

December 15, 2008

Dear ADC Administrators,

All of the needed files and instructions for the 2008 Progress Reports (Type 5) will be posted on the NACC website at <https://www.alz.washington.edu/NONMEMBER/progprep.html> .

Instructions that will remain the same:

1. Use the PHS 2590 forms. Electronic forms are available on the NIH website at <http://grants.nih.gov/grants/funding/2590/2590.htm> . Use the current instructions, which are dated "Revised 11/2007."
2. Table of Contents and the structure of the Progress Report remains the same as last year.
3. The paper submission will continue to be sent only to the NIH Division of Extramural Activities Support, OER.

**Division of Extramural Activities Support, OER
National Institutes of Health
6705 Rockledge Drive, Room 2207, MSC 7987
Bethesda, MD 20892-7987 (for regular or US Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express mail delivery only)
Phone Number: (301) 594-6584**

4. Continue to send a CD containing your appendices to Nina Silverberg (her address is listed in the ADC Directory). Do not send the CD along with your paper application to OER, and do not send the papers themselves. See notes below regarding publications.

Changes to last year's procedures are highlighted and are related to a clarification on the time frame of the 2008- 2009 progress report, publications and additional information to be included in the Education and Information Core Table 2. See the appropriate sections below for these changes.

There is an overall emphasis on quality rather than quantity.

General comments:

Please read over these guidelines and follow them, if appropriate for your center. You are welcome to provide feedback to the administrative core steering committee and/or Nina Silverberg regarding these guidelines.

Time frame for progress report:

All progress reports should cover one year from last progress report. Centers that are submitting a competing renewal application in 2009 SHOULD submit an annual progress report. The only exception is for Centers that submitted competing renewal applications in May, 2008. If you are going to be funded, you will NOT submit a progress report in 2009. Your competing renewal application will serve as your progress report and your 2009 budget (first year of your renewal) has already been detailed in the renewal application.

Overview:

- Don't copy first paragraph (or more) of each section to make up the Overview. This section should highlight how the cores and projects 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.

Individual cores/projects:

- Admin or Ed Cores: Emphasize training of young investigators.
- Admin core: please list EAC members (may be included with EAC report instead)
- Admin Tables 1-6 should be included in the Admin core section (and not be repeated in other core sections), and should therefore represent the whole Center, rather than a single core.
- Satellites [defined as either a) originally funded with separate funding specifically for a satellite, or b) was a satellite, but is now rolled into clinical core]: provide a separate budget for the satellite. Include Satellite after the clinical core.

For each core:

- “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?
- **Bold 3-6 key publications in the Publications list at the end of each core and project.**
- In general, we want to focus on quality rather than quantity; the exception is with the Ed core, where it is important to show that outreach and education are reaching a large number of people. Of course, quality is important there as well.
- All sections should be proofread by someone other than the author, particularly sections written by non-native English speakers.

Publications:

- The same publication may be listed in multiple sections if it is relevant; e.g., data core and project. Data cores should list all pubs on which they were authors.
- Publications should only be included for the funded year. Please do not include all papers since the Center was funded. Remember to cite the grant number in the publication.
- PDFs are only needed for publications that cannot easily be retrieved from PubMed; i.e., if the grant number is referenced or are available online for free. Otherwise (if the journal is not listed in PubMed, or online access requires a subscription, or if the papers are in press, etc.), please provide the PDFs **in the Appendix.**
- **For the full list of publications for the whole center, please do not include duplicates. The list should be in alphabetical order by first author. There should NOT be separate lists within the complete list, either by core or by author.**

Inclusion/enrollment Table:

Administrators should be familiar with NIH requirements for human subjects tracking (e.g. the definitions of

'human subject research' and the distinctions when using biospecimens or images; see <http://grants.nih.gov/grants/policy/hs/glossary.htm#hs> for more information) and should assure that all investigators with funded studies using human subjects provide the appropriate tables. (Targeted Enrollment tables are only necessary if there has been a change in targeted enrollment since the competing submission of the grant.)

Please attempt to verify that numbers add up correctly. (you can insert formulas to do this automatically in Word) **See the Enrollment Table with formulas on the website.**

Clinical core and ongoing projects at centers funded prior to the most recent RFA should provide two tables for each: Two inclusion/enrollment tables are requested. One should follow the standard PHS instructions for this table: cumulative enrollment since the beginning of the most recent competing renewal to the present (end date of this progress report) for the clinical core and any other component that enrolls human subjects. The second table should report cumulative enrollment since the historical beginning of the center. For example, the University of Pittsburgh was funded September 29, 1985. Our last competing renewal began April 1, 2005. Therefore our two tables would have the following dates: April 1, 2005 to present and September 29, 1985 to present.

