leaving a screen (section) in order to retain data entered on that screen.

Section D – Participants

Section D – Participants allows VA-ORD to know who has worked on the project to gauge and report performance in promoting partnerships and collaborations.

D.1. What individuals have worked on the project? (Required for Final RPPR)

Provide or update the information for: (1) PDs/PIs, mentor(s); and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of the compensation.

Provide the name and identify the role the person played in the project. The RPPR template now allows for one decimal point in the level of effort for all participants so the actual person months that the individual worked on the project can be reflected in the report (Calendar, Academic, Summer). For example, if the individual worked 2.5 person months, you may now enter 2.5 person months. A zero (0) can no longer be entered for person months as level of effort. Show the most senior role in which the person has worked on the project for any significant length of time.

Required fields are marked with a RED asterisk (*).

Do not include Other Significant Contributors (OSCs) who are not committing any specified measurable effort to this project.

eRA Commons User ID: Entering the User ID allows selection of "Populate from Profile" which will partially populate the individual's information.

Senior/Key Personnel are defined as the PD/PI *and other individuals (e.g., mentors)* who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries or compensation are requested under the award.

Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level should be included if their involvement meets the definition of Senior/Key Personnel. Consultants and those with a postdoctoral role should also be included if they meet the definition of Senior/Key Personnel. Senior/Key Personnel must devote measurable effort to the project whether or not salaries or compensation are requested – "0"/zero percent" effort or "as needed" are not acceptable levels for those designated as Senior/Key Personnel.

Last 4 digits of Social Security number and Month/Year of birth: The provision of the partial Social Security number and month/year of birth are voluntary.

Project Role: PD/PI name(s) and information from their Commons Profile(s) will be prepopulated. To update the PD/PI information as displayed, go to the Commons Profile and save the changes there. For all other personnel, select from a dropdown menu of the following options:

- **Co-Investigator**
- **Faculty – i.e., Mentor(s) for Career Development Awards**
- **Postdoctoral (scholar, fellow or other postdoctoral position)**
- **Technician**
- **Staff Scientist (doctoral level)**
- **Statistician**
- **Graduate Student (research assistant) – No salary allowed**
- **Non-Student Research Assistant**
- **Undergraduate Student – No salary allowed**
- **High School Student – No salary allowed**
- **Consultant – No salary allowed for VA or non-VA clinicians** (a licensed practitioner with a doctoral degree, M.D., D.O., D.D.S., Ph.D., etc.)
- **Other (specify)** – (i.e., Interagency Personnel Agreement [IPA])

Supplement Support: NOT APPLICABLE

Person Months: The metric for expressing the effort (amount of time) devoted to a specific project. The effort is based on the type of appointment of the individual with the organization; e.g., calendar year, academic year, and/or summer term; and the organization's definition of such.

Include (1) the PD/PI regardless of effort devoted to the project, and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation.

The RPPR template now allows for one decimal point in the level of effort for all participants so the actual person months that the individual worked on the project can be reflected in the report.

For example, if the individual worked 2.5 person months, indicate 2.5 person months. A zero (0) can no longer be entered for person months as level of effort.

Hours per 40 hour work week spent on the project	Calendar Months Effort	Percent Effort (based on 40 Hour Work Week)
1	0.3	2.5
5	1.5	12.5
10	3.0	25.0
15	4.5	37.5
20	6.0	50.0
25	7.5	62.5
30	9.0	75.0
35	10.5	87.5
40	12.0	100.0

Joint University and Department of Veterans Affairs (VA) Appointments.

Calendar months for VA investigators must be based on the VA 40-hour workweek (e.g., a 5/8th VA appointment = 25 hours/week = 7.5 calendar months). If an individual has multiple appointments their combined effort may exceed 12 calendar months (from the combination of multiple appointments). *In all cases, an individual's combined total professional effort must meet a test of reasonableness.*

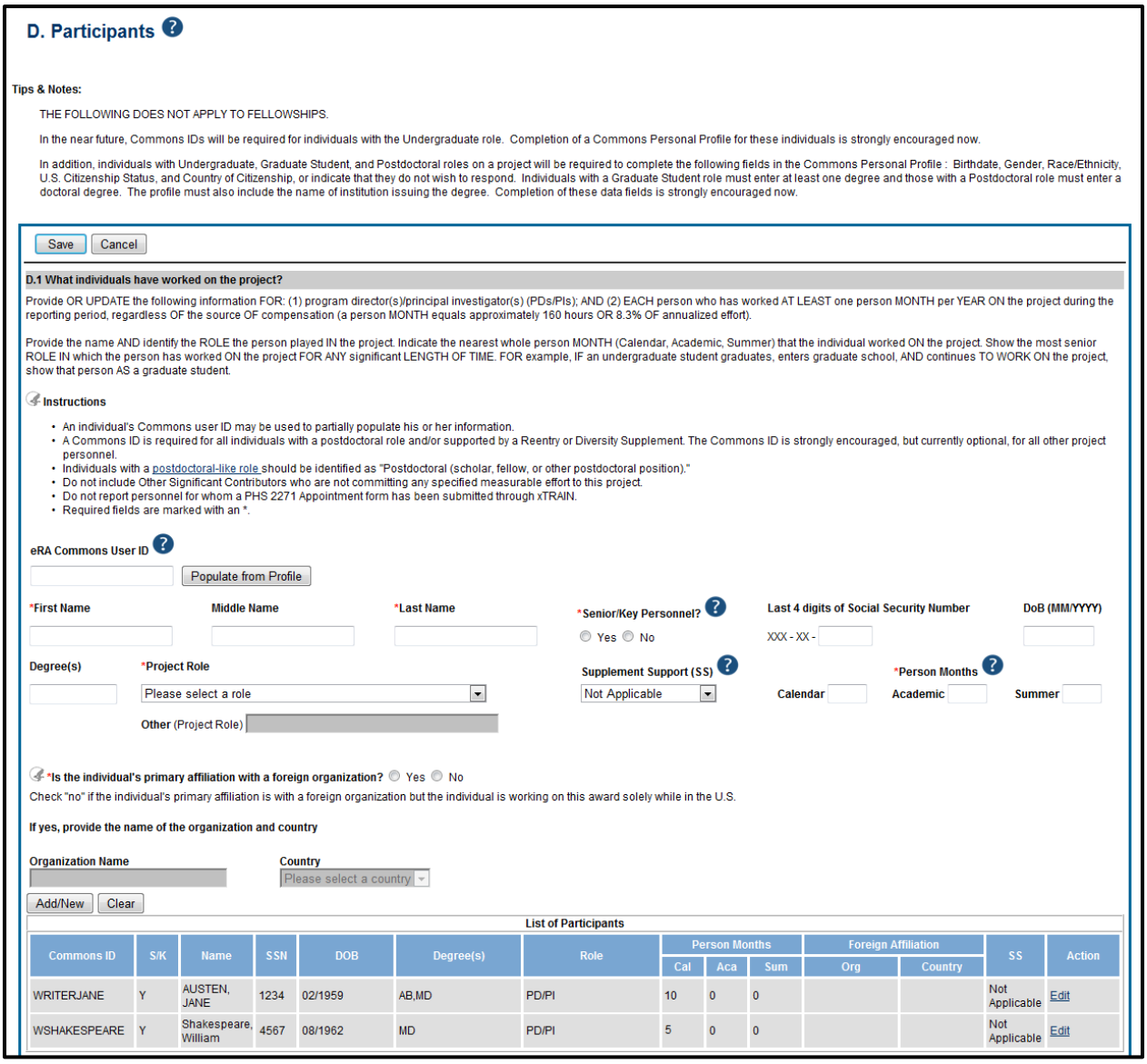
Although it is now possible to report that the PD/PI worked 0.1 to 0.4 person months, a PD/PI must have measurable effort. Change in Level of Effort for the PD/PI(s) and other senior key/personnel designated in the VA-ORD Notice of Award or Funding Letter is reported under D.2.a below.

Is the individual's primary affiliation with a foreign organization?

Check **No** if the individual's primary affiliation is with a foreign organization but the individual is working on this award solely while in the U.S.

If **YES**, provide the name of the organization and country. VA-ORD requires a letter of support from the VAMC Director for all foreign collaborations. See ORD Guidance on Approval of International Research.

Significant changes in key personnel ***require prior written approval*** (through a project modification request) by the awarding R&D Service within VA-ORD. See ORD Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification.



D. Participants

Tips & Notes:

THE FOLLOWING DOES NOT APPLY TO FELLOWSHIPS.

In the near future, Commons IDs will be required for individuals with the Undergraduate role. Completion of a Commons Personal Profile for these individuals is strongly encouraged now.

In addition, individuals with Undergraduate, Graduate Student, and Postdoctoral roles on a project will be required to complete the following fields in the Commons Personal Profile : Birthdate, Gender, Race/Ethnicity, U.S. Citizenship Status, and Country of Citizenship, or indicate that they do not wish to respond. Individuals with a Graduate Student role must enter at least one degree and those with a Postdoctoral role must enter a doctoral degree. The profile must also include the name of institution issuing the degree. Completion of these data fields is strongly encouraged now.

Save | Cancel

D.1 What individuals have worked on the project?

Provide OR UPDATE the following information FOR: (1) program director(s)/principal investigator(s) (PDs/PIs); AND (2) EACH person who has worked AT LEAST one person MONTH per YEAR ON the project during the reporting period, regardless OF the source OF compensation (a person MONTH equals approximately 160 hours OR 8.3% OF annualized effort).

Provide the name AND identify the ROLE the person played IN the project. Indicate the nearest whole person MONTH (Calendar, Academic, Summer) that the individual worked ON the project. Show the most senior ROLE IN which the person has worked ON the project FOR ANY significant LENGTH OF TIME. FOR example, IF an undergraduate student graduates, enters graduate school, AND continues TO WORK ON the project, show that person AS a graduate student.

