Medical School

NIH Research Proposal

Review Checklist

This checklist serves as a reference guide for Medical School departments/units when reviewing NIH research grants prior to routing for approval. This document provides a quick reference to address the most common mistakes in proposal preparation. Research Administrators are encouraged to review NIH research proposal submissions using this tool in order to make the Medical School’s sponsored project review process more efficient. Using this checklist should reduce review questions during routing.

Questions & comments are welcome. Please email to the Grant Services & Analysis Office (msgrants@umich.edu). Check here for updates!
Use of the document is most effective after the project team has completed the entire NIH 424 research application and PAF and is using the information to review the packet prior to routing. This is not intended to be a replacement of the sponsor directions and specific sponsor requirements for all sections of the application.

Using the Checklist

Symbols
In this document, you will find text bubbles in two colors:

- Medical School will review for accuracy and data integrity as part of the routing process
- Departments/units are responsible to ensure accuracy and will not be re-reviewed by the school. Departments may also wish to review yellow bubbles are to ensure fewer questions about the form content in the routing and review process.

- Useful information (included in green boxes)
- Helpful tips (included in gray boxes)

Abbreviations

- GS&A = Grant Services & Analysis, the Dean’s Office Review step.
- Dept = Any administrative home department / unit / center

Suggested Steps

- You may wish to compare the review application side by side with this document.
  * Open 424 application in eRPM. Click on Edit/View Grant Application in the left panel.
  * Align this checklist next to the application so that the two windows are side by side.
- Compare the reviewed page to the corresponding page in this checklist. At a minimum, verify all the fields with blue bubbles are correctly filled out.
- Repeat with the fields of the Proposal Approval Form (PAF) and PAF Summary in eRPM.

You may wish to keep the 424 application window open. Some fields on the PAF will be compared against those in the application.
SF424 R&R Cover Page - Page 1

- Always Application when first routed by Dept. GS&A will change if application is submitted >1x
- New application: blank
- Renewal/Resubmission/Revision: Use Previous NIH grant # -> 2 letters + 6 numbers
- Skip this field unless specified in the FOA. Applications in response to Notice of Special Interest must include the notice number (NOT-IC-FY-XXX).
- Applicant Identifier = PAF ID; do not leave out leading 0s.
- Previous Grants.gov ID: Dept: Leave blank. GS&A will complete if application is submitted >1x.

Many fields prepopulate when the 424 is created or information from the PAF is copied into the 424. It is always good to read over the fields to be sure nothing is accidentally replaced.

The contact is automatically populated. Verify your ORSP Project Representative’s contact info here.

Complete. Refer to NIH Glossary for definitions.

- Confirm this is no earlier than the earliest start date allowed by the NIH.
- Start date must be a future date or the Grants.gov system will error.
- For Renewals: Confirm no date overlap with current grant.
14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

<table>
<thead>
<tr>
<th>Prefix</th>
<th>Last Name</th>
<th>First Name</th>
<th>Title</th>
<th>Organization Name</th>
<th>Division</th>
<th>Department</th>
<th>Street 1</th>
<th>Street 2</th>
<th>City</th>
<th>County</th>
<th>State</th>
<th>Country</th>
<th>Phone Number</th>
<th>Fax Number</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ottman</td>
<td>Heather</td>
<td>Director</td>
<td>Regents of the University of Michigan</td>
<td>Medical School</td>
<td>Research Office</td>
<td>NCRC 520-5173</td>
<td></td>
<td>Ann Arbor</td>
<td>USA</td>
<td>UNITED STATES</td>
<td>734-763-4272</td>
<td></td>
<td><a href="mailto:hmills@umich.edu">hmills@umich.edu</a></td>
<td></td>
</tr>
</tbody>
</table>

Confirm PI’s information is the same as shown on the PAF.

15. ESTIMATED PROJECT FUNDING

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Total Federal Funds Requested</td>
<td>$3,135,729.00</td>
</tr>
<tr>
<td>b. Total Non-Federal Funds</td>
<td>$0.00</td>
</tr>
<tr>
<td>c. Total Federal &amp; Non-Federal Funds</td>
<td>$3,135,729.00</td>
</tr>
<tr>
<td>d. Estimated Program Income</td>
<td>$0.00</td>
</tr>
</tbody>
</table>

Total must match the sum on R&R BUDGET Cumulative Budget page, Section K.

Unless the federal program requires a specific match, don’t enter cost sharing amount.

17. By signing this application, I certify (1) to the statements contained in the list of certifications and (2) that the statements herein are true, complete and accurate to the best of my knowledge and belief. I understand that I accept an award, I am in agreement to comply with all applicable terms and conditions if I accept an award, and I agree to accept any resulting terms if I refuse to comply with any resulting terms if I refuse to accept an award. I agree to the penalties. (U.S. Code, Title 31, Section 3302).

[X] I agree

* The list of certifications and assurances, or an internet site where you might obtain this list, is contained in the announcement or agency specific instructions.

Make sure the box is checked. If non-faculty PI, assurance statement should also be signed and uploaded to the PAF.

18. SFLLL or other Explanatory Document

The contact is automatically populated. Verify it is completed.

GS&A manually replaces the ORSP email address with GS&A email if they will submit.

