
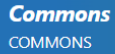




Sample eRA RPPR module screenshots.

Note: screenshots are not all-inclusive as system user interface may vary depending on grant mechanism and application attributes. Some screenshots provided also represent mock-ups of system features currently under development (e.g., changes to C.5.c. as part of this revision request).

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RPPR | [Grant List](#) | [Rppr Menu](#) | [PD/PI Assurance Report](#) | **A. Cover Page** | [B. Accomplishments](#) | [C. Products](#) | [D. Participants](#) | [E. Impact](#) | [F. Changes](#) | [G. Special Reporting Req](#) | [H. Budget](#)

A. Cover Page ?

 Remember to save all your changes before leaving the page.

[Expand/Collapse All](#)

<p>Award Information</p> <p>Award Number 5R01AG070072-04</p> <p>Project Title Brain-selective estrogen therapy for menopausal hot flushes in an advanced translational animal model</p>	<p>A.4 Recipient Organization Information</p> <p>Organization Name UNIVERSITY OF MARYLAND BALTIMORE</p> <p>Address UNIVERSITY OF MARYLAND BALTIMORE 620 W LEXINGTON ST, 4TH FL BALTIMORE MD 212011508</p> <p>DUNS 188435911</p> <p>UEI Z9CRZKD42ZT1</p> <p>EIN 1526002036A1</p> <p>Recipient ID ⓘ <input type="text"/></p>				
<p>A.1 Program Director/Principal Investigator (PD/PI) Information</p> <p>Name MERCHENTHALER, ISTVAN JOZSEF</p> <p>E-mail eRAStage@mail.nih.gov</p> <p>Phone: (410) 706-1350</p> <p>A.1.a</p> <p>Is there a change of contact PD/PI on a multiple-PI award?</p> <p><input type="radio"/> N/A <input type="radio"/> Yes <input checked="" type="radio"/> No</p> <p>A.1.b Not Applicable</p>	<p>Project/Grant Period</p> <table><thead><tr><th>Start Date</th><th>End Date</th></tr></thead><tbody><tr><td>01/15/2021</td><td>12/31/2025</td></tr></tbody></table>	Start Date	End Date	01/15/2021	12/31/2025
Start Date	End Date				
01/15/2021	12/31/2025				
<p>A.2 Signing Official Information</p> <p>Name <input type="text" value="FAHNESTOCK, KENNETH E"/></p> <p>E-mail eRAStage@mail.nih.gov</p> <p>Phone 4103225691</p>	<p>Reporting Period</p> <table><thead><tr><th>Start Date</th><th>End Date</th></tr></thead><tbody><tr><td>01/01/2023</td><td>12/31/2023</td></tr></tbody></table>	Start Date	End Date	01/01/2023	12/31/2023
Start Date	End Date				
01/01/2023	12/31/2023				
<p>A.3 Administrative Official Information</p> <p>Name <input type="text" value="SORENSEN, GREGORY J"/></p> <p>E-mail eRAStage@mail.nih.gov</p> <p>Phone 4107061186</p>	<p>Requested Budget Period</p> <table><thead><tr><th>Start Date</th><th>End Date</th></tr></thead><tbody><tr><td>01/01/2024</td><td>12/31/2024</td></tr></tbody></table> <p>Report Frequency Annual</p> <p>Other Frequency</p>	Start Date	End Date	01/01/2024	12/31/2024
Start Date	End Date				
01/01/2024	12/31/2024				

 Cancel

 Save

Sample eRA RPPR module screenshots.

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B. Accomplishments ?

Remember to save all your changes before leaving the page.

[Expand/Collapse All](#)

▼ 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).

List the major goals below

The overall goal of this project is to test the efficacy of a brain-selective estrogen in mitigation of the symptoms of hot flush within an advanced animal model.

The most immediate and patient reported 'unbearable' symptom of the menopause are hot flushes, which cause not only physical discomfort but also negatively impact mood, behavior and general quality of life. Among current treatments of hot flushes, only estrogen therapy (ET) and hormone therapy (HT, estrogens and progestins) have satisfactory efficacy. Although ET/HT prevents hot flushes, they have unwanted side effects in the periphery, including the stimulation of the uterus and breast leading to a significantly increased cancer risk in these organs.

We developed an old-world advanced translational animal model which undergoes a menopausal process that is hormonally identical to that of women. This also involved development of novel use of non-invasive thermal imaging to detect these events, alleviating the need for older train-and-restrain models used in this species for hot flush research in the past. Using this model, we propose to test a novel estrogen prodrug therapy using 10 β ,17 β -dihydroxyestra-1,4-dien-3-one (DHED). In the prodrug form it is highly shelf-stable at room temperature, can be taken orally, has no

6372 characters remaining

B.1.a Have the major goals changed since the initial competing award or previous report? Yes No

▼ 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)
4. key outcomes or other achievements

Include a discussion of stated goals not met. As the project progresses, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Goals are equivalent to specific aims. In the response, emphasize the significance of the findings to the scientific field. Include the approaches taken to ensure robust and unbiased results. For most NIH awards the response should not exceed 2 pages.

