RESEARCH PERFORMANCE PROGRESS REPORT (RPPR) - ALZHEIMER'S DISEASE RESEARCH CENTER GUIDELINES JANUARY, 2025

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Dear ADRC Administrators,

The National Institutes of Health (NIH) requires all grantees to submit all type 5 progress reports using the Research Performance Progress Report (RPPR) module in eRA Commons (see <u>https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-014.html</u>). The NIH Research Performance Progress Report (RPPR) Instruction Guide [October 2024] and other PHS Agency and additional resources can be found on the National Alzheimer's Coordinating Center website, <u>Progress Reports to NIA</u>..

This document is not intended to be a replacement for the comprehensive NIH RPPR Instructions but is to be used as supplement to the NIH RPPR Instruction Guide. This document includes additional clarifying information to address commonly asked questions collected from ADRC Administrators and Core Leads. This document is also a living document. The ADRC Administrative Steering Committee is open to feedback on the content and how to make it most helpful to all.

Important RPPR Notes:

- 1. **Time Frame for Progress Report:** RPPR summary sections, enrollment reports, and administrative tables should reference information and data from your current, 5-year P30 cycle. For example, do not include enrollment counts obtained during a previous 5-year cycle.
 - a. All progress reports should cover one year from the last progress report. If this is your first year on the P30 mechanism, you report only from the start date of the P30.
 - b. Determine the date range for reporting and be consistent throughout your report.
- 2. **Due Date:** The due date for Progress Reports is the 1st of the month preceding the month in which the current budget period ends (e.g., if the budget period ends 11/30, the due date is 10/1). If the 1st falls on a weekend or Federal holiday, the due date is automatically extended to the next business day.

Thank you all for your dedication to reporting your Center's important work and assistance in streamlining this process. If you would like to provide feedback to improve this document, please email your suggestion(s) to **NACCmail@uw.edu**.

If you have specific questions regarding NIH or NIA rules or the RFA, please contact your program officer.

Best,

ADRC Administrator Steering Committee

I. INITIATING YOUR RPPR:

- a. Grantees will need to create the 'component types' (Core, Project, Other) within the RPPR module, which is similar to the ASSIST (Application Submission System & Interface for Submission Tracking) system used to submit competing applications to the NIH/NIA. Upon submission to the NIA, the system will generate a PDF of the entire progress report (including a Table of Contents) that can be viewed from the RPPR menu using the VIEW button. Once submitted, the final version of the RPPR (in PDF format) will be accessible in Commons via the STATUS INFORMATION screen.
- b. Please review Sections 5.1, 5.2 and 5.3 of the <u>NIH RPPR Instruction Guide</u> to initiate and edit your Center's RPPR (see). To initiate the RPPR, the PI or delegate logs into eRA Commons, finds the "status" tab in the top banner, selects the list of applications/ grants, and chooses the Center's grant number. In the corresponding "Action" column, there is an RPPR hyperlink that will bring you to the RPPR menu. Select initiate (link to step-by-step instructions: <u>https://era.nih.gov/erahelp/commons/default.htm#cshid=1032</u>).

II. RPPR MODULE: Adding Components and Developmental Projects:

- **a.** On the RPPR menu that corresponds to your Center's grant number, select 'yes' in response to the question 'Does the project have components'. The Overall component for your Center will be automatically available for your use and edits.
- b. Click on the 'edit' link found in the ACTIONS box of the Overall component, and you will see separate screens corresponding to each of these sections: (A) Cover Page, (B) Accomplishments, (C) Products, (D) Participants, (E) Impact, (F) Changes, (G) Special Reporting Requirements, (H) Budget, and (I) Outcomes, if applicable (Final or Interim RPPR). Follow the instructions that are provided in the NIH RPPR Instructions to complete each section. Note that users may work on various sections in any order; however, please remember to click the SAVE button found in the navigation bar before leaving a screen!
- **c.** Click 'Manage RPPR' to return to the RPPR menu. You will get a pop-up box asking if you are sure that you want to leave the current page. Select 'Leave this page'.
- d. Select 'Admin Core' from the COMPONENT TYPE drop-down menu, enter 'Core A Administrative Core' into the COMPONENT PROJECT TITLE box, indicate the PD/PI of the Core in the appropriate section, and hit the 'ADD COMPONENT' box to establish the Administrative Core component of your report. Click on its own 'edit' link found in the ACTIONS box of the component, and you will once again see sections (A) (H) that will be used to report on the various elements pertinent to the Admin Core.
- e. Select 'Core' from the COMPONENT TYPE drop-down menu, enter 'Core B Clinical Core' into the COMPONENT PROJECT TITLE box, indicate the PD/PI of the Core in the appropriate section, and hit the 'ADD COMPONENT' box to establish the Clinical Core component of your report. Click on its own 'edit' link found in the ACTIONS box of the component, and you will once again see sections (A) - (H) that will be used to report on the various elements pertinent to the Clinical Core.
- f. Repeat instructions detailed in steps #4 and #5 for each of the required Cores (Core C Data Management and Statistical Core; Core D Neuropathology Core; Core E Outreach, Recruitment and Engagement Core; Core F Biomarker Core; Core G Research Education Component (RL5)), and then for the optional Cores for your Center, in the order that is listed below.
 - i. Order of Cores/Components
 - 1. Overall Component
 - 2. Core A: Administrative Core
 - 3. Core B: Clinical Core
 - 4. Core C: Data Management and Statistical Core
 - 5. Core D: Neuropathology Core