NEW:

- If application proposed to use human fetal tissue (HFT) from elective abortions, a statement about HFT involvement must be included in the Cover Letter.
- Cover letter must not be used to request application assignments. The PHS Assignment Form is to be used for that purpose.
R&R Project/Performance Site Location(s)

Project/Performance Site Location(s)

[ ] I am submitting an application as an individual, and not on behalf of a company, state, local or tribal government, academia, or other type of organization.

Verify.

If the U-M VA is the sole location, then VA is the Primary Location.

Work with subcontract organization(s) to ensure accuracy.

List all other participating organizations, sites, or contributing entities (subcontracts, VA, etc.) here.

Frequently required proposal documents and data can be found on the ORSP website.
**R&R Other Project Information**

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
</table>
| 1.1. Are Human Subjects Involved? | [ ] Yes  [ ] No  
  If YES to Human Subjects:  
  Is the Project Exempt from Federal regulations?  [ ] Yes  [ ] No  
  If yes, check appropriate exemption number:  [1]  [2]  [3]  [4]  [5]  [6]  [7]  [8]  
  If no, is the IRB review Pending?  [ ] Yes  [ ] No  
  IRB Approval Date:  
  Human Subject Assurance Number: 00004969  
  Animal Welfare Assurance Number: A3114-01  |
| 2.1. Are Vertebrate Animals Used? | [ ] Yes  [ ] No  
  If YES to Vertebrate Animals:  
  Is the IACUC review Pending?  [ ] Yes  [ ] No  
  IACUC Approval Date:  |
| 3. Are proprietary privileged information included in the application? | [ ] Yes  [ ] No  
  If yes, please explain:  
  4. Does this Project Have an Actual or Potential Impact – positive or negative - on the environment? | [ ] Yes  [ ] No  
  If yes, please explain:  
  5. Is the research performance site designated, or eligible to be designated, as a historic place? | [ ] Yes  [ ] No  
  If yes, please explain:  
  6. Does this project involve activities outside the U.S.? If yes, identify countries:  
  Canada  |
| 7. Project Narrative | Narrative.pdf  
  Abstract.pdf  
  References.pdf  
  Include PMCID in citations.  
  Facilities and Equipment available at all performance sites should be included.  
  Foreign Justification.pdf |
| 8. Project Narrative | Narrative.pdf  
  Abstract.pdf  
  References.pdf  
  Include PMCID in citations.  
  Facilities and Equipment available at all performance sites should be included.  
  Foreign Justification.pdf |
  Include PMCID in citations.  
  Facilities and Equipment available at all performance sites should be included.  
  Foreign Justification.pdf |
| 10. Facilities & Other Resources |  
  Equipment  |
| 11. Other Attachments |  
  Foreign Justification.pdf |

**Tips:**
- **Narrative:** 2 to 3 sentences.
- **Abstract:** 30 lines or less.
- If international collaboration, all countries must be listed.
- If "Human Subjects" is "Yes", this assurance number is required.
- If "Vertebrate Animals" is "Yes", this assurance number is required.
- Scenarios in sections 3, 4, 5 are unusual. Contact the GS&A office for advice.
- If Yes: Upload a document titled Foreign Justification in item 12 (on this page).
**R&R Senior/Key Person Profile**

**RESEARCH & RELATED Senior/Key Person Profile (Expanded)**

**Position/Title:** e.g., Professor, not Project Role (e.g., PD/PI).

**Organization Name** is required for all Senior/Key Personnel to help determine potential review conflicts of interest.

- **Mandatory for ALL PD/PI(s) — Verify login name on ORSP website.**
  - Typos may cause submission failure. Verify institutional affiliation and role.
  - ORCID ID must be associated with PD/PI eRA Commons Profile for Fellowship and Career applications.

Five Page Limit. No effort or award amount may be reflected in the Research Support section. Click [here](#) for format, instructions and samples.

Use **Display Order** function to assign a specific order, so that all PD/PIs are listed first.

**Multiple PD/PIs?** eRA Commons usernames must be included for all PD/PIs. Don’t forget the **Multiple PD/PI Leadership Plan** on PHS 398 Research Plan form.

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Questions? msgrants@umich.edu
## PHS 398 Cover Page Supplement, Part I

### 1. Vertebrate Animals Section

Are vertebrate animals euthanized?  
[X] Yes

If “Yes” to euthanasia

| Is method consistent with American Veterinary Medical Association (AVMA) guidelines? | [X] Yes | [ ] No |

If “No” to AVMA guidelines, describe method and provide scientific justification

### 3. Program Income Section

| Is program income anticipated during the periods for which the grant support is requested? | [ ] Yes | [X] No |

If you check “Yes” (or anticipated), then use the format below to reflect the amount and source(s).

| *Budget Period* | *Anticipated Amount ($) | *Source(s)* |
### 3. Human Embryonic Stem Cells

- **Question:** Does the proposed project involve human embryonic stem cells?  
  - [ ] Yes  
  - [X] No

  If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: [http://stemcells.nih.gov/research/registry/](http://stemcells.nih.gov/research/registry/). Or, if a specific stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used.

  Cell Line(s) (Example: 0004):  
  - If Yes: Cell line code should be listed. It is composed of 4 numbers (e.g., 0004).

### 4. Human Fetal Tissue Section

- **Question:** Does the proposed project involve human fetal tissue obtained from elective abortions?  
  - [X] Yes  
  - [ ] No

  Required if YES. See NIH Notice [NOT-OD-19-137](http://stemcells.nih.gov/research/registry/) for HFT Clarification.