Instructions

- An individual's Commons user ID may be used to partially populate his or her information.
- A Commons ID is required for all individuals with a postdoctoral role and/or supported by a Reentry or Diversity Supplement. The Commons ID is strongly encouraged, but currently optional, for all other project personnel.
- Individuals with a postdoctoral-like role should be identified as "Postdoctoral (scholar, fellow, or other postdoctoral position)."
- Do not include Other Significant Contributors who are not committing any specified measurable effort to this project.
- Do not report personnel for whom a PHS 2271 Appointment form has been submitted through xTRAIN.
- Required fields are marked with an *.

eRA Commons User ID | Populate from Profile

*First Name | Middle Name | *Last Name | *Senior/Key Personnel? Yes No | Last 4 digits of Social Security Number XXX - XX - | DoB (MM/YYYY)

Degree(s) | *Project Role: Please select a role | Other (Project Role) | Supplement Support (SS): Not Applicable | *Person Months: Calendar | Academic | Summer

*Is the individual's primary affiliation with a foreign organization? Yes No

Check "no" if the individual's primary affiliation is with a foreign organization but the individual is working on this award solely while in the U.S.

If yes, provide the name of the organization and country

Organization Name | Country: Please select a country

Add/New | Clear

List of Participants

Commons ID	S/K	Name	SSN	DOB	Degree(s)	Role	Person Months			Foreign Affiliation		SS	Action
							Cal	Aca	Sum	Org	Country		
WRITERJANE	Y	AUSTEN, JANE	1234	02/1959	AB,MD	PD/PI	10	0	0			Not Applicable	Edit
WSHAKESPEARE	Y	Shakespeare, William	4567	08/1962	MD	PD/PI	5	0	0			Not Applicable	Edit

Figure 10: RPPR Section D. Participants – Question D1

D.2. Personnel Updates (Not Required for Final RPPR)

D.2.a. Level of effort

Has there been an increase/decrease of 25% or more in the level of effort from what was approved by VA-ORD for the PD/PI(s) or other senior/key personnel designated in the Notice of Award or Funding Letter?

Entering "0/zero" is not an appropriate answer to indicate no change in level of effort for senior/key personnel in the reporting period.

Increases/decreases are cumulative, i.e., the 25% threshold may be reached by two or more successive reductions that total 25% or more. Provide a description/explanation of current level of effort for each senior/key personnel in the text box.

EXAMPLE: Reduction from 40% effort to 30% effort equals a 25% reduction.

Once approval by the awarding R&D Service within VA-ORD has been given for a significant change in the level of effort, then all subsequent increases/decreases are measured against the approved adjusted level. Selecting **YES** does not constitute a request for VA-ORD to approve a change in level of effort.

Significant changes in level of effort ***require prior written approval*** (through a project modification request) by the awarding R&D Service within VA-ORD. See ORD Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification.

D.2.b. New senior/key personnel (Not Required for Final RPPR)

Are there, or will there be, new senior/key personnel?

Senior/Key personnel are those identified by the VAMC as individuals who contribute in a substantive measurable way to the scientific development or execution of the project, whether or not salaries are requested. Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered senior/key personnel if the involvement meets this definition. Consultants may be considered senior/key personnel if they meet this definition.

NOTE: **For Career Development Awards**, changes in mentors and/or mentoring commitments must be submitted as project modification requests to the appropriate R&D Service Director for approval 60 days prior to the change (See VHA Handbook 1200.04 ORD Research Career Development Program). See ORD Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification. ***If a project modification request has been approved, upload a copy of the signed project modification form or R&D Service approval letter.***

If YES, upload biosketches and other support for all new senior/key personnel.

If you select YES, the link to upload an attachment of a biosketch(es) will become active.

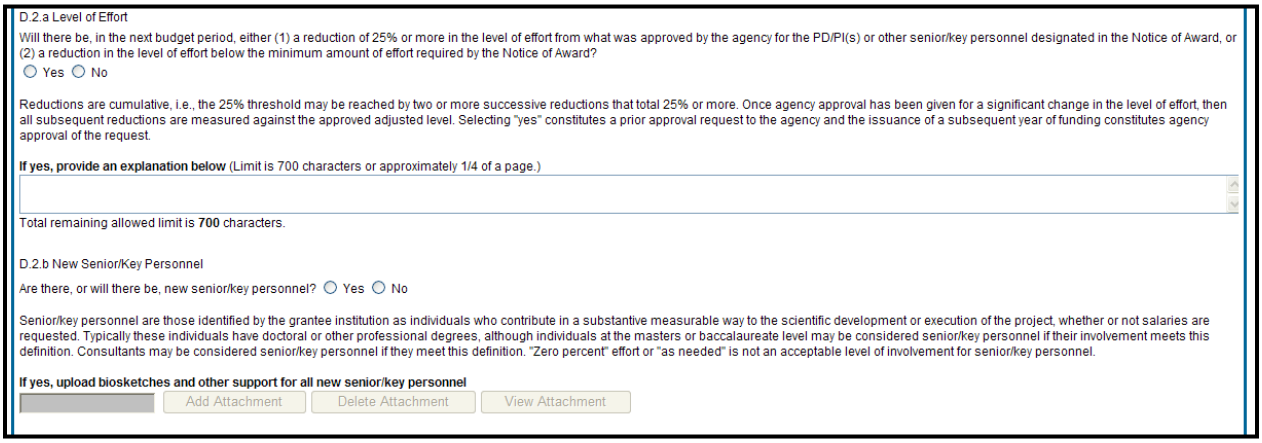


Figure 11: RPPR Section D. Participants – Questions D2a & D2b

D.2.c. Changes in other support (Not Required for Final RPPR)

Has there been a change in the active other support of senior/key personnel since the last reporting period?

If YES, upload active other support ONLY for PD/PI(s) whose support has changed and indicate what the change has been. List the award for which the progress report is being submitted and include the effort that will be devoted in the next reporting period.

If a previously active award has terminated and/or if a previously pending award is now active, upload complete Other Support Information and annotate what has changed from the funded application or previous RPPR submission. The changes must be marked in the text of the application by bracketing, indenting, or change of typography. Do not underline or shade the changes. Deleted information should be described but not marked as deletions.

Other Support Information should be submitted ONLY for PD/PI(s) for which there has been a change in other support. Do NOT include other support information for non-PD/PI(s) (other senior/key personnel) and Other Significant Contributors (OSCs).

D.2.d. New other significant contributors (Not Required for Final RPPR)

Are there, or will there be, new other significant contributors?

OSCs are individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort (i.e., person months) to the project. *Do NOT upload biographical sketches for new OSCs.*

If YES, you must communicate to the R&D Service within VA-ORD for appropriate guidance or submission of a project modification request. The RPPR is not an appropriate vehicle to request such a change. See ORD Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification. ***If a project modification request has been approved, upload a copy of the signed project modification form or R&D Service approval letter.***

D.2.e. Will there be a change in the MPI Leadership Plan for the next budget period?

(Not Required for Final RPPR)

Any change in the Multiple PD/PI Leadership Plan (VA-ORD Application Guide SF424 R&R, Other Project Information, Item 12. Other Attachments) requires prior approval by the awarding R&D Service within VA-ORD. ***Do NOT upload a revised MPI Leadership Plan here.***

If YES, you must communicate to the awarding R&D Service within VA-ORD for appropriate guidance or submission of a project modification request. The RPPR is not an appropriate vehicle to request such a change. See ORD Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification. ***If a project modification request has been approved, upload a copy of the signed project modification form or R&D Service approval letter.***

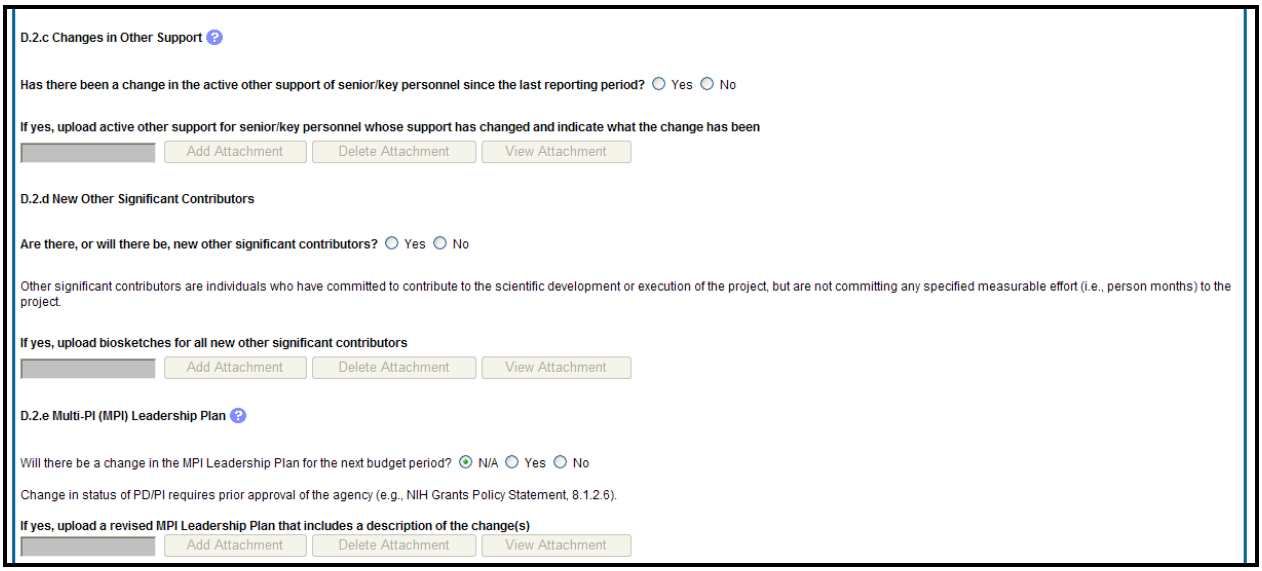


Figure 12: RPPR Section D. Participants – Questions D2c – D2e

NOTE: It is important to click the SAVE button in the navigation bar before leaving a screen (section) in order to retain data entered on that screen.