Upload accomplishments

Drop files here to upload, or [browse](#).

Max File Count: 1 Accepted File Types: PDF Max File Size: 6MB

RPPR_Accomplishments_010123-123123.pdf



▼ 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? Yes No

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

[+ Add/New](#)

Sample eRA RPPR module screenshots.

Note: screenshots are not all-inclusive as system user interface may vary depending on grant mechanism and application attributes. Some screenshots provided also represent mock-ups of system features currently under development (e.g., changes to C.5.c. as part of this revision request).

Add Revision Supplement ✕

Revision/Supplement #

or Revision/Supplement Title

255 characters remaining

Describe the specific aims for this Revision/Supplement below *

700 characters remaining

Describe the accomplishments for this Revision/Supplement below *

700 characters remaining

Cancel + Add

Sample eRA RPPR module screenshots.

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[+ Add/New](#)

▼ 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 this 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, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

For all projects reporting graduate student and/or postdoctoral participants in Section D. Participant, grantees are encouraged to describe the use of Individual Development Plans (IDPs) for those participants. Do not include the actual IDP; instead include information to document that IDPs are used to help manage the training for those individuals.

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.

Nothing to Report

Upload Description and Diversity Report, as applicable

Drop files here to upload, or [browse](#).

Max File Count: 1 Accepted File Types: PDF Max File Size: 6MB

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

Describe how the results have been disseminated to communities of interest. Include any outreach activities that have been undertaken to reach members of communities who are not usually aware of these research activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

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

Nothing to Report

or enter response below

7983 characters remaining

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Add Revision Supplement ✕

Revision/Supplement #

or Revision/Supplement Title

255 characters remaining

Describe the specific aims for this Revision/Supplement below *

700 characters remaining

Describe the accomplishments for this Revision/Supplement below *

700 characters remaining

[Cancel](#) [+ Add](#)

▼ 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 (e.g., NIH Grants Policy Statement, 8.1.2.).
- 🔗 Include any important modifications to the original plans. Provide a scientific justification for any changes involving research with human subjects or vertebrate animals. A detailed description of such changes must be provided under Changes.



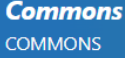

Enter response below

7892 characters remaining

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RPPR | [Grant List](#) | [Rppr Menu](#) | [PD/PI Assurance Report](#) | [A. Cover Page](#) | [B. Accomplishments](#) | **[C. Products](#)** | [D. Participants](#) | [E. Impact](#) | [F. Changes](#) | [G. Special Reporting Req](#) | [H. Budget](#)

C. Products ?

Remember to save all your changes before leaving the page.

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▼ [C.1 Publications](#)

Are there publications or manuscripts accepted for publication in a journal or other publication (e.g., book, one-time publication, monograph, or preprint) during the reporting period resulting directly from this award? Yes No

▼ All publications associated with this project in My NCBI

NIH Manuscript Submission System Status: Available

Note: Citations marked with a gold lock icon are associated with funding via NIHMS and cannot be removed from this RPPR. If your award did not support this paper, contact the [NIHMS help desk](#). Additional information and instructions are also available at the FAQ found here: "[This award did not support this research.](#)"

If yes, select from the table below to affiliate publications with this progress report.
If you need to login to My NCBI account please use this link: [My NCBI](#)

Associate with this RPPR	Public Access Compliance ^	Citation
Nothing Reported		

▼ Publications not associated with this project in My NCBI


Associate with this RPPR	Public Access Compliance ^	Citation
Nothing Reported		

Sample eRA RPPR module screenshots.

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▼ 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. If the website disseminates a product that falls into other product categories, please select the appropriate category(ies) from the pull-down menu (select multiple categories by holding down the Ctrl button while selecting the categories). Limit the response to this reporting period. For awards not designed to create or maintain one or more websites, select "Nothing to Report".

Nothing to Report
or list URL(s) for Internet site(s) and provide description(s) below

[+ New Web/Internet Site](#)


▼ 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.

 If the technology or technique falls into other product categories, please select the appropriate category(ies) from the pull-down menu (select multiple categories by holding down the Ctrl button while selecting the categories). If the product(s) has been reported or shared through a publication, please include the full reference and/or PubMed ID in the product description. Limit the response to this reporting period. If there are no technologies or techniques to report select "Nothing to Report"

Nothing to Report
or list URL(s) for Internet site(s) and provide description(s) below

[+ New Technology/Technique](#)

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


Have inventions, patent applications and/or licenses resulted from the award during this reporting period? Yes No

If yes, has this information been previously provided to the PHS or to the official responsible for patent matters at the grantee organization?
 Yes No

Reporting of inventions through [iEdison](#) is strongly encouraged.

▼ C.5 Other products and resource sharing

Identify any other significant products that were developed under this project.