- 6. Core E: Outreach, Recruitment and Engagement Core
- 7. Core F: Biomarker Core
- 8. Core G: Research Education Component
- 9. Core H-Z: All other optional cores
- 10. Developmental Projects

g. Developmental Projects:

- i. An annual report of progress should be reported for each developmental project.
- ii. Include 3 sets of reports, if necessary:
 - <u>New Developmental Project</u>: Applications must include an abstract, biosketch, HSS Targeted/Planned Enrollment Table (for projects with human subjects recruiting outside the Clinical Core) and budget at minimum OR a full proposal packet may be submitted.
 - 2. <u>Interim Developmental Project:</u> Progress reports should clearly state the status of the project and the plans to finalize the project. All progress accomplished in the second year including Inclusion Enrollment table (if applicable) is included in an interim report.
 - 3. <u>Final Developmental Project:</u> Reports should summarize all progress and/or results of the project while also including the final cumulative Inclusion Enrollment Table (if applicable) after 2 years, or when study is completed.
- iii. Select 'Other' from the COMPONENT TYPE drop-down menu and establish each developmental project according to the below naming convention:
 - 1. Developmental Project Numbering: Projects should be numbered according to the year of the grant they were awarded (e.g., 2.1, 2.2 and 2.3, for three projects from year 2).
 - 2. Developmental Project Naming: Project should be named in the following format:

[Year.Project Number]_[TITLE]_[PD/PI of the Project]_[new/interim/final] *Example: 3.1_Comorbidities in Alzheimer's Disease_Smith_new*

-The following year: 3.1_Comorbidities in Alzheimer's Disease_Smith_interim

-The final year: 3.1_Comorbidities in Alzheimer's Disease_Smith_final

- 3. The only part of this name that will change from year to year is the suffix (i.e., new, interim, final).
- iv. Click on its own 'edit' link found in the ACTIONS box of the component, and you will once again see sections (A) - (H) that will be used to report on the various elements pertinent to the Developmental Project. Repeat for each of the Interim Developmental Projects to be reported for your Center.

III. DATA ENTRY, PDF ATTACHMENTS AND STYLE:

- a. Most text entry boxes have an 8,000-character limit (~ 3 pages), and text exceeding 8,000 characters will be cut to 8,000 when using the *cut and paste* feature. Note the 700 characters limit (~1/4 page) for Sections B.3 (Competitive Revisions/Administrative Supplements), *D.2.a* (Level of Effort), *G.9* (Foreign Component), *G.10.b* (Unobligated Balance), and 1,300-character limit (~1/2 page) for Sections G.5 (Human Subjects Education Requirement) and *G.10.c* (Carryover balance description).
- **b.** Grantees should generate text attachments using any word processing software and then convert those files to PDF before attaching the files to the appropriate section in RPPR. All PDF attachments must be submitted as individual files and may not be more than 6 megabytes (6MB). Although some software packages allow bundling of multiple PDFs into a single file, eRA systems cannot support "Bundling" or "Portfolio" features at this time. Paginated PDF files are also discouraged since they can interfere with system pagination of the entire RPPR document upon submission to the agency. Save all files with descriptive file names of 50 characters or less and be sure to use only standard characters in files names. Do not use any special characters (e.g., *, #, /) or spacing in the file name, and for word separation, use an underscore (e.g., My_Attached_File.pdf).

- **c.** Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger. (A Symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.) Type density, including characters and spaces, must be no more than 15 characters per inch.
- **d.** Type may be no more than 6 lines per inch. Use standard paper size (8.5 by 11). Use at least $\frac{1}{2}$ inch margins (top, bottom, left, right) for all pages. <u>No information should appear in the margins, including the PI's name and page number.</u>

IV. OVERALL SECTION NOTES

The Overall section of your report should serve as an Executive Summary of the report and include the most significant scientific discoveries and innovations coming out of your Center during the past year. Do not copy the first paragraph of each section to make up the Overview. This section should highlight how the Cores are integrated to make up a whole greater than the sum of the parts and describe how the existence of the Center has led to novel techniques, ideas, and research findings.

Many required pieces of the progress report will only appear in Overall, not in the individual components. This includes, but is not limited to: Publications, Targeted Enrollment and Inclusion Enrollment Tables, Participants, Supplements, Dissemination, Websites or Other Internet Sites, Technologies or Techniques, Inventions, Patent Applications or Other Licenses, Other Products and Resource Sharing, and Other Support.

Section B

B.3: Supplements: If your Center has a Diversity or Administrative Supplement, it should be included in Section B.3 (Competitive Revisions/Administrative Supplements) of the Overall Section.