Section E – Impact

Section E. Impact will be used to describe ways in which the work, findings, and specific products of the project have had an impact during this reporting period.

E.1. NOT APPLICABLE

E.2. What is the impact on physical, institutional, or information resources that form infrastructure?

Describe ways, if any, in which the project made an impact, or is likely to make an impact, on physical, institutional, and information resources that form infrastructure, including:

- physical resources (such as facilities, laboratories, or instruments);
- institutional resources (such as establishment or sustenance of societies or organizations); or
- information resources, electronic means for accessing such resources or for scientific communication, or the like.

In addition, describe the perceived impact of the project (anticipated or observed) on Veterans (e.g., improved quality of care, better outcomes), the VA health care system (e.g., improved management, lower costs) and/or the general public. Also, describe implications for other areas of research or practice such as clinical applications or policy.

Example of Impact Section:

By examining the patterns, barriers, and influences on ambulatory care use by women Veterans with different levels of physical and/or mental health disease burden, the VA may better understand the physical and mental health care needs of women Veterans in ways that will contribute toward identifying potential health care system gaps and approaches for enhancing VA's ability to meet these needs.

If the award is not intended to support physical, institutional, or information resources that form infrastructure, select **Nothing to Report**.

E.3. NOT APPLICABLE

E.4. What dollar amount of the award's budget is being spent in foreign country(ies)?

Appropriate foreign component approval by the VAMC Director must be in place prior to the disbursement of funds. Provide the dollar amount obligated for this reporting period. Dollars provided should reflect total costs. If more than one foreign country, identify the distribution between the foreign countries.

Select the **Add/New** button to add the data to the table.

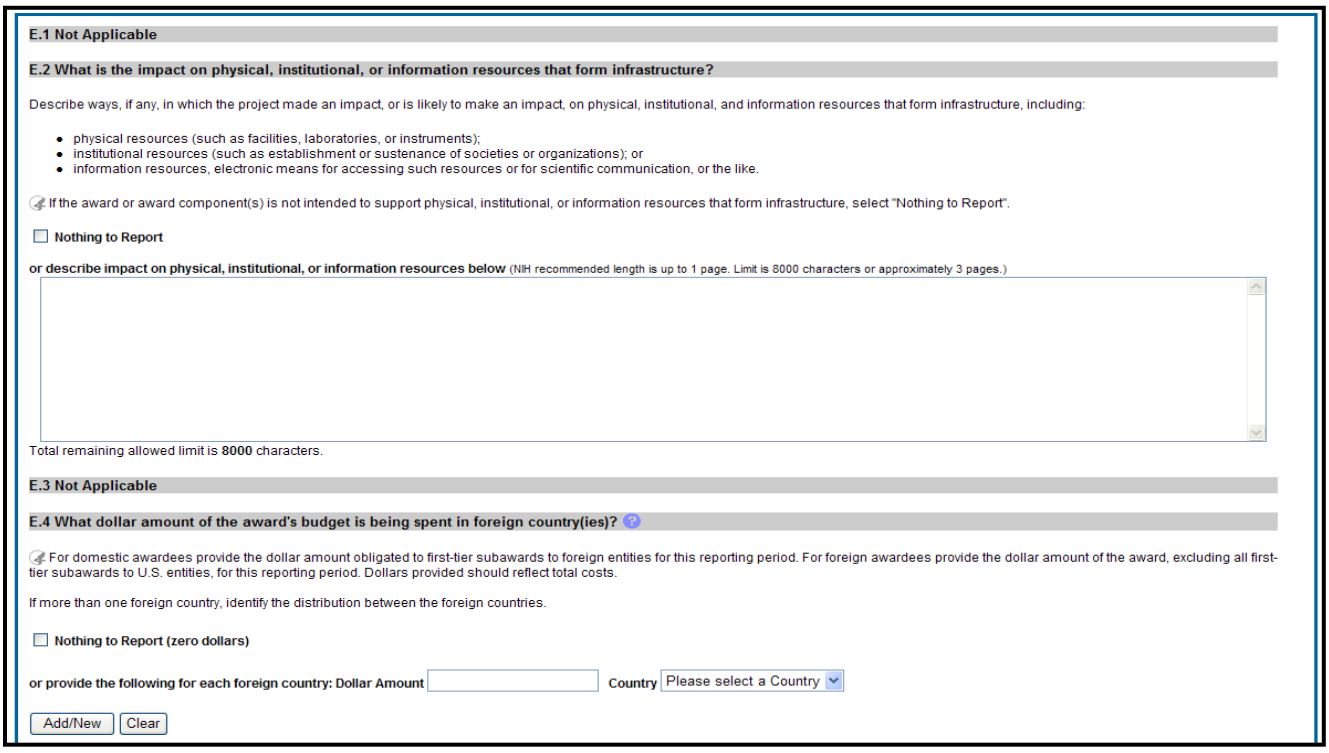


Figure 13: RPPR Section E. Impact – Questions E1 through E4

NOTE: It is important to click the SAVE button in the navigation bar before leaving a screen (section) in order to retain data entered on that screen.

Section F – Changes (Not Required for Final RPPR)

Section F. addresses Changes. Significant changes in objectives and scope ***require prior written approval*** (through a project modification request) by the awarding R&D Service within VA-ORD. ***The RPPR is not an appropriate vehicle to request such a change.*** See ORD Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification.

F.1. NOT APPLICABLE

F.2. Actual or anticipated challenges or delays and actions or plans to resolve them.

Describe challenges or delays encountered during the reporting period and actions or plans to resolve them.

Describe only significant challenges that may impede the research (e.g., accrual of patients, hiring of personnel, need for resources or research tools), focusing primarily on their resolution.

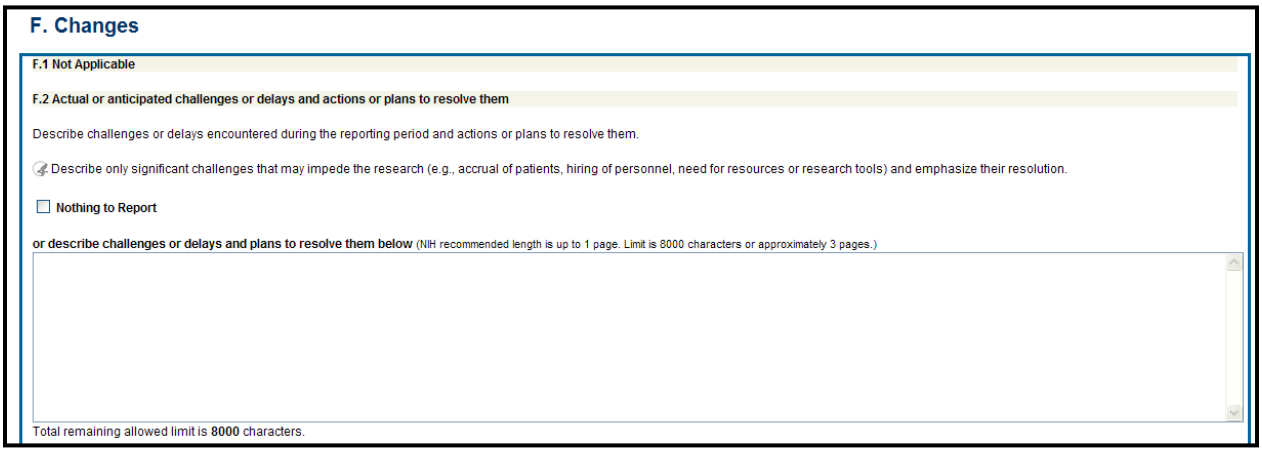


Figure 14: RPPR Section F. Changes – Questions F1 & F2

F.3. Significant changes to human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for human subjects, vertebrate animals, biohazards and/or select agents during this reporting period. Remember that significant changes in objectives and scope may require prior approval of the awarding R&D Service within VA-ORD. Please consult with the appropriate R&D Service for its requirements on this issue. If there are changes in any of the following areas, check the appropriate box and provide a description of the changes.

F.3.a. Human Subjects

VA-ORD does not enter data in the NIH *Human Subjects System (HSS)*.

Do NOT select "No Change". You must upload a current, completed VA-ORD Inclusion Enrollment Table using the VA-ORD table template for each progress report year (see G.4.a.).

NOTE: A **'flat file' PDF of this table must be uploaded** in order to retain the report content within eRA. A PDF "flat file" is not editable and does not have comments associated with it. If a PDF attachment is submitted that has editable (fill-able) fields or uses comments, data will be lost when the application image is created. To save a flattened PDF document: File, Save As Other, Optimized PDF, 'Check/Mark' Discard Objects (i.e., make sure it is selected so that objects will be removed), OK. If you do not have the appropriate rights/permissions to edit a file in your PDF creating software, you may print, scan and then re-upload the file in order to flatten it. When selecting a PDF to attach, Save As, and select the 'Restrict Editing' box. Click 'Preview' to review the uploaded PDF for content prior to final submission to ensure the document can be read in its entirety with all data viewable.

If human subject protocols are or will be different from the previous submission, also include a description and explanation of how the protocols differ and provide a new or revised Protection of Human Subjects Section as described in the VA-ORD Application Guide SF424 (R&R), 12. Other Attachments, 4. Human Subjects.

