INSTRUCTIONS FOR RPPR CONTENT

Section A – Cover Page

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 and Administrative Official, 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 RPPR. The appropriate signing official will be determined when reviewed at SPA.

<table>
<thead>
<tr>
<th>A. Cover Page</th>
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<thead>
<tr>
<th>Grant Information</th>
<th>A.4 Recipient Organization Information</th>
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<tr>
<td>Grant Number: 5K23HD123456-03</td>
<td>Organization Name: PRESIDENTIAL UNIVERSITY</td>
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<tr>
<td>Project Title: A New Model for the Delivery of Well-Child Care</td>
<td>Address: PRESIDENTIAL UNIVERSITY</td>
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<tr>
<td></td>
<td>Office of Research Administration</td>
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<td></td>
<td>777 University Drive</td>
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<td></td>
<td>Oak Ttow, MD 20755</td>
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<tr>
<td>Name: JEFFERSON, THOMAS</td>
<td>DUNS: 012345678</td>
</tr>
<tr>
<td>E-mail: <a href="mailto:Jefferson@email.com">Jefferson@email.com</a></td>
<td>EIN: 12345678901</td>
</tr>
<tr>
<td>Phone: (703) 505-1775</td>
<td>Recipient ID:</td>
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<table>
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<tr>
<th>A.1.1 Program Director/Principal Investigator (PD/PI) Information</th>
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<td>Is there a change of contact PD/PI on a multiple PI award?</td>
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<td>If yes, provide the eRA Commons ID of the new contact PD/PI</td>
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<td>Report Frequency: Annual ☐ Other ☐</td>
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<th>A.2 Signing Official Information</th>
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<tbody>
<tr>
<td>Name:</td>
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<th>A.3 Administrative Official Information</th>
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<td>Name:</td>
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<td>E-mail:</td>
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<td>Phone:</td>
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Section B – Accomplishments

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

List the major goals of the project as stated in the approved application or as approved by the agency. 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 goals will not change from one reporting period to the next. However, if the awarding agency approved changes to the goals during the reporting period, list the revised goals and objectives. Also explain any significant changes in approach or methods from the agency approved application or plan.

Goals are equivalent to specific aims. Significant changes in objectives and scope require prior approval of the agency (e.g., NIH Grants Policy Statement, 8.1.2).

The specific aims must be provided in the initial RPPR (i.e., first non-competing type 5 submission). In subsequent RPPRs this section will pre-populate with the aims/goals previously entered, and may be amended by answering Yes to question B.1.a.

List major goals below (NIH recommends length up to 1 page) Place cursor between scroll bars to begin typing.

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

Select Yes if the major goals/specific aims have changed since the initial competing award or previous report, and provide a revised description of major goals/specific aims. Remember that written prior approval from the awarding agency grants official is required for significant changes in the project or its direction. The RPPR is not an appropriate vehicle to request such a change.

The first year that an RPPR is submitted any revised goals should be entered into the text box for B.1. In subsequent years, if the user selects Yes the text box under B.1.a for entering revised major goals will be provided.

List revised major goals below.
B.2 What was accomplished under these goals? (SEND ATTACHMENT TO COORDINATOR)

For this reporting period describe: 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 goals not met. As the project progresses, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Goals are equivalent to specific aims. In the response, emphasize the significance of the findings to the scientific field. For most NIH awards the response should not exceed 2 pages.

B.3 Competitive Revisions/Administrative Supplements.

For this reporting period, is there one or more Revision/Supplement associated with this award for which reporting is required?

If yes, identify the Revision(s)/Supplements(s) by grant number (e.g., 3R01CA098765-01S1) or title and describe the specific aims and accomplishments for each Revision/Supplement funded during this reporting period. Include any supplements to promote diversity or re-entry, or other similar supplements to support addition of an individual or a discrete project.

The NoA will indicate any reporting requirements. Be advised that the NoA incorporates requirements of the FOA that may also include reporting requirements.

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 to report during this reporting period, state “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 all projects reporting graduate students and/or postdoctoral participants in Section D. Participant, grantees are encouraged to describe the use of Individual Development Plans (IDPs) for those participants. Do not include the actual IDP, instead include information to document that IDPs are used to help manage the training for those individuals. This requirement is Not Applicable for AHRQ grantees.

