2024 LA CaTS Center RPPR Guide

Description: NIH requires grantees to submit an annual Research Performance Progress Report (RPPR). The RPPR is the application for the yearly non-competing continuation of an award, also known as a "Type 5" year. The report is due **60 days before the end of your current active budget period (typically due May 1st)**. The information reported in the RPPR should be for the most recent budget period only and must not duplicate progress narratives or publications from prior reporting periods. Refer to the RPPR Instructional Guide here. Grantees should start working on the RPPR early following these instructions to allow enough time to request guidance from NIH staff and handle technical issues during the submission process promptly. If the report is submitted late, if required information is missing, or if there are inconsistencies in the RPPR, the Type 5 award could be issued late as NIH Staff will need to follow up to obtain the missing or clarifying information. Repetitive failure to submit complete or accurate reports on time can lead to administrative actions. Effective 10/01/23, SIRS reporting is no longer required for IDeA grantees (see NOT-GM-23-046). **NIGMS has provided some suggested tables to use as a template for reporting progress. If using suggested tables for reporting, upload each as a separate attachment in Question G.1. Special Reporting Requirements of the Overall Component**.

LA CaTS Tracking & Evaluation Notes:

- We have combined, below, both NIH's overall RPPR instructions with NIGMS guidance on reporting specifically for CTRs. This document should be updated annually and/or as directions are provided from the NIH and/or NIGMS.
- Table numbers will be updated in each relevant section of the report.
- This guide is intended to be a reference for our LA CaTS Center Cores to leverage throughout the year.

Reporting Timeline leading to annual report:

- Quarter 1: 7/1 – 9/30
  - Quarterly Report due approximately 2 weeks after 9/30
- Quarter 2: 10/1 – 12/31
  - Quarterly Report due approximately 2 weeks after 12/31
- **Quarter 3: 1/1 – 3/31**
  - **Quarterly Report due 4/1; used for annual reporting**
  - **Draft narrative report due to Executive Committee approximately 1 week after 4/1**
  - **Draft budget, All Personnel, Publications, and other administrative information due to PBRC Office of Sponsored Projects approximately 2 weeks after 4/1**
  - **NIH Annual Report due 5/1**
- Quarter 4: 4/1 – 6/30
  - Quarterly Report due approximately 2 weeks after 6/30

Helpful Links:

- 2021 RFA we were awarded under: PAR-20-175
- NIH and Other PHS Agency Research Performance Progress Report (RPPR) Instructional Guide, June 23, 2022
- For questions: tracking@lacats.org; Director of Tracking & Evaluation: brian.melancon@pbrc.edu

Required Reporting with Instructions, Notes, and Required Tables

Individual Components– General Information: *Components should auto-populate.* Verify/edit the component title and type, subproject number, and last name of the lead individual for the component. In the rare event that a component does not exist, you will need to create one, **but do not create separate components for the projects supported by the Pilot or HR Cores (PPs, DPs, MCPs) – these do not get reported as individual components.** To create new Cores, use the format and examples below:

- Component name ####-LeadLastName
- "Genomics Core 5678-Jones"

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).

B.2 What was accomplished under these goals?

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 this section should shift from reporting activities to reporting accomplishments.
(Note: If citing references in this section, please provide a full citation in MLA format. List all products from this reporting period in section C.)

Overall Component: Question B.2. of the Overall Component should provide an overview of the progress and activities of the CTR. It should include accomplishments of the CTR as a whole, its participants, and details on the completion of the proposed Specific Aims. It is especially important to outline how the CTR is fulfilling the goals of the program (U54, P50, P20), including funding accomplishments from CTR participants.

- Describe the outcomes of CTR-supported investigators and the growth/development at participating organizations. You may use the **suggested Table 1** and upload as an attachment under **Question G.1. Special Reporting Requirements**.
- Describe any educational or outreach activities conducted during the reporting period. You may use the **suggested Table 2** and upload as an attachment under **Question G.1. Special Reporting Requirements**.
- If a *Plan for Enhancing Diverse Perspectives (PEDP)* was included in the original application (CTR-N, CTR-D), describe the progress made in accomplishing the goals, timelines, and milestones outlined in the PEDP.

Administrative Core: Grantees must report on the administrative activities of the CTR. The Administrative Core Narrative (**Question B.2**) should detail the progress in accomplishing the proposed Specific Aims of the CTR, including the scientific and career development goals of the project leaders, the research resources made available to CTR investigators, any outreach activities (e.g., symposia, workshops, and retreats), and an overall evaluation with plans for improvement in subsequent years. This section may also include outcomes for SPs if additional space is needed, or for SPs that ended in a prior year.

Other Cores: Each Core must be reported as an individual component. The core Narrative (**Question B.2**) is expected to contain core-specific information and must not duplicate reporting included in other components. It should include a description of the annual userbase, methods employed to grow the numbers of users, any fee structures in place, support from other entities (e.g., other IDeA programs, other grants or organizational support, expansions/reductions in services offered, and personnel changes, if any). For each Core except the Administrative Core, you may use the suggested Core Table template (Table 3) to report the number of users, services provided, and whether core use contributed to a grant submission or publication. Number the tables sequentially and indicate the name of the Core. PIs should encourage core users to cite the grant number in their publications and report those under **Question C.1 Publications** in the **Overall component.**

Suggested Table 3: Core Use. Complete this table for each Core except the **Admin Core**. The first Core listed will be Table 3, the next will be Table 4, etc. Enter the data indicated for each Project that made use of Core services. Provide the type of user, the name of the project, the technology/instrumentation/services/consultations provided, the number of individual users per project, and indicate whether core use contributed to a grant application or publication listed in Overall Question C.1; an example for the last column is 2G, 4P. Note that all HHS grantees must cite any grants funded with HHS money that supported their work upon publication or presentation.

Core Table X. Investigators Assisted by LA CaTS Center Cores during the current reporting period				
Core User; Institution	**Project Name**	**Technology, instrumentation, services, or consultations provided**	**# of individual users per project**	**# that contributed to grant applications (G) or publications (P) listed in Overall C.1.**
Total User Labs		***Total Users***		

Core-Specific Guidance for Core Question B.2 Narrative.

BERD (U54)/RDCD (P50 and P20) Core: Describe the BERD/RDCD activities for the year being reported. Describe progress on managing the Electronic Health Records (EHRs) and other large clinical datasets. In addition, describe the number of research protocols that received IRB approval through this Core and the number of investigators assisted by biostatisticians for dataset curation/integration. The numbers of database queries, research validation, and bias prevention using methodological methods as well as the outcome of these services (e.g., publications, new funding, etc.) should be listed in a Table (see suggested Table 3 template). Describe details of any workshops that provided guidance on human subjects and clinical trials, including risk assessment, safety, intervention models, and federal regulatory reporting requirements; you may list each in a Summary Table of the Overall Component (see suggested Table 2).

Community Engagement and Outreach (CEO) Core: Provide details of outreach activities conducted during the reporting period, including symposia, seminars, workshops, webinars, conferences, and retreats. You should also list each in a Summary Table of the Overall Component (see suggested Table 2). Also describe activities to establish/enhance community advisory boards, identify health issues and concerns of communities and populations within the CTR's region, and how the core promotes bi-directional engagement between researchers and community groups. Describe the numbers of community clinics affiliated with the CTR along with activities to engage their clinical staff and patients.

Professional Development (PD) Core: Provide details of research topics, seminar series, grant-writing workshops, skills training and mentoring guidance meetings and describe whether any community clinic (PBRN) staff or patient representatives participated. Describe trainings on federal and institutional policies for human subject research, vertebrate animals, and/or biohazards and how the Core interacts with the similar activities organized by the BERD/RDCD and other Cores. You may also list each activity in a Summary Table of the Overall Component (see suggested Table 2).

Pilot Projects Program (PPP) Core (U54)/Health Research (HR) Core (P50/P20): All research projects, including pilot projects (PP), developmental projects (DP) and multisite collaborative projects (MCP) that were supported during the reporting period should be described in this section. Do not create separate components for each project. A suggested format is to list each research pilot separately and include the following information for each, followed by a 1-3 paragraph summary of the project: Project Lead Name, Project Title, Project Start Date, Project End Date (or indicate Ongoing).

You may continue to report new outcomes even after funding has ended. Note that all publications resulting from CTR support must cite the grant and be reported in **Question C.1 Publications** in the **Overall** component. Progress reports of projects funded entirely with non-CTR funds (i.e., institutional funds) that did not require prior approval by NIGMS are not required but may be included. The RPPR cannot be used to request new PPs.

Optional Technology/Service Cores (U54, P50): Each Optional Core must be reported as an individual component. Include a description of services provided by the core and progress made according to the goal proposed in the funded application. You may also list each activity in a Summary Table of the Overall Component (see suggested Table 2).

B.3 Competitive Revisions/Administrative Supplements*

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

Competitive Revisions/Administrative Supplements for current reporting period/active revision(s)/supplement(s)			
Revision/Supplement #	**Revision/Supplement Title**	**Specific Aims**	**Accomplishments****
3U54GM104940-XXXX	From NOA or Distinct Title	XXXX character limit	XXXX character limit

** If additional space is required, or if outcomes are achieved after the supplement award has expired, you may use the Narrative under Question B.2. Publications and other products resulting from the supplemental funding must be reported in Question C.1.

B.4 What Opportunities for Training and Professional Development has the project provided?

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

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. Training activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include (but are not limited to) 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., 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. This information is not required for AHRQ recipients.

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. Follow the instructions found in the Supplemental Instructions for Training, Education, and Career RPPRs. Do not reiterate what is reported under Accomplishments. Limit the response to this reporting period.

Direction from NIH on 4/29/24 (Erin Iturriaga): Per the RPPR instructions, Section B.4 requires specific content for trainees (students/postdocs/fellows), so it is different from suggested Table 2. Table 2* is intended to capture CTR activities from all Cores in a single Table. If you have been using Section B.4 of the Overall Component to report this (and not reporting it in individual cores), you may continue to do so (as B.4 is a descriptive narrative that can also include tables and figures), but we strongly urge you to upload Table 2 as well.
* *Table 2. Educational and Outreach Activities Listed below*

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 undertaken to reach members of communities who are not usually aware of these research activities with 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 recipient 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.