B.5: Dissemination: Describe how the results have been disseminated to communities of interest in Section B.5. Include any outreach activities that have been undertaken to reach members of communities who are not usually aware of these research activities, for the purpose of enhancing public understanding. **Not Applicable is not an acceptable statement.**

Section C

C.2: Websites or Other Internet Sites: List the URL for any Internet site(s) that disseminates data sharing instructions for research activities in *Section C.2*. A short description of how researchers can use the URL for requesting data from the Center should be provided. Not Applicable is not an acceptable statement

C.3: Technologies or Techniques (If applicable): Identify technologies or techniques that have resulted from the research activities. Describe the technologies or techniques and how they are being shared in *Section C.3.*

C.4: Inventions, Patent Applications, and/or Licenses (If applicable): Inventions, patent applications and/or licenses in *Section C.4*. 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 or to the official responsible for patent matters at the grantee organization? Reporting of inventions through iEdison is strongly encouraged.

C.5a: Other Products and Resource Sharing: Identify any data and sample sharing that was accomplished during this project period in *Section C.5.* Not Applicable is not an acceptable statement.

Section F

F.3: Updates in IRB and IACUC - If there are (or will be) significant changes in human subject protocols and/or the uses of vertebrate animals since the last reporting period, you will need to provide a description and explanation of the changes in Section F.3.a. (Human Subjects) and/or F.3.b (Vertebrate Animals) of the Overall component.

Section G

Section G.5: Human Subjects Education Requirement - The Overall component will capture your Center personnel's human subjects training. If your Center has any NEW personnel in the upcoming funding year, simply type in their names, title of the human subjects education program completed by the individual, and a one-sentence description of the program. Unlike previous paper submission of the progress reports, you will no longer need to submit Human Subjects Education certificates.

Budget:

A summary budget will be system-generated based on the budgets completed for each of the RPPR components. Include the relevant budget and budget justification information for each Core and new Developmental Project Proposals in their respective component. For components that have zero budget amounts going forward (e.g., completed Developmental Projects), please select 'SF424 Research and Related Budget' from the drop-down menu in Section H of the budget, complete the required fields (denoted by *) on the form, and hit 'save''. Once you run a "check for error', you may get a yellow-box warning indicating that no budget amount has been allocated for the component; you may ignore this message.

Personnel:

List each person who worked at least 1 person month per year during the reporting period in Section D (Participants) of the Overall component, regardless of their source of compensation. However, you will not need to list the eRA Commons ID for everyone – just those for senior/key personnel and individuals who have a postdoctoral, graduate, or undergraduate role. NOTE: For individuals with a postdoctoral, graduate role, please ensure that they have entered their date of birth, gender, race/ethnicity, US citizenship status, country of citizenship, and institutions affiliated with their degrees (or indicate that they do not wish to provide such data) in their eRA Commons profiles. Otherwise, you will receive a red-box warning upon running a 'check for error' for the RPPR application.

Other Support:

Submit other support for all *new* senior/key personnel and *update* other support for all senior/key personnel for whom there has been a change since the last reporting period. Provide only active and pending support for all new senior/key personnel. If a previously active grant has terminated and/or if a previously pending grant is now active update accordingly.

Biosketch:

A biosketch is required for *new* Senior/Key Personnel added since the last progress report. The page limit of the biosketch is 5 pages. Researchers are allowed to describe up to 5 of their most significant contributions to science along with the historical background that framed their research. Each description can be accompanied by a listing of up to 4 relevant peer-reviewed publications or other non-publication research products (e.g., instruments or equipment). NOTE: All publications listed that were published after 4/7/08 need to be compliant with the NIH Open Access Policy and include the PMCID in the reference. In addition to the descriptions of specific contributions and documentation, researchers will be allowed to include a link to a full list of their published work as found in a publicly available digital database such as <u>MyBibliography</u> or <u>SciENcv</u>.

TIP: Template and instructions for Other Support and Biosketch documents can be found at:

- <u>https://grants.nih.gov/grants/forms/othersupport.htm</u>
- <u>https://grants.nih.gov/faqs#/other-support-and-foreign-</u> components.htm?anchor=alphaHeader4226
- https://grants.nih.gov/grants/forms/biosketch.htm

Publications: Public Access Policy information is required for all peer-reviewed publications resulting from work directly supported by the ADRC, NIH Public Access Policy Requirements: https://sharing.nih.gov/public-access-policy/public-access-policy/public-access-policy-overview