In addition, ***if reporting data on Clinical Trials under Section G.4.b.***, you must upload (to this section) a copy of the most recently approved minutes from the Data Monitoring Committee (DMC), Data Safety and Monitoring Board (DSMB), and/or Institutional Review Board (IRB) of record.

Significant changes in human subjects ***require prior written approval*** (through a project modification request) by the awarding R&D Service within VA-ORD. ***The RPPR is not an appropriate vehicle to request such a change.*** See ORD Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification. ***If a project modification request has been approved, upload a copy of the signed project modification form or R&D Service approval letter.***

F.3.b. Vertebrate Animals

If there have been significant changes to the uses of vertebrate animals from the previous submission, provide a description of the changes. Examples of changes considered to be significant include, but are not limited to, changing animal species, changing from noninvasive to invasive procedures, new project/performance site(s) where animals will be used, etc.

Information about approved changes in protocols for use of vertebrate animals is required in the progress report. Note that any request to make a significant change in a protocol for the use of vertebrate animals must first be approved by the local IACUC of Record before the change may be implemented.

Significant changes in vertebrate animals ***require prior written approval*** (through a project modification request) by the awarding R&D Service within VA-ORD. ***The RPPR is not an appropriate vehicle to request such a change.*** See ORD Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification. ***If a project modification request has been approved, upload a copy of the signed project modification form or R&D Service approval letter.***

F.3.c. Biohazards

If biohazards are not being used, select No Change.

If the use of biohazards is or will be different from that in the previous submission, provide a description and explanation of the difference(s) and upload as an attachment.

F.3.d. Select Agents

If the possession, use, or transfer of Select Agents is or will be different from that proposed in the previous submission, including any change in the select agent research location and/or the required level of biocontainment, provide a description and explanation of the differences and upload as an attachment. If the use of Select Agents was proposed in the previous submission but has not been approved by regulatory authorities, provide an explanation. If studies involving Select Agents are planned and were not part of the originally proposed research design, provide a description of the proposed use, possession, transfer, and research location as described in the VA-ORD Application Guide SF424 (R&R).

CDC and USDA Federal Select Agent Program, Federal Select Agent and Toxins List

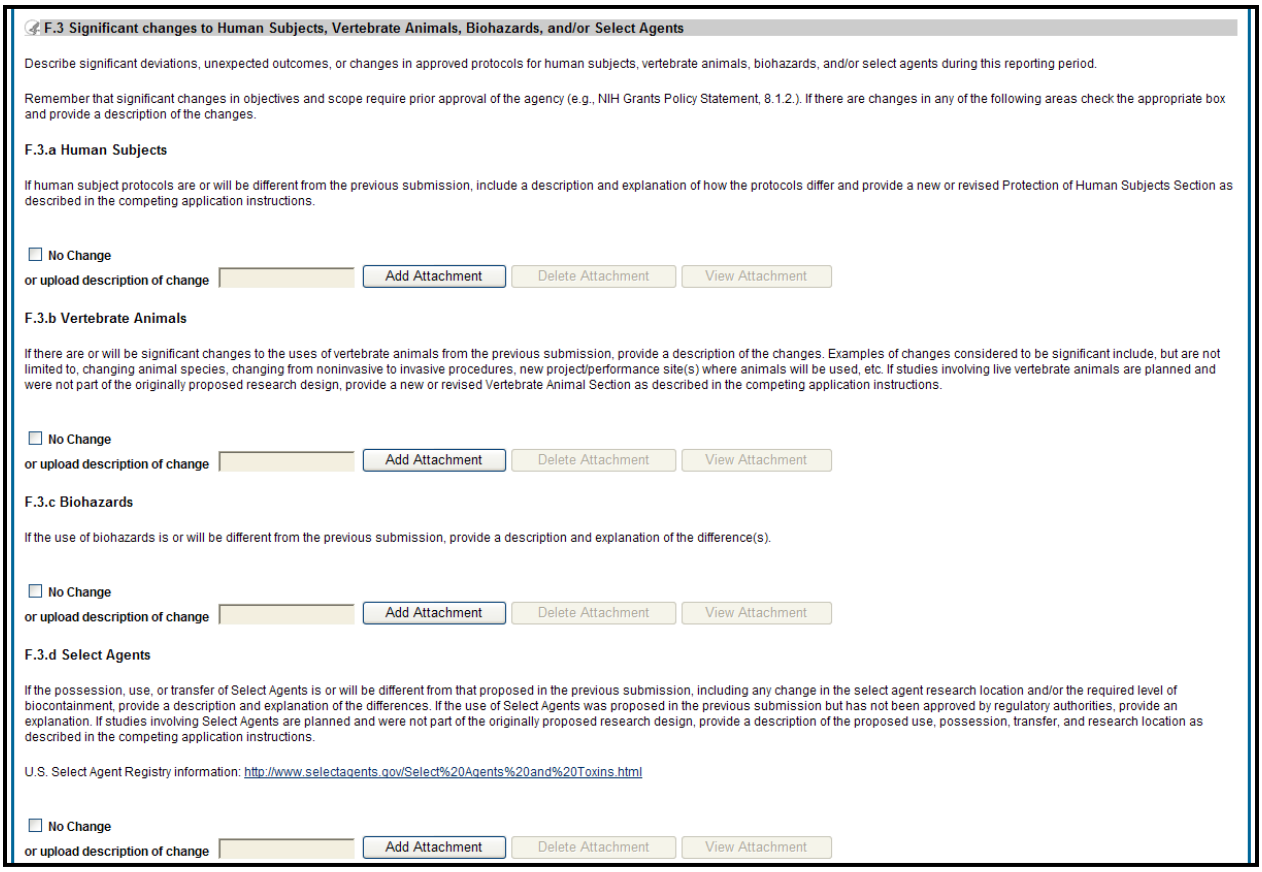


Figure 15: RPPR Section F. Changes – Question F3

NOTE: It is important to click the SAVE button in the navigation bar before leaving a screen (section) in order to retain data entered on that screen.

Section G – Special Reporting Requirements

Section G - Special Reporting Requirements address VA-ORD-specific award terms and conditions, as well as any award specific reporting requirements.

G.1. Special Notice of Award Terms and Funding Opportunity Announcement (FOA)/Request for Applications (RFA) Reporting Requirements

NOT APPLICABLE. Select **Nothing to Report**.

G.2. Responsible Conduct of Research

See Supplemental Instructions for K-Series (Career Development, Nursing Research Initiative and Research Career Scientist) awards.

G.3. Mentor's Report

NOT APPLICABLE *for most VA-ORD awards.* See Supplemental Instructions for Career Development, Nursing Research Initiative and Research Career Scientist awards.

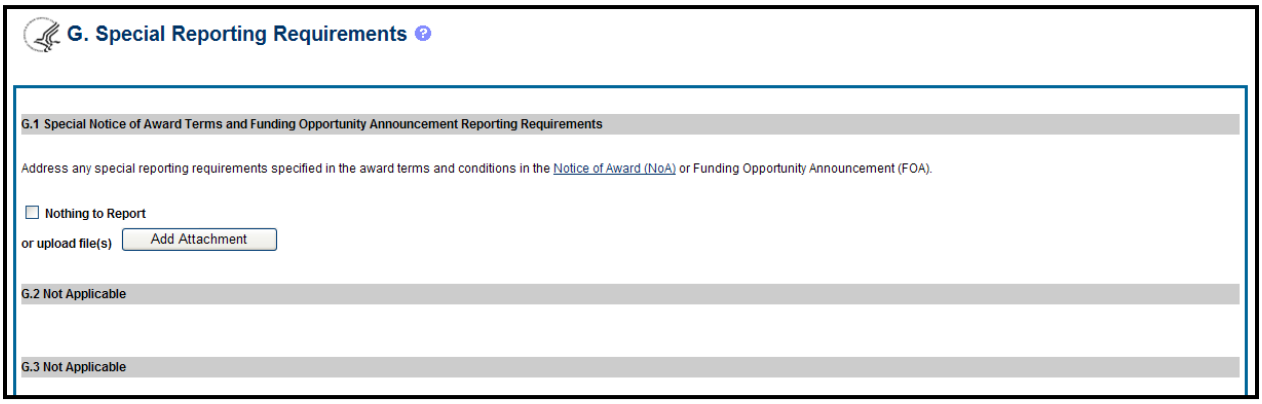


Figure 16: RPPR Section G. Special Reporting Requirements – Questions G1 through G3

G.4. Human Subjects

G.4.a. Does the project involve human subjects?

If research activities involving human subjects are planned at any time during the next budget period at the VAMC or at any other project/performance site or collaborating institution, select **YES**. Select **YES** even if the project is exempt from the Federal Policy for the Protection of Human Subjects ("Common Rule") and does not require Institutional Review Board (IRB) approval. Select **NO** if research activities involving human subjects are not planned at any time during the next budget period.

VA-ORD policy on research involving human subjects, including definitions, can be found in the VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research, Amended June 29, 2017.

Is the research exempt from Federal regulations on Human Subjects protections?

An IRB must determine if your research activity is exempt from IRB review and approval. For VA-ORD, if you have received an exemption from the IRB and your study has been declared R&D only, you must answer YES, and select the appropriate exemption code (See 5 U.S.C. 301; 42 U.S.C. 289(a). If changes have been made to approved protocols, including inclusion and exclusion criteria, the IRB may need to reevaluate your exemption status.

Does this project involve a clinical trial?

NOT APPLICABLE unless the answer to G.4.a. is **YES**. VA-ORD currently uses a definition for clinical trials that is similar to that used by the International Committee of Medical Journal Editors (ICMJE) and the World Health Organization. This definition 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." If your study meets this definition, you must work with your funding R&D Service to ensure registration has been completed in clinicaltrials.gov. (See Section G.4.c.)

If YES, is this a NIH defined Phase III Clinical Trial?

NOT APPLICABLE. Select NO.