For T, F, K, R25, R13, D43 and other awards or award components 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.

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

Describe how the results have been disseminated to communities of interest. 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 and increasing interest in learning and careers in science, technology, and the humanities.

Reporting the routine dissemination of information (e.g., websites, press releases) is not required. For awards not designed to disseminate information to the public or conduct similar outreach activities, a response is not required and the grantee should select **Nothing to Report**. A detailed response is only required for awards or award components that are designed to disseminate information to the public or conduct similar outreach activities. Note that scientific publications and the sharing of research resources will be reported under *Products*.

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

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

Remember that significant changes in objectives and scope require prior approval of the agency (e.g., NIH Grants Policy Statement, 8.1.2.).

Include any important modifications to the original plans. Provide a scientific justification for any changes involving research with human subjects or vertebrate animals. A detailed description of such changes must be provided under Section F. Changes.
Section C – Products

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 the award?

PD/PIs are required to report all publications that arise from their NIH award in this section. 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. If there are no publications to report select No. The tables draw information from the PD/PI’s My NCBI account. PD/PIs can log in to their My NCBI account via the My NCBI link at the top of C.1. PD/PIs that do not have a My NCBI account can create one by simply logging in to My NCBI with their eRA Commons credentials, which will automatically create a My NCBI account. Any changes they make to their My Bibliography collection will be reflected in the RPPR once the screen is refreshed (i.e., by clicking the Save button). For more information on My NCBI, see: Get Started with My NCBI: Access My NCBI, Register, and Sign In

Edit Your My Bibliography Settings (Add a Delegate)

- The first table, All Publications Associated with this Project in My NCBI, lists all publications that are in the PD/PI’s My Bibliography collection, are associated with this award, and have not been reported in previous electronic progress reports for this award.
- The first column Associate with this RPPR is automatically checked. Leaving the box checked upon submission associates the publication with this progress report, results in the publication being displayed in RePORT, and makes the award-publication association in My NCBI permanent and the association will be reported in PubMed. Unchecking the box disassociates the publication with this progress report and, upon submission of the RPPR to NIH, removes the award-publication association in My NCBI.
- The second column, NIH Public Access Compliance, indicates the current compliance status with the NIH Public Access Policy. This information is from My NCBI. Publications that fall under the Public Access Policy and are non-compliant still must be reported. Generally, publications can be brought into compliance within 10 business days; PD/PIs are advised to do so as soon as possible to ensure their award is renewed in a timely manner. For more information, see Manage Compliance with the NIH Public Access Policy in My NCBI and the NIH Public Access website. The compliance status for AHRQ grantees will be indicated as NA (not applicable) until such time as AHRQ implements a public access policy.

Note that the publication data in these tables is dynamic until the progress report is submitted to the agency. Any change to the data occurring in PubMed, PubMed Central, the PD/PI’s My Bibliography account, or in the compliance status of a publication will refresh upon saving the C.1 Products section, or opening the RPPR in another session. When the progress report is submitted to the agency, the publication data is frozen in the progress report.

- The second table, Publications not associated with this project in MyNCBI, lists all other publications that are in the PD/PI’s My Bibliography collection but do not have an association with this award. Checking Associate with this RPPR box will associate a publication with the award both in the progress report and in My NCBI. Refreshing this screen (i.e., clicking the Save button) will also move 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.
- The final table, Publications previously reported for this project, lists publications reported in a previous electronic progress report for this award. Grantees are responsible for ensuring that these publications comply with the Public Access policy even if they were provisionally compliant (listed as in Progress) when previously reported.

The report may be submitted with noncompliant publications; however the system will generate an automated email to the PD/PI (with cc to the AO and SO) requesting that the grantee 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 two weeks prior to the next budget start date. The grantee must respond either via an email to the GMS and PO, or may respond via the Progress Report Additional Materials (PRAM) link found on the eRA Commons Status page. The PRAM link provides a text box in which the grantee may respond through the eRA Commons. The grantee will be able to view the PRAM in the grant folder. See Section 5.10 Public Access Progress Report Additional Materials (PRAM) for more information.

Publications listed in other parts of a progress 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.2 Website(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.

For awards not designed to create or maintain one or more websites, select **Nothing to Report**. A description is only required for awards designed to create or maintain one or more websites. Limit the response to this reporting period.