- Tissue or other biospecimens from deceased persons do not count as human subjects and do not need to be reported.

Pilot projects:

- Progress reports for pilots should be included after the cores and after the projects (where applicable); they should be submitted on progress report forms similar to a core or project.
- Pilot progress report should cover the period funded by the Center. If the study is continuing under other funding, progress (including enrollment) does not need to be reported (although it is good to let NIA know that it is continuing).
- Include 3 sets of reports if necessary:
 - new pilot applications
 - an interim pilot progress report (if a pilot is not completed before your progress report is due) and enrollment tables The interim report may be very brief, e.g., "this work is 50% complete, the specific aims have not changed."
 - final pilot progress report and enrollment table after 2 years, or when study is completed (final progress reports for pilots may be sent in separately; however, **a note should be included to state when this should be expected along with a brief explanation for the delay).**
- Put pilot budgets up front with all other budgets or in both places (up front and with new pilot application) but they should definitely be with all of the other budgets.
- Other than the budget keep everything together for pilots (biosketches, etc.)

REMEMBER: Pilot projects should be numbered according to the year of the grant; e.g., 17.1, 17.2 and 17.3, for three pilots from year 17.

IRB Approvals:

- Include IRB approvals at end of report after External Advisory Report and before summary publication list (see example Table of Contents)

If you have questions or comments, please contact Nina Silverberg (silverbergn@mail.nih.gov) or Leslie Dunn (dunnlo@upmc.edu).

Best wishes,

Leslie

NIA Instructions for Progress Report Submission

In October 2004, NIH began centralizing the receipt and initial processing of all NIH **non-competing** progress reports (Type 5), and all applications are now scanned into electronic format. Non-competing progress reports (PHS 2590) should continue to be sent to the centralized mailing address for all NIH Institutes/Centers:

Division of Extramural Activities Support, OER National Institutes of Health 6705 Rockledge Drive, Room 2207, MSC 7987 Bethesda, MD 20892-7987 (for regular or US Postal Service express mail only)
Bethesda, MD 20817 (for other courier/express mail delivery) **Phone Number: (301) 594-6584**

Reminder: This affects only non-competing progress reports (type 5s) currently mailed directly to NIH. It does **NOT** reflect the mailing address to be used for all new and competing grants forwarded to the Center for Scientific Review, nor does it change that review process.

In summary:

1. Send non-competing progress reports to the centralized mailing address (blue type above); NIA does not want a copy of your progress report on CD-ROM.
2. It is important to label the subsections as spelled out in recent RFAs, to allow indexing for electronic filing.
3. Send all appendices on CD-ROM to Nina Silverberg (address provided below); do not include a copy of your progress report.

For Alzheimer's Disease Centers Progress Reports, follow the mailing procedure outlined above, but do NOT send an electronic copy of the progress report itself to the NIA on CD-ROM. Send only electronic copies of appendix material (publications, newsletters, etc.) on CD-ROM directly to:

**Nina Silverberg,
Assistant Director
Alzheimer's Disease Centers Programs
Dementias of Aging Division of Neuroscience
National Institute on Aging
Gateway Building, Suite 350
7201 Wisconsin Ave., MSC 9205
Bethesda, MD 20892-9205** (for regular or U.S. Postal Service express mail only)
Bethesda, MD 20814 (for other courier/express mail delivery)
Phone number: (301) 496-9350
Please do NOT forward paper copies of appendix material. The CD-ROM should include electronic copies of all publications in the appendices for the funding year only.

Instructions for Table of Contents

Please include a Table of Contents using the format indicated on the enclosed sample page as a guideline. Not all of the information is applicable to all Centers.