B.6 What do you plan to do during 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.

Discuss efforts to ensure that the approach is scientifically rigorous and results are robust and unbiased.

Remember that significant changes in objectives and scope require prior approval of the agency (i.e., 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.

C.1 Publications: *Are there publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, monograph, preprint) during the reporting period resulting directly from the award?*

What to Report

Recipients must report publications in section C.1 if: (1) the publication was accepted for publication or made public during the initial reporting period and the period since the last progress report was submitted and (2) the publication directly arises from the award (e.g., the award supported trainees or 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 can include preprints, which are complete and public draft of a scientific document. Preprints are typically un-reviewed versions of peer-reviewed journal articles. Publications that are not peer-reviewed are not covered by the NIH Public Access Policy. See FAQs for more information. To claim an interim research product as a product of an NIH award, the NIH expects that the awardee has:

- Made the product publicly available. To maximize the impact of an interim research product, the NIH strongly encourages awardees to select a Creative Commons Attribution (CC-BY) license or dedicate their work to the public domain.
- In the text of the document:
    - Acknowledged NIH funding in accordance with NIH Grants Policy Statement Chapter 8.2.1

- Clearly stated that the work is not peer-reviewed
- Declared any competing interests, as an author would do for any journal article

Publications that fall under the NIH Public Access Policy and are non-compliant must be reported. NIH awardees are responsible for public access compliance of all the publications listed in section C1. Generally, it takes weeks to bring non-compliant publications into compliance; 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.

When an award's only contribution to a publication is non-personnel resources (e.g., materials, equipment, data), applicants should not list the paper in section C. The awardee is neither responsible for providing a full listing of these publications, nor for ensuring compliance of these publications with the public access policy. Awardees submitting an RPPR may list these papers in Section B.2 which requests a description of accomplishments, including other achievements. These publications will not count against the section B.2's two-page limit and will not be tracked as a product of this award.

How to Report

If there are publications to report, select **Yes** and ensure that the **Associate with this RPPR** box is checked when appropriate. If there are no publications to report, select No. The tables draw information from the PD/PI's My NCBI account.

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.

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

The first table, **All Publications Associated with this Project in My NCBI**, lists all publications that are (1) in the PD/PI's My Bibliography collection, (2) are associated with this award, and (3) 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 does the following: (1) associates the publication with this progress report, (2) results in the publication being displayed in RePORT, and (3) makes the award-publication association in My NCBI permanent and the association will be reported in PubMed. Unchecking the box does the following: (1) disassociates the publication with this progress report, and (2) 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.

AHRQ recipients should refer to NOT-HS-16-008 (https://grants.nih.gov/grants/guide/notice-files/noths-16-008.html) for AHRQ's Policy for Public Access to AHRQ-Funded Scientific Publications.

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

The second table, Publications not associated with this project in My NCBI, lists all other publications that are listed in the PD/PI's My Bibliography collection with no association to 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.

Table 3: Publications Previously Reported for this Project

The final table, **Publications previously reported for this project**, only lists publications reported in a previous electronic progress report for this award. Recipients are responsible for ensuring that these publications comply with the Public Access policy even if they were provisionally compliant (listed as in Process) when previously reported.

Submitting an RPPR with Noncompliant Publications

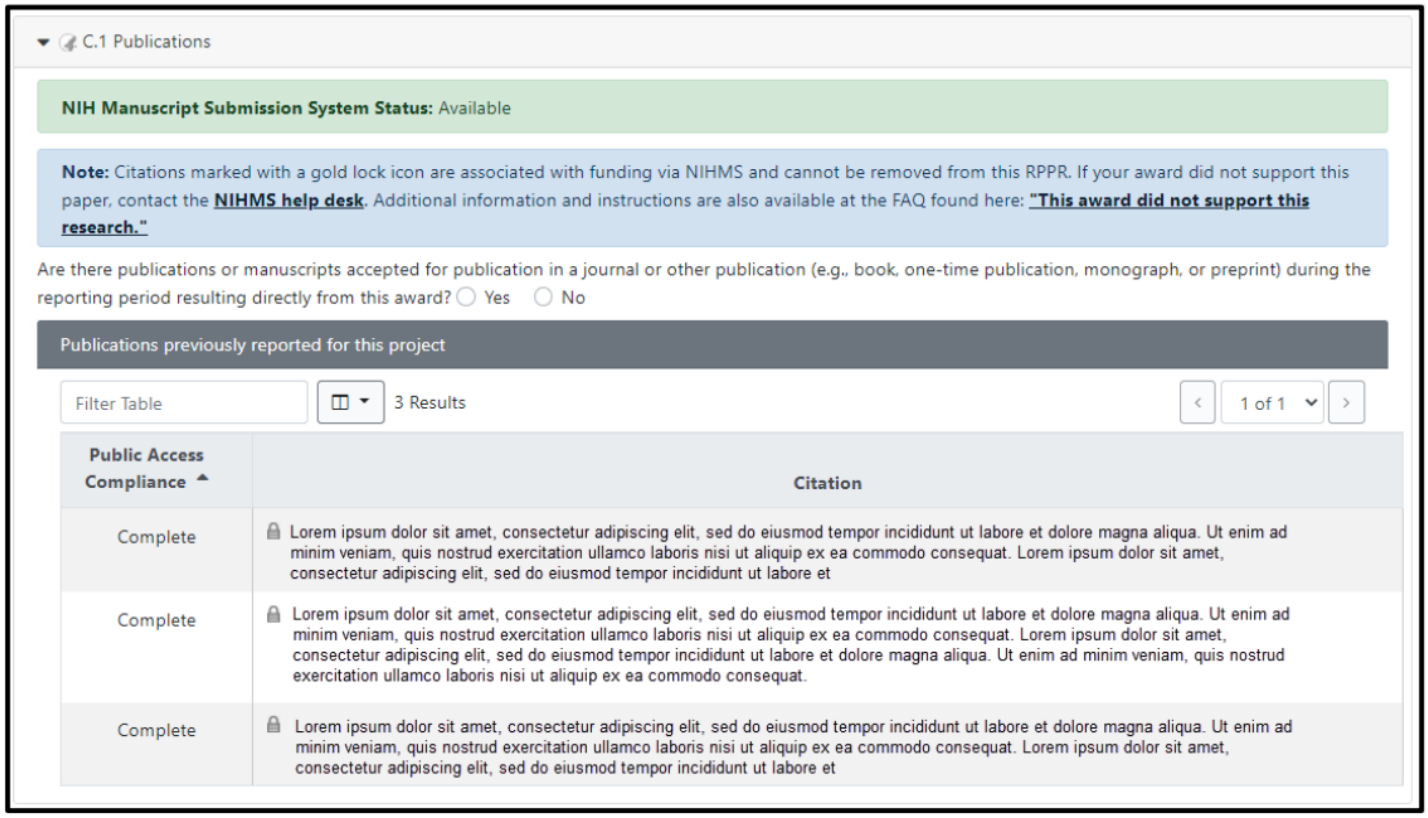


Figure 102 RPPR Section C. Products – Question C1

Publications that fall under the NIH Public Access Policy and are non-compliant still must be reported. When non-compliant papers are reported, the system will generate an automated email to the PD/PI (with cc to the AO and SO) requesting that the recipient provide evidence of compliance or an explanation by a specified due date two weeks prior to the next budget start date.

Responding to Non-compliance Notifications

To bring a publication into compliance, please follow the submission instruction wizard at http://publicaccess.nih.gov/determine-applicability.htm. NIH cannot accept anything other than compliance with the policy except in the rarest of circumstances, such as a death of the sole author.

The recipient must respond to this non-compliance notification 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 simplest way to provide evidence of compliance is to generate a My NCBI PDF report (https://www.ncbi.nlm.nih.gov/books/NBK53595/#mybibliography.Creating_an_Award_Complia) of the formerly non- compliant publications. The PRAM link provides a text box in which the recipient may respond through the eRA Commons and link to attach the My NCBI PDF report. The recipient will be able to view the PRAM in the grant folder. See the topic in this document titled Public Access Progress Report Additional Materials (PRAM) for more information.

My NCBI Management
PD/PIs can log in to their My NCBI account. 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 made 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 http://publicaccess.nih.gov/communications.htm, and My NCBI Help.

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.

A description is only required for awards designed to create or maintain one or more websites. Limit the response to this reporting period. If the website disseminates a product that falls into one or more of the other product categories, please click the Add Web/Internet Site button and select the appropriate category(ies) in the popup that appears (select multiple categories, if appropriate, by holding down the Ctrl button while selecting the categories). 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. If the website disseminates a product that falls into one or more of the other product categories, please click the **Add Web/Internet Site** button and select the appropriate category(ies) in the popup that appears (select multiple categories, if appropriate, by holding down the Ctrl button while selecting the categories). For awards not designed to create or maintain one or more websites, select **Nothing to Report**.

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.

PD/PIs are required to report all technologies or techniques that arise from their NIH award in this section. If there are technologies or techniques to report, select **Yes** and enter a short description. If the technology or technique falls into one or more of the product categories, please click the **New Technology/Technique** button and select the appropriate category(ies) in the popup that appears (select multiple categories, if appropriate, by holding down the **Ctrl** button while selecting the categories). If there are no technologies or techniques to report, select **Nothing to Report**. Limit the response to this reporting period.