- **a.** Work with affiliated authors frequently and from early stages of the report generation to bring publications into compliance before progress reporting deadlines.
- b. Include your Center's entire list of publications that are relevant to the *current* Progress Report in Section C.1 (Products) of the Overall component of the RPPR. Publications associated with your Center in My NCBI (<u>www.ncbi.nlm.nih.gov/myncbi/</u>) will 'pre-populate' Section C.1 of the component. Place a checkmark under the 'ASSOCIATE WITH THIS RPPR' column to include it with your RPPR.
- c. Publications not associated with your Center in My NCBI (<u>www.ncbi.nlm.nih.gov/myncbi/</u>) will 'pre-populate' Section C.2 of the component. Place a checkmark under the 'ASSOCIATE WITH THIS RPPR' column if these should be included with your RPPR. Do not include publications under Section C.1 (Publications) of each Core. NOTE: If this is your first time using RPPR for your ADRC grant, it is likely that you will *not* be able to deselect publications from outside the current reporting period. RPPR will automatically pull *all* publications linked with your grant number. This should change with the second RPPR for a given grant, such that you can select only publications from the current reporting period.
- **d.** Centers have the discretion to include a list of publications in the PDF that is uploaded for *Section B.2* (Accomplishments) of the relevant component. Note: Publications for this list will pull from all PI/PD's for any multiple PI/PD center.
- e. If any publications are included that are not compliant with the NIH Open Access Policy, the funds for your next grant year will be delayed until Open Access compliance is achieved. If you submit your progress report with any noncompliant publications, you will ultimately need to correct the status of these publications (once compliance has been achieved) using the Progress Report Additional Materials (PRAM) feature. The system will send an automated email to the PD/PI requesting verification that all publications are in compliance with the NIH Public Access Policy. For more information, please see the RPPR Instruction Guide (*Section 5.10* of the NIH RPPR Instruction Guide).
- f. Public Access Policy compliancy will be evaluated by the NIH Public Access Support Center. Email communication will be from <u>publicaccess@mail.nih.gov</u>
- **g.** The inclusion of publications **indirectly** supported by the ADRC (authors were not supported by the Center) in the progress report is optional. If Centers wish to include these in the annual progress report, they may include them on the PDF that is uploaded to **Section B.2** (Accomplishments) of the relevant component.
- **h.** To include indirectly supported publications in Overall Section C.1, the publications will have to be linked with your ADRC grant number through My NCBI. These publications must also be Open Access compliant.
- V. Human Subject System (HSS): HSS is used for reporting participant sex/gender, race, and ethnicity information. Access is through the Human Subjects link in the RPPR or the eRA Commons Status page. Signing Officials will submit all study records associated with an application at one time rather than separately. Delegation authority is expected to be available in a future enhancement of HSS.
 - **a.** Use the HSS within eRA Commons to report sex/gender, race and ethnicity information as required by the <u>NIH Policy on the Inclusion of Women and Minorities in Clinical Research</u>.
 - b. NIH grantees completing their RPPR will be prompted in Section G.4.b to access and update the inclusion records directly in HSS as needed. See <u>https://grants.nih.gov/policy/clinicaltrials/human-subjects- system.htm</u> for more information about the HSS.

- VI. Inclusion Enrollment Table(s): Please find the revised IER instructions for RPPRs outlined below. The relevant policy guidance is available here: <u>G.500 - PHS Human Subjects and Clinical Trials</u> <u>Information (nih.gov)</u> (Section 2.9. Inclusion Enrollment Report(s), SF424 (R&R) Forms Version H October 25, 2022).
 - a. <u>The Planned Enrollment Table(s)</u>: This section may include 1 or more tables and are usually prepopulated with the numbers your site provided in your most recent renewal application submission.
 - i. If this is your first P30 5-year cycle, you will see 1 table with your projected planned new enrollment numbers.
 - ii. If this is your 2nd (or more) cycle of the P30 mechanism, you will see 2 planned enrollment tables:
 - 1. Table 1: Projected continuing participants from your previous P30 cycle(s)
 - 2. Table 2: Projected <u>new participants enrolled</u> in your current P30 cycle.
 - iii. If applicable, you also may need to submit Planned Enrollment for your Research Registry (more below in section VI.c.).
 - iv. If applicable, you also may need to submit Targeted/Planned Inclusion Enrollment Tables for each relevant Core or Developmental Project.
 - v. If you need to edit or create your Planed Enrollment tables, first click on the 'Inclusion' link, then click on 'Submit New Planned Inclusion Record' link, then enter the Study Title and enrollment numbers using both the 'Edit Planned Enrollment' and "Edit Cumulative Enrollment' links.
 - 1. Remember to hit 'save' prior to exiting each screen! If you are submitting a 2year Progress Reportnyou should include Targeted/Planned Enrollment Tables and Inclusion Enrollment Tables for any completed pilots or Developmental Projects that enrolled human participants.
 - 2. Note that these tables will still appear under Overall in future Progress Reports, but you will not update these numbers further after this year. Some ADRCs have reported seeing tables under Overall from other completed components not relevant to the current reporting period; as long as the numbers from these components have not changed, you can just leave the tables as is with the old numbers.
 - 3. If needed, update the values in the individual enrollment count cells as necessary and select the Save and Release Lock button. To leave the form without saving any changes, select the Cancel and Release Lock button instead. Saving and canceling both return you to the Study Record(s) screen. See Section 5.3.6 (Editing Inclusion Enrollment Data) of the NIH RPPR Instruction Guide for more information.
 - b. <u>The Cumulative IER table(s)</u> is(are) updated with the latest enrollment from the current progress period. If a given study will continue with the same enrollment or additional enrollment, or if new studies are proposed, provide a new IER for each as described in the instructions below.
 - i. If this is your first P30 5-year cycle, you will provide 1 table of your cumulative enrollment counts.
 - ii. If this is your 2nd (or more) cycle of the P30 mechanism, you will create 2 cumulative enrollment tables:
 - 1. "<u>Continued participants from the previous cycle</u>": Submit the cumulative number of participants from a previous grant cycle, seen in the current progress period. For these participants, use their enrollment age when they were first seen in previous cycle.
 - 2. Second IER entitled "<u>New enrollments for the requested cycle</u>": Submit the cumulative number of new participants enrolled in the current progress period. For these participants, use their enrollment age at their first visit in this current cycle.