C.3 Technologies or techniques.

Identify technologies or techniques that have resulted from the research activities. Describe the technologies or techniques and how they are being shared.

Limit the response to this reporting period.

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 or to the official responsible for patent matters at the grantee organization?*

Reporting of inventions through iEdison is strongly encouraged.
C.5 Other products and resources.

C.5.a Other products

Identify any other significant products that were developed under this project. Describe the product and how it is available to be shared with the research community. Do not repeat information provided above. Limit the response to this reporting period.

Examples of other products are: audio or video products; data and research material (e.g., cell lines, DNA probes, animal models); databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware.

C.5.b Resource Sharing

PD/PIs and grantee 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 http://grants.nih.gov/grants/sharing.htm.

If the initial research plan addressed, or the terms of award require, a formal plan for sharing final research data, model organisms, Genome Wide Association Studies data, or other such project-specific data, describe the progress in implementing that plan. For sharing model organisms, include information on the number of requests received and number of requests fulfilled during this reporting period. If the sharing plan is fully implemented, provide a final statement on data sharing.

![Image of data entry interface](image-url)
Section D – Participants

The RPPR Section D. allows the agency 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?

Provide or update the 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.

NIH 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. AHRQ only requires a Commons ID for individuals in a postdoctoral role.
- 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: Entering the User ID allows selection of “Populate from Profile” which will partially populate the individual’s information. Those with an Administrator role in the eRA Commons may search for user IDs by following the instructions at:


Senior/key personnel are defined as the PD/PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered senior/key personnel if their involvement meets this definition. Consultants and those with a postdoctoral role also may be considered senior/key personnel if they meet this definition.

Last 4 digits of SS# and Month/Year of birth: The provision of the partial Social Security number and month/year of birth are voluntary, and the information is used only for program management purposes.

Project Role: PD/PI names 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
- Postdoctoral (scholar, fellow or other postdoctoral position)
- Technician
- Staff Scientist (doctoral level)
- Statistician
- Graduate Student (research assistant)
- Non-Student Research Assistant
- Undergraduate Student
- High School Student
- Consultant
- Other (specify)

**Supplement Support:** If personnel are supported by a Reentry or Diversity Supplement indicate type of supplement in this field.

**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. For instance, some institutions define the academic year as a 9-month appointment while others define it as a 10-month appointment.

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.

Round to the nearest whole person month that the individual worked on the project. For example, if the individual worked 2.25 person months, indicate 2 person months. If the individual worked 4.7 person months, indicate 5 person months. If the PD/PI worked 0.5 to 1 person month, round up to 1 person month. If the PD/PI worked 0.1 to 0.4 person month, round down to 0 (zero).

To calculate person months, multiply the percentage of effort associated with the project by the number of months of the appointment. For example:

- 25% of a 9 month academic year appointment equals 2.25 (academic year) person months (.25 x 9 = 2.25). Round down to 2.
- 90% of a 12 month calendar appointment equals 10.8 (calendar year) person months (.90 x 12 = 10.8). Round up to 11.
- 35% of a 3 month summer term appointment equals 1.05 (summer) person months (.35 x 3 = 1.05). Round down to 1.
- If the regular pay schedule of an institution is a 9 month academic year and the PD/PI will devote 9 academic months at 30% time/effort and 3 months summer term at 30% time/effort, then 3 academic months (.30% x 9 = 2.7, round up to 3), and 1 summer month (.30 x 3 = .9, round up to 1) should be reported.

**Person months reported on the RPPR are intentionally rounded to the nearest whole number to provide for generalized reporting consistent across federal agencies that support research activities.** Although it is possible to report 0 (zero) person month for the PD/PI on the RPPR if the PD/PI worked .1 to .4 person month, 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 NoA 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.
D.2 Personnel Updates.

D.2.a Level of effort.

Will there be, in the next budget period, either (1) a reduction of 25% or more in the level of effort from what was approved by the agency for the PD/PI(s) or other senior/key personnel designated in the Notice of Award, or (2) a reduction in level of effort below the minimum amount of effort required by the Notice of Award?