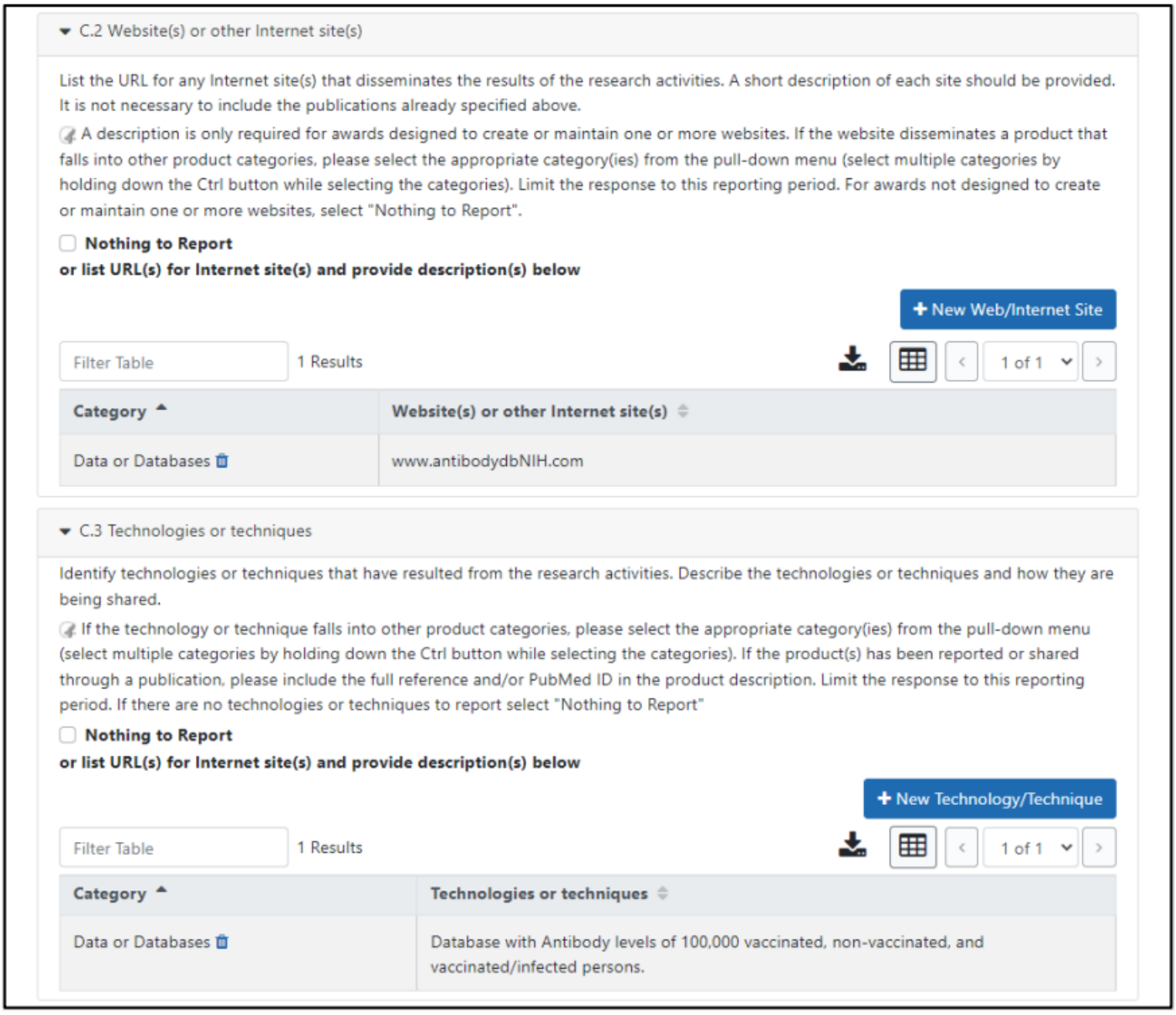


Figure 103 RPPR Section C. Products – Questions C2 & C3

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

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

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

Reporting of inventions through iEdison is mandatory.

C.5 Other products and resource sharing.

If Products cannot be filed in sections C.1-C.4, please utilize this section.

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 person months, rounded to the nearest one-tenth (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 information
- A Commons ID is required for all individuals with a postdoctoral, graduate or undergraduate role (NOT-OD-13-097). The Commons ID is also required for individuals supported by a Reentry or Diversity Supplement. For all other project personnel with an established Commons ID, it should be provided; the Commons ID is strongly encouraged but currently optional**. AHRQ** recipients should refer to NOT-OD-21-109 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-109.html) for information regarding what Personnel are required to have a Commons ID.
- 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: Search for Commons User Accounts.

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.

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 (per NIH instructions provided via email by Erin Iturriaga on 4/9/24):

- PD/PI
- Trainee --specify as Postdoctoral (includes clinical fellows), Graduate Student (includes those enrolled in MD and other health professional programs), Undergraduate Student, High School Student
- Consultant (includes EAC, IAC, SC and EC members if effort ≥ 1 month)
- Other --do not specify; this category includes research staff, post bacs, statisticians, IT support, and all consultants (includes EAC, SC, EC members)
    - For all other roles, use only the following designations:
    - Other – Program Coordinator
    - Other - Core Lead
    - Other - Mentor
    - Other - Project Leader (indicate as PP, SP, DP, or MCP Leader)
    - Other – Admin Staff
    - Other – Research/Core Staff

Do not create categories other than those listed above. As a reminder, a Commons ID is required for all individuals with a postdoctoral, graduate, or undergraduate role (per NOT-OD-13-097). While not required, other project personnel are encouraged to have their own Commons ID.

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 recipient 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 and pending other support for all new senior/key personnel. Combine all biosketches and other support into a single PDF

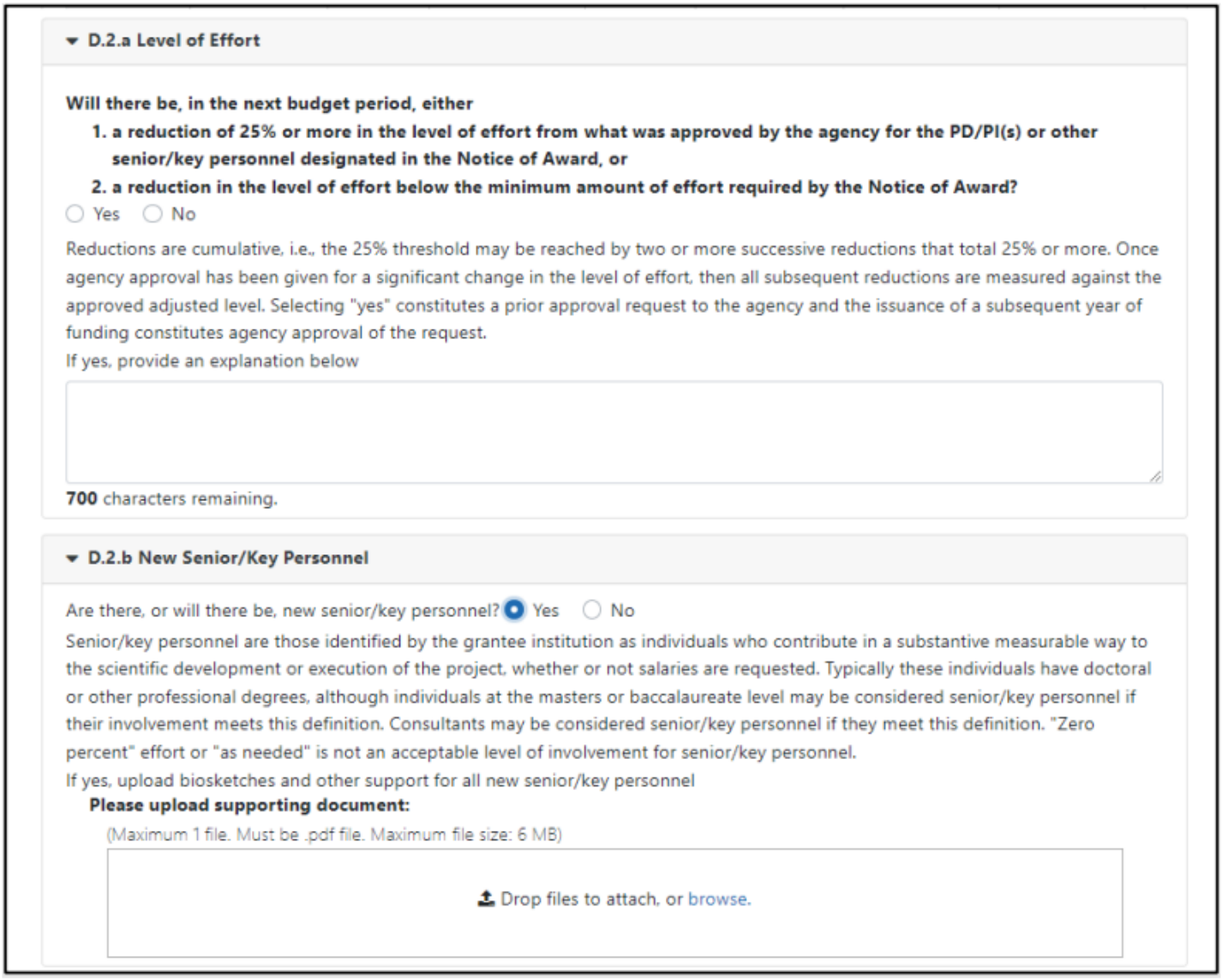


Figure 106 RPPR Section D. Participants – Questions D2a & D2b

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?

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

If yes, upload updated active and pending support for senior/key personnel whose support has changed. List the award for which the progress report is being submitted and include the effort that will be devoted in the next reporting period.

Submit complete Other Support information using the suggested format and instructions found at https://grants.nih.gov/grants/forms/othersupport.htm.

Other support information should be submitted only for the PD/PI and for those individuals considered by the recipient 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 be 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 its impact (if any) 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.