G.4.b. Inclusion enrollment data.

Reporting the cumulative enrollment is REQUIRED for research involving recruitment of human subjects in all progress reports (even if there is "0"/zero enrollment) – See Section F.3.a to upload file. All studies involving human subject data (even if previously collected) must report the distribution of human subjects by sex/gender, race, and ethnicity (if available). If subject data is not available, please upload the document file (in Section F.3.a.), state total number of subjects enrolled and include a note that states sex/gender, race and ethnicity are not available.

If there are details or concerns related to your inclusion enrollment progress or if the enrollment data does not reflect the targeted enrollment by race, ethnicity, and/or sex/gender, the reasons for this should be addressed in Section F.3.a.

Guidance for Collecting and Reporting Inclusion Data: Below are instructions for how to collect and report data on the basis of sex/gender, race, and ethnicity with additional guidance for handling subpopulations, non-U.S. populations, and changes to planned enrollment data.

Standards for Collecting Data from Study Participants: The Office of Management and Budget (OMB) Directive No. 15 defines minimum standards for maintaining, collecting and presenting data on ethnicity and race for all Federal reporting purposes. The categories in this classification are social-political constructs and should not be interpreted as being anthropological in nature. The standards were revised in 1997 and now include two ethnic categories: Hispanic or Latino, and Not Hispanic or Latino. There are five racial categories: American Indian or Alaska Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and White. Reports of data on ethnicity and race should use these categories. The definitions below apply for the ethnic and racial categories.

Ethnic Categories:

Hispanic or Latino: A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino".

Not Hispanic or Latino

Racial Categories:

American Indian or Alaska Native: A person having origins in any of the original peoples of North, Central, or South America and maintains tribal affiliation or community.

Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.

Black or African American: A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."

Native Hawaiian or Other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.

White: A person having origins in any of the original peoples of Europe, North Africa, or the Middle East.

Collecting and Reporting Data on Race and Ethnicity: Use the above standards and definitions for race and ethnicity to allow comparisons to other Federal databases, especially the Census and National health databases. Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

When collecting data on ethnicity and race, as well as sex/gender, use the categories listed to obtain the data from individuals on the basis of self-identification. Participants should be asked to identify their ethnicity and their race. OMB recommends collecting this information using two separate questions, with ethnicity information collected first followed by race, with the option to select more than one racial designation (Office of Management and Budget (OMB) Directive No. 15). Report your data using the VA-ORD inclusion enrollment form. Study participants who self-identify with more than one of the racial categories should be reported in the aggregate in the "More Than One Race" category.

Additional VA-ORD Required Information: If total number of human subjects recruited includes non-Veterans, upload a separate inclusion enrollment form with data indicating what percentage (%) of enrolled subjects are Veterans. **NOTE:** The PD/PI must justify inclusion of non-Veterans and the IRB must provide specific approval for recruitment of non-Veterans (See VHA Handbook 1200.05, 24. Participation of Non-Veterans as Research Subjects). ***The RPPR is not an appropriate vehicle to request inclusion of non-Veteran participants – a prior approved waiver is required.***

Collecting and Reporting Data on Subpopulations: Each ethnic/racial group contains subpopulations that are delimited by geographic origins, national origins, and/or cultural differences. It is recognized that there are different ways of defining and reporting racial and

ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting of specific origins and/or cultural heritage. Attention to subpopulations also applies to individuals who self-identify with more than one ethnicity or race. These ethnic/racial combinations may have biomedical, behavioral, and/or social-cultural implications related to the scientific question under study. The collection of greater detail is encouraged, e.g., on ethnic/racial subpopulations; however, any collection that uses more detail needs to be organized in such a way that the additional categories can be aggregated into OMB categories for reporting data on ethnicity, race, and more than one race. Investigators who have data on subpopulations are encouraged to provide that information in the Comments field of the Inclusion Enrollment Report and/or in the text of their progress report.

Collecting and Reporting Data on Non-U.S. Populations: Permission is required by your local VAMC Director for the use of non-U.S. subjects or biological samples in VA funded research. Enrollment of participants at non-U.S. sites should be reported to VA-ORD on a separate inclusion enrollment form from that for reporting participants at U.S. sites, even if they are part of the same study. For additional guidance related to this topic**,** please refer to VHA Handbook 1200.05**,** **2**6. International Research.

If conducting clinical research outside of the United States, design culturally sensitive and appropriate data collection instruments that allow participants to self-identify their ethnic and/or racial affiliation in a way that is meaningful in the cultural and scientific contexts of the study. However, investigators will need to use OMB-defined categories for reporting sex/gender, race and ethnicity to VA-ORD (see definitions for each ethnic and racial category above), which will allow for completion of the inclusion enrollment form(s). Since OMB categories reference world-based geographic origin, this should facilitate completion of the form(s).

Changes to Planned Enrollment: If there are changes from the planned enrollment originally approved for funding, contact the awarding R&D Service SPM within VA-ORD to discuss updating/revising the planned enrollment table and uploading the file in Section F.3.a. If changes are significant, such as requiring local IRB approval, a project modification request may be needed.

Reporting Data on Clinical Trials: If conducting a Clinical Trial, report on the cumulative enrollment (as described above) and indicate in Section F.3.a., if any data analysis has begun for the trial. If analysis has begun or data have been published, report any progress made in evaluating potential differences on the basis of sex/gender, racial, and/or ethnicity.

G.4.c. ClinicalTrials.gov

Does this project include one or more applicable clinical trials that must be registered in ClinicalTrials.gov under FDAAA?

VA-ORD clinical trials continue to be registered and updated using the ART system. For more information, please see the following sites:

Registration of Clinical Trials
http://www.research.va.gov/resources/ORD_Admin/clinical_trials/

VA Cooperative Studies Program (CSP)

http://www.research.va.gov/programs/csp/

If YES, provide the ClinicalTrials.gov identifier, NCT number (e.g., NCT00654321), for those trials.

NOTE: ClinicalTrials.gov must be updated EVERY 6 months. When completing your RPPR, you should also review and confirm all data is current with your clinical trial.

See FAQ When must an applicable clinical trial be registered? If the (grant) award number was entered into ClinicalTrials.gov, the ClinicalTrials.gov identifier (NCT number) may be readily identified by using the ClinicalTrials.gov Advanced Search and entering the award number in the *Study IDs* field.

Select the **Add/New** button to add the data to the table.

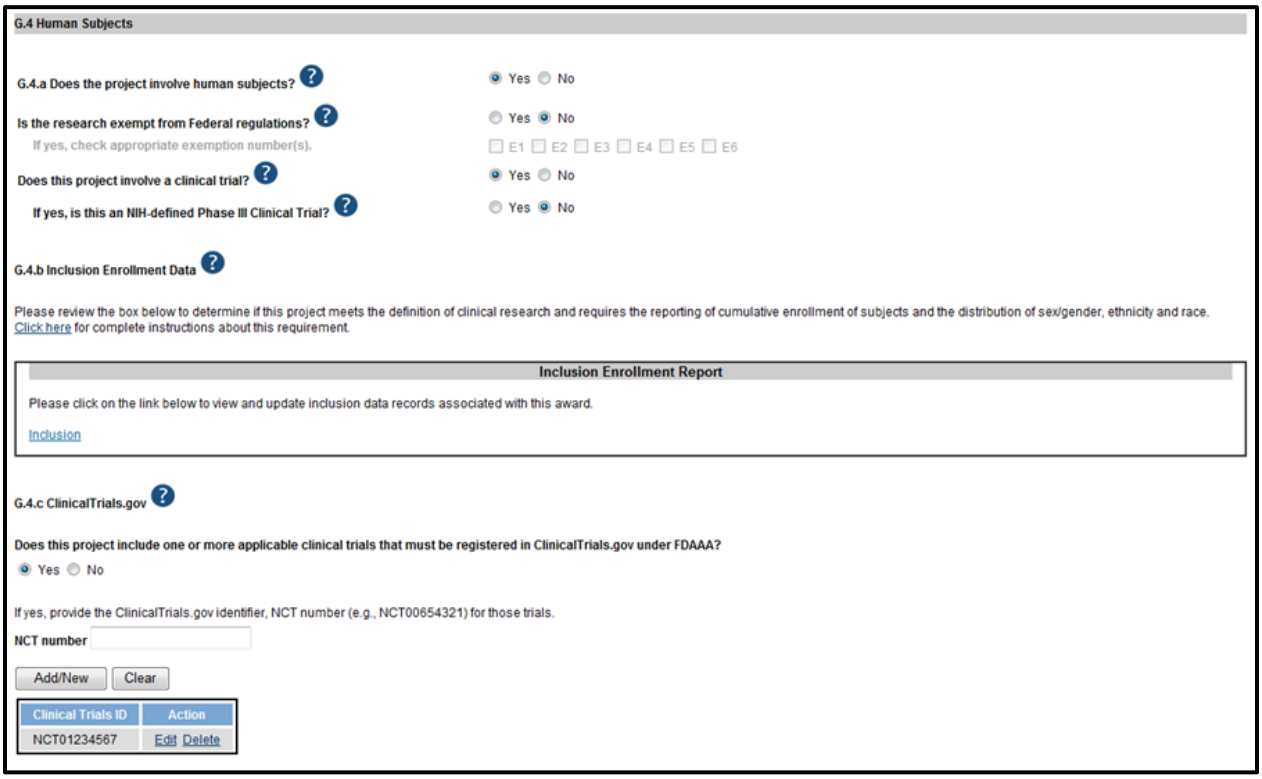


Figure 17: RPPR Section G. Special Reporting Requirements – Question G4

G.5. Human Subjects Education Requirement

Are there personnel on this project who are or will be newly involved in the design or conduct of human subjects research?

NOT APPLICABLE. Select NO.