 PD/PIs are required to report all products that arise from their NIH award in section C. If there are other products to report not covered in Sections C1 - C4, enter a description for the product and choose the appropriate product category(ies) from the pull down menu (select multiple categories by holding down the Ctrl button while selecting the categories). If there is more than one product to report, select "add product" to create a workspace to report an additional product. Limit the response to this reporting period.

Nothing to Report
or list URL(s) for Internet site(s) and provide description(s) below

[+ New Product/Resource](#)

[← Cancel](#) [Save](#)

Sample eRA RPPR module screenshots.

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Add Website(s) or other Internet site(s) ✕

Required Fields*

Category *

- Audio or video
- Data or Databases
- Research Material
- Educational aids or curricula
- Evaluation Instruments
- Instruments or equipment
- Models

Website(s) or other Internet site(s) *

2000 characters remaining

Cancel + Add

Add Technologies or techniques ✕

Required Fields*

Category *

- Audio or video
- Data or Databases
- Research Material
- Educational aids or curricula
- Evaluation Instruments
- Instruments or equipment
- Models

Technologies or techniques *

2000 characters remaining

Cancel + Add

Sample eRA RPPR module screenshots.

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Add Other products and resource sharing ✕

Required Fields *

Category *	Other products and resource sharing *
<ul style="list-style-type: none">Audio or videoData or DatabasesResearch MaterialEducational aids or curriculaEvaluation InstrumentsInstruments or equipmentModels	<div style="border: 1px solid #ccc; height: 100px;"></div> <p>2000 characters remaining</p>

Cancel + Add

C.5.b Resource Sharing

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

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

Nothing to Report

Progress implementing the resource sharing plan

ex:

8000 characters remaining

Sample eRA RPPR module screenshots.

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C.5. c Data Management and Sharing

Describe activities related to the approved Data Management and Sharing Plan. For each Data Type identified in the approved DMS Plan, provide the following information, as applicable:

Applicable Not Applicable

[+Add DMSP Information](#)

**If data has not been generated and/or shared as outlined in the approved Plan, describe why, and identify any corrective actions that have or will be taken to comply with the approved plan.*

Description

2000 characters remaining

Are significant prospective changes to the Data Management and Sharing Plan being requested for the coming year (e.g., change in repository, change in timeline, or change in scientific direction)?

No Change

If yes, enter description of the change(s) and upload revised Data Management and Sharing Plan for approval.

Enter description of change

2000 characters remaining

Upload revised Data Management and Sharing Plan

 Drop files to attach, or [browse](#).

Files should not exceed 6MB.
Files can only be the following format: .pdf

Sample eRA RPPR module screenshots.

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Data Management and Sharing Plan Information ✕

Data Type *

ex: Scientific data

2000 characters remaining

Has data been generated to date? * Yes No

Has the data been shared? (i.e. made available for use by others) Yes No

If data has NOT been shared, what is the status of data sharing?

e.g., Being prepared for submission, submitted to repository, not yet expected to be shared



2000 characters remaining




<p>Repository</p> <div style="border: 1px solid #ccc; padding: 5px; min-height: 40px;">e.g., Datahub</div> <p>2000 characters remaining</p>	<p>Unique Identifiers/Digital Object Identifier (DOI)</p> <div style="border: 1px solid #ccc; padding: 5px; min-height: 40px;">eg: ABC12345</div> <p>2000 characters remaining</p>
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[Cancel](#) [Add DMSP Information](#)

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RPPR |

[Grant List](#)
[Rppr Menu](#)
[PD/PI Assurance Report](#)
[A. Cover Page](#)
[B. Accomplishments](#)
[C. Products](#)
[D. Participants](#)
[E. Impact](#)
[F. Changes](#)
[G. Special Reporting Req](#)
[H. Budget](#)

D. Participants ?

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Remember all files must be flattened PDF files for successful submission. This ensures that PDFs cannot be edited following submission.

[Instructions for flattening PDFs](#)

The following applies to all NIH Awards EXCEPT FELLOWSHIPS:

- For NIH awards, Commons IDs are now required for individuals with the Undergraduate, Graduate Student, and Postdoctoral roles. Commons IDs can be created by going to the eRA Commons Home Page and Creating an Account or by contacting the signing official of their organization.
- Individuals with these roles on a project are required to complete their Commons Personal Profile.
- Individuals with a Graduate Student role must enter at least one degree, and those with a Postdoctoral role must enter a doctoral degree. Degrees can be entered under the individual's Personal Profile found after they log into Commons.

[Expand/Collapse All](#)

D.1 What individuals have worked on the project?

Provide or update the following information for:

- program director(s)/principal investigator(s) (PDs/Pis); and
- each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours or 8.3% of annualized effort).

Provide the name and identify the role the person played in the project. Indicate the nearest whole person month (Calendar, Academic, Summer) that the individual worked on the project. Show the most senior role in which the person has worked on the project for any significant length of time. For example, if an undergraduate student graduates, enters graduate school, and continues to work on the project, show that person as a graduate student.