### 5. Inventions and Patents (RENEWAL)

- **Question:** Inventions and Patents:  
  - Yes [ ]  
  - No [ ]

  *Previously Reported:  
  - Yes [ ]  
  - No [ ]

Answer this section **ONLY** when Type 2 Submission, i.e.,  
- Renewal or  
- Resubmission of renewal.
PHS 398 Cover Page Supplement, Part III

6. Change of Investigator / Change of Institution Section

[ ] Change of Project Director/Principal Investigator
  Name of former Project Director/Principal Investigator:
    Prefix:
    *First Name:
    Middle Name:
    *Last Name:
    Suffix:

[ ] Change of Grantee Institution
  *Name of former institution:

Complete this item only when changing the PD/PI during a proposal submission (not common).

Complete this item only when transferring a grant.
### R&R Budget - Section A & B

#### RESEARCH & RELATED BUDGET – Budget Period:

<table>
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<tr>
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<th>ORG in Name of Organization:</th>
<th>Regents of the University</th>
<th>ORG Start Date: 04/01/2022</th>
<th>ORG End Date: 03/30/2023</th>
<th>Budget Period: 1</th>
<th>Budget Period Start Date:</th>
<th>Budget Period End Date:</th>
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#### A. Senior/Key Person

<table>
<thead>
<tr>
<th>Prefix</th>
<th>First Name</th>
<th>Middle Name</th>
<th>Last Name</th>
<th>Suffix</th>
<th>Project Role</th>
<th>Base Salary ($)</th>
<th>Cal. Months</th>
<th>Acad. Months</th>
<th>Sum. Other</th>
<th>Total Other</th>
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<td>Jane M</td>
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<td>PGPI</td>
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</table>

#### B. Other Personnel

<table>
<thead>
<tr>
<th>Number of Personnel</th>
<th>Type</th>
<th>Cal. Months</th>
<th>Acad. Months</th>
<th>Sum. Months</th>
<th>Total Requested Salary ($)</th>
<th>Fringe Benefits ($)</th>
<th>Total Funds Requested ($)</th>
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<td>12</td>
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<td>12</td>
<td>$52,704.00</td>
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<td>$33,721.00</td>
<td>$3,602.00</td>
<td>$37,323.00</td>
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<td>2</td>
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<td>12</td>
<td>$32,000.00</td>
<td>$9,600.00</td>
<td>$41,600.00</td>
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<td></td>
<td>$198,736.00</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Total Other Personnel: $147,438.00</td>
</tr>
</tbody>
</table>

#### Notes
- **Only the primary applicant organization selects Project.**
- **Start Date must be the same as that in R&R Cover Page 1, item 12.**
- **Base Salary** must match U-M institutional base salary (not full-time rate) or NIH salary cap; OR you may leave the field blank.
- **Base Salary** must match U-M institutional base salary (not full-time rate) or NIH salary cap; OR you may leave the field blank.
- **Project Role** must EXACTLY match that in R&R Senior/Key Person Profile form.
- **Headcount of people in each category.**
- **Any listing of effort in the Budget Justification** must match.
- **The Month field must be > 0 or Grants.gov will error. If truly no effort, use 0.01 CM.**
- **Every Senior/Key personnel must have measurable effort.**

#### Instructions
- List only U-M personnel with effort on this page.
- Click [here](#) for examples of calendar month calculation. OR call the GS&A office for help with partial appointments.
### Equipment Definition

- **Equipment definition:**
  - > 1-year lifetime **AND** cost ≥ $5K

### Participants

- **Participants** are trainees from outside U-M. Click [here](#) for the full definition.
  - This section is **NOT** for subject fees or any costs related to U-M affiliated personnel.
  - Generally, this section is used if specified listed in the Request for Application (RFA) and is used infrequently in the Medial School.

- GS&A is happy to answer questions as budgets are developed.
This # must be manually entered. See Subcontract Section (page 15), for the text bubble next to Section K, for calculation instructions.

If using human fetal tissue (HFT) from elective abortions, you must include a “Human Fetal Tissue Costs” item. The name must match exactly (without quotation marks). If no cost is incurred, enter 0. The line item cannot be combined with any “other costs”.

Lines 8-10 (Other) may also be used for direct costs related to the use of sIRB for multi-site human subjects research.

If Total Direct Costs ≤ $250K, use R&R Modular Budget Form — unless Human Fetal Tissue.

Graduate tuition should be entered here in Section F, not in Section E.

Make sure these two #s are correctly reflected on PAF, 3. Budget, Budget and Time Period, item 3.12.

Cognizant Federal Agency
Department of Health and Human Services, Matthew Dito (214) 767-3764

I. Total Direct and Indirect Costs

- Budgets should reflect details in the Budget Justification.
- Make sure #s in the Budget Justification are consistent with those in this budget form.
How to Calculate Modified Total Direct Costs (Indirect Cost Base)

For EACH subcontract, locate the $$ in R&R BUDGET, SUBAWARD, BUDGET PERIOD X, Section I.
- If ≤ $25K, use “$0” as you have not yet met the excluded amount.
- If > $25K, calculate “$$ - $25K” and use the $$ difference as excluded amount.