- c. <u>Research Registry table(s)</u>: IER tables are required unless the registry is a category of research that qualifies for exemption as defined in the Common Rule for the Protection of Human Subjects. These regulations can be found at <u>45 CFR 46</u>.
 - i. If this is your first P30 5-year cycle, you will provide:
 - 1. A table of your planned (expected) number of individuals in your registry for the grant cycle.
 - 2. A table of the cumulative number of individuals in your research registry at the time of your current progress report period.
 - ii. If this is your 2nd (or more) cycle of the P30 mechanism, you will create 2 sets of tables:
 - 1. Submit a table of planned and another table of the cumulative number of "Continued participants from the previous cycle" you estimate in the current grant cycle.
 - 2. Submit a table of planned and another table of the cumulative number of ""<u>New</u> <u>enrollments for the reporting period</u>" that you actually have in your registry at the time of your current progress report period.
 - iii. Additional registry reporting: Please describe any research registry information and include any site-specific recruitment/enrollment data tables in the <u>Clinical Core</u> <u>summary section.</u>
 - 1. The participants in the registry may be considered a trial-ready cohort and may be assessed remotely by telephone, web-based assessment, or another mobile assessment tool.
 - 2. The registry should track the number and reasons for those lost to follow-up and conduct longitudinal follow up of registry participants.
 - 3. Describe efforts to include and retain participants from groups traditionally understudied in research in the registry.

Tip: Always calculate the age at enrollment from the participant's first visit in your center's P30 cycle(s). For sites on their second (or more) cycle of the P30, this age would be pulled from the previous grant cycle if the person is a "continued participant" from your last 5-year cycle.

Tip: Check for errors in the ASSIST application as each record is completed. Enter HSS information early. The ASSIST HSS section must be approved and submitted by your University before it will pull to the main progress/final report.

Tip: Make sure to check for errors for the human subject's inclusion enrollment table in ASSIST. Do not wait till the last minute to upload the inclusion enrollment table(s).

- VII. THE INCLUSION ACROSS THE LIFESPAN policy applies to all grant applications submitted for due dates on or after January 25, 2019 (see <u>NOT-OD-18-116</u>). NIH recipients/offerors must submit individual-level data on participant age at enrollment in progress reports.
 - **a.** Age at enrollment of the participants included in your cumulative tables must be provided along with information on sex/gender, race, and ethnicity in the Inclusion Enrollment Report. See also above Section VI.b.ii and the "Tip box" on which age to report as the "age at enrollment."
 - b. Units for reporting age at enrollment range from "minutes" to "years". Helpful links below, particularly the video. NOTE: The excel spreadsheet needs to match the format *exactly* as described in order to upload successfully.
 - 1. Inclusion Across the Lifespan Policy
 - 2. <u>eRA: Inclusion Enrollment Report</u>
 - 3. Entering Inclusion Data Using the Participant Level Data Template (video)

Tip: The Participant level data format cannot be revised. That includes no revisions to formatting, categories, and data sample categories. These must be used as detailed in the sample or an error will occur in the upload.

Helpful instructions: How to Edit, View & Submit Human Subjects Studies

NOTE: Only your NIA Program Officer or designee can make changes to the HSS records/tables.

VIII. ADDITIONAL INSTRUCTIONS FOR RPPR DEVELOPMENTAL PROJECTS AND INDIVIDUAL CORES

a. REQUIRED TABLES:

- Core A: Administrative Core (Tables A1-A7) should be handled as follows: A summary of the results from all Administrative Core tables should be included in the Admin Core Section B.2 (Accomplishments). Tables A1-A3, A5, and A6-A7 should be included as part of the PDF that is uploaded to the Admin Core Section B.2 (Accomplishments). Table A4 should be included as part of the PDF that is uploaded to the Admin Core Section B.4 (Training).
- ii. **Core E:** ORE Core (Tables E1- E2) should be included as part of the PDF that is uploaded to the ORE Core *Section B.2* (Accomplishments).
- iii. **Core G:** Research Education Component (RL5), will have two tables (Tables G1-G2) that list trainees, scholars, and events under the REC. This should be included as a PDF that is uploaded to the RL5 *Section D* (Participants). Tables G1 and G2 should be included in REC *Section B.4* (Training) at the end.