[Instructions](#)

- An individual's Commons user ID may be used to partially populate his or her information.
- A Commons ID is required for all individuals with a postdoctoral role and/or supported by a Reentry or Diversity Supplement
- 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 *.

[+ Add Participant](#)

[Filter Table](#) 7 Results

<
1 of 1
>

Name	Commons ID	S/K	Degree(s)	Role	Person Months			Foreign Affiliation		SS
					Calendar	Academic	Summer	Org	Foreign Country	
MERCHANT ALER, ISTVAN Jozsef	IMERCHENTHALER	Y	DSC, PHD, MD	PD/PI	4.0	0	0			Not Applicable
PROKAI, LASZLO	LPROKAI	Y	BS, MS, PHD	PD/PI	1.2	0	0			Not Applicable
PUCHE, ADAM C	APUCHE	Y	PHD	PD/PI	1.2	0	0			Not Applicable
URBANSKI, HENRYK F	URBANSKI	N	PHD, MS, BS, DSC	Co-Investigator	1.0	0	0			Not Applicable
Hoorfar, Hamid	HHOORFAR	N	PHD	Postdoctoral Scholar, Fellow, ...	12.0	0	0			Not Applicable
Nguyen, Vien L	VIENNGUYEN	N		Staff scientist (Doctoral level)	1.3	0	0			Not Applicable
Lane, Malcolm		N		Non-Student Research Assistant	4.8	0	0			Not Applicable

[D.2 Personnel Update](#)

Sample eRA RPPR module screenshots.

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Add Participant ✕

***Required Fields**

eRA Commons User ID

First Name *

Middle Name

Last Name *

Senior/Key Personnel? * Yes No

Degree(s)

Supplement Support (SS)

Project Role *

Other(Project Role)

Person Months*

Calendar
Number between 0.0 and 12.0

Academic
Number between 0.0 and 9.0

Summer
Number between 0.0 and 3.0

Is the individual's primary affiliation with a foreign organization?* Yes No

Check "no" if the individual's primary affiliation is with a foreign organization but the individual is working on this award solely while in the U.S.

If yes, provide the name of the organization and country

Organization Name

Country

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[/ D.2 Personnel Update](#)

▼ 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 the level of effort below the minimum amount of effort required by the Notice of Award?

Yes No

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.

If yes, provide an explanation below

700 characters remaining

▼ D.2.b New Senior/Key Personnel

Are there, or will there be, new senior/key personnel? Yes No

Senior/key personnel are those identified by the grantee institution as individuals who contribute in a substantive measurable way to the scientific development or execution of the project, whether or not salaries are requested. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered senior/key personnel if their involvement meets this definition. Consultants may be considered senior/key personnel if they meet this definition. "Zero percent" effort or "as needed" is not an acceptable level of involvement for senior/key personnel.

If yes, upload biosketches and other support for all new senior/key personnel

Please upload supporting document:

Drop files here to upload, or [browse](#).

Max File Count: 1 Accepted File Types: PDF Max File Size: 6MB

▼ 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? Yes No

If yes, upload active other support for senior/key personnel whose support has changed and indicate what the change has been

Please upload supporting document:

Drop files here to upload, or [browse](#).

Max File Count: 1 Accepted File Types: PDF Max File Size: 10MB

Combined_OS.pdf

▼ D.2.d New Other Significant Contributors

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

Other significant contributors are individuals who have 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.

Please upload supporting document:

Drop files here to upload, or [browse](#).

Max File Count: 1 Accepted File Types: PDF Max File Size: 6MB

▼ D.2.e Multi-PI (MPI) Leadership Plan

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

Change in status of PD/PI requires prior approval of the agency (e.g., NIH Grants Policy Statement, &1.2.6).

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

Please upload supporting document:

Drop files here to upload, or [browse](#).



Max File Count: 1 Accepted File Types: PDF Max File Size: 6MB

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[RPPR](#) | [Grant List](#) | [Rppr Menu](#) | [PD/PI Assurance Report](#) | [A. Cover Page](#) | [B. Accomplishments](#) | [C. Products](#) | [D. Participants](#) | **[E. Impact](#)** | [F. Changes](#) | [G. Special Reporting Req](#) | [H. Budget](#)

E. Impact ?

Remember to save all your changes before leaving the page.

[Expand/Collapse All](#)

E.1 Not Applicable

✓ E.2 What is the impact on physical, institutional, or information resources that form infrastructure?

Describe ways, if any, in which the project made an impact, or is likely to make an impact, on physical, institutional, and information resources that form infrastructure, including:

- physical resources (such as facilities, laboratories, or instruments);
- institutional resources (such as establishment or sustenance of societies or organizations); or
- information resources, electronic means for accessing such resources or for scientific communication, or the like.

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

Nothing to Report

or describe impact on physical, institutional, or information resources below

7983 characters remaining

E.3 Not Applicable

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

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

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

Nothing to Report (zero dollars)

[+ Add Amount](#)

[← Cancel](#) [Save](#)

Sample eRA RPPR module screenshots.