Add up the excluded $$ across ALL subcontracts. Plug the sum to the formula above.

If you do not reach $25K for any given subcontract, instead start excluding in a subsequent year when the cumulative total costs reach $25K.

Let’s Take the Application in Year 1 as an Example

- Total Direct Costs: $444,110
- Total Subcontract (after 1st $25K): $10,000
- Renovations: $(143,640 - $25,000) = $118,640
- Research Patient Care costs: -$13,734
- Tuition: -$12,000
- Lease: $0

Total Direct Costs - Equipment - Participant Support - Each SubK ( > $25K) - Renovations - Tuition - Research Patient Care - Lease = $289,736
### R&R Budget - Cumulative Budget

**i** Numbers on this page are automatically calculated. If individual budgets are correct, the cumulative budget is correct.

<table>
<thead>
<tr>
<th>Section A, Senior/Key Person</th>
<th>Total ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$0.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Section B, Other Personnel</th>
<th>Total ($)</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>$620,348.00</td>
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</table>

<table>
<thead>
<tr>
<th>Section C, Equipment</th>
<th>Total ($)</th>
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<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Section D, Travel</th>
<th>Total ($)</th>
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</thead>
<tbody>
<tr>
<td>1. Domestic</td>
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<tr>
<td>2. Foreign</td>
<td>$0.00</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Section E, Participant/Trainee Support Costs</th>
<th>Total ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Tuition/Fees/Health Insurance</td>
<td>$0.00</td>
</tr>
<tr>
<td>2. Stipends</td>
<td>$0.00</td>
</tr>
<tr>
<td>3. Travel</td>
<td>$0.00</td>
</tr>
<tr>
<td>4. Subsistence</td>
<td>$0.00</td>
</tr>
<tr>
<td>5. Other</td>
<td>$0.00</td>
</tr>
<tr>
<td>6. Number Of Participants/Trainees</td>
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</table>

<table>
<thead>
<tr>
<th>Section F, Other Direct Costs</th>
<th>Total ($)</th>
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</thead>
<tbody>
<tr>
<td>1. Materials and Supplies</td>
<td>$55,771.00</td>
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<tr>
<td>2. Publication Costs</td>
<td>$15,000.00</td>
</tr>
<tr>
<td>3. Consultant Services</td>
<td>$0.00</td>
</tr>
<tr>
<td>4. ADP/Computer Services</td>
<td>$0.00</td>
</tr>
<tr>
<td>5. Subawards/Consortium/Contractual Costs</td>
<td>$0.00</td>
</tr>
<tr>
<td>6. Equipment or Facility Rental/User Fees</td>
<td>$0.00</td>
</tr>
<tr>
<td>7. Alterations and Renovations</td>
<td>$0.00</td>
</tr>
<tr>
<td>8. Other</td>
<td>$0.00</td>
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<tr>
<td>9. Other</td>
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</tr>
<tr>
<td>10. Other</td>
<td>$0.00</td>
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<table>
<thead>
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<th>Section G, Direct Costs (A thru F)</th>
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<td>$706,119.00</td>
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<table>
<thead>
<tr>
<th>Section H, Indirect Costs</th>
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<table>
<thead>
<tr>
<th>Section I, Total Direct and Indirect Costs (G + H)</th>
<th>Total ($)</th>
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<tbody>
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<td></td>
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<table>
<thead>
<tr>
<th>Section J, Fee</th>
<th>Total ($)</th>
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<tr>
<th>Section K, Total Costs and Fees (I + J)</th>
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<tr>
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Make sure these #s are correctly reflected on the **PAF, 3. Budget, Budget and Time Period**, item 3.12.

Make sure this # is correctly reflected on **R&R Cover Page 2, item 15a.**
<table>
<thead>
<tr>
<th>Senior/Key Person</th>
<th>Prefix</th>
<th>First Name</th>
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<th>Salary</th>
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<td></td>
<td></td>
<td>$0.00</td>
<td>$0.00</td>
<td>$0.00</td>
</tr>
</tbody>
</table>

Total Senior/Key Person: $0.00

Additional Senior Key Persons:

<table>
<thead>
<tr>
<th>Number of Personnel</th>
<th>Project Role</th>
<th>Cal Months</th>
<th>Acad Months</th>
<th>Sum Months</th>
<th>Requested Salary ($)</th>
<th>Fringe Benefits ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Post Doctoral Associates</td>
<td>12</td>
<td></td>
<td></td>
<td>$40,000.00</td>
<td>$12,000.00</td>
<td>$52,000.00</td>
</tr>
<tr>
<td></td>
<td>Graduate Students</td>
<td></td>
<td></td>
<td></td>
<td>$0.00</td>
<td>$0.00</td>
<td>$0.00</td>
</tr>
<tr>
<td></td>
<td>Undergraduate Students</td>
<td></td>
<td></td>
<td></td>
<td>$0.00</td>
<td>$0.00</td>
<td>$0.00</td>
</tr>
<tr>
<td></td>
<td>Secretarial/Clerical</td>
<td></td>
<td></td>
<td></td>
<td>$0.00</td>
<td>$0.00</td>
<td>$0.00</td>
</tr>
<tr>
<td>1</td>
<td>Lab Manager</td>
<td>9</td>
<td></td>
<td></td>
<td>$50,000.00</td>
<td>$15,000.00</td>
<td>$65,000.00</td>
</tr>
</tbody>
</table>

Total Number Other Personnel: $117,000.00

Total Salary, Wages and Fringe Benefits (A+B): $117,000.00

Make sure correct **Budget Type** is selected.