G.6. Human Embryonic Stem Cell(s)

Does this project involve human embryonic stem cells?

Research in which the focus is either a fetus, or human fetal tissue, in-utero or ex-utero (or uses human fetal tissue) cannot be conducted by VA investigators while on official duty, at VA facilities, or at VA-approved off-site facilities. Only hESC lines listed as approved in the NIH

Registry may be used in VA-ORD funded research (see VHA Handbook 1200.05, 17. Research Involving Pregnant Women, Human Fetuses, and Neonates as Subjects).

If YES, identify the hESC Registration number(s) from the NIH Registry.

If there is a change in the use of hESCs provide an explanation. Significant changes in use of hESCs ***require prior written approval*** (through a project modification request) by the awarding R&D Service within VA-ORD. See ORD Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification.

G.7. Vertebrate Animals

Does this project involve vertebrate animals?

See VHA Handbook 1200.07, Use of Animals in Research, for specific VA-ORD requirements and accreditation information.

Significant changes in the care and use of vertebrate animals require VA OLAW and local IACUC concurrence and ***require prior written approval*** (through a project modification request) by the awarding R&D Service within VA-ORD. See ORD Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification.

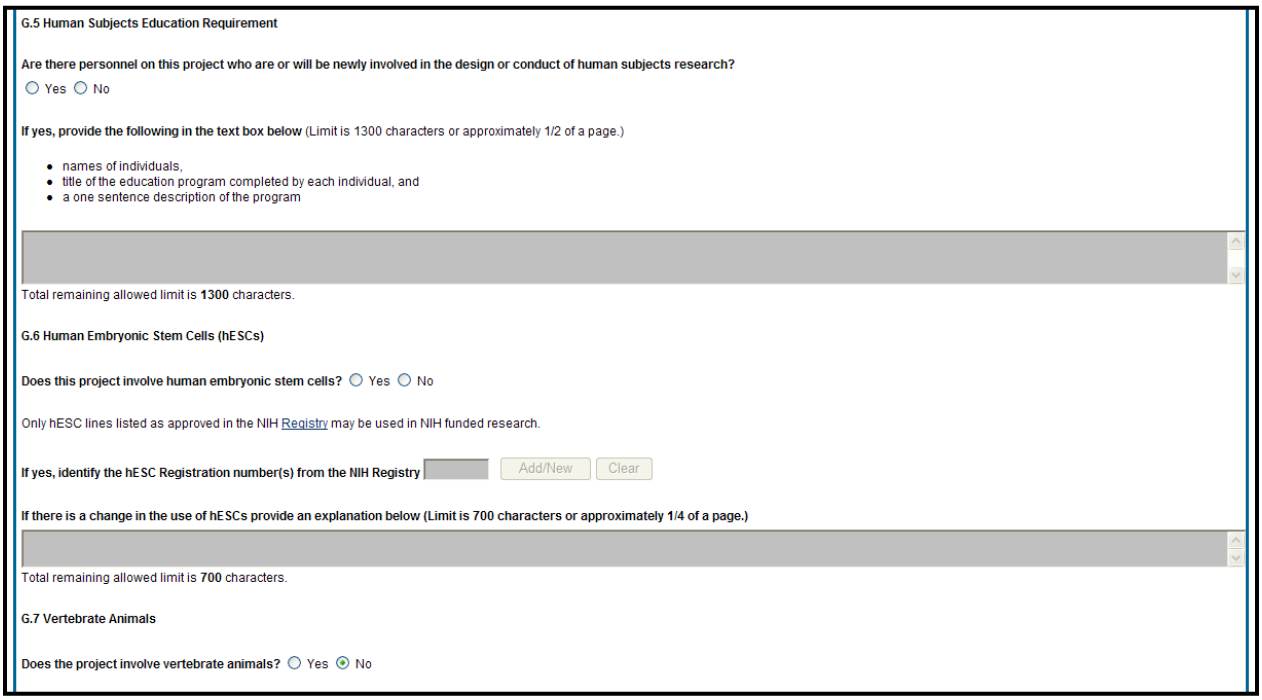


Figure 18: RPPR Section G. Special Reporting Requirements – Questions G5 through G7

G.8. Project/Performance Sites

If there are changes to the project/performance site(s) displayed, edit as appropriate.

One of the sites indicated must be the identified as the Primary Performance Site. If including a new Project/Performance Site where either human subjects or vertebrate animals will be involved, address the change under Section **F.3.a or F.3.b**.

Significant changes in a performance site(s) ***require prior written approval*** (through a project modification request) by the awarding R&D Service within VA-ORD. See ORD Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification.

Select the **Add/New** button to add the data to the table.

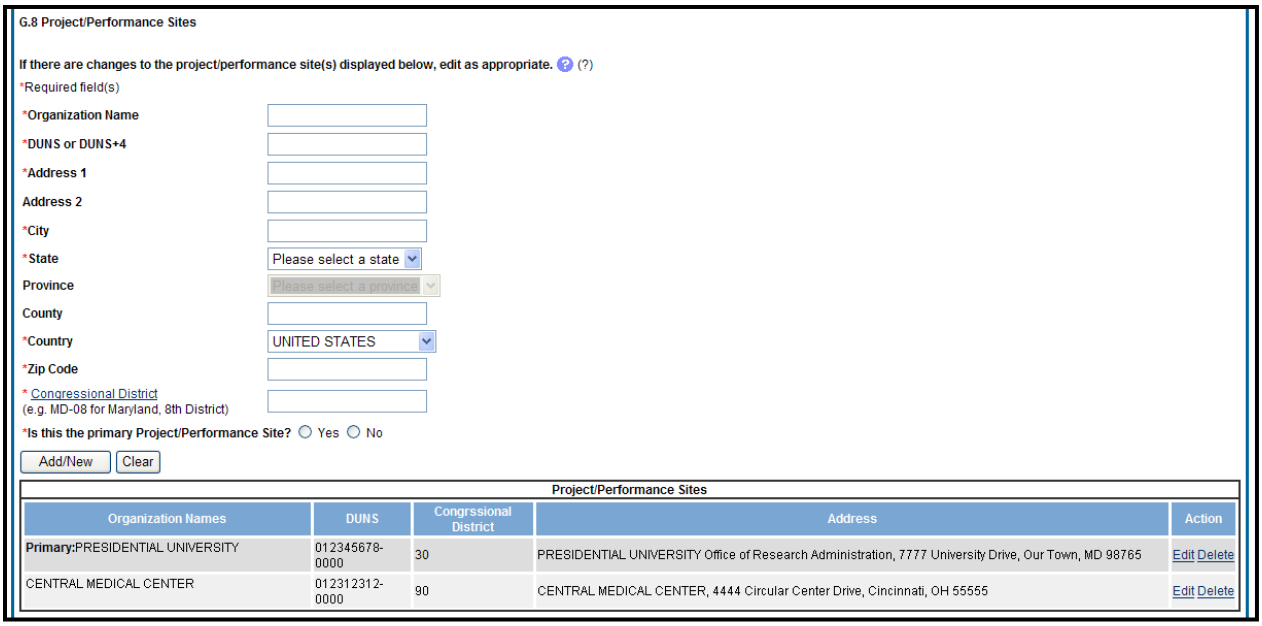


Figure 19: RPPR Section G. Special Reporting Requirements – Question G8

G.9. Foreign Component

Although having a Foreign Component is unlikely for VA-ORD funded research, any foreign activity within a project with prior VAMC Director approval, must report under this section.

Provide the organization name, country, and description of each foreign component.

Foreign component is defined as significant scientific activity that was performed outside of the United States, either by the awardee or by a researcher employed by a foreign organization, whether or not award funds were expended. The following award-related activities are significant and must be reported:

- involvement of human subjects or research with live vertebrate animals;
- receiving or sending data or biospecimens from humans, regardless of identifiability;
- extensive foreign travel by awardee project staff to collect data, or conduct surveys or sampling activities;
- any awardee activity that may have an impact on U.S. foreign policy.

Examples of other award-related activities that *may* be significant are:

- collaborations with investigators at a foreign site anticipated to result in co-authorship;
- use of facilities or instrumentation at a foreign site; or

- receipt of financial support or resources from a foreign entity.

Foreign travel for consultation does not meet the definition of foreign component.

The addition of a foreign component(s) ***requires prior written approval*** from the VAMC Director (See VHA Handbook 1200.05, 26. International Research and ORD Guidance on Approval of International Research); and significant changes to or the addition of a foreign component(s) ***also requires prior written approval*** by the awarding R&D Service within VA-ORD (through a project modification request). See ORD Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification.

Select the **Add/New** button to add the data to the table.