Note: screenshots are not all-inclusive as system user interface may vary depending on grant mechanism and application attributes. Some screenshots provided also represent mock-ups of system features currently under development (e.g., changes to C.5.c. as part of this revision request).

Add Foreign Spent Amount [Close]

Required Fields*

Country * [Please select a Country ▼] **Dollar Amount *** [0]

[Cancel] [+ Add Amount]

Sample eRA RPPR module screenshots.

Note: screenshots are not all-inclusive as system user interface may vary depending on grant mechanism and application attributes. Some screenshots provided also represent mock-ups of system features currently under development (e.g., changes to C.5.c. as part of this revision request).



National Institutes of Health
Office of Extramural Research



RPPR	Grant List	Rppr Menu	PD/PI Assurance Report	A. Cover Page	B. Accomplishments	C. Products	D. Participants	E. Impact	F. Changes	G. Special Reporting Req	H. Budget
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F. Changes ?

Remember to save all your changes before leaving the page.

[Expand/Collapse All](#)

F.1 Not Applicable

∨ 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.

Nothing to Report

or describe challenges or delays and plans to resolve them below

One challenge encountered during the current reporting period is the significant increase in dosage of DHED.

7891 characters remaining

Sample eRA RPPR module screenshots.

Note: screenshots are not all-inclusive as system user interface may vary depending on grant mechanism and application attributes. Some screenshots provided also represent mock-ups of system features currently under development (e.g., changes to C.5.c. as part of this revision request).

✓ F.3 Significant changes to Human Subjects, Vertebrate Animals, Biohazards, and/or Select Agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for human subjects, vertebrate animals, biohazards, and/or select agents during this reporting period.
Remember that significant changes in objectives and scope require prior approval of the agency (e.g., NIH Grants Policy Statement, 8.1.2.). If there are changes in any of the following areas check the appropriate box and provide a description of the changes.

F.3.a Human Subjects

If human subject protocols are or will be different from the previous submission, include a description and explanation of how the protocols differ and provide a new or revised Protection of Human Subjects Section as described in the competing application instructions.

Nothing to Report

or upload description of change

Drop files here to upload, or [browse](#).
Max File Count: 1 Accepted File Types: PDF Max File Size: 6MB

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.

Nothing to Report

or upload description of change

Drop files here to upload, or [browse](#).
Max File Count: 1 Accepted File Types: PDF Max File Size: 6MB

F.3.c Biohazards

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

Nothing to Report

or upload description of change

Drop files here to upload, or [browse](#).
Max File Count: 1 Accepted File Types: PDF Max File Size: 6MB

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](#)

Nothing to Report

or upload description of change




Drop files here to upload, or [browse](#).
Max File Count: 1 Accepted File Types: PDF Max File Size: 6MB

Cancel

Save

Sample eRA RPPR module screenshots.

Note: screenshots are not all-inclusive as system user interface may vary depending on grant mechanism and application attributes. Some screenshots provided also represent mock-ups of system features currently under development (e.g., changes to C.5.c. as part of this revision request).

? ☎ 👤

RPPR |Grant ListRppr MenuPD/PI Assurance ReportA. Cover PageB. AccomplishmentsC. ProductsD. ParticipantsE. ImpactF. Changes**G. Special Reporting Req**H. Budget

G. Special Reporting Requirements ?

Remember to save all your changes before leaving the page.

[Expand/Collapse All](#)

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

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

Nothing to Report

Please upload supporting document:

📁 Drop files here to upload, or [browse](#).

Max File Count: 100 Accepted File Types: PDF Max File Size: 6MB

▼ G.2 Not Applicable

▼ G.3 Not Applicable

▼ G.4 Human Subjects

This project is not coded as human subjects research. If you need to add exempt or non-exempt human subjects research to this project, discuss with your Program Official and then follow the procedures for requesting prior approval ([Click here](#) to view procedures for requesting prior approval).

▼ 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?

Yes No

▼ G.6 Human Embryonic Stem Cells (hESCs)

Does this project involve human embryonic stem cells? Yes No

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

+ Add hESC Number

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

700 characters remaining

▼ G.7 Vertebrate Animals

Does the project involve vertebrate animals? Yes No

Sample eRA RPPR module screenshots.

Note: screenshots are not all-inclusive as system user interface may vary depending on grant mechanism and application attributes. Some screenshots provided also represent mock-ups of system features currently under development (e.g., changes to C.5.c. as part of this revision request).

Add hESC Number ✕

*** Required Fields**

Only hESC lines listed as approved in the NIH [Registry](#) may be used in NIH funded research.

hESC Registration number from the NIH Registry *

Cancel **+ Add hESC Number**

Sample eRA RPPR module screenshots.