Make sure each Subaward budget period matches U-M project’s.

Only Senior/Key Persons from the subcontract organization should be listed on the subaward pages.
R&R Budget, **Subaward** - Section C, D & E

**ORGANIZATIONAL DUNS**: 259999779  
**Budget Type**: Subaward/Consortium  
**Enter name of Organization**: The Governing Council of the University of Toledo  
**Start Date**: 04/01/2021 **End Date**: 09/30/2022 **Budget Period**: 1

### C. Equipment Description

List items and dollar amount for each item exceeding $5,000

<table>
<thead>
<tr>
<th>Equipment item</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td>Total funds requested for all equipment listed in the attached file</td>
</tr>
<tr>
<td></td>
<td><strong>Total Equipment</strong> $0.00</td>
</tr>
</tbody>
</table>

**HELPFUL TIPS**

- Subcontracts have similar budget practice to U-M. They need reviewed by U-M, but remember:
  - Other institutions have different financial rules than U-M.
  - Their institutional official signs off to ensure their budget follows local requirements.
  - Usually you are reviewing for $$ accuracy (do 2 trips @ $500 each = $1,000?) vs. how cost items are treated (should they recover F&A on travel?).

If anything raises a red flag, ask the institutional contact.

### D. Travel

<table>
<thead>
<tr>
<th>Description</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)</td>
<td>$3,000.00</td>
</tr>
<tr>
<td>2. Foreign Travel Costs</td>
<td></td>
</tr>
</tbody>
</table>

**Total Travel Cost** $3,000.00

### E. Participant/Trainee Support Costs

<table>
<thead>
<tr>
<th>Item</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Tuition/Fees/Health Insurance</td>
<td></td>
</tr>
<tr>
<td>2. Stipends</td>
<td></td>
</tr>
<tr>
<td>3. Travel</td>
<td></td>
</tr>
<tr>
<td>4. Subsistence</td>
<td></td>
</tr>
<tr>
<td>5. Other</td>
<td></td>
</tr>
</tbody>
</table>

**Number of Participants/Trainees**  
**Total Participant/Trainee Support Costs** $0.00
Under the Uniform Guidance,
1. **Domestic subcontractor** SHOULD have a federally-negotiated rate.
   If they don’t, U-M may offer 10%. Contact GS&A for questions.
2. **International subcontractor**: Indirect cost rate is limited to 8%.

- Budget should be produced from the **Budget Justification**.
- Make sure #s in the **Budget Justification** are consistent with those in this budget form.
- Add the $$ in **Section K** of ALL subawards (for the corresponding period).
- Enter the sum to U-M Budget page, item F5.
R&R Budget, **Subaward** - Cumulative Budget

<table>
<thead>
<tr>
<th>Section</th>
<th>Total ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Senior/Key Person</td>
<td>$0.00</td>
</tr>
<tr>
<td>B. Other Personnel</td>
<td>$620,348.00</td>
</tr>
<tr>
<td>Total Number Other Personnel</td>
<td></td>
</tr>
<tr>
<td>Total Salary, Wages and Fringe Benefits (A+B)</td>
<td>$620,348.00</td>
</tr>
<tr>
<td>C. Equipment</td>
<td>$0.00</td>
</tr>
<tr>
<td>D. Travel</td>
<td>$15,000.00</td>
</tr>
<tr>
<td>E. Participant/Trainee Support Costs</td>
<td>$0.00</td>
</tr>
<tr>
<td>1. Tuition/Fees/Health Insurance</td>
<td>$0.00</td>
</tr>
<tr>
<td>2. Stipends</td>
<td>$0.00</td>
</tr>
<tr>
<td>3. Travel</td>
<td>$0.00</td>
</tr>
<tr>
<td>4. Subsistence</td>
<td>$0.00</td>
</tr>
<tr>
<td>5. Other</td>
<td>$0.00</td>
</tr>
<tr>
<td>6. Number Of Participants/Trainees</td>
<td></td>
</tr>
<tr>
<td>F. Other Direct Costs</td>
<td></td>
</tr>
<tr>
<td>1. Materials and Supplies</td>
<td>$55,771.00</td>
</tr>
<tr>
<td>2. Publication Costs</td>
<td>$15,000.00</td>
</tr>
<tr>
<td>3. Consultant Services</td>
<td>$0.00</td>
</tr>
<tr>
<td>4. ADP/Computer Services</td>
<td>$0.00</td>
</tr>
<tr>
<td>5. Subawards/Consortium/Contractual Costs</td>
<td>$0.00</td>
</tr>
<tr>
<td>6. Equipment or Facility Rental/User Fees</td>
<td>$0.00</td>
</tr>
<tr>
<td>7. Alterations and Renovations</td>
<td>$0.00</td>
</tr>
<tr>
<td>8. Other 1</td>
<td>$0.00</td>
</tr>
<tr>
<td>9. Other 2</td>
<td>$0.00</td>
</tr>
<tr>
<td>10. Other 3</td>
<td>$0.00</td>
</tr>
<tr>
<td>Total</td>
<td>$706,119.00</td>
</tr>
</tbody>
</table>

Numbers on this page are automatically calculated. If individual budgets are correct, the cumulative budget is correct.