b. INSTRUCTIONS FOR TABLES:

- i. Core A: Administrative Core Tables A1-A7
 - Table A1. Federal Funded Grants Supported by Resources of the ADRC Year XX: This table includes federally funded grants that use any resources of your ADRC. Resources include data of any type, neuroimages, biosamples (any biofluids (including DNA) or tissue), participants, or expertise In the far-right columns, indicate Yes or No (Y/N) as to whether your center contributed these resources to other federal grants. NOTE: If the federal grant is a therapeutic trial, it should <u>only</u> be listed in table A3.
 - Table A2. Non-Federal (e.g., Foundation) Funded Grants Supported by Resources of the ADRC – Year XX: This table is the same as the previous table

 with funding from non-federal sources. NOTE: If the non-federal grant is a therapeutic trial, it should <u>only</u> be listed in table A3.
 - 3. Table A3. Therapeutic Trials Supported by Resources of the ADRC Year XX: This table is for therapeutic trials, regardless of their funding source. Indicate funding source from these four options: 1 = U.S. National Institutes of Health; 2 = Other U.S. Federal agencies (Food and Drug Administration, Department of Defense, Centers for Disease Control and Prevention, U.S. Department of Veterans Affairs); 3 = Industry (pharmaceutical and device companies); 4 = All others (including individuals, universities, and community-based organizations). In the far-right columns, provide the number of participants that have been referred and if known, consented to a clinical trials program. If you do not track the number of participants consented, please response "unknown."
 - *a.* **Referred** means there was a conversation between the ADRC and participant about a given trial and the participant agreed to give their contact information to the trial for further recruitment communication.
 - *b.* If a participant is reported as referred for a given trial in Table A3, that indicates there was a warm handoff between the ADRC and the trial.
 - *c.* If the therapeutic trial is funded through a federal grant, it should <u>only</u> be listed in table A3.
 - 4. Table A4. Training Grants Associated with the ADRC Year XX: This table includes funded training grants. Training programs (CTSI, T, F, and K programs) should be reported here, as well as fellowships, Physician Scientist Awards, Underrepresented group Fellowships, etc. The Pl/mentor listed here should be affiliated with the ADRC in some capacity. *NOTE:* REC Scholars should only be listed in table G1.
 - 5. **Table A5. ADRC Collaborations Year XX:** This table includes the NACC Projects and other collaborations, relationships with industry, Alzheimer's

Association chapters, and other institutions. There is likely to be some overlap with this table and some of the other tables. Try to be as complete as possible.

- 6. **Table A6. Underrepresented Group (URG) Related Grants Year XX:** This table includes all Underrepresented Group (URG) funded grants. The main focus should be underrepresented group/diversity/health disparity topics. A study that is about something else, but which attempts to recruit a large number of underrepresented groups would not be included. There is likely to be some overlap with this table and some of the other tables.
- Table A7. Biomarkers Year XX: This table includes the type of biomarkers collected by the Center. Each line requires a Yes/No response with additional details requested.
- ii. Core E: Reporting Underrepresented Group (URG) Study Population Activities in your Progress Report: In order to organize the reporting of URG activities so that it is more systematic across Centers, we will continue to use the three tables as well as a narrative section.
 - 1. Table A6 (URG Related Grants) is provided in the Administrative Core section of the progress report.
 - 2. The other two URG tables (labeled E1-Table 1 and E2-Table 2) should be included in the ORE Core section.
 - a. For each of these forms, the <u>URG/diversity/health disparities</u> aspect should be the main focus. If a grant focuses on a topic not specific to URG issues (even if it is recruiting URG participants) the study should not be included in this table of URG grants.
 - b. Similarly, if a conference does not focus on topics related to URGs or on issues regarding health disparities, do not include it in the table. These guidelines should not be completely restrictive, if you have a project that

you believe is related to URG activities that you would like to include, please do, and flag it with an explanation.

- c. These tables are uploaded in the ORE Core, even if activities took place in a different Core. Please note: This information is meant to be a useful tool for each Center, not a time-consuming burden. Please include the ratio information that is readily available and provide any needed explanation.
 - i. **Table E1. Underrepresented Group Events and Activities:** Please provide estimated number of attendees or participants for the events and activities reported. Please only report the URGrelated events and activities for the current reporting period (i.e., up to one year time period).
 - ii. Table E2. Summary Table of Underrepresented Group (URG)-Related Activities: The ratio of URG participants contributing to one or more non-Clinical Core studies (pilots, projects, and clinical trials) to the <u>total number</u> of participants contributing to non-Clinical Core studies.
- 3. Instructions for the Underrepresented Group (URG) Related Activities Narrative.
 - a. Please fill in the section entitled 'URG Related Activities Narrative.' This information is used by NIA for the purposes listed here: <u>https://files.alz.washington.edu/progress-reports/4 Reason for Diversity Reporting.pdf</u> as well as for other purposes.
 - b. If you feel that you have already provided this information concisely within the text elsewhere, please do not repeat the information; instead, reference the component and RPPR section where the information can be found.

