RPPR SECTION BY SECTION GUIDE

The RPPR consists of separate screens for each of the sections listed below:

A. Cover Page
B. Accomplishments
C. Products
D. Participants
E. Impact
F. Changes
G. Special Reporting Requirements
H. Budget
I. Outcomes (Interim and Final Progress Reports Only)

You may complete the RPPR sections in any order.

A. COVER PAGE

Pre-populated information.
Review and if necessary, update the Research Administrative & Signing Officials:

- Administrative Official: Your Research Administrator
- Signing Official: Your Research Administrative Director

B. ACCOMPLISHMENTS

This section allows NIH to assess whether satisfactory progress was made during the reporting period.

B.1 WHAT ARE THE MAJOR GOALS OF THIS PROJECT?

Fill in the text box. (NIH recommended length up to 1 page. Limit is 8,000 characters or approximately 3 pages.)

Note: Goals are equivalent to specific aims. Significant changes in objectives and scope require prior NIH approval.

- The specific aims must be provided in the first non-competing type 5 submission for the award. In subsequent RPPRs, this section will prepopulate with the aims/goals previously entered, and may be amended by answering Yes to question B.1.a.
- 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.

B.1.A HAVE THE MAJOR GOALS CHANGED SINCE THE INITIAL COMPETING AWARD OR PREVIOUS REPORT?

Answer either **Yes** or **No.**

If **Yes**, 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.

B.2 WHAT WAS ACCOMPLISHED UNDER THESE GOALS?

PDF upload – up to 2 pages.

Goals are equivalent to specific aims. In the response, emphasize the significance of the findings to the scientific field. Include the approaches taken to ensure robust and unbiased results.
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.

Note: If citing references in this section, please provide a full citation. List all products from this reporting period in section C.

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?

Answer **Yes** or **No.**

- If yes, identify the Revision(s)/Supplements(s) by grant number (e.g., 3R01CA123123-01S1) or title and in the text box (700-character limit) 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.

B.4 WHAT OPPORTUNITIES FOR TRAINING AND PROFESSIONAL DEVELOPMENT HAS THE PROJECT PROVIDED?

Select "Nothing to Report" or Upload PDF document.

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.

Address these items in the uploaded document:

- For all projects reporting graduate students and/or postdoctoral participants in Section D., describe whether your institution has established Individual Development Plans (IDPs) for those participants. Do not include the actual IDP, instead include information to describe how IDPs are used, if they are used, to help manage the training for those individuals.

- 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 RESULTS BEEN DISSEMINATED TO COMMUNITIES OF INTEREST?

Select "Nothing to Report" or fill out text box.

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 (usually the case for most R01, R21 or R03 awards) , you will select "Nothing to Report."

If this question is applicable to your award, describe how the results have been disseminated to communities of interest. Include any outreach activities 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.

B.6 WHAT DO YOU PLAN TO DO FOR THE NEXT REPORTING PERIOD TO ACCOMPLISH THE GOALS?

Fill in the text box. (NIH recommended length up to 1 page. Limit is 8,000 characters or approximately 3 pages.)

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives. Discuss efforts to ensure that the approach is scientifically rigorous and results are robust and unbiased.
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.

C. PRODUCTS

This section allows NIH to assess and report both publications and other products to Congress, communities of interest, and the public. Limit the response to this reporting period.

C.1 PUBLICATIONS

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

Grantees must report publications in section C.1 if: (1) the publication was accepted for publication or made public during the reporting period; and (2) the publication directly arises from the award (e.g. the award supported personnel activity that contributed to the publication, such as authorship, consulting with authors, preparing manuscripts, running analyses reported in the publication). Publications listed in other parts of the RPPR will not be tracked as award products.

Publications that fall under the NIH Public Access Policy and are non-compliant still must be reported. The next budget period will not be awarded until the publication(s) are compliant. You must either respond to the non-compliance notification via an email to the NIH Grants Management Specialist and Program Office, or submit a Progress Report Additional Materials (PRAM) through the eRA Commons.

<u>How to Report</u>

- 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.**

Additional information and instructions may be found in the NIH RPPR Instruction Guide on Pages 76-78.

C.2 WEBSITE(S) OR OTHER INTERNET SITE(S).