- Check the #s against the **executed** Subrecipient Agreement form.
- Make sure these #s are correctly reflected on the [PAF, 3. Budget, 3.11 Subcontracts](mailto:msgrants@umich.edu), for the corresponding subcontract.
# PHS 398 Research Plan

<table>
<thead>
<tr>
<th>Section</th>
<th>File Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>Introduction.pdf</td>
</tr>
<tr>
<td>Research Plan Section</td>
<td>Specific Aims.pdf</td>
</tr>
<tr>
<td>Research Strategy</td>
<td>Research Strategy.pdf</td>
</tr>
<tr>
<td>Other Research Plan Sections</td>
<td>Vertebrate Animals.pdf</td>
</tr>
<tr>
<td>Select Agent Research</td>
<td></td>
</tr>
<tr>
<td>Multiple PD/PI Leadership Plan</td>
<td>Multiple PI Leadership Plan.pdf</td>
</tr>
<tr>
<td>Consortium/Contractual Arrangements</td>
<td>Consortium Arrangement.pdf</td>
</tr>
<tr>
<td>Letters of Support</td>
<td>LOS.pdf</td>
</tr>
<tr>
<td>Resource Sharing Plan(s)</td>
<td>Resource Sharing Plan.pdf</td>
</tr>
<tr>
<td>Authentication of Key Biological and/or Chemical Resources</td>
<td>Authentication.pdf</td>
</tr>
</tbody>
</table>

## Appendix

- **If applicable:** Required to implement Rigor and Transparency policy ([NOT-OD-16-011](#)). 1 page is recommended; [NIH FAQs](#).
- **If not applicable:** Add a brief statement indicating so.

### Eligible Appendix documents:
- Blank consent forms, blank surveys, and FOA-specified items.

### NOT-OD-18-126:
Applications will be withdrawn and not reviewed if they are submitted with appendix materials that are not specifically listed in this Notice or the FOA as allowed or required.

---

**Questions?** msgrants@umich.edu
Read the FOA; make sure the selected Institute/Center participate(s) in the funding opportunity.

Added “Rationale for assignment suggestions” text box

Do not enter names of individuals; limit your answers to expertise.
PHS Human Subjects and Clinical Trials Information

Use of Human Specimens and/or Data:

* Does any of the proposed research in the application involve human specimens and/or data? [ ] Yes [ ] No

Provide an explanation for use of human specimens and/or data to be human subjects research.

If "Yes", make sure an explanation document is uploaded.

This information is auto-populated from the R&R Other Project Information form; if editing is needed, go to Other Project Information page.

If No to Human Subjects

Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.

If Yes to Human Subjects

Add a record for each proposed Human Subject Study by selecting ‘Add New Study’ or ‘Add New Delayed Onset Study’ as appropriate. Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide the study name and a justification for omission of human subjects study information.

Other Requested Information

Study Record(s)

If human subjects are to be involved in the project, create one Study Record for each study.

Delayed Onset Study(s): Human subjects research is anticipated within the period of award but definite plans for this involvement cannot be described in the application.
PHS Human Subjects and Clinical Trials Information
Study Record, Section 1, 2

Study Record: PHS Human Subjects and Clinical Trials Information

Section 1 - Basic Information

1.1. * Study Title (each study title must be unique)
Study record for immunotherapy

1.2. * Is this Study Exempt from Federal Regulations?

1.3. Exemption Number

1.4. * Clinical Trial Questionnaire
If the answers to all four questions below are yes, this study needs to be classified as a clinical trial.
- 1.4.a. Does the study involve human participants?
- 1.4.b. Are the participants prospectively assigned to an intervention?
- 1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?
- 1.4.d. Is the effect that will be evaluated a health-related, biomedical, or behavioral outcome?

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT00000001) for this trial, if applicable.

Clinical Trial Questionnaire: If the four answers are all “Yes”, the study is deemed an NIH clinical trial.

Section 2 - Study Population Characteristics

2.1. Conditions or Focus

2.2. Eligibility Criteria
Eligibility Criteria: List inclusion and exclusion criteria as bullet points.

2.3. Inclusion of Individuals Across the Lifespan

2.4. Inclusion of Women, Minorities, and Children

2.5. Recruitment and Retention Plan

2.6. Recruitment Status

2.7. Study Timeline

2.8. Enrollment of First Participant
Renamed “Enrollment of First Subject” field to “Enrollment of First Participant”

Inclusion Enrollment Report(s)

Inclusion Enrollment Reports are required unless study is exemption 4.

Eligibility Criteria: List inclusion and exclusion criteria as bullet points.

Maximum age: If applicable, consider “No limit”, to be in line with the NIH Policy on the Inclusion of Individuals Across the Lifespan (NOT-OD-18-116).

Exclusion of any specific age group should be justified here.

Questions? msgrants@umich.edu
If U-MI RBMED is contemplated to serve as the sIRB, IRBMED must approve the request and prepare the sIRB plan for uploading in this section. Information/request forms are at https://az.research.umich.edu/medschool/guidance/multi-site-research-msr. Contact IRBMED as soon as possible for evaluation of this request (8 weeks prior to grant submission is ideal).

Answer required. N/A can only be used for studies exempt from federal regulations.