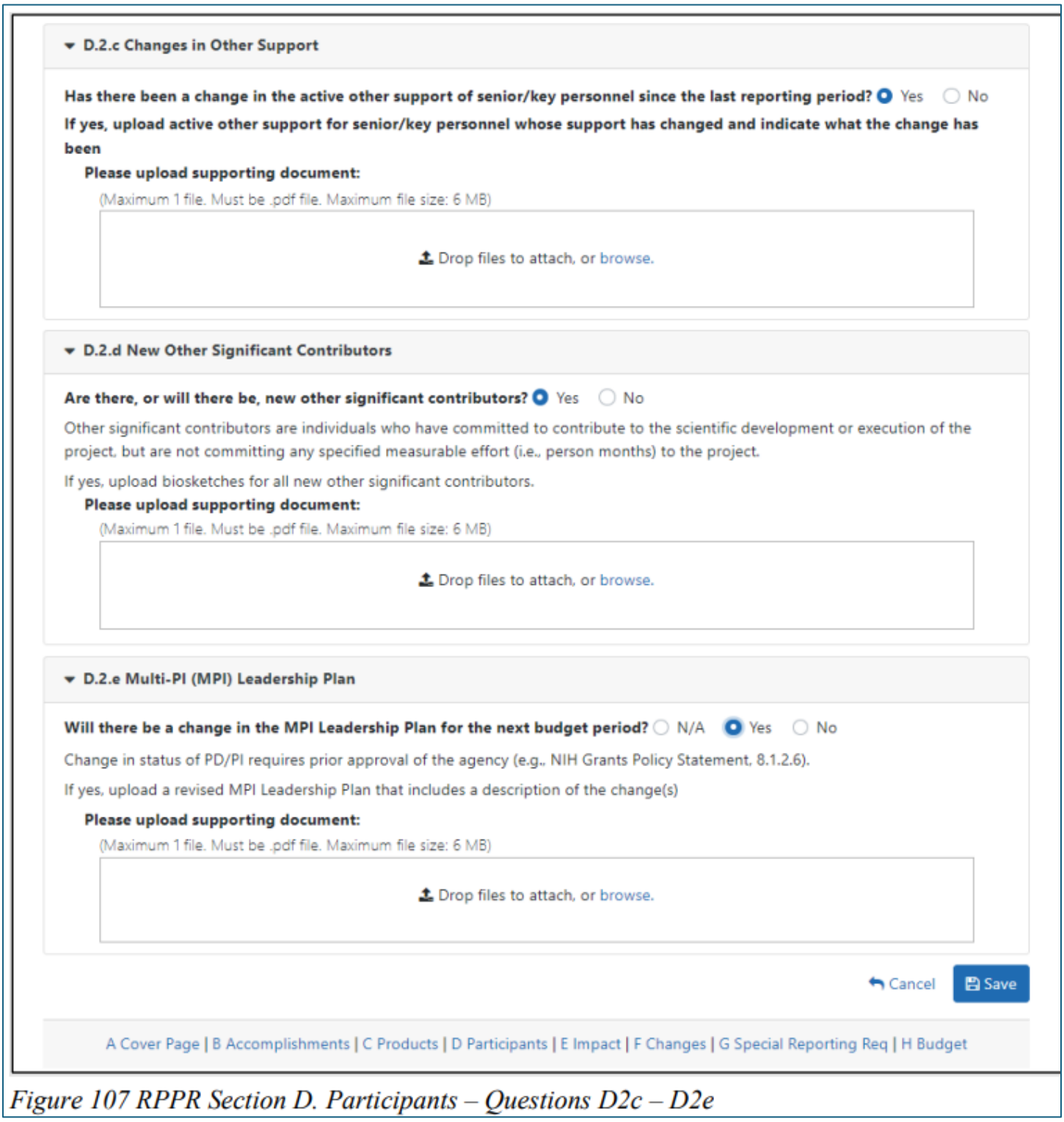


Figure 107 RPPR Section D. Participants – Questions D2c – D2e

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, such as 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.**

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.

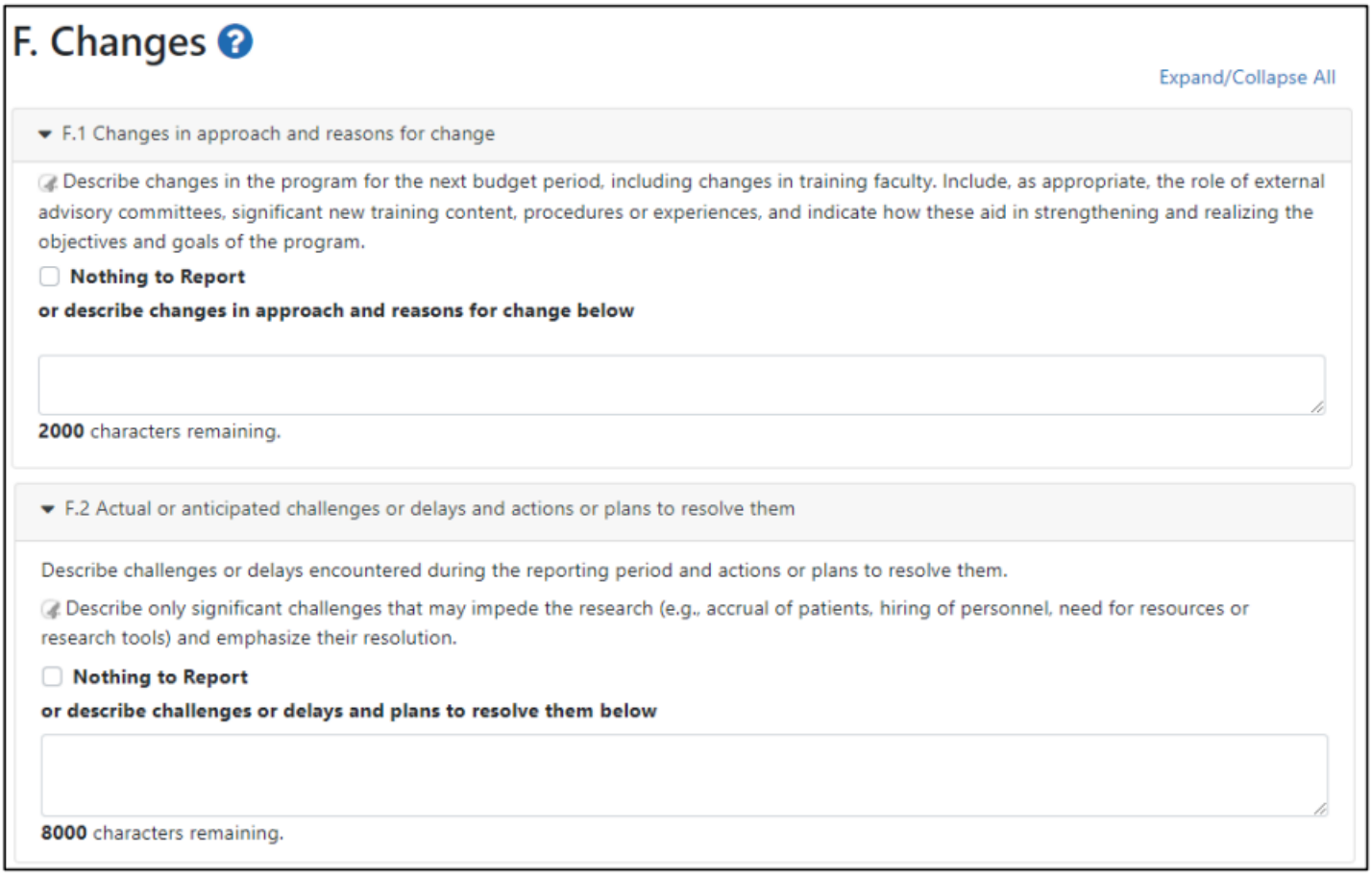


Figure 109 RPPR Section F. Changes – Questions F1 & F2

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

Describe significant deviations, unexpected outcomes, or changes in approved protocols for human subjects, vertebrate animals, biohazards and/or select agents during this reporting period. Remember that significant changes in objectives and scope 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 studies are or will be different from the previous submission, include a description and explanation of how the studies differ and provide new or revised Protection of Human Subjects Section and Inclusion of Women, Minorities, and Children sections as described in the competing application instructions. Additional or modified inclusion enrollment reports may also be necessary and should be provided by clicking the Human Subjects link in Section. G.4 of the RPPR to make necessary updates in the Human Subjects System (HSS).

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.