- i. Description of community partnerships/integration:
- ii. Recruitment/retention strategies/plans:
- iii. Barriers (successes, failures, steps to overcome)
- iv. Individual events, brochures etc. (*if there are any that you would like to provide further detail other than that provided in the table*)
- v. Future plans

iii. Core G: RL5 Research Education Component (Tables G1-G2)

- 1. **Table G1. Summary Table of REC Scholars and Trainees Year XX:** This table will summarize the trainees that are receiving education through the component.
- 2. **Table G2. Summary Table of REC Events Year XX:** This table will summarize the events hosted or supported by the component.
- **c. EXTERNAL ADVISORY REPORT:** Your Center's External Advisory Report should be included in *Section B.2* (Accomplishments) of the Admin Core component. The report should contain the list of committee members.

d. EACH CORE/COMPONENT:

- i. "Significance" section should receive a good amount of attention why does this matter, how does your work further knowledge about and finding treatments for AD?
- ii. Each Core is expected to emphasize the scientific premise and rigorous approaches taken to ensure robust and unbiased results. Reporting on rigor in RPPR will help NIH implement and evaluate the policy for both current and new awards. This will also prepare non-competing renewals for the next competitive renewal. (Link to notice: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-011.html)
- iii. In general, we want to focus on quality rather than quantity; the exception is with the ORE Core, where it is important to show that outreach and engagement are reaching a large number of people. Of course, quality is important there as well.
- iv. Someone other than the author should proofread all sections, particularly sections written by non-native English speakers.
- e. APPENDIX: An Appendix is no longer part of the RPPR application. NIA staff will no longer accept CDs of these materials. If you wish to highlight papers that were published within the current progress report period, please include the URL (e.g., <u>http://www.yourfavoritejournal.org</u>) for the paper in the text of your report when discussing.
- f. DATA MANAGEMENT AND SHARING: Effective with RPPRs submitted on and after October 1, 2024, recipients with awards subject to the <u>NIH DMS Policy</u> will be required to report on DMS Plan activities (see <u>NOT-OD-24-123</u>, <u>NOT-OD-24-175</u>).
 - i. Important links re: DMSP
 - 1. Implementation Details for the NIH Data Management and Sharing Policy https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-189.html
 - 2. Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023 https://grants.nih.gov/grants/guide/notice-files/not-od-22-198.html

IX. SPECIAL REPORTING MILESTONES - Interim RPPR, Final RPPR, and Close Out:

a. FINAL RPPR: In November 2016, NIH implemented Final Research Performance Progress Reports (Final RPPR) as a new eRA Commons module (See <u>NOT-OD-17-022</u>). A Final RPPR is required for any grant that has passed its project end date and will not be extended through the award of a new competitive segment. The report is due within <u>120</u> calendar days of the end of the project/funding period indicated on the notice of award (NOA).

- **b. INTERIM RPPR:** Used when you are submitting a Competing Renewal application (Type 2). If you opt NOT to apply for a Competing Renewal, complete the Final RPPR as you normally would within 120 days of the project end date. If you are going to complete a Competing Renewal application (or have already submitted such an application), you will submit an Interim RPPR.
 - i. This must be submitted within 120 days of the project end date.
 - ii. If you are awarded the renewal, the Interim RPPR will be treated as your annual RPPR and no other progress reporting will be needed for that segment of the study.
 - iii. If the application is NOT awarded, then the Interim RPPR will be accepted as the Final RPPR.
- c. Both the Interim RPPR and the Final RPPR are identical in process and information required. Data entry is done through the RPPR screens in eRA Commons. The information submitted will be the same as the annual RPPR (with the exception of budget and plans for the upcoming year) and summarize progress made toward the achievement of scientific aims and identifies significant outcomes. This will be used as part of the grant closeout process to submit project outcomes in addition to the information above. In the Project Outcomes section, provide a concise summary (1/2 page; 2,000 characters) of the cumulative outcome or finding of the Center. The concise summary will be made public and represents the summary of your P20 or P30 award (See <u>NOT-OD-18-103</u>). See Section 6.9 (Section I Outcomes) of the NIH RPPR Instruction Guide for more information.
- d. CLOSE OUT REPORT: Closeout of an award is the process by which NIH determines that the grantee and NIH have completed all applicable administrative actions and all required work of an award. See <u>NOT-OD-14-484</u> for updates on the Grant Closeout Policies. See the Notice of Award for additional instructions on the final federal financial reports. Use <u>https://grants.nih.gov/grants/closeout/index.htm</u> and Section 8.6 of the <u>NIH Grant Policy Statement</u> to review the NIH Closeout Requirements and find additional resources.

X. FINAL RPPR NOTES

In ASSIST there is only one Overall section. Cores and Development Projects/Pilot grants do not have separate sections.