NIH: Single IRB plan no longer required. A statement naming the sIRB of record will be provided at Just-In-Time.

If not a clinical trial, you should stop here.
PHS Human Subjects and Clinical Trials Information
Study Record, Section 4, Part I

Section 4 - Protocol Synopsis

4.1. Study Design

4.1.a. Detailed Description

Renamed “Narrative Study Description” attachment to “Detailed Description”

4.1.b. Primary Purpose

Primary Purpose: If “Device Feasibility” is selected, note clinical trials for this purpose are not considered “applicable clinical trials”.

4.1.c. Interventions

Intervention: Each intervention used should be added to each record. Thus, if there are two arms with different interventions, be sure to include both.

4.1.d. Study Phase

Is this an NIH-defined Phase III clinical trial? [ ] Yes [ ] No

4.1.e. Intervention Model

4.2.f. Masking

[ ] Yes [ ] No

[ ] Participant [ ] Care Provider [ ] Investigator [ ] Outcomes Assessor

4.2.g. Allocation

4.2. Outcome Measures

Outcome Type

 Primary & Secondary: The results will be required to be reported to ClinicalTrials.gov.

 Other & Exploratory: The results are not required for reporting.

Name: Brain imaging
Type: Primary
Time Frame: Once all patients complete the book club to 2 months after the book club. The book club will last six months.
Brief Description: Brain study

4.3. Statistical Design and Analysis

4.4. Subject Participation Duration

4.5. Will the study use an FDA-regulated intervention? [ ] Yes [X] No

4.6. Will the study use an Investigational New Drug (IND)/Investigational Product (IP) and Investigational New Drug

The word “use” is approximately equivalent to “evaluate” as defined at ClinicalTrials.gov.

4.6.2. Is this an applicable clinical trial under FDAAA? [X] Yes

4.7. Dissemination Plan

Dissemination Plan: Read the SF424 instructions carefully and address all the required points. Sample language is available at the end of this checklist (last page).

4.6.3. Is this an applicable clinical trial under FDAAA? [X] Yes

Section 5 - Other Clinical Trials

5.1. Other Clinical Trials

New question and checkbox
Required Attachments in the Study Record Form

<table>
<thead>
<tr>
<th>Attachments</th>
<th>E4</th>
<th>Non-Clinical Trials</th>
<th>Clinical Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.4 Inclusion of Women, Minorities</td>
<td>Optional</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2.5 Recruitment &amp; Retention Plan</td>
<td>Optional</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2.7 Timeline</td>
<td>Optional</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>3.1 Protection of Human Subjects</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>3.2 sIRB Plan, if “Yes” to Q3.2*</td>
<td>N/A</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>3.3 Data and Safety Monitoring Plan</td>
<td>Optional</td>
<td>Optional</td>
<td>Yes</td>
</tr>
<tr>
<td>3.5 Overall Structure of the Study Team</td>
<td>Optional</td>
<td>Optional</td>
<td>Yes</td>
</tr>
<tr>
<td>4.4 Statistical Design &amp; Power</td>
<td>N/A</td>
<td>N/A</td>
<td>Yes</td>
</tr>
<tr>
<td>4.7 Dissemination Plan</td>
<td>N/A</td>
<td>N/A</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*If IRBMED is contemplated to serve as the sIRB, sIRB Plan is completed by IRBMED. Contact IRBMED [https://az.research.umich.edu/medschool/guidance/multi-site-research-msr](https://az.research.umich.edu/medschool/guidance/multi-site-research-msr) for request.

Contact Diane Wilson (dlehman@med.umich.edu) at Regulatory Affairs for questions on ClinicalTrials.gov.
PAF Summary - Print Version

<table>
<thead>
<tr>
<th>Project Title:</th>
<th>R01 - Research</th>
<th>Project Long Title:</th>
<th>On-Campus Research (2000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAF ID:</td>
<td>20-PAF0534</td>
<td>Proposal Type/Class Code:</td>
<td>Proposal/Other</td>
</tr>
</tbody>
</table>

Make sure the **Project Long Title** EXACTLY matches the title in the application on R&R Cover Page 1, item 11.

School/College Deadline: Required Medical School field. Refer to [MS deadline calculator](#).

Submission deadline: The last date by which a proposal must be submitted.

**ORSP's Proposal Submission Deadline Policy**

This section must reflect all faculty. **PLUS for sponsors following Financial Conflict of Interest (FCOI) requirements**, all Investigators (any role with the word Investigator, PD/PI, Co-I, Research Investigator, Mentor) & those listed as Key Personnel.

A Proposal Approval Form (PAF) should reflect what is being sent to the sponsor. All information on the PAF should match and reflect what is in the proposal. Even if partially completing the PAF prior to filling out the 424, a cross-check through the PAF is necessary to verify that the final information is represented.

Questions? msgrants@umich.edu
### Mandatory in the Medical School

Check against the application (R&R Other Project Information, item 1), including Yes/No answer and Approval Date (if applicable).

Check against the application (R&R Other Project Information, item 2), including Yes/No answer and Approval Date (if applicable).

Biosafety questions: Check against Project Abstract to ensure consistency.