- 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.
- List the URL for any Internet site(s) that disseminates the results of the research activities. Provide a short description of each site.

C.3 TECHNOLOGIES OR TECHNIQUES

Select from list or click “Nothing to Report.”

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

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

Select **Yes** or **No.**

If yes, has this information been previously provided to the PHS or to the official responsible for patent matters at the grantee organization?

Report inventions through iEdison.

C.5 OTHER PRODUCTS AND RESOURCES

C.5.a Other products

- Select from list or click “Nothing to Report.”
- Identify any other significant products that were developed under this project. Describe the product and how it is available to share with the research community. Do not repeat information provided above.
- 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

- Fill in text box or click “Nothing to Report.”
- 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.
- 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.

D. PARTICIPANTS

This section allows NIH 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, WHETHER PAID OR UNPAID, INCLUDING INDIVIDUALS AT SUBCONTRACTING INSTITUTIONS?

- Please list individuals, their role (i.e. GRA, Post-doc, Co-I, Technician, etc.), the amount of effort (months) for each appointment, regardless of if effort of the source of funds for the effort (paid or cost-shared).
- Show the most senior role in which the person has worked on the project for any significant length of time.

A Commons ID is required for all individuals with a postdoctoral, graduate or undergraduate role. A Commons ID is also required for individuals supported by a Reentry or Diversity Supplement. If this role is missing an eRA Commons ID, it will generate an error in the system and will prevent submission to NIH. If you need a commons ID for one of your staff, please reach out to your research administrator.

Any person who did not work for 1 person month or more on the project will not be listed. *Round person months up or down to the next whole number. Those who worked less than 0.5 months will be rounded down and thus not included on the report.*

Tips for adding Participants in Section D.1:

- Enter individual's Commons ID and select "Populate from Profile" which will partially populate the individual's information.
- After all required information is entered for individual, select the **"Add/New"** button to add the data to the table. **Add/New acts as "Save" for this section.**

Additional instructions for the Section D – Participants may be found in Chapter 6 of the NIH RPPR Guide.

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 named 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?

- Select **Yes** or **No.**
- If **Yes,** provide an explanation in the text box.

D.2.b New senior/key personnel

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

Select **Yes** or **No.**

- If **Yes,** upload biosketch and other support for all 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.

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? (i.e. new research support, support that ended, etc.)

- Select **Yes** or **No.**
- Select **Yes** only if active support *has changed* for the PD/PI(s) or senior/key personnel (consultants do not have to be included).

- If **Yes,** upload active other support for senior key personnel whose support has changed and indicate what the change has been. List the NIH award for which the progress report is being submitted and include the effort that will be devoted in the next reporting period.
- 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.

D.2.d New other significant contributors
Are there, or will there be, new other significant contributors?

- Select **Yes** or **No.**
- If **Yes,** upload biosketches for all 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.

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

- Select **Yes** or **No.**
- 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 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.

E. IMPACT

This section is 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 ONLY APPLICABLE TO SBIR/STTR -R41, R42, U43 AND U44 AWARDS

E.2 WHAT IS THE IMPACT ON PHYSICAL, INSTITUTIONAL, OR INFORMATION RESOURCES THAT FORM INFRASTRUCTURE?

- Fill in text box or click “Nothing to Report.”
- If the award is not intended to support physical, institutional, or information resources that form infrastructure, select “Nothing to Report.”
- 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.

E3. NOT APPLICABLE TO MOST AWARDS

E4. WHAT DOLLAR AMOUNT OF THE AWARD'S BUDGET IS BEING SPENT IN FOREIGN COUNTRY(IES)?

List amount & country or click "Nothing to Report."

Provide the dollar amount obligated to first-tier subawards to foreign entities for this reporting period. If you list more than one foreign country, identify the distribution between the 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.

F. CHANGES

This section addresses changes. Significant changes in objectives and scope require prior NIH approval.

F1. NOT APPLICABLE TO MOST AWARDS

F2. ACTUAL OR ANTICIPATED CHALLENGES OR DELAYS AND ACTIONS OR PLANS TO RESOLVE THEM

- Fill in Text box or click "Nothing to Report."
- 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 NIH approval. 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

Upload PDF attachment or click "No Change."