Note: screenshots are not all-inclusive as system user interface may vary depending on grant mechanism and application attributes. Some screenshots provided also represent mock-ups of system features currently under development (e.g., changes to C.5.c. as part of this revision request).

▼ G.8 Project/Performance Sites

[+ Add Project/Performance Sites](#)

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

Filter Table 4 Results ↓ 🗪 ⏪ 1 of 1 ⏩

Organization Names	UEI	Congressional District	Address
University of Maryland, Baltimore Primary ***	Z9CRZKD42 ZT1	MD-007	Office of Research and Development 620 W.Lexington St., Baltimore, MD 212011508,UNITED STATES
Oregon Health & Science University ***	NPSNT86JK N51	OR-001	3181 S.W. Sam Jackson Park Rd., Portland, OR 972393098,UNITED STATES
University of Maryland School of Medicine ***	Z9CRZKD42 ZT1	MD-007	Epidemiology & Public Health, MSTF 10 S. Pine St., Baltimore, MD 212011116,UNITED STATES
University of North Texas Health Science Center at Fort Wort ***	JE8AKPCR2K A4	TX-012	Office of Sponsored Programs 3500 Camp Bowie Blvd, Fort Worth, TX 761072699,UNITED STATES

▼ G.9 Foreign Component

"Foreign component" is defined as significant scientific activity that was performed outside of the United States, either by the grantee or by a researcher employed by a foreign organization, whether or not grant funds were expended. The following grant-related activities are significant and must be reported:

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

Examples of other award-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.

No foreign component

or provide the organization name, country, and description of each foreign component

[+ Add 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? Yes No

[AHRQ Special Instructions](#)

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

If yes, provide the estimated unobligated balance.

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

700 characters remaining

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](#)

1300 characters remaining

Sample eRA RPPR module screenshots.

Note: screenshots are not all-inclusive as system user interface may vary depending on grant mechanism and application attributes. Some screenshots provided also represent mock-ups of system features currently under development (e.g., changes to C.5.c. as part of this revision request).

Project/Performance Sites ✕

Required Fields *

Organization Name *	Unique Entity Identifier (UEI) *
<input type="text"/>	<input type="text" value="ex: ABCDEF1GHL2"/>
Address Line 1 *	Address Line 2
<input type="text"/>	<input type="text"/>
City *	County
<input type="text"/>	<input type="text"/>
Country *	
<input type="text" value="Begin Typing and Select One"/>	
Zip Code *	
<input type="text" value="ex: 12345 or 123451234"/>	

Primary Site

[Cancel](#) [+ Add Project/Performance Site](#)

Sample eRA RPPR module screenshots.

Note: screenshots are not all-inclusive as system user interface may vary depending on grant mechanism and application attributes. Some screenshots provided also represent mock-ups of system features currently under development (e.g., changes to C.5.c. as part of this revision request).

▼ G.11 Program Income

Is program income anticipated during the next budget period? Yes No
If yes, use the format below to reflect the amount and source(s)

[+ Add Program Income](#)

▼ G.12 F&A Costs

Is there a change in performance sites that will affect F&A costs? Yes No
If yes, provide an explanation below (Limit is 1300 characters.)

1300 characters remaining

G.13 Not Applicable

[← Cancel](#) [Save](#)

[A. Cover Page](#) | [B. Accomplishments](#) | [C. Products](#) | [D. Participants](#) | [E. Impact](#) | [F. Changes](#) | [G. Special Reporting Req](#) | [H. Budget](#)

Add Program Income ✕

Required Fields *

Source *

Anticipated Amount* \$

[Cancel](#) [+ Add Program Income](#)

Sample eRA RPPR module screenshots.

Note: screenshots are not all-inclusive as system user interface may vary depending on grant mechanism and application attributes. Some screenshots provided also represent mock-ups of system features currently under development (e.g., changes to C.5.c. as part of this revision request).

The screenshot shows the Commons RPPR module interface. At the top is a navigation bar with the Commons logo and NIH logo. Below it is a menu with tabs: Grant List, Rppr Menu, PD/PI Assurance Report, A. Cover Page, B. Accomplishments, C. Products, D. Participants, E. Impact, F. Changes, G. Special Reporting Req, and H. Budget (which is highlighted). Below the menu is a section titled "H. Budget" with a help icon. A blue banner contains the text "Remember to save all your changes before leaving the page." Below this is a link for "Expand/Collapse All" and the text "Not Applicable". At the bottom right is a "Cancel" button. A breadcrumb trail at the bottom reads: "A. Cover Page | B. Accomplishments | C. Products | D. Participants | E. Impact | F. Changes | G. Special Reporting Req | H. Budget".