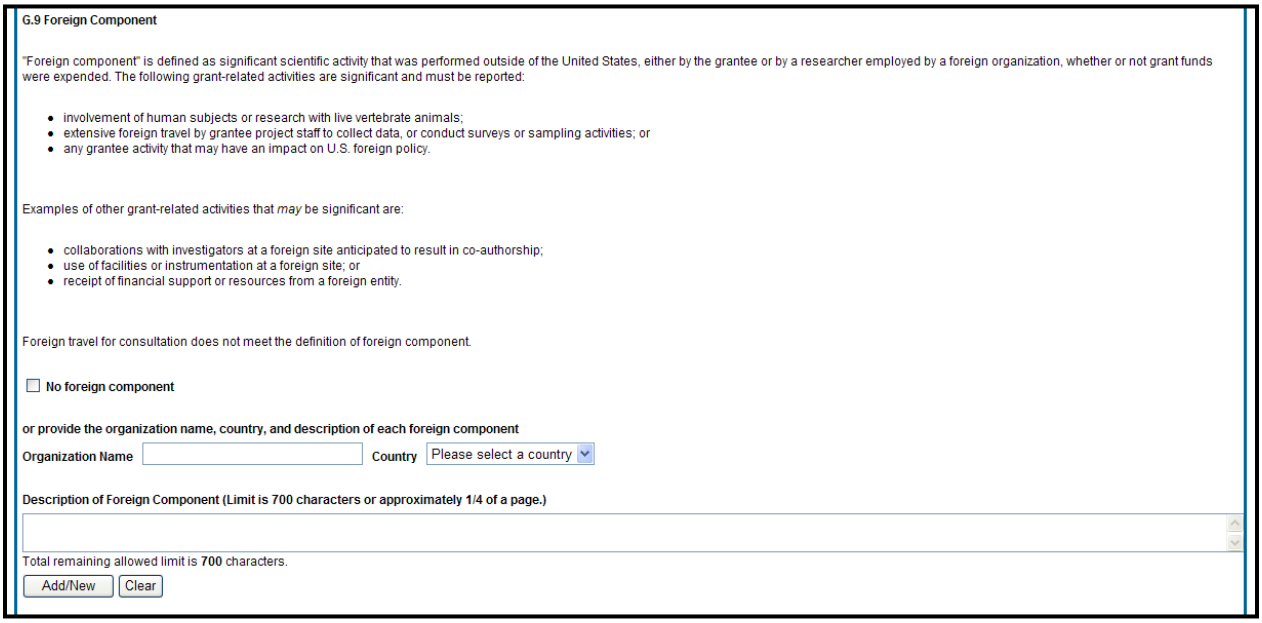


Figure 20: RPPR Section G. Special Reporting Requirements – Question G9

G.10. Estimated unobligated balance

G.10.a. Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25% of the current year's total approved budget?

If YES, provide the estimated unobligated balance.

If an estimated unobligated balance that will be greater than **4%** of the current fiscal year's total approved budget is expected, you must inform the specific R&D Service within VA-ORD. Your local R&D or Finance Office should have this financial information. **NOTE:** Carry over funds must be spent by March of the next fiscal year (e.g., FY18 funds must be spent by March 2019).

Budget changes greater than **4%** ***require prior written approval*** (through a project modification request) by the awarding R&D Service within VA-ORD. See ORD Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification.

G.10.b. Provide an explanation for unobligated balance.

In addition to providing an explanation in this report, if there is an expected unobligated balance that requires a redistribution of funds, you must contact the specific awarding R&D Service within VA-ORD. See ORD Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification.

G.10.c. If authorized to carryover the balance, provide a general description of how it is anticipated that the funds will be spent. To determine carryover authorization, see the Notice of Award or Funding Letter.

Carryover at the facility is only authorized by VA-ORD Finance.

G.11. Program Income

If program income may/has result(ed) from a technology, etc., that was licensed, answer YES and enter the anticipated/known dollar amount and source for this field even if you entered "$0" on the VA-ORD SF424 (R&R) application cover page (15. Estimated Project Funding, d. Program Income).

G.12. F&A Costs

NOT APPLICABLE. The answer to this question must be NO. Facilities and administrative (F&A) costs, formerly known as indirect costs and overhead related to facilities operations and general administration, are not covered by VA-ORD award funds.

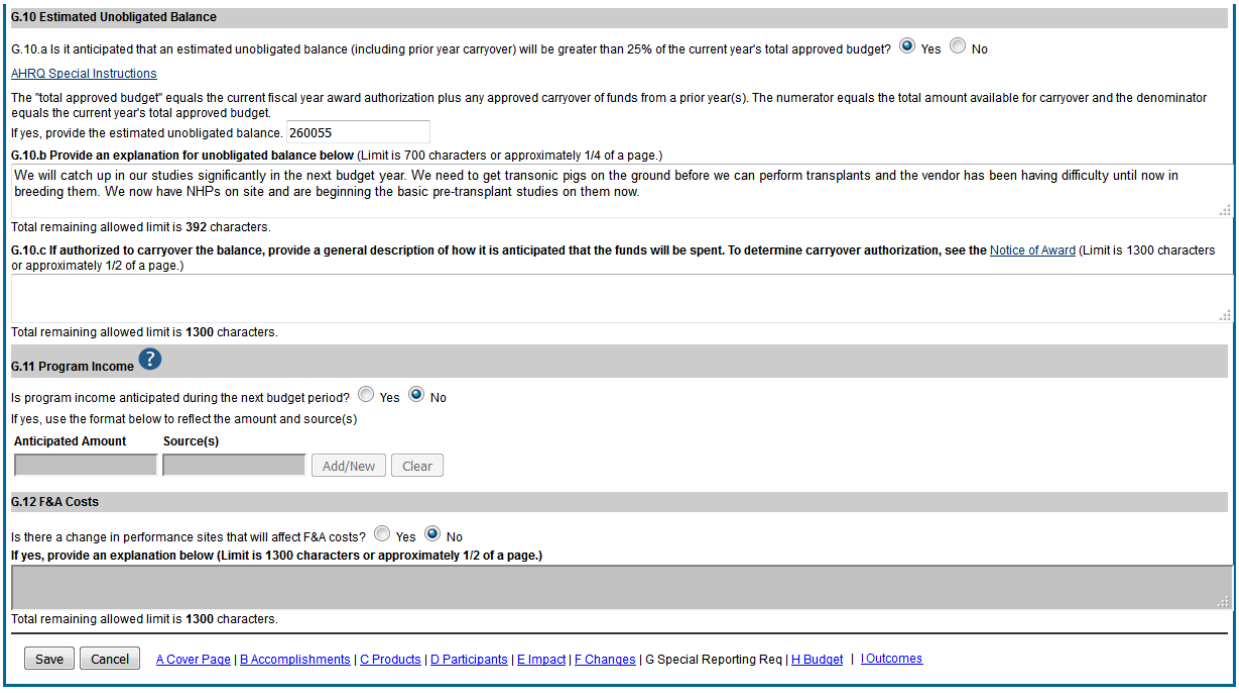


Figure 21: RPPR Section G. Special Reporting Requirements – Questions G10 through G12

NOTE: It is important to click the SAVE button in the navigation bar before leaving a screen (section) in order to retain data entered on that screen.

Section H – Budget

NOT APPLICABLE for RPPRs or Final RPPRs

Section I – Outcomes

Required for Final RPPRs only. The main differences between this and Section B.2 are: 1) the information requested here is cumulative, i.e., for the entire project period; and, 2) this section should be written for the general public*, whereas Section B should address the technical, scientific accomplishments in relation to the project aims, and should be written for an audience of scientists in that particular field. The length should not exceed a half page (2000 characters).

Provide a summary of your project's outcomes for the entire project period, which must include, but not be limited to the following:

- completion of specific aims or targeted data development;
- changes to practice (i.e., clinical, policy, etc.);
- additional funded awards/grants both internal and external to VA;
- negative outcomes;
- new collaborations;
- new innovative technologies, methodologies, etc.; and
- an approximate date that you expect to report final results to Clinical Trials (if Human Subjects are involved and study is registered).

*__NOTE__: For VA-ORD awards, Section I. Outcomes will NOT be made publicly available in RePORT.

NOTE: For Career Development Awards and Research Career Scientist Awards, please refer to the Special Instructions for RPPRs for the appropriate award type.

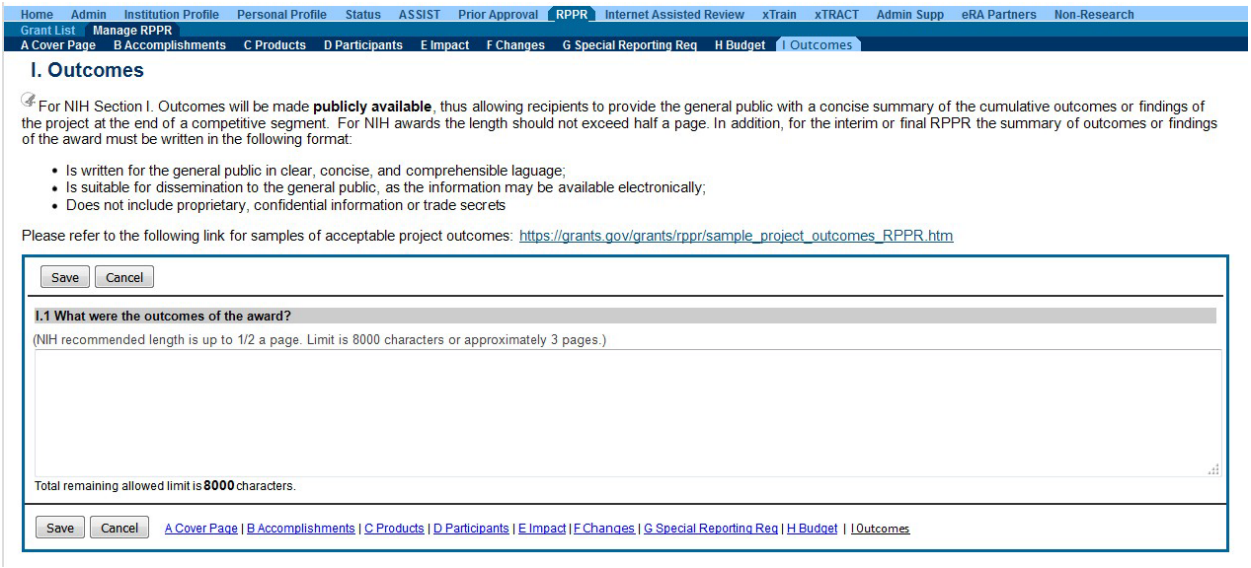


Figure 22: Final RPPR Section I. Outcomes

Supplemental Instructions for Specific Award Types

For awards noted below, see the applicable supplemental instructions that either replace or are in addition to the Instructions for RPPR Sections A–I.