Reductions are cumulative, i.e., the 25% threshold may be reached by two or more successive reductions that total 25% or more. Once agency approval has been given for a significant change in the level of effort, then all subsequent reductions are measured against the approved adjusted level. Selecting Yes constitutes a prior approval request to the agency and the issuance of a subsequent year of funding constitutes agency approval of the request.

D.2.b New senior/key personnel.

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

Senior/key personnel are those identified by the grantee institution 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.

If yes, upload biosketches and other support for all new senior/key personnel.
Follow the biosketch instructions in the competing application guide and provide active other support for all new senior/key personnel. Combine all biosketches and other support into a single PDF.

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?

If yes, upload active other support for senior/key personnel 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.

Select Yes only if active support has changed for the PD/PI(s) or senior/key personnel.

If a previously active grant has terminated and/or if a previously pending grant is now active, submit complete Other Support information using the suggested format and instructions found at http://grants.nih.gov/grants/funding/2590/2590othersupport.doc. Annotate this information so it is clear what has changed from the previous submission.

Submission of other support information is not necessary if support is pending or for changes in the level of effort for active support reported previously.

Other support information should be submitted only for the PD/PI and for those individuals considered by the grantee to be key to the project for whom there has been a change in other support. Senior/key personnel are defined as individuals who contribute in a substantive measurable way to the scientific development or execution of the project, whether or not a salary is requested. Do not include other support information for Other Significant Contributors; e.g., those that may contribute to the scientific development or execution of the project, but are not committing any specified measurable effort to the project.

D.2.d New other significant contributors.

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

Other significant contributors 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.

If yes, upload biosketches for all new other significant contributors.

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

Change in status of PD/PI requires prior approval of the agency (e.g., NIH Grants Policy Statement, 8.1.2.6). In accord with the NIH GPS, 9.5, revision of the Leadership Plan during the project period may be accomplished through a joint decision of the PD/PIs and reported in the RPPR. Prior approval of a change in the MPI Leadership Plan is not required.

If yes, upload a revised MPI Leadership Plan that includes a description of the change(s).

All multiple PD/PI awards have a Leadership Plan that describes the roles and areas of responsibility of the named PD/PIs, the process for making decisions concerning scientific directions, allocation of resources, disputes that may arise, and other information related to the management of the proposed team science project. If there has been any change in
the governance and/or organizational structure of the Leadership Plan, provide a description, including communication plans and procedures for resolving conflicts, and any changes to the administrative, technical, and scientific responsibilities of the PD/PIs. If the progress report includes a change in the Contact PD/PI (Cover Page, A.1) address this change and the impact, if any, the change has on the administrative, technical, and scientific responsibilities of the PD/PIs. A request to change from a multiple PD/PI model to a single PD/PI model, or a change in the number or makeup of the PD/PIs on a multiple PD/PI award, requires the prior approval of the GMO. The progress report is not the appropriate vehicle to request such a change.

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### B.2.c Changes in Other Support

- Has there been a change in the active support of senior/key personnel since the last reporting period?  
  - Yes  
  - No

If yes, upload a description and indicate what the change has been.

### B.2.d New Other Significant Contributors

- Are there, or will there be, new other significant contributors?  
  - Yes  
  - No

Other significant contributors are individuals who have contributed to the scientific development or execution of the project, but are not committing any specified measurable effort (i.e., person months) to the project.

If yes, upload biosketches for all new other significant contributors.

### B.2.e Multi PI (MPI) Leadership Plan

- Will there be a change in the MPI Leadership Plan for the next budget period?  
  - N/A  
  - Yes  
  - No

Change in status of PD/PI requires prior approval of the agency (e.g., NIH Grants Policy Statement, 8.1.2.6).

If yes, upload a revised MPI Leadership Plan that includes a description of the change(s).
Section E – Impact

The RPPR 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 for most awards.  See chapter 7 Supplemental Instructions.

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.

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

E.3 Not Applicable for most awards.  See chapter 7 Supplemental Instructions.

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

For domestic awardees provide the dollar amount obligated to first-tier subawards to foreign entities for this reporting period. For foreign awardees provide the dollar amount of the award, excluding all first-tier subawards to U.S. entities, for this reporting period. Dollars provided should reflect total costs.

If more than one foreign country identify the distribution between the foreign countries.