Personnel: Report only on the last year. List each person who worked at least 1 person month per year during the reporting period in *Section D* (Participants) of the Overall component, regardless of their source of compensation. However, you will not need to list the eRA Commons ID for everyone – just those for senior/key personnel and individuals who have a postdoctoral, graduate, or undergraduate role. NOTE: For individuals with a postdoctoral, graduate, or undergraduate role, please ensure that they have entered their date of birth, gender, race/ethnicity, US citizenship status, country of citizenship, and institutions affiliated with their degrees (or indicate that they do not wish to provide such data) in their eRA Commons profiles. Otherwise, you will receive a redbox warning upon running a 'check for error' for the Final RPPR application.

Publications: See Publications section above in RPPR instructions. For the Final RPPR centers will need the entire list for the full cycle. The publications list can be downloaded from NCBI. The Final RPPR does show non-compliant papers.

Major Goals/Specific Aims: This section cannot be edited and is downloaded directly from eRA Commons.

Main Other Sections: Address significant results and major activities. A few paragraphs for each core that include key outcomes – for each core/component and each (project/pilot) provide a summary (brief final report for the P30 ADRC Developmental projects).

Administrative Core: Must include a paragraph on robust and unbiased results. In the Accomplishments Section – 2 pages mentioning all the cores.

Section B

Supplements: If your Center has a Diversity or Administrative Supplement, it should be included in *Section B.3* (Competitive Revisions/Administrative Supplements) of the Overall Section. I above. Provide a summary report on all of them that ended in the last year of the grant. If needed, recommend reaching out to NIA Program for further guidance.

Section B4: Summarize all training on 1 page.

Section B5: In your narrative description, please split this section into two parts - dissemination to the scientific and lay community.

Section C

C.2 Websites or Other Internet Sites: List the URL for any Internet site(s) that disseminates data sharing instructions for research activities in *Section C.2*. A short description of how researchers can use the URL for requesting data from the Center should be provided. Not Applicable is not an acceptable statement.

C.3 Technologies or Techniques (If applicable): Identify technologies or techniques that have resulted from the research activities. Describe the technologies or techniques and how they are being shared.

C.4 Inventions, Patent Applications, and/or Licenses (If applicable): 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 or to the official responsible for patent matters at the grantee organization? Reporting of inventions through iEdison is strongly encouraged. There is a separate form for Inventions and Patents. The ADRC PI/PD has to go into the Final RPPR to complete it based on answer (Y/N).

C.5a Other Products and Resource Sharing: Identify any data and sample sharing that was accomplished during this project period. Not Applicable is not an acceptable statement.

C.5b Resource Sharing: PD/PIs and recipient organizations are expected to make the results and accomplishments of their activities available to the research community and to the public at large. For additional information on NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources see <u>https://sharing.nih.gov/</u>.

C.5c Data Management and Sharing: Describe activities related to the approved Data Management and Sharing Plan; see <u>http://grants.nih.gov/grants/sharing.htm</u>. For each Data Type identified in the approved DMS Plan, provide the following information, as applicable:

- i. Data Type
- ii. Has data been generated to date? (Y/N) *
- iii. Has the data been shared (i.e., made available for use by others)? (Y/N) *
- iv. If data has NOT been shared, what is the status of data sharing (e.g., being prepared for submission, submitted to repository, not yet expected to be shared)
- v. Repository
- vi. Unique Identifiers/Digital Object Identifier (DOI)

Tables for Final RPPR:

Summarize information pertaining only to the last year. Some centers have submitted tables, while others have just summarized them. NIA requests that tables be submitted in Section B.2 (see below).

Provide summary in Administrative Core for all tables for the Final year. Include the ORE Core (E1 and E2) and REC tables from the Final Year of the award in B.2*. Include an update on the completion status of the pilot projects as well as a summary of the progress of the pilot projects in section B.2. Summarize the <u>Admin tables</u> – (e.g.: take last year programs report and get new grant

and those that continue in the last year of funding)

- A1 Federal Funded Grants Supported by Resources of the ADRC
- A2 Non-Federal (e.g. Foundation) Funded Grants Supported by Resources of the ADRC
- A3 Therapeutic Trials Supported by Resources of the ADRC
- A4 Training Grants Associated with the ADRC
- A5 ADRC Collaborations (e.g.: ranging from US to Canada to other international collaborations)
- A6 Underrepresented Group (URG) Related Grants
- A7 Biomarkers

XI. IMPORTANT CONTACT INFORMAITON

- a. If you have questions or comments, please email: <u>NACCmail@uw.edu</u>. and copy Grayson Donley (<u>grayson.donley@nih.gov</u>), Nina Silverberg (silverbergn@mail.nih.gov), and Cerise Elliott (<u>elliottce@mail.nih.gov</u>).
- **b.** Questions regarding the eRA Commons should be addressed to the eRA Commons Help Desk:
 - i. Web: <u>http://grants.nih.gov/support/index.html (preferred method of contact)</u>
 - ii. Phone: +1-866-504-9552 (toll-free) or 301-402-7469
 - iii. Hours: Mon-Fri, 7am to 8pm EST

NOTE: Any questions pertaining specifically to RFAs must be directed to NIA staff. Neither administrators nor NACC are authorized to answer questions related to RFAs.