- Include students **regardless** of whether they are receiving compensation.
- If they are funded in this project, check if this is reflected in the R&R Budget form and **Budget Justification**.
**PAF Summary - Print Version, Continued**

### LEGACY: Use of biological agents or toxin on the Federal Select Agents and Toxins list?
- **Use of infectious agents (i.e., bacteria, viruses, parasites, fungi, prions)?**  
  - **Yes**
- Use of biological toxins (i.e., toxic substances produced by bacteria, fungi, protozoa, insects, animals, or plants)?
  - **Yes**
  - The biological toxins to be used:
    - Botulinum toxin
- Are any of these biological toxins on the Federal Select Agents and Toxins List?
  - **Yes**
- Use in a UM research laboratory of human-derived substances (including cell lines, blood products, body fluids, tissues, pathology materials, organs, body parts, cadavers):  
- Use of animal-derived substances (i.e., cells, tissues, fluids from non-human primates, ruminants, swine, fowl, or any wild vertebrate animal):
  - **Yes**
  - The species of transgenic animals to be used:
    - Mouse
- Will any of the following be administered to vertebrate animals: DNA, RNA, infectious agents, biological toxins, human-derived substances (including cell lines, blood products, body fluids, tissues, pathology materials, organs, body parts, cadavers), animal-derived substances (including cells, tissues, fluids from non-human primates, ruminants, swine, fowl, or any wild vertebrate animal)?
  - **Yes**

### Check against Project Summary/Abstract in the application (R&R Other Project Information, item 7).

**Check against Project Summary/Abstract in the application (R&R Other Project Information, item 7).**

### Related IBC Applications:

**Check against Project Summary/Abstract in the application (R&R Other Project Information, item 7).**

- **Not yet submitted/Funding**
- **State**
- **PI Last Name**
- **PI Username**
- **Last Approval Date**
- **Expiration Date**
- **Related IBC Registrations:**
  - There are no items to display

**Restrictions on openness of research?**
- **No**

**Does the research project involve possible export controls or delivery of a physical item, such as a product or material, including models and prototypes?**
- **No**

**Provide further detail on the possible export controls:**

**Are there any enhanced security requirements for this project (e.g., CUI, FISMA, or classified research)?**
- **No**
  - **Please provide further detail on the security requirements:**
  - **Use of radioactive materials for (non-human) research?**
    - **No**
  - **Use of unbound engineered nanoscale particles or nanofabrication technology?**
    - **No**
  - **Are there any non-financial agreements (e.g., material transfer, data use, software license, non-disclosure, confidentiality, or teaming agreements) in place related to this proposal?**
    - **Yes**

**Related UFAs**

<table>
<thead>
<tr>
<th>ID</th>
<th>Title</th>
<th>State</th>
<th>Category</th>
<th>PI Last Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>15-UFAB00652</td>
<td>Human Carboxic Anhydrase II</td>
<td></td>
<td>Active Material Transfer Agreement</td>
<td>Piana</td>
</tr>
</tbody>
</table>

**Use of controlled substances (as defined by the federal Controlled Substances Act) or Propofol in a U-M research laboratory?**
- **No**

**Is a disclosure (e.g., technology, software, or research tool) related to this proposal on file in the Office of Technology Transfer?**
- **No**
The IDC rate should be the rate on the first day of the project.

This # is auto-populated.

Check against the application (R&R BUDGET, BUDGET PERIOD 1, Section G & H).

Click here for Space FAQs.

Quick References for UMHS Space:
- List space details (building & room); OR
- List as "Adequate Space" and for each line: Indicate Medical School or Hospital space.
  ⇒ If hospital, further list whether Hosp Clinic or Hosp Office.

Remember for Hospital/Clinic,
- CDA must approve (email or sign PAF); OR
- An authorized signer is added as an ad hoc reviewer on the PAF.
The IDC rate should be the rate on the first day of the project.

- If modular budget, each year’s exclusions should be listed in the Comments field.
- If a U-M Personnel’s project effort is concurrent with their career development award (e.g., K award), reflect the award number and end date in the Comments field.

**University Cost Sharing:** When any resources are listed in the proposal without a financial source and will be covered by U-M, they should be listed here, with the exact dollar values.

**UM Other Commitments:** When any UM resources are listed in the proposal without a specific dollar value.

**Internal UM Agreements:** When one or more unit(s) of U-M make(s) a commitment to provide a resource if the project is funded, but the arrangement is not referenced in the proposal and has not been shared with the sponsor.

**Non-UM Cost Sharing & Other Commitments:** If any non-UM organizations are listed in the proposal as providing a financial resource.
PAF Summary - Print Version, Continued

- Check amount against the application R&R BUDGET, SUBAWARD Cumulative Budget, Section K.
- Also check against the institutional Subrecipient Agreement form.
- If multiple subawards, the total costs of EACH subaward should be checked.

Not a required Medical School field; if completed, the information must match the application (R&R Budget, BUDGET PERIOD 1, Section A & B) and Budget Justification.

Since NIH applications (unless via ASSIST) are linked to PAF, proposal documents do not need to be uploaded if already in the SF424. If there are uploads, be sure to capture the most recent version of the application for consistency purposes.

The COI question must be answered.

Make sure PI has signed; if multiple PD/PIs, all the PIs must sign the PAF.
Review the details of the ORSP instructions.

For all DHHS, including NIH, applications, check “Yes”.

Add additional instructions/helpful background information for ORSP in this field. If the PD/PI is using their continuous submission eligibility, add a statement in this field.