Report only cumulative first-tier subawards dollars by country. Do not report foreign travel, purchases, etc., unless part of a first-tier subaward to a foreign country.
Section F – Changes

The RPPR Section F addresses Changes. Grantees are reminded that significant changes in objectives and scope require prior approval of the agency.

F.1 Not Applicable to most awards. See chapter 7 Supplemental Instructions.

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) and emphasize their resolution.

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 require prior approval of the agency (e.g., NIH Grants Policy Statement, 8.1.2.). 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

If human subject protocols are or will be different from the previous submission, 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 competing application instructions.

F.3.b Vertebrate Animals

If there are or will be 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. If studies involving live vertebrate animals are planned and were not part of the originally proposed research design, provide a new or revised Vertebrate Animal Section as described in the competing application instructions.

F.3.c Biohazards

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).

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. 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 competing application instructions.

Section G – Special Reporting Requirements

G.1 Special Notice of Award and Funding Opportunity Announcement Reporting Requirements

Address any special reporting requirements specified in the award terms and conditions in the Notice of Award (NoA) or Funding Opportunity Announcement (FOA).

G.2 Not Applicable to most awards. See chapter 7 Supplemental Instructions.

G.3 Not Applicable to most awards. See chapter 7 Supplemental Instructions.

G.4. Human Subjects

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

If activities involving human subjects are planned at any time during the next budget period at the grantee organization or at any other project/performance site or collaborating institution, select Yes. Select Yes even if the project is exempt from the Regulations for the Protection of Human Subjects. Select No if activities involving human subjects are not planned at any time during the next budget period.

Policy on research involving human subjects, including definitions, can be found in the NIH Grants Policy Statement or in the competing application instructions.

Is the research exempt from federal regulations? Not applicable unless the answer to G.4.a. is Yes. If all of the proposed human subjects research meet the criteria for one or more of the exemptions from the requirements in the DHHS regulations (45 CFR 46.101(b)), Yes should be selected, and the appropriate exemption number(s) checked. The six categories of research exempt from the DHHS human subject regulations appear in Part III of the competing application instructions, under Definitions, Human Subjects.

If in doubt, consult with the Office for Human Research Protections (OHRP), Department of Health and Human Services, or the NIH Office of Extramural Research, Office of Extramural Programs at OEPMailbox@mail.nih.gov.

Note that if the proposed research involves only the use of human data or biological specimens, first determine whether the research involves human subjects. The exemptions do not apply if the research does not involve human subjects. For help determining whether research that involves the use of human data or biological specimens is human subjects research, refer to the NIH Research Involving Human Subjects website.

Does this project involve a clinical trial? Not applicable unless the answer to G.4.a. is Yes. The NIH defines a clinical trial as a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Behavioral human subjects research involving an intervention to modify behavior (diet, physical activity, cognitive therapy, etc.) fits this definition of a clinical trial.

Human subjects research to develop or evaluate clinical laboratory tests (e.g. imaging or molecular diagnostic tests) might be considered to be a clinical trial if the test will be used for medical decision making for the subject or the test itself imposes more than minimal risk for subjects.

Biomedical clinical trials of experimental drug, treatment, device or behavioral intervention may proceed through four phases:
Phase I clinical trials test a new biomedical intervention in a small group of people (e.g., 20-80) for the first time to evaluate safety (e.g., to determine a safe dosage range and to identify side effects).

Phase II clinical trials study the biomedical or behavioral intervention in a larger group of people (several hundred) to determine efficacy and to further evaluate its safety.

Phase III studies investigate the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.

Phase IV studies are conducted after the intervention has been marketed. These studies are designed to monitor effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

If yes, is this an NIH defined Phase III Clinical Trial?

An NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or controlled intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

G4.b Inclusion enrollment data.

Unless otherwise notified by the program official, reporting the cumulative enrollment of subjects and the distribution by sex/gender, race, and ethnicity is required for NIH-defined clinical research as defined in the competing application instructions. If you have inclusion enrollment, update the Inclusion Enrollment Report, with the total cumulative data collected to-date. You may have more than one Inclusion Enrollment Report. 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 the text of the progress report.

In Section F.3.a of the RPPR, please describe details or concerns related to your inclusion enrollment progress.