When Budget Forms are Required

The screenshot shows the "SF424 Research & Related Budget" form. The navigation bar is the same as in the previous screenshot. The form title is "SF424 Research & Related Budget" with a help icon. A blue banner contains the text "Remember to save all your changes before leaving the page." Below this is a link for "Expand/Collapse All" and the text "Component ID: Core-5152". The form contains several input fields: "OMB Number: 0925-0001", "Unique Entity Identifier (UEI)" with value "Z9CRZKD42ZT1", "Organization Name" with value "UNIVERSITY OF MARYLAND BALTIMORE", "Budget Period" with value "1", "Start Date" with value "07/01/2024", "Budget Type" with value "Project", and "End Date" with value "06/30/2025". Below these fields are two sections: "A. Senior/Key Person" with an "Add Senior/Key Person" button, and "B. Other Personnel" which contains a table. The table has columns for "Number of Personnel", "Project Role", "Person Months" (Calendar, Academic, Summer), "Requested Salary", "Fringe Benefits", and "Funds Requested". The table is currently empty. Below the table are summary rows: "Total Number Other Personnel", "Total Other Personnel:", "Total Salary, Wages and Fringe Benefits (A+B):", and "Funds Requested". Below the table is a section "C. Equipment Description" with an "Add Equipment Item" button.

Number of Personnel *	Project Role *	Person Months			Requested Salary *	Fringe Benefits *	Funds Requested
		Calendar	Academic	Summer			
	Post Doctoral Associates	0.00	0.00	0.00	\$ 0.00	\$ 0.00	0.00
	Graduate Students	0.00	0.00	0.00	\$ 0.00	\$ 0.00	0.00
	Undergraduate Students	0.00	0.00	0.00	\$ 0.00	\$ 0.00	0.00
	Secretarial/Clerical	0.00	0.00	0.00	\$ 0.00	\$ 0.00	0.00
		0.00	0.00	0.00	\$ 0.00	\$ 0.00	0.00
		0.00	0.00	0.00	\$ 0.00	\$ 0.00	0.00
		0.00	0.00	0.00	\$ 0.00	\$ 0.00	0.00
		0.00	0.00	0.00	\$ 0.00	\$ 0.00	0.00
0 : Total Number Other Personnel					Total Other Personnel:		\$0.00
					Total Salary, Wages and Fringe Benefits (A+B):		\$0.00

Sample eRA RPPR module screenshots.

Note: screenshots are not all-inclusive as system user interface may vary depending on grant mechanism and application attributes. Some screenshots provided also represent mock-ups of system features currently under development (e.g., changes to C.5.c. as part of this revision request).

Add Senior/Key Person ✕

Prefix	First Name *	Middle Name	Last Name *	Suffix
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Person Months *

Calendar	Academic	Summer
<input type="text" value="0.00"/>	<input type="text" value="0.00"/>	<input type="text" value="0.00"/>

Base Salary	Requested Salary *	Fringe Benefits *
<input type="text" value="\$ 0.00"/>	<input type="text" value="\$ 0.00"/>	<input type="text" value="\$ 0.00"/>

Project Role *

Cancel + Add Senior/Key Person

Add Equipment ✕

Equipment Item *

Funds Requested *

Cancel + Add Equipment

Sample eRA RPPR module screenshots.

Note: screenshots are not all-inclusive as system user interface may vary depending on grant mechanism and application attributes. Some screenshots provided also represent mock-ups of system features currently under development (e.g., changes to C.5.c. as part of this revision request).

▼ D. Travel

Enter Funds Requested

1. Domestic Travel Costs
(Incl. Canada, Mexico, and U.S. Possessions)

\$

2. Foreign Travel Costs

\$

Total Travel Costs

▼ E. Participant/Trainee Support Costs

Enter Funds Requested

1. Tuition/Fees/Health Insurance

\$

2. Stipends

\$

3. Travel

\$

4. Subsistence

\$

5. Other

\$

Number of Participants/Trainees

Total Participant/Trainee Support Costs

Sample eRA RPPR module screenshots.

Note: screenshots are not all-inclusive as system user interface may vary depending on grant mechanism and application attributes. Some screenshots provided also represent mock-ups of system features currently under development (e.g., changes to C.5.c. as part of this revision request).

▼ F. Other Direct Costs

Funds Requested

1. Materials and Supplies (\$)
\$

2. Publication Costs
\$

3. Consultant Services
\$

4. ADP/Computer Services
\$

5. Subawards/Consortium/ Contractual Costs
\$

6. Equipment or Facility Rental/User Fees
\$

7. Alterations and Renovations
\$

8. Other Cost

\$

9. Other Cost

\$

10. Other Cost

\$

11. Other Cost

\$

12. Other Cost

\$

13. Other Cost

\$

14. Other Cost

\$

15. Other Cost

\$

16. Other Cost

\$

17. Other Cost

\$

Total Other Direct Costs

Sample eRA RPPR module screenshots.

Note: screenshots are not all-inclusive as system user interface may vary depending on grant mechanism and application attributes. Some screenshots provided also represent mock-ups of system features currently under development (e.g., changes to C.5.c. as part of this revision request).