Critical components of the Table of Contents:

- Order of the forms: Please use the order indicated in the sample. This makes it easier for our program officials to find what they need.
- Titles of Cores: Please use the titles and letters of the Cores as indicated in the RFA (and listed below), and include the name of the Core Leader or Project PI.
 - Core A: Administrative
 - Core B: Clinical
 - Core C: Data Management and Statistics
 - Core D: Neuropathology
 - Core E: Education and Information
 - Other Cores not listed can be added with letters F, G, etc.
- Details:
 - Use the current NIH guidelines for completing the PHS 2590 forms (<http://grants.nih.gov/grants/funding/2590/2590.htm>).
 - **All** Budgets/Justifications (including new pilots) are to be grouped together at the beginning of the Progress Report, immediately after the Table of Contents.
 - New Pilot Project Proposals should be included as indicated and numbered as mentioned in the letter of instruction, just before the External Advisory Report.
 - Overview should be included, using the comments in the letter of instruction.
 - Required tables associated with the Cores should be listed individually and named as indicated on the table.
 - Each Core and project should have its own list of Tables/Figures and Publications
 - **NOTE: For all Progress Report Summaries using human subjects:**
 - If you have previously reported human subjects, use the *Inclusion Enrollment Report* (Rev. 09/04, Reissued 4/2006).
 - If this is a new project, such as a new pilot, please use the “*Targeted/Planned Enrollment*” forms (Rev. 09/04, Reissued 4/2006). The table should be placed at the end of each section of your Clinical Core (i.e., there should be a table for each satellite if they are reported separately).
- Remember to include:
 - External Advisory Report
 - Summary Publications List
 - Consortia pages – The only forms required for subcontracts are the budget pages which should be included with all budgets at front of report.
 - Checklist
 - Key Personnel
- Appendix: **NO LONGER PART OF THE PAPER APPLICATION**

Instructions for Required Tables

Please use these tables until further notice. Label Cores as in your P50 application or, if you are a P30, as you did on your last Progress Report.

NOTE: All tables require a header which indicates the name of the Core and the name of the Core Leader, as shown in the samples. This information should also be listed in the Table of Contents for each Core. There may be overlapping listings between tables.

Core A: Administrative Core (Tables 1 thru 6)

o Table 1. Federal Funded Grants supported by Resources of the _____ ADC – Year XX.

This table includes federally funded grants that use any resources of your ADC. Resources include subjects for any projects, tissue (autopsy tissue, blood, DNA, cell lines, etc.) from these subjects, or data from these subjects. In the far right column, Role of the ADC should include the numbers of subjects, autopsy cases, etc.

o Table 2. Non-Federal (e.g. Foundation) Funding Supported by Resources of _____ ADC – Year XX.

This table is exactly the same as the previous table – with funding from non-federal sources. In the far right column, Role of the ADC should include the numbers of subjects, autopsy cases, etc.

o Table 3. Funding for Therapeutic Trials and Other Grants from Industry – Year XX

This table is for clinical trials, regardless of their funding source. In the far right column, Role of the ADC should include the numbers of subjects, autopsy cases, etc.

o Table 4. Training Awards – Year XX

This table includes fellowships, Physician Scientist Awards, Minority Fellowships, etc. Personnel listed here should be involved in the ADC in some capacity.

o Table 5. _____ ADC Collaborations – Year XX

This table includes the NACC Projects and other collaborations, relationships with industry, Alzheimer's Association chapters, and other institutions. There is bound to be some overlap with this table and some of the other tables. Try to be as complete as possible.

o Table 6. Minority-Related Grants – Year XX

The main focus should be minority/diversity/health disparities. A study that is about something else but which attempts to recruit a large number of minorities would not be included. If you have more detailed information you would like to include, please do so.

Core E: Education and Information Core (Tables 1 and 2)

o Table 1. Minority Events and Activities – Year XX

Similar to Admin Table 6 above, listings in this table should have as their main focus minority/diversity/health disparities issues or topics. A conference that is not specifically ABOUT minority or health disparity issues should not be listed. If you have more detailed information you would like to include, please do so.

o Table 2. Summary Table of Minority-Related Activities – Year XX

See info above for Education Core Table 1. We have added two items to the summary table to reflect the interest of External Advisory Committees and review committees in the extent to which

minorities participate in research studies other than the Clinical Core evaluations. The first item is the number of minority subjects participating in one or more non clinical core studies by the total number of active minority subjects. The second item refers to provision of DNA samples by minorities.

Please fill in the section entitled 'Minority Related Activities Narrative.' This information is used by NIA for the purposes listed here: <https://www.alz.washington.edu/NONMEMBER/SPR07/nina.pdf> as well as others. If you feel that you have already provided this information concisely within the text elsewhere, please do not repeat the information; instead, insert a page number where the information may be found.

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