If the system determines that the RPPR does not require inclusion monitoring or if the inclusion enrollment data records have a Closed status, the Inclusion Enrollment section of the form displays the following message:

The RPPR does not have any Inclusion Enrollment Reports or the report records have a status of Closed. If you have any questions, please contact your NIH Program Official [PO’s name] at [email address].

If the system determines that the RPPR does require inclusion monitoring, the Inclusion Enrollment section of the form displays the following message:

You are required to complete Inclusion Enrollment Report for the following studies: [list of all protocols]

If it is determined that inclusion monitoring is required and one or more inclusion enrollment data records exist for the previous budget period, inclusion enrollment data records are created in the RPPR Population Tracking tables. If the inclusion enrollment data records from the current budget period are in an Open status, the existing enrollment data is refreshed with the data from the previous year.

If inclusion monitoring is required, but inclusion enrollment data records from the previous support year do not exist, a default inclusion enrollment data record is created for the RPPR. Additionally, an email notification is sent to the NIH Program Official associated with the RPPR.

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, foreign populations, changes to target data, and NIH-defined Phase III clinical trials.

For questions about the NIH policies for inclusion, please refer to:
http://grants.nih.gov/grants/funding/women_min/women_min.htm or contact your program officer.

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 (including NIH) 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 if the original peoples of the Far East, Southern 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.

**Reporting Data on Race and Ethnicity:** NIH is required to 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. The 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 (http://www.whitehouse.gov/omb/fedreg_directive_15). The Inclusion Enrollment Report format is not designed for use as a data collection instrument. Collect the data using instruments prepared for the study and use the information from the study database to fill out the Inclusion Enrollment Report. Study participants who self-identify with more than one race should be reported in the aggregate in the "More Than One Race" category.

When reporting these data to NIH, include the following items:

Part A of the Inclusion Enrollment Report:

a) the total number of subjects in each ethnic category or who did not self-identify with an ethnic category (unknown or not reported);

b) the total number of Hispanic or Latino and Not Hispanic or Latino subjects who selected only one category from each of the five racial categories;

c) the total number of Hispanic or Latino and Not Hispanic or Latino subjects who selected more than one racial category reported as the number selecting “more than one race”;

d) the total number of Hispanic or Latino and Not Hispanic or Latino subjects who did not self-identify with any racial category (unknown or not reported); and,

Part B of the Inclusion Enrollment Report:

a) the total number of Hispanic or Latino subjects who selected only one of the five racial categories as well as Hispanic or Latino subjects who selected more than one racial category or who did not self-identify with a racial category (unknown or not reported).

In completing the race sections of the Inclusion Enrollment Report, individuals who identify as Hispanic or Latino should be included in both race tables: the table where all participants’ races are reported (Part A) and the table where only the race of individuals identifying as Hispanic or Latino is reported (Part B).
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 the 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 Foreign Populations: 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. These items, however, should be designed in a way that allows the information to be aggregated into the OMB minimally required ethnic and racial categories and which will allow you to complete the inclusion enrollment report(s). Enrollment of foreign participants should be reported to NIH in an Inclusion Enrollment Report separate from that for reporting domestic participants.

Changes to Targeted/Planned Enrollment: If there are changes from the Targeted/Planned Enrollment Table originally approved for funding, contact your Program Officer to discuss updating/revising your Targeted/Planned Enrollment Table and address the change in Section F.3.a of the RPPR.

Reporting Data on NIH-defined Phase III Clinical Trials: If conducting an NIH-defined Phase III Clinical Trial, report on the cumulative enrollment (as described above) and indicate if data analysis has begun for the trial. If analysis has begun, report on progress made in conducting valid analyses for sex/gender, racial, and/or ethnic differences.

G.4.c ClinicalTrials.gov.

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

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

See What NIH Grantees Need to Know About FADAA, and FAQ When must an applicable clinical trial be registered? If the grant 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 grant number in the Study IDs field.

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?

If yes, provide the following:
• names of individuals,
• title of the human subjects education program completed by each individual, and
• a one-sentence description of the program.

**G.6 Human Embryonic Stem Cell(s).**

*Does this project involve human embryonic stem cells?*

Only hESC lines listed as approved in the [NIH Registry](https://nihresearch.nih.gov/hesc) may be used in NIH funded research. 