▼ G. Direct Costs

Total Direct Costs (A thru F)

▼ H. Indirect Costs

[+ Add Indirect Cost Item](#)

Cognizant Federal Agency (Agency Name, POC Name and POC Phone Number)

180 characters remaining

▼ I. Total Direct and Indirect Costs

Total Direct and Indirect Institutional Costs (G + H)

▼ J. Fee

Funds Requested

\$

▼ K. Total Costs and Fees

Total Institutional Costs and Fees (I + J)

L. Budget Justification ^

Please upload supporting document:

Drop files here to upload, or [browse](#).

Max File Count: 1 Accepted File Types: PDF Max File Size: 6MB

[Cancel](#) [Save](#)

A. Cover Page | B. Accomplishments | C. Products | D. Participants | E. Impact | F. Changes | G. Special Reporting Req | H. Budget

Sample eRA RPPR module screenshots.

Note: screenshots are not all-inclusive as system user interface may vary depending on grant mechanism and application attributes. Some screenshots provided also represent mock-ups of system features currently under development (e.g., changes to C.5.c. as part of this revision request).

Add Indirect Cost Item ✕

Indirect Cost Type *	<input type="text"/>	Indirect Cost Rate (%)	<input type="text"/>
Indirect Cost Base	<input type="text" value="0.00"/>	Funds Requested *	<input type="text" value="0.00"/>

Final/Interim-RPPR Outcomes

I. Outcomes ?

Remember to save all your changes before leaving the page.

For NIH Section I, Outcomes will be made **publicly available**, thus allowing recipients to provide the general public with a concise summary of the cumulative outcomes or findings of the project at the end of a competitive segment. For NIH awards the length should not exceed half a page. In addition, for the interim or final RPPR, the summary of outcomes or findings of the award must be written in the following format:

- Is written for the general public in clear, concise, and comprehensible language;
- Is suitable for dissemination to the general public, as the information may be available electronically;
- Does not include proprietary, confidential information or trade secrets

Please refer to the following link for samples of acceptable project outcomes: https://grants.nih.gov/grants/rppr/sample_project_outcomes_RPPR.htm

Expand/Collapse All

1.1 What were the outcomes of the award?

Outcomes of Award

8000 characters remaining

A. Cover Page | B. Accomplishments | C. Products | D. Participants | E. Impact | G. Special Reporting Req | I. Outcomes

Sample eRA RPPR module screenshots.

Note: screenshots are not all-inclusive as system user interface may vary depending on grant mechanism and application attributes. Some screenshots provided also represent mock-ups of system features currently under development (e.g., changes to C.5.c. as part of this revision request).

Complex/Multi-project RPPR Menu

? ☎ 👤

RPPR | **Grant List** | Rppr Menu | A. Cover Page | B. Accomplishments | C. Products | D. Participants | E. Impact | F. Changes | G. Special Reporting Req | H. Budget

RPPR Menu ?

The RPPR has been successfully initiated. ✕

Overall

Award Number 5P01AI125181-09 ...	Program Director(PD)/Principal Investigator(PI) Foulke-Abel, Jennifer; KAPER, JAMES B (Contact); Nataro, James P.	Due Date 05/01/2024	Current Reviewer KAPER, JAMES B	Status PD/PI Work in Progress
Institution UNIVERSITY OF MARYLAND BALTIMORE	Project Title Pathogenesis of E. coli and Shigella infections in human enteroid models			

Has Components ? Yes

[+ Add Component](#)

Filter Table

6 Results



ID ^	Date ↕	Type ↕	Title ↕
Admin-5151 ...	2/22/2024	Admin	Administrative Core
Core-5152 ...	2/22/2024	Core	Enteroid Core
Core-5153 ...	2/22/2024	Core	Immunology Core
Project-5154 ...	2/22/2024	Project	Immunomodulatory role of Pic in EAEC Pathogenesis
Project-5155 ...	2/22/2024	Project	Modeling Shigella Interaction with Innate Cells in Enteroid Co-Cultures to Inform Vaccine Development
Project-5156 ...	2/22/2024	Project	Innate defenses against enterotoxigenic E. coli as potential therapeutic contributors

[Cancel](#)

Sample eRA RPPR module screenshots.

Note: screenshots are not all-inclusive as system user interface may vary depending on grant mechanism and application attributes. Some screenshots provided also represent mock-ups of system features currently under development (e.g., changes to C.5.c. as part of this revision request).

The screenshot shows a window titled "Add New Component" with a close button (X) in the top right corner. Below the title bar, there are two required fields, each marked with a red asterisk (*). The first field is "Component Project Title", which is an empty text input box. The second field is "Component Project Type", which is a dropdown menu. The dropdown menu is open, showing a list of options: "Select Component Type" (highlighted in blue), "Core", "Admin Core", "Project", "Training", "Career Development", and "Other". Below the dropdown menu, the text "Project Title" is visible.

Annual RPPR:

Public reporting burden for this collection of information is estimated to average 9 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0002). Do not return the completed form to this address.

Final RPPR:

Public reporting burden for this collection of information is estimated to average 11 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0002). Do not return the completed form to this address.