Applicable Supplemental Instructions	Award Activity Codes
Career Development Awards (CDA), VA-ORD Historically Black College and University Research Scientist Training Program (HBCU), and Nursing Research Initiative (NRI) awards	IK1, IK2 and IK3
Research Career Scientist (RCS) Awards	IK6
Centers, Centers of Innovation (COINs), Research Enhancement Award Programs (REAPs), Quality Enhancement Research Initiative (QUERI)	I50

VA-ORD Career Development (IK1, IK2, IK3) Award Reports

The VA-ORD Career Development Program includes Nursing Research Initiative (IK3 activity codes within HSR&D); Historically Black College and University Research Scientist Training Program (IK2 activity codes within all VA-ORD Services); and Career Development Awards (IK1 activity code for CDA1 awards and IK2 activity codes for CDA2 awards in RR&D; and IK2 activity code in HSR&D and BLR&D/CSR&D).

You must follow the Instructions for RPPR Sections A–I, with the exceptions noted below:

B.4. What opportunities for training and professional development has the project provided?

Describe activities such as teaching, mentoring, clinical care, professional consultation, service on advisory groups, and administrative activities. Indicate percent of time spent in each of these activities and the relationship to the awardee's research career development.

In addition, provide a description of the awardee's participation in training activities during this period, including formal courses, seminars, data sessions, laboratory meetings, journal clubs, lecture series, etc. Describe basic content as well as frequency of training activities. Identify any variation from that proposed in the awardee's application; explain the reason for the change. Include recommendations for enhancing or improving the training program, if applicable.

Provide a description of the awardee's interactions with mentors, to include frequency, duration, and nature of interactions. Provide examples of the ways in which these interactions were critical to a project or career plan (e.g., resolving a research problem, data generation, establish collaboration, etc.). Identify any variation from the mentor/trainee relationship proposed in the awardee's application, and, if applicable, any changes in the mentor's obligations which could

impact on the trainee. Include recommendations for enhancing or improving the mentor-trainee relationship.

B.6. What do you plan to do for the next reporting period to accomplish the goals?

Provide a timeline for the activities planned for the next year, including plans to apply for subsequent award support.

NOTE: Some VA-ORD Services do not accept merit or small project application submissions until an awardee has completed at least a portion of their currently funded CDA (see Service-specific FOA/RFA for guidance).

D.2.b. New senior/key personnel

Are there, or will there be, new senior/key personnel? For CDAs, changes in mentors and/or mentoring commitments must be submitted as requests to the appropriate Service Director for approval 60 days prior to the change (see VHA Handbook 1200.04, ORD Research Career Development Program).

E.2. What is the impact on physical, institutional, or information resources that form infrastructure?

NOT APPLICABLE

G.1. Special Notice of Award Terms and Funding Opportunity Announcement (FOA)/Request for Application (RFA) Reporting Requirements

NOT APPLICABLE

G.2. Responsible Conduct of Research

Describe the responsible conduct of research instruction received (or instruction given as a course director, discussion leader, etc.) by formal and/or informal means, during this reporting period. If instruction or participation as a course director/discussion leader occurred in a prior budget period, note the dates of occurrence. Any activities undertaken to individualize instruction appropriate to career stage should be discussed. Address the five components: Format, Subject Matter, Faculty Participation, Duration, and Frequency.

G.3. Mentor's Report

For mentored awards, provide a letter signed by each of the mentors in PDF format, assessing your progress and performance during this reporting period, both in research and in terms of development into an independent investigator in the area of the award. Include information on the availability of support for your research project during the next budget segment. If required to submit letters from more than one mentor, letters should be assembled in one PDF file.

In addition, letters from your mentor(s) should contain the following information: 1) any changes from the application in the distribution of the mentors' time in research, patient care, teaching and administration. If there are no changes, the letter should so state; 2) any changes from the application in the mentor's current obligations, including the number of residents, fellows and other trainees who the mentor is currently supervising as well as projected trainees (if there are no changes, the letter should so state); 3) a description of the mentor's interactions with the awardee during the performance period, including the awardee's role in the mentor's research program, the mentor's role in the awardee's research program, formal training experiences completed, the percentage of the mentor's time devoted to the awardee, and the nature and quality of the interactions with the awardee; 4) an assessment of the progress the awardee has made in accomplishing the research objectives of the award; and 5) whether the awardee is compliant with VA-ORD policies as stated in VHA Handbook 1200.19 Presentation of Research Results.

In addition, provide a letter from your VAMC Associate Chief of Staff/Research (ACOS/R) in PDF format, that includes an overall evaluation of whether or not you are receiving appropriate training and support in order to facilitate your move toward becoming an independent VA researcher.

VA-ORD Research Career Scientist (IK6) Award Reports

For VA-ORD Research Career Scientist (IK6) awards follow the Instructions for RPPR Sections A–I, with the exceptions noted below:

B.1. What are the major goals of the project?

Provide an overall summary of your research program for the current reporting time period (immediate preceding year). Include a description, in lay terms, the potential impact of your work on Veteran health care and state any changes that may have affected your productivity (positive or negative).

B.1.a. Have the major goals changed since the initial competing award or previous report?

NOT APPLICABLE

B.2. What was accomplished under these goals?

In this attachment, briefly describe any: 1) new or ongoing collaborations established with VA and non-VA scientists; and 2) associated outcomes from the project(s).

B.4. What opportunities for training and professional development has the project provided?

Describe activities such as teaching, professional consultation, service on advisory groups, and administrative activities. Indicate percent of time spent in each of these activities and the relationship to the awardee's research career development. For awards that include a requirement

to mentor others (e.g., IK6), indicate the percent of time devoted to mentoring activities (i.e., CDA), individuals mentored during the reporting period, the frequency and kinds of mentoring, financial and other support provided to mentees, and the productivity of the mentoring relationship.

For **RCS Final RPPRs**, report on opportunities for training and professional development for the entire award period.

B.6. What do you plan to do for the next reporting period to accomplish the goals?

NOT APPLICABLE

C.1. Publications

This RCS award **MUST** be acknowledged on **ALL** presentations, abstracts and publications. As IK6 awards provide salary support for projects funded by other agencies, you must also include non-VA supported project publications in this section.

For **RCS Final RPPRs**, acknowledge all presentations, abstracts and publications for the entire award period – five or seven years.

You are responsible for ensuring that these publications comply with the VA Public Access policy (see VHA Handbook 1200.19 Presentation of Research Results) **even if they were provisionally compliant (listed as *in Progress*) when previously reported.** In addition, you must notify the VHA Research Communications Office of the publications (See VA-ORD Pubtracker).

D.1. What individuals have worked on the project?

Only the RCS awardee should be named in this section.

D.2. Personnel Updates

D.2.a. Level of effort

Will there be, in the next budget period, a reduction of 8ths in the level of effort from what was approved by VA-ORD for the RCS awardee?

A request for approval for a change in 8ths must be submitted via a project modification request (See ORD Request for Administrative Project Modification form and Criteria and Instructions for Requesting a Project Modification) directly to the awarding R&D Service within VA-ORD. Any reduction in the level of effort below 5/8ths is not allowed or revocation of the award will ensue. Selecting **YES** does not constitute a request for VA-ORD to approve this reduction. ***The RPPR is not an appropriate vehicle to request such a change.*** If **YES** is selected, an explanation in the box below is required.

D.2.a. Level of effort

NOT APPLICABLE for RCS Final RPPRs.

D.2.b. New senior/key personnel

Are there, or will there be, new senior/key personnel?

NOT APPLICABLE for the RCS award.

D.2.c. Changes in other support

Has there been a change in the active other support of senior/key personnel since the last reporting period?

You must answer YES to this question and provide a current Other Support Information. Please delineate funding sources (e.g., NIH, DoD, non-profits, etc.).

For **RCS Final RPPRs**, indicate if a RCS renewal application will be submitted.

D.2.d. New other significant contributors

NOT APPLICABLE for the RCS award.

D.2.e. Will there be a change in the MPI Leadership Plan for the next budget period?

NOT APPLICABLE for the RCS award.

E.2. What is the impact on physical, institutional, or information resources that form infrastructure?

NOT APPLICABLE for the RCS award.

E.4. What dollar amount of the award's budget is being spent in foreign country(ies)?

NOT APPLICABLE for the RCS award.

Sections F.2. through F.3.

NOT APPLICABLE for the RCS award.

Sections G.1. through G.7.

NOT APPLICABLE for the RCS award.

Sections G.9. through G.12.

NOT APPLICABLE for the RCS award.

Section I. Outcomes

For **RCS Final RPPRs**, please provide a summary of your project's outcomes, which must include, but not be limited to the following:

- completion of specific aims or targeted data development or program development milestones (RCS);
- changes to practice (i.e., clinical, policy, etc.);
- additional funded awards/grants both internal and external to VA;
- negative outcomes;
- new collaborations or new recruitments to VA/RCS program or mentored career development awardees;
- new innovative technologies, methodologies, intellectual property, invention disclosures, novel therapeutics, etc.;
- new shared research resource for VA investigators (RCS); and
- an approximate date that you expect to report final results to Clinical Trials (if Human Subjects are involved and study is registered).

VA Rehabilitation Research and Development Service (RR&D) Centers and Research Enhancement Award Programs (REAPs) Reports

For RR&D Center and REAP awards (i.e., I50), submission of progress and final reports using the RPPR is not available at this time.

VA Health Services Research and Development Service (HSR&D) Centers of Innovation (COINs) and Quality Enhancement Research Initiative (QUERI) Reports

For HSR&D COIN and QUERI awards (i.e., I50), submission of progress and final reports using the RPPR is not available at this time.

NOTE: When preparing progress and final reports for Collaborative Research to Enhance and Advance Transformation and Excellence (CREATE) Initiative awards (i.e., I01), this guidance document should be followed.