*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.*

**G.7 Vertebrate Animals**

*Does this project involve vertebrate animals?*

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**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 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 F.3.a or F.3.b. If a Project/Performance Site is engaged in research involving human subjects, the grantee organization is responsible for ensuring that the Project/Performance Site operates under an appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other NIH human subject related policies described in Part II of the competing application instructions and the [NIH Grants Policy Statement](https://grants.nih.gov/grants/policy/). 

For research involving live vertebrate animals, the grantee organization must ensure that all Project/Performance Sites hold OLAW-approved Assurances. If the grantee organization does not have an animal program or facilities and the animal work will be conducted at an institution with an Assurance, the grantee must obtain an Assurance from OLAW prior to the involvement of vertebrate animals.
G.9 Foreign component.

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 grantee or by a researcher employed by a foreign organization, whether or not grant funds were expended. The following grant-related activities are significant and must be reported:

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

Examples of other grant-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.
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?

The total approved budget equals the current fiscal year award authorization plus any approved carryover of funds from a prior year(s). The numerator equals the total amount available for carryover and the denominator equals the current year’s total approved budget.

If yes, provide the estimated unobligated balance.

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

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.

Grantees not authorized to carryover unobligated balances automatically must submit a prior approval request to the awarding IC. See instructions in NIH Grants Policy Statement Section 8.1.2.4 Carryover of Unobligated Balances.

G.11 Program Income.

Is program income anticipated during the next budget period?

If yes, provide the amount and source(s).

Program Income is defined as gross income earned by the grantee organization, a consortium participant, or a contractor under the grant that is directly generated by the grant-supported project or activity or earned as a result of the award. Program income includes, but is not limited to, income from fees for services performed; charges for the use or rental of real property, equipment or supplies acquired under the grant; the sale of commodities or items fabricated under an award; charges for research resources; registration fees for grant-supported conferences, and license fees and royalties on patents and copyrights. Program income from license fees and royalties from copyrighted material, patents, and inventions is exempt from reporting requirements unless otherwise specified in the terms and conditions of award.

G.12 F&A Costs [applicable to SNAP awards only]

Is there a change in performance sites that will affect F&A costs?

If yes, provide an explanation.
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? ○ Yes ○ No

The “total approved budget” equals the current fiscal year award authorization plus any approved carryover of funds from a prior year(s). The numerator equals the total amount available for carryover and the denominator equals the current year’s total approved budget.

If yes, provide the estimated unobligated balance

G.10.b Provide an explanation for unobligated balance below (Limit is 700 characters or approximately 1/4 of a page.)

Total remaining allowed limit is 700 characters.

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 (Limit is 1300 characters or approximately 1/2 of a page.)

Total remaining allowed limit is 1300 characters.

G.11 Program Income

Is program income anticipated during the next budget period? ○ Yes ○ No

If yes, use the format below to reflect the amount and source(s):

Anticipated Amount Source(s) Add/Line Clear

G.12 F&A Costs

Is there a change in performance sites that will affect F&A costs? ○ Yes ○ No

If yes, provide an explanation below (Limit is 1300 characters or approximately 1/2 of a page.)

Total remaining allowed limit is 1300 characters.
Section H – Budget [Pilot Only] [Applicable to non-SNAP awards only]

H.1 Budget Form

To complete the detailed budget for this award select the SF424 Research and Related Budget from the drop down menu and follow the instructions in the SF424 (R&R) Application Guide for NIH and Other PHS Agencies, Section 1, 4.7 Budget Form, to complete the R&R budget, sections A-K, and the R&R Cumulative Budget, for the remainder of the project period. The budget justification should be uploaded as item K and must include detailed justification for those line items and amounts that represent a significant change from previously recommended levels (e.g., total rebudgeting greater than 25 percent of the total award amount for this budget period).

NOTE: If subaward budgets are completed, the system will not calculate the budget line item F.5 for the main budget (see figure below). Total consortium costs for the main budget MUST be computed and entered manually into budget line item F.5.
H.2 Subaward Budget Form

For awards with subaward/consortium budgets, select the SF424 Research and Related Budget Subaward Budget from the drop down menu and follow the SF424 (R&R) Application Guide for NIH and Other PHS Agencies, Section I, 4.8 Special Instructions for Preparing Applications with a Subaward/Consortium.