U.S. Select Agent Registry information: https://www.selectagents.gov/

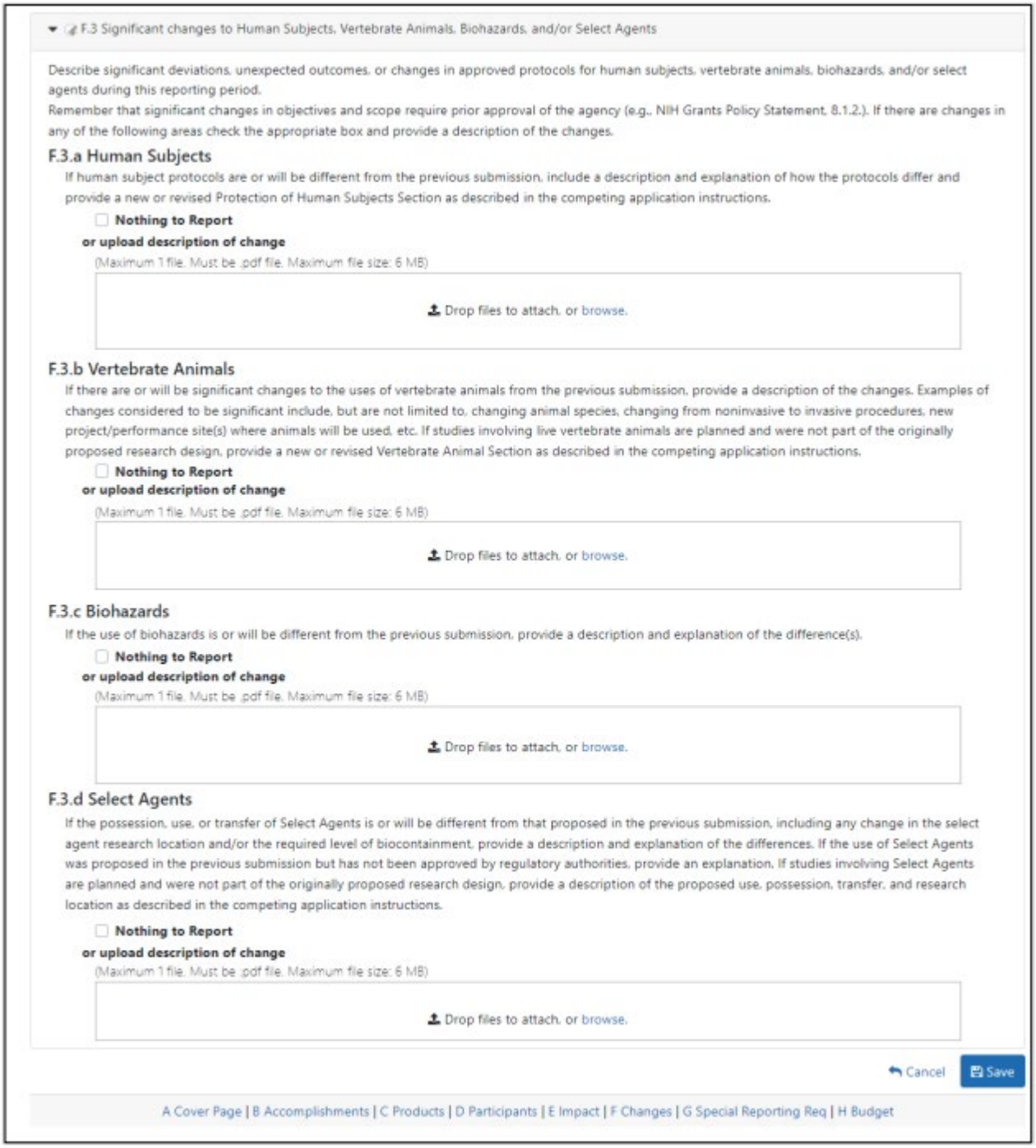


Figure 110 RPPR Section F Changes- Question F3

G.1 Special Notice of Award Terms and Funding Opportunities Announcement Reporting Requirements (reported in the Overall Section)

Per NIH instructions via email by Erin Iturriaga on 4/9/24:

The following attachments corresponding to the **Overall Component** of the grant should be uploaded onto this section:

- **External Advisory Committee** (EAC): Submit the EAC evaluation as an attachment here. The report must clearly indicate the name, title, and institution of each active EAC member. The attachment should include an overview of the progress and strengths of the CTR and areas for improvement as well as approval for any proposed changes to the CTR organizational structure (including cores and core directors).

- **CTR Funding Accomplishments:** Grantees should report details on grant applications and funding received by CTR-supported investigators. You may use suggested Table 1 below as a template.

  Suggested Table 1: CTR Funding Accomplishments. Grantees should report details on grant applications that were submitted by and awarded to CTR participants during the current budget period. If an application is submitted and funded in the same budget period, report it only once under # New/Renewal Awards Funded.

  Table 1A: Enter the number of grant applications that were submitted in the current budget period, the number that were funded, and the dollar amount (total costs) of the applications.

Table 1A: CTR Funding Accomplishments in Current Budget Period				
Report only for the current project period	**NIH**	**Federal, non-NIH**	**Non-Federal Sources**	**Total for Budget Period**
# Applications Submitted/Pending	28	4	16	48
# New/Renewal Awards Funded	19	8	29	56
Total Award Costs (entire period of performance)	$25,132,475	$15,333,540	$7,931,041	$48,397,056

Table 1B: Enter the number of grant applications that were submitted and/or awarded by the following program participants: Pilot Project Leaders (PPLs), Supplement Project Leaders (SPLs), Developmental Project Leaders (DPLs, CTR-N/CTR-D only), Multisite Collaborative Project Leads (MCPLs, CTR-N only), Core staff (include the PD/PI in this tally), and other staff associated with the CTR. **Only include Project Leads who have been supported during the grant's current 5-year period of performance.**

Table 1B: CTR Funding Accomplishments in Current Budget Period by Role						
Breakdown of Table 1A by Role	**PPLs**	**SPLs**	**DPLs**	**MCPLs**	**Core Staff including PD/PI**	**Others**
# Applications Submitted/ Pending	0	0	3	0	26	19
# New/Renewal Awards Funded	6	1	0	0	21	28
Total Award Costs (entire period of performance)	$2,387,329	$1,842,658	$ -	$ -	$ 20,815,902	$ 23,351,167

- **CTR Educational and Outreach Activities:** Summarize CTR-related educational or outreach activities led by CTR cores and personnel from participating CTR organizations. You may use the suggested Table 3 (Labeled Table 2 Below) for reporting on these activities, which are managed by the Administrative Core. Details should be provided in the Narrative (Section B.2) of the most appropriate Core.

Suggested Table 2: Education and Outreach Activities: Include any education or outreach activities conducted during the current reporting period. Indicate the type of activity such as course-based research experiences, symposia, seminars, workshops, webinars, conferences, and retreats. List the core and/or institution that led/offered the activity, the delivery method (I=In-person, V=Virtual, or H=Hybrid), and the # of participants by role (Trainees includes clinician fellows, postdocs and students).

Table 2. Educational and Outreach Activities				
Activity Type	Activity provider (Core or Institution)	Delivery Method (I, V, H)	# of Faculty/Staff Participants	# of Trainee Participants

Information that reported in the Overall LA CaTS Center B.2 Overall Accomplishments Section of the report

Overall Table 1: LA CaTS Center Core Collaborations during the 7/1/23-3/31/24 reporting period					
Core Reporting Collaboration	What LA CaTS Center Core or Core Personnel did you collaborate with?	If applicable, please provide the Name(s) of the collaborating organization(s) that are NOT LA CaTS Center Cores	Type of collaboration	Briefly describe the collaboration.	Summary of next steps, outputs or outcomes from the collaboration
Abbreviations: Admin Core – Administrative Core; BERD Core – Biostatistics, Epidemiology & Research Design Core; CE Core – Cyberinfrastructure Core; CEO – Community Engagement and Outreach Core; CRR Core – Clinician Research Resources Core; ERKC – Ethics and Regulatory Knowledge Core; HL Core – Health Literacy Core; LSUH-NO – LSU Health New Orleans; LSUH-S – LSU Health Shreveport; PD Core – Professional Development Core; PGP Core – Pilot Grants Program Core; T&E Core – Tracking and Evaluation Core					

Overall Table 2: LA CaTS Center Personnel Participation on Peer Review Panels during the 7/1/23-3/31/24 project period						
Core	Core Personnel Name	Internal or External to LA CaTS?	Review Panel Name	Name of the University, Agency, or Organization that organized this panel.	Core Personnel's Role on this Panel?	Date of Panel

Overall Table 3: LA CaTS Center Personnel Committee Service during the 7/1/23-3/31/24 project period						
Core	Core Personnel Name	Internal or External to LA CaTS?	Committee Name	Name of the University, Agency, or Organization that organized this committee.	Core Personnel's Role on this Committee?	Date of Committee
Abbreviations: Admin Core – Administrative Core; BERD – Biostatistics, Epidemiology & Research Design Core; CRR Clinician Research Resources Core; LSUH-NO – LSU Health Sciences Center New Orleans						

Overall Table 4: Publications not linked to RPPR with a publication date during this reporting period				
Pub Type	Was LA CaTS Cited?	PMID (if avail)	Publication Title	Publication Date

Overall Table 5: LA CaTS Center Presentations during the 7/1/23-3/31/24 project period

Core	Author (s)	Presentation Title	Pres Type	Event	Type of Attendance	Oral or Poster	Location	Presentation Date
Abbreviations: Admin Core – Administrative Core; HL Core – Health Literacy Core; PD Core – Professional Development Core								

G.4 Human Subjects

NIH applicants only:

In RPPR, for question G.4, click the **Human Subjects** link:

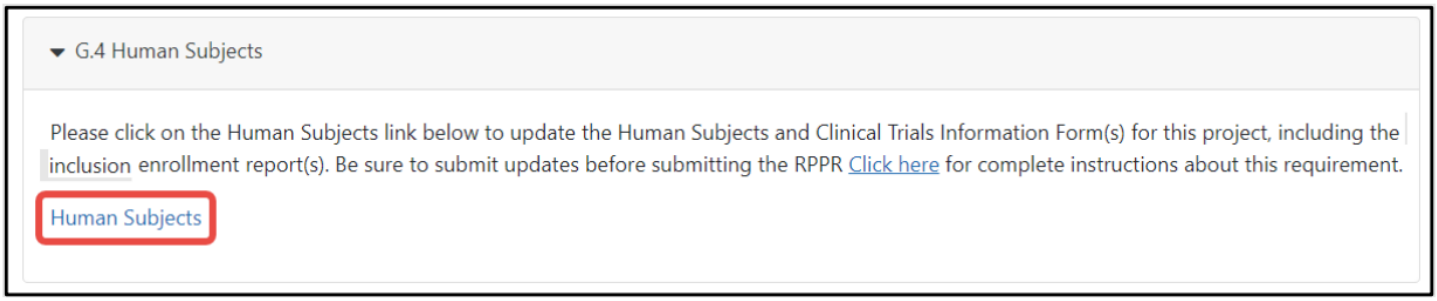


Figure 112 Human Subjects Link

Clicking the **Human Subjects** link opens up the Human Subjects System (HSS), shown below:

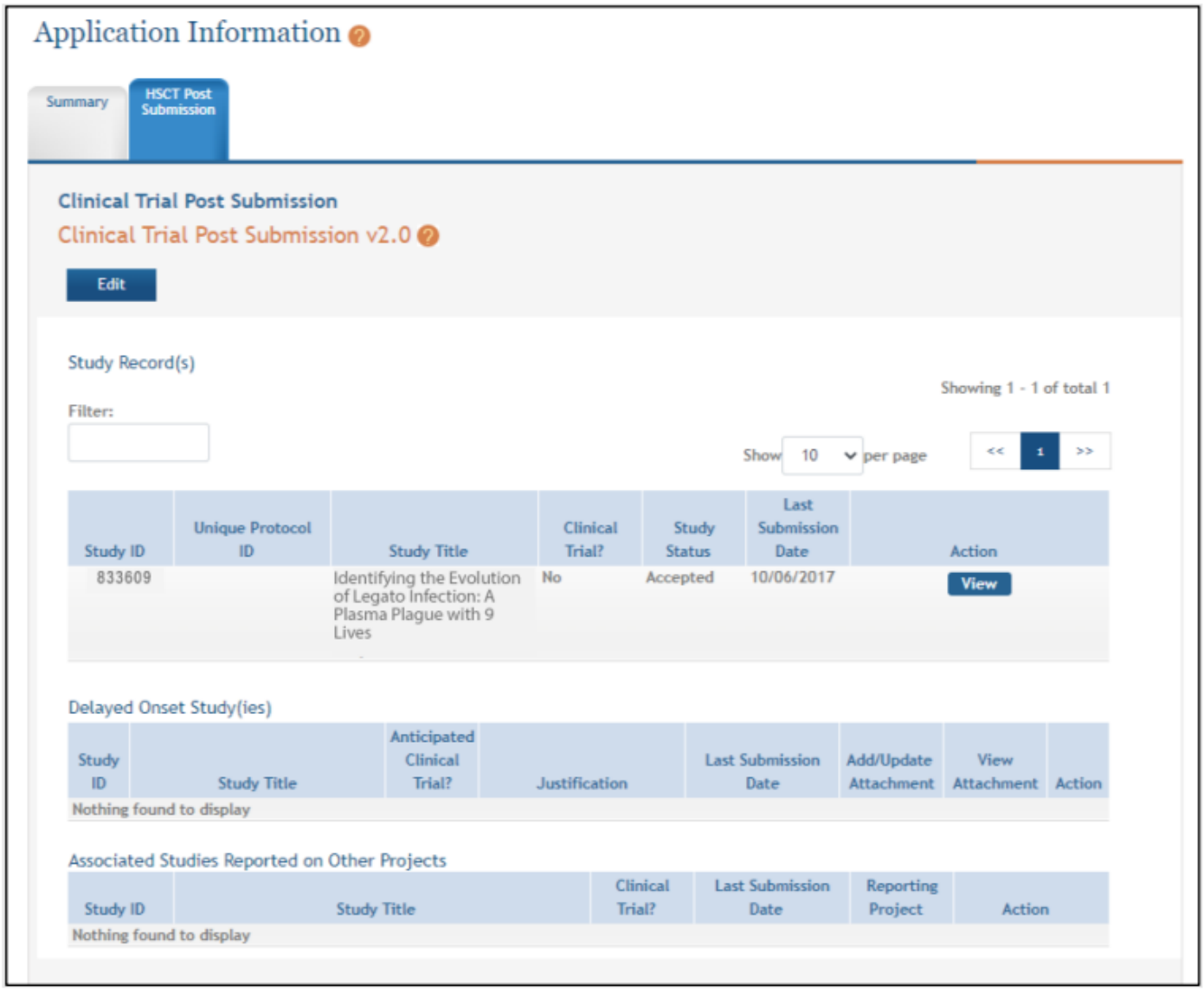


Figure 113 HSCT Post Submission tab in ASSIST (for Human Subjects)

If conducting NIH-defined clinical research, reporting the cumulative enrollment of subjects and the distribution by sex/gender, race, and ethnicity is required, as defined in the competing application instructions. If there are details or concerns related to inclusion enrollment progress, or if the cumulative enrollment data does not reflect the planned enrollment by sex/gender, race, and/or ethnicity, the reasons for this should be addressed in Section F.3.a of the RPPR.

Update the inclusion enrollment with the total cumulative enrollment data collected to-date on the inclusion enrollment report(s) for each study record. If the last competing application was submitted for due dates January 25, 2019 or later, recipients must update enrollment data by submitting deidentified individual-level participant data using the spreadsheet template available in the Human Subjects System (HSS). See the Inclusion Across the Lifespan policy page for more information. Recipients should follow instructions in the HSS online help to edit studies as appropriate.

Recipients can edit the inclusion enrollment record(s) in the Human Subjects System using the "How Do I Edit Studies?" instructions in the HSS Online Help.

Recipients may have more than one inclusion enrollment report. Each inclusion enrollment report must have a unique title. If new clinical studies have started and planned enrollment was not previously provided, create a new Planned Enrollment record in the Human Subjects System. Inclusion enrollment data updates must be submitted in the Human Subjects System prior to submitting the RPPR. Recipients will receive a warning if inclusion enrollment data are not updated prior to submitting the RPPR.

Guidance for Collecting and Reporting Inclusion Data: Below are instructions for how to collect and report data on the basis of sex/gender, race, age, and ethnicity with additional guidance for handling subpopulations, non-U.S. populations, changes to planned enrollment 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 the 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, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.
Black or African American: A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."
Native Hawaiian or Other Pacific Islander: A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
White: A person having origins in any of the original peoples of Europe, North Africa, or the Middle East.

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 (https://www.govinfo.gov/content/pkg/FR-1997-10-30/pdf/97-28653.pdf). **The NIH inclusion enrollment format is not designed for use as a data collection instrument**. Collect the data using instruments prepared for the study and use that information to complete the NIH inclusion enrollment form(s). Study participants who self-

identify with more than one of the racial categories should be reported in the aggregate in the "More Than One Race" category.

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 forms and/or in the text of their progress report.

Collecting and Reporting Data on Non-U.S. Populations: If conducting NIH-defined clinical research outside of the United States, design culturally appropriate data collection instruments that allow participants to self-identify their ethnic and/or racial affiliation in a way that is meaningful in the cultural and scientific contexts of the study. However, investigators will need to use the OMB-defined categories for reporting sex/gender, race and ethnicity to NIH (see definitions for each ethnic and racial category above), which will allow for completion of the inclusion enrollment form(s). Since OMB categories reference world-based geographic origin, this should facilitate completion of the form(s). **Enrollment of participants at non-U.S. sites should be reported to NIH on a separate inclusion enrollment form from that for reporting participants at U.S. sites, even if they are part of the same study**. For additional guidance and FAQs related to this topic, please refer to: http://grants.nih.gov/grants/funding/women_min/women_min.htm or contact the program officer.

Reporting Data on Age: Recipients who submitted the last competing application January 25, 2019, or later must include deidentified data on sex/gender, race, ethnicity and age at enrollment for each study participant. Age may be reported in units ranging from minutes to years. Data must be provided in .csv format using the template provided. See tip sheet and video for additional details.

Changes to Planned Enrollment: If there are changes from the planned enrollment originally approved for funding, contact the program officer to discuss updating/revising the planned enrollment, address the change in Section F.3.a of the RPPR, and revise the existing Planned Enrollment for that study by clicking the Human Subjects link to update the record in the Human Subjects System.

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 in Section F.3.a if any data analysis has begun for the trial. If analysis has begun or data have been published, report any progress made in evaluating potential differences on the basis on sex/gender, racial, and/or ethnicity.

Additional Instructions for Clinical Trials:
Studies involving clinical trials must provide the Clinicaltrials.gov identifier (NCT) in Section 1 of the PHS Human Subjects and Clinical Trials Information Form within 21 days of enrollment of the first participant. Recipients may use the 'populate' button to bring forward data from Clinicaltrials.gov once the NCT is entered. See the HSS Online Help for additional information about using this feature.