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

Upload PDF attachment or click "No Change."

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

Upload PDF attachment or click "No Change."

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

F.3.D SELECT AGENTS
Upload PDF attachment or click "No Change."

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 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.

G. SPECIAL REPORTING REQUIREMENTS

This section addresses agency-specific award terms and conditions, as well as any award specific reporting requirements.

G.1 SPECIAL NOTICE OF AWARD AND FUNDING OPPORTUNITY ANNOUNCEMENT REPORTING
Not applicable to most awards

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

G.3 NOT APPLICABLE TO MOST AWARDS

G.4 HUMAN SUBJECTS

G.4.a does this project involve human subjects?

- Select **Yes** or **No.**
- If **Yes,** answer the rest of questions under this section.

Is the research exempt from Federal regulations?

- Select **Yes** or **No.**
  If yes, check appropriate exemption number.

Does this project involve a clinical trial?

- Select **Yes** or **No.**
  If yes, is this an NIH defined Phase III Clinical Trial?

G.4.B INCLUSION ENROLLMENT DATA

If the project meets the definition of clinical research and requires the reporting of cumulative enrollment of subjects, follow the below steps to update the inclusion data records associated with this award.

*Before selecting the Human Subjects link, hit **Save** on the RPPR to save all your work in Section G. Failure to do so will result in a loss of data on your report.*

- Select Human Subjects link.
- On the next screen, click on the "HCST Post Submission" tab.
- Click on "View" to bring up the appropriate study.
- You will see the existing study has an "Edit" button available. There are additional buttons to add regular or delayed onset studies.

- Click on the link in Section 2 of the Study Record screen to initiate the Inclusion Enrollment Report.
- For each Inclusion Enrollment Report (below Section 2.7), you will need to indicate whether an existing dataset or resource will be used and whether the enrollment location type is domestic or foreign.
- Update the cells in the existing Inclusion Enrollment Report.
- After updating the IER, click the "Save and Release Lock" button on the bottom of the page. The submission status will update to "Work in Progress."
- Select "Ready for submission" on the pull-down menu.
- **This is important:** click the "continue without adding a comment button" (if no comments).
- Research Administration will get an email saying that the application is ready for approval.
- The signature official will log into ASSIST and find the appropriate application and submit application. ASSIST is the interface with Human Subjects System.
- After the SO submits the IER, the human subjects cumulative enrollment numbers are connected to the RPPR application.

Additional guidance and information may be found on the NIH eRA Help page.

G.4.c Does this project include one or more applicable clinical trials that must be registered in ClinicalTrials.gov under FDAAA?

- Select **Yes** or **No.**
- If **Yes,** provide the ClinicalTrials.gov identifier, NCT number (e.g., NCT0065321) for those trials.

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?

Select **Yes** or **No.**

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 (this is usually CITI training).

G.6 Human Embryonic Stem Cell(s)

Does this project involve human embryonic stem cells?

- Select **Yes** or **No.**
- Not applicable to most awards
- If **Yes,** identify the hESC Registration number from the NIH Registry. Only hESC lines listed as approved in the NIH Registry may be used in NIH funded research.

G.7 Vertebrate Animals

Does this project involve vertebrate animals?

Select **Yes** or **No.**

G.8 Project /Performance Sites

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

G.9 Foreign component

- Add required information or select "No Foreign Component."
- Provide the organization name, country, and description of each foreign component.
- Foreign component is defined as a significant scientific activity that was performed outside of the U.S., 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?

- Select **Yes** or **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.

Your Research Administrator will help determine the anticipated unobligated balance by checking the account balance in Workday.

NIH does review the balance and will ask if they see a large balance when this question is answered as "no" in the RPPR. It may delay the release of the next NOA.

G.10.b If yes, provide an explanation for unobligated balance below.
Fill in Text box.

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 NOA.
Fill in Text box

G.11 PROGRAM INCOME

Is program income anticipated during the next budget period?
Select **Yes** or **No.**
If **Yes,** provide the amount and source(s).

G.12 F&A COSTS

Is there a change in performance sites that will affect F&A costs?
Select **Yes** or **No.**
If **Yes,** provide an explanation an explanation in text box.