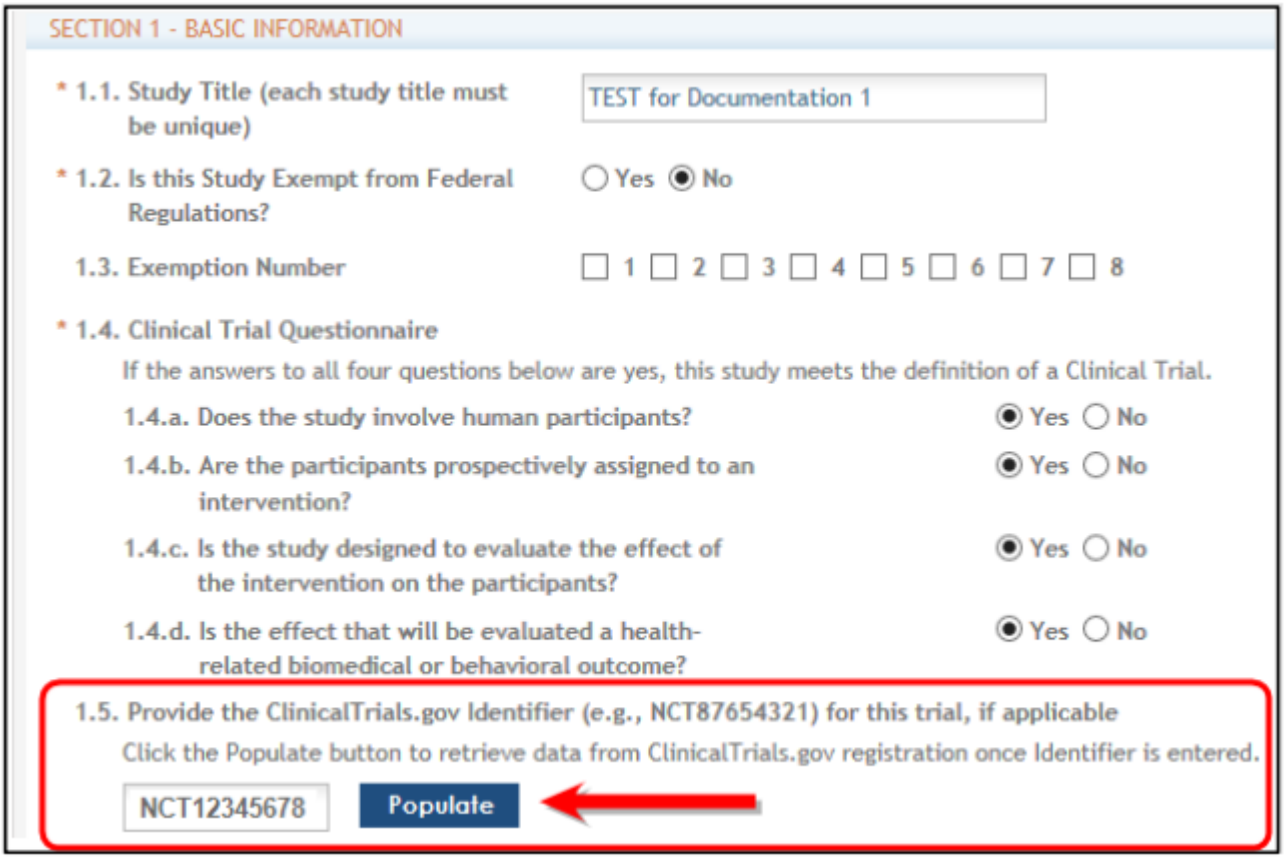


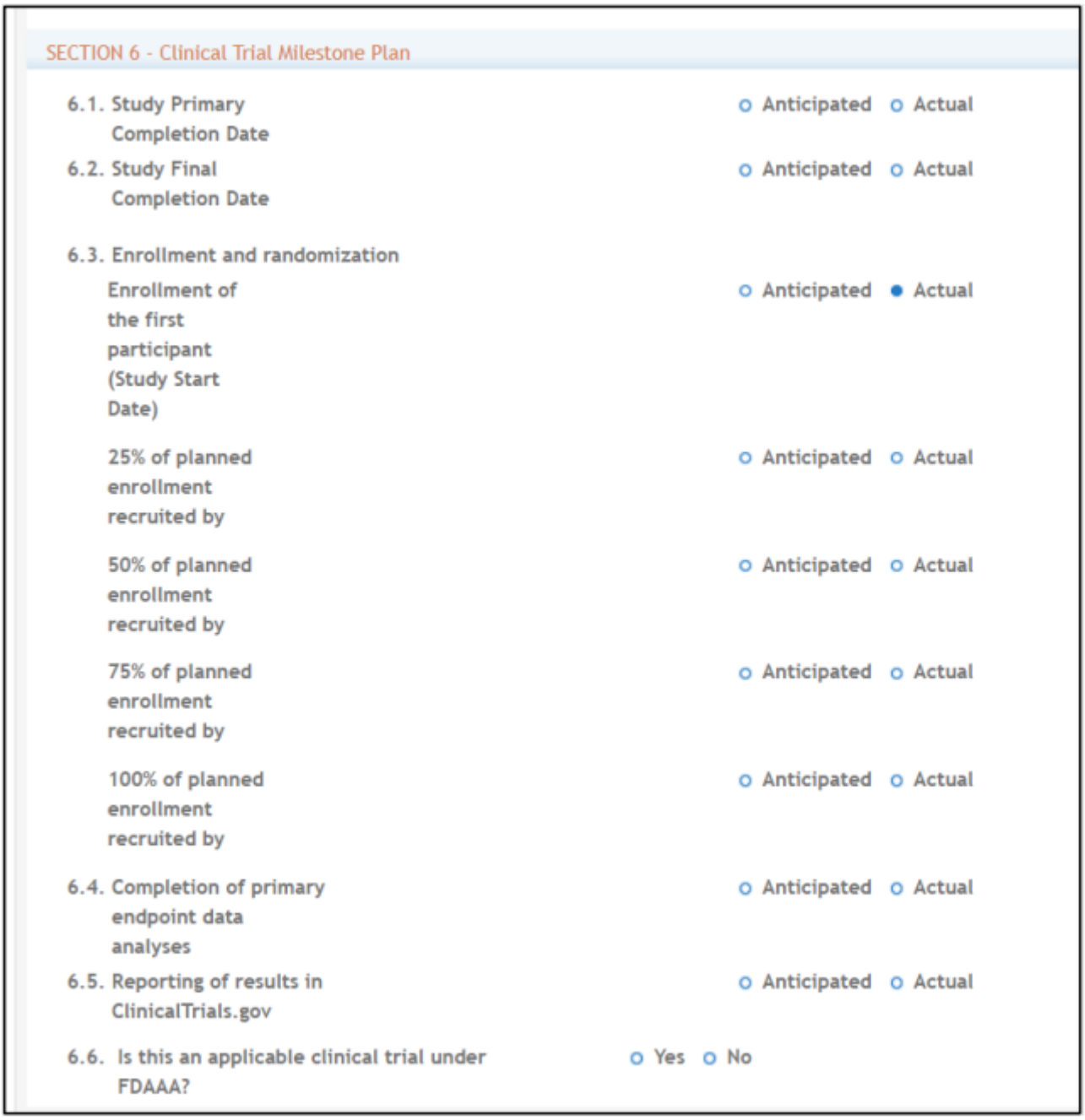
Figure 115 Section 1: Basic Information of HSCT Tab in ASSIST with Populate Button

See What NIH Recipients Need to Know About FDAAA & NIH Clinical Trial Policy, and FAQ When must an applicable clinical trial be registered? If the grant number was entered into ClinicalTrials.gov, the https://clinicaltrials.gov/ct2/home identifier (NCT number) may be readily identified by using the ClinicalTrials.gov Advanced Search and entering the grant number in the Study IDs field.

NOTE: Recipients will receive an error preventing submission of an RPPR if there are studies involving clinical trials associated with the RPPR where the registration is due under FDAAA and/or NIH Policy on Dissemination of NIH-Funded Clinical Trial Information (e.g., study is 21 days after enrollment of the first participant) and no NCT has been entered into the Human Subject Clinical Trial (HSCT) form. To address this error the recipient will need to either provide the NCT number issued by ClinicalTrials.gov or provide the registration receipt that is received upon submission of the trial registration to ClinicalTrials.gov.

To provide the ClinicalTrials.gov registration receipt, the recipient must upload the receipt to the other attachments section of the HSCT form (Section 5.1) as a PDF document. The file name must be CTgov_Registration_Receipt.pdf.

Recipients must complete Section 6 – Clinical Trial Milestone Plan (shown below) for all studies involving clinical trials. Note: All anticipated dates entered in Section 6 must be future dates. All actual dates must be the current date or a later date.



SECTION 6 - Clinical Trial Milestone Plan

6.1. Study Primary Completion Date	○ Anticipated	○ Actual
6.2. Study Final Completion Date	○ Anticipated	○ Actual
6.3. Enrollment and randomization		
Enrollment of the first participant (Study Start Date)	○ Anticipated	● Actual
25% of planned enrollment recruited by	○ Anticipated	○ Actual
50% of planned enrollment recruited by	○ Anticipated	○ Actual
75% of planned enrollment recruited by	○ Anticipated	○ Actual
100% of planned enrollment recruited by	○ Anticipated	○ Actual
6.4. Completion of primary endpoint data analyses	○ Anticipated	○ Actual
6.5. Reporting of results in ClinicalTrials.gov	○ Anticipated	○ Actual
6.6. Is this an applicable clinical trial under FDAAA?	○ Yes	○ No

Figure 116 Clinical Trial Milestone Plan, which is on the HSCT form in the Human Subjects System (HSS)

6.1 Study Primary Completion Date

Enter the date (MM/DD/YYYY) that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical study concluded according to the pre-specified protocol or was terminated. In the case of clinical studies with more than one primary outcome measure with different completion dates, this term refers to the date on which data collection is completed for all the primary outcomes. Select whether this date is anticipated or actual. **This date cannot be modified once set to actual.**

6.2 Study Final Completion Date

Enter the date (MM/DD/YYYY) the final participant was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events (for example, last

participant's last visit), whether the clinical study concluded according to the pre-specified protocol or was terminated. Select whether this date is anticipated or actual.

6.3 Enrollment and randomization
Enrollment of the first participant (Study Start Date): Enter the date (MM/DD/YYYY) of the enrollment of the first participant into the study. From the dropdown menu, select whether this date is anticipated or actual. **This date cannot be modified once set to actual.**

25% of planned enrollment recruited by: Enter the date (MM/DD/YYYY) by which 25% of participants were or will be enrolled. Select whether this date is anticipated or actual.

50% of planned enrollment recruited by: Enter the date (MM/DD/YYYY) by which 50% of participants were or will be enrolled. Select whether this date is anticipated or actual.

75% of planned enrollment recruited by: Enter the date (MM/DD/YYYY) by which 75% of participants were or will be enrolled. Select whether this date is anticipated or actual.

100% of planned enrollment recruited by: Enter the date (MM/DD/YYYY) by which 100% of participants were or will be enrolled. Select whether this date is anticipated or actual.

6.4 Completion of primary endpoint analyses
Enter the date (MM/DD/YYYY) by which the primary endpoint analysis was or will be completed. Select whether this date is anticipated or actual.

6.5 Reporting of results in Clinicaltrials.gov
Enter the date (MM/DD/YYYY) by which results were or will be submitted to Clinicaltrials.gov. Results may be submitted but not yet be posted because they are pending quality control (QC) review by the National Library of Medicine (NLM) or the sponsor or investigator is addressing QC review comments provided by NLM. Select whether this date is anticipated or actual.

6.6 Is this an applicable trial under FDAAA?
Indicate whether the trial is an applicable trial, subject to the registration and reporting requirements in Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (PL 110-85). See What NIH Recipients Need to Know About FDAAA & NIH Clinical Trial Policy.

Note: Clinical Trials Reporting Requirement: Recipients will receive an error preventing submission of an RPPR if there are studies involving clinical trials associated with the RPPR where results are due under FDAAA and/or NIH Policy on Dissemination of NIH-Funded Clinical Trial Information (e.g., study is one year after the primary completion date) and have not been submitted in ClinicalTrials.gov. To address this error the applicant will need to submit the results to ClinicalTrials.gov. This error can also be addressed by providing the submission receipt for a (1) Good Cause extension request or (2) Certification of Delayed Submission of Results Information from ClinicalTrials.gov.

To provide the ClinicalTrials.gov Good Cause Extension request submission receipt or Certification of Delayed Submission Results Information from ClinicalTrials.gov, the applicant will need to upload the receipt to other attachments section of the HSCT form (Section 5.1) as a PDF document. The file name must be CTgov_Extension_Receipt.pdf.

Per the 1993 NIH Revitalization Act, PL 103-43, enacted June 10, 1993, and the 21st Century Cures Act, PL 114-255, enacted December 13, 2016, NIH requires entities conducting NIH-defined Phase III Clinical Trials to include results of valid analyses by sex/gender, race, and ethnicity, in addition to submission in ClinicalTrials.gov.

Clicking the **Human Subjects** link opens up the Human Subjects System, shown below:

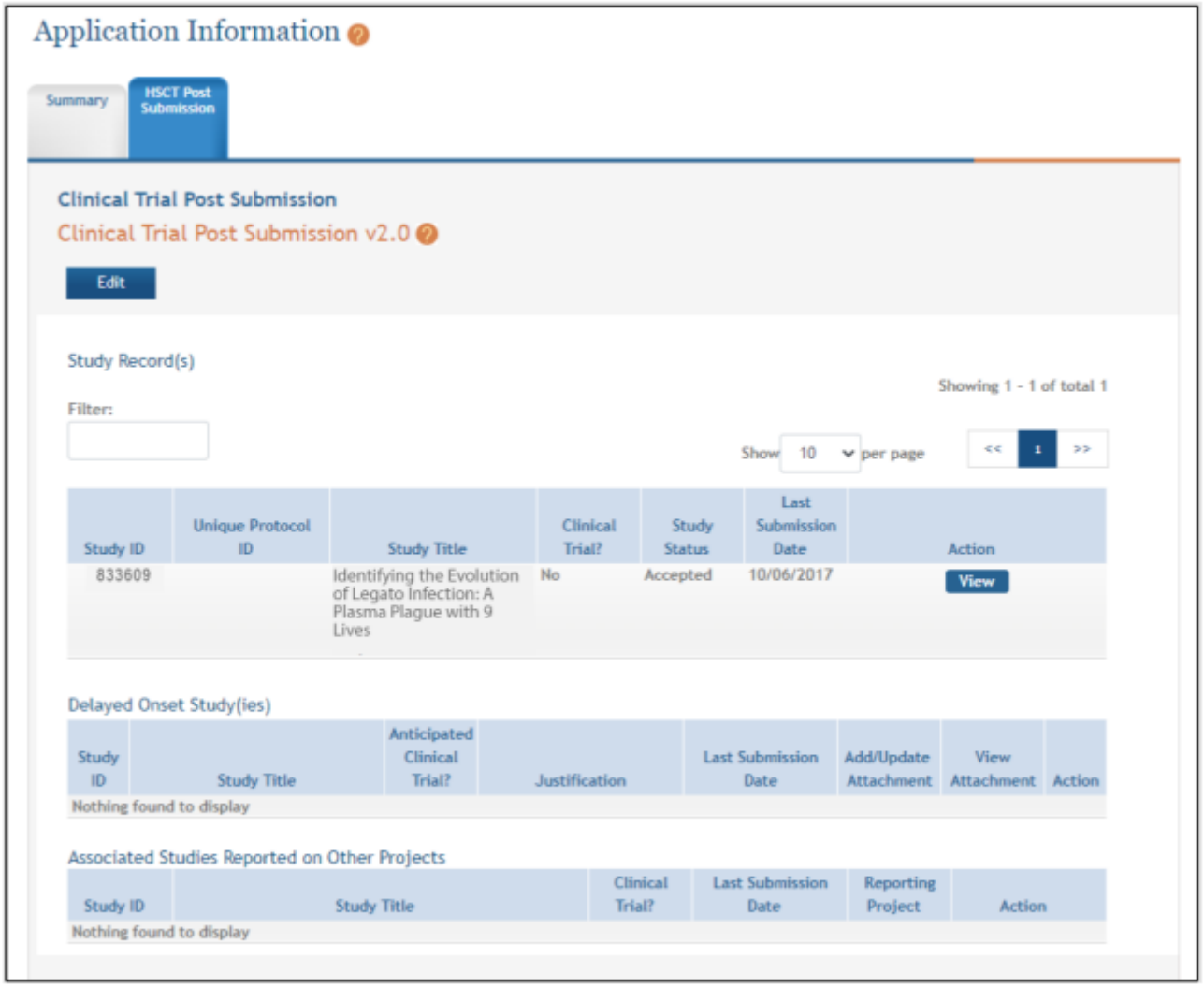


Figure 117 RPPR Section G. Special Reporting Requirements – Question G.4

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 may be used in NIH funded research.

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

Select the **Add hESC Number** button to add the data to the table.

If there is a change in the use of hESCs provide an explanation.

G.7 Vertebrate Animals

Does this project involve vertebrate animals?

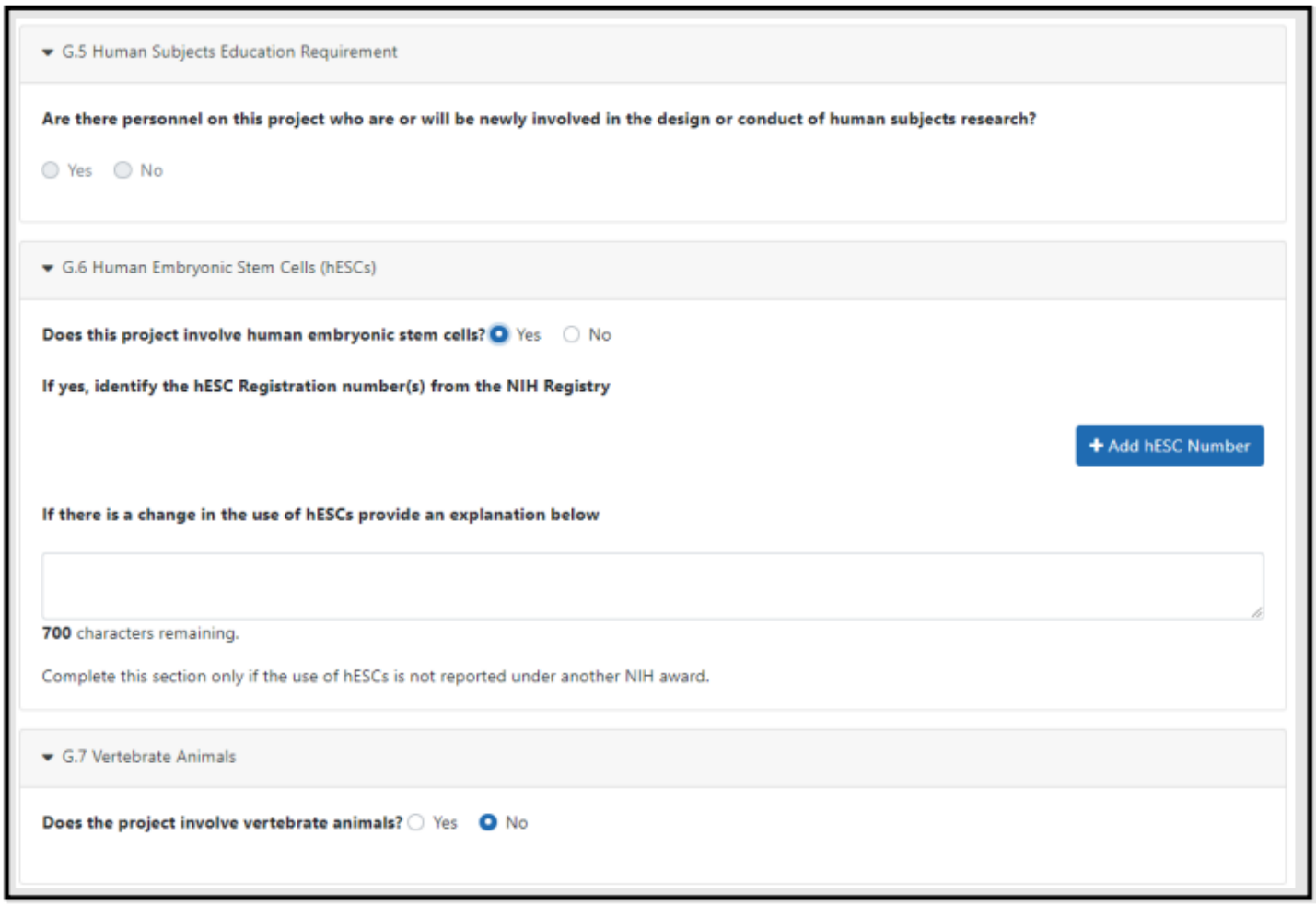


Figure 118 RPPR Section G. Special Reporting Requirements – Questions G5 through G7

G.8 Project/Performance Sites

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

One of the sites indicated must be 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 recipient 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.

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

Select the **Add Project/Performance Sites** button to add the data to the table

G.10 Estimated Unobligated Balance

The grantee must indicate whether the estimated unobligated balance (including any authorized prior-year carryover) at the end of the current budget year is expected to 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 the answer to the question is "yes", the grantee must provide the estimated unobligated balance, an explanation for the unobligated balance, and outline plans for its expenditure in the new budget year. CTR awards do not have automatic carryover. This question cannot be used as a prior approval request for carryover.

NIGMS staff will assess the available unobligated balance for each individual award based on the most recently approved FFR in addition to any estimated unobligated balance reported in G.10 of the RPPR. Note that the FFR reports the *actual* unobligated balance that has accumulated since the start of the grant's five-year cycle and not the estimated balance reported in the RPPR. Funds awarded may be reduced or offset as necessary in cases where the award has had a history of large unobligated balances that have accumulated, per the NIH Grants Policy Statement.

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

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.

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.

Recipients 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, or HHS GPS, Part II, Prior Approval Requirements, as applicable.