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)
- FORMS-F changes

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.

You may wish to keep the 424 application window open. Some fields on the PAF will be compared against those in the application.
NIH Research Proposal Review Checklist

SF424 R&R Cover Page - Page 1

1. TYPE OF SUBMISSION
   - [ ] Pre-application
   - [x] Application
   - [ ] Changed/Corrected Application

2. DATE SUBMITTED
   - Applicant Identifier: 20-PAF05534

5. APPLICANT INFORMATION
   - Legal Name: Regents of the University of Michigan
   - Street 1: 3003 S. State St
   - City: Ann Arbor
   - State: MI, Michigan
   - Country: USA, UNITED STATES
   - ZIP / Postal Code: 48109-1274

9. NAME OF FEDERAL AGENCY:
   - National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:
    - 93.855

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:
    - R01 - Revalidation of Renewal, Clinical Trial, Multiple PDiPI, VA appointment, R01

12. PROPOSED PROJECT:
    - Start Date: Change Date
    - Early Start Date

- 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
- 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.
- 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).
- Verify
- 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.
- Complete. Refer to NIH Glossary for definitions.
- The Medical School checks against the PAF Project Long Title.
- Verify
- 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
Prefix: First Name: Heather
Last Name: Otthaus
Position/Title: Director
Organization Name: Regent's of the University of Michigan
Department: Research Office
Street 1: NCRC 520-5178
City: Ann Arbor
State: MI
County: USA: UNITED STATES
Country: USA
Phone Number: 734-763-4272
Email: hnnills@umich.edu
Fax Number: 

15. ESTIMATED PROJECT FUNDING
a. Total Federal Funds Requested: $3,136,729.00
b. Total Non-Federal Funds: $0.00
c. Total Federal & Non-Federal Funds: $3,136,729.00
d. Estimated Program Income: $0.00

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. I am aware of and accept the penalties. (U.S. Code, Title 42, Section 236b. I agree)

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.

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

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.

Make sure the box is checked. If non-faculty PI, assurance statement should also be signed and uploaded to the PAF.
R&R Project/Performance Site Location(s)

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

Never check this box.

Verify.

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

Work with subcontract organization(s) to ensure accuracy.

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

RESEARCH & RELATED Other Project Information

1. Are Human Subjects Involved? [ ] Yes [X] No
   1.a. If YES to Human Subjects
       Is the Project Exempt from Federal regulations? [ ] Yes [X] No
       If yes, check appropriate exemption number: 1 2 3 4 5 6 7 8
       If no, is the IRB review Pending? [ ] Yes [X] No
       IRB Approval Date: __________________________
       Human Subject Assurance Number: 00004969

2. Are Vertebrate Animals Used? [ ] Yes [X] No
   2.a. If YES to Vertebrate Animals
       Is the IACUC review Pending? [ ] Yes [X] No
       IACUC Approval Date: __________________________
       Animal Welfare Assurance Number: A3114-01

3. Is proprietary/privileged information included in the application? [ ] Yes [X] No

4. Does this Project Have an Actual or Potential impact – positive or negative on the environment? [ ] Yes [X] No

5. Is the research performance site designated, or eligible to designated, as a historic place? [ ] Yes [X] No

6. Does this project involve activities outside of the United States? [ ] Yes [X] No

7. Project Narrative
   Abstract: 30 lines or less. Narrative: 2 to 3 sentences.

8. Project Narrative
   Abstract.pdf
   Narrative.pdf

9. Bibliography & References Cited
   References.pdf

10. Facilities & Other Resources
    Facilities and Equipment available at all performance sites should be included.

11. Equipment

12. Other Attachments
    Foreign Justification.pdf

Scenarios in sections 3, 4, 5 are unusual. Contact the GS&A office for advice.

In the box below:

- If “Human Subjects” is “Yes”, this assurance number is required.
- If “Vertebrate Animals” is “Yes”, this assurance number is required.
- The Medical School checks against the PAF.
- If international collaboration, all countries must be listed.
- Abstract: 30 lines or less.
- If Yes: Upload a document titled Foreign Justification in item 12 (on this page).
- Include PMCID in citations.
**R&R Senior/Key Person Profile**

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

**PROFILE – Project Director/Principal Investigator**

- **Prefix:**
- **Last Name:**
- **Middle Name:** M
- **Suffix:**
- **Position/Title:** e.g., Professor, not Project Role (e.g., PD/PI).
- **Organization Name:**
- **City:** Ann Arbor
- **State:** MI: Michigan
- **Country:** USA: UNITED STATES
- **Phone Number:** 734-763-4272
- **E-Mail:** hmls@umich.edu
- **Credential, e.g., agency login:**
- **Project Role:** PD/PI
- **Degree Type:**
- **Degree Year:**
- **Attach Biographical Sketch:** Biosketch_Offhaus.pdf
- **Attach Current & Pending Support**

---

**PROFILE(S) Senior/Key Person 1-99**

1. **PROFILE - Senior/Key Person(s)**

<table>
<thead>
<tr>
<th>View</th>
<th>Sierra</th>
<th>Jane</th>
<th>Research Office</th>
<th>Associate PD/PI Director</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>View</th>
<th>Allen</th>
<th>Crystal</th>
<th>Pharmaceutical Professor Co-Investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

**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.
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 if estimated), then use the format below to reflect the amount and source(s).

*Budget Period Anticipated Amount ($) *Source(s)

Yes = Uncommon. If you think you may have income, contact the GS&A office.

If “Vertebrate Animals” is “Yes” on R&R Other Project Information form, this section must be answered.
PHS 398 Cover Page Supplement, Part II

3. Human Embryonic Stem Cells
*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/. 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:

Specific stem cell line cannot be referenced at this time. 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
*Does the proposed project involve human fetal tissue obtained from elective abortions? [X] Yes [ ] No

If “yes” then provide the HFT Compliance Assurance:
HFT Compliance Assurance.pdf
If “yes” then provide the HFT Sample IRB Consent Form:
HFT Sample IRB Consent Form.pdf

Required if YES. See NIH Notice NOT-OD-19-137 for HFT Clarification.

5. Inventions and Patents (RENEWAL)
*Inventions and Patents: [ ] Yes [ ] No
If the answer is “Yes” then please answer the following:

*Previously Reported: [ ] Yes [ ] No

Answer this section ONLY when Type 2 Submission, i.e.,
- Renewal or
- Resubmission of renewal.
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**

**Start Date** must be the same as that in R&R Cover Page 1, item 12.

- Only the primary applicant organization selects Project.
- Every Senior/Key personnel must have measurable effort.
- The Month field must be > 0 or Grants.gov will error. If truly no effort, use 0.01 CM.
- Base Salary must match U-M institutional base salary (not full-time rate) or NIH salary cap; OR you may leave the field blank.

**Headcount of people in each category.**

**Project Role** must EXACTLY match that in R&R Senior/Key Person Profile form.

**Any listing of effort in the Budget Justification must match.**

- 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.
### R&R Budget - Section C, D & E

<table>
<thead>
<tr>
<th>Equipment Description</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leica Fluorescence Micro</td>
<td>$10,000.00</td>
</tr>
<tr>
<td></td>
<td>Total Equipment</td>
</tr>
</tbody>
</table>

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

**Additional Equipment:**
- Be careful to specify by category (domestic vs. foreign) in budget categories and **Budget Justification**.

<table>
<thead>
<tr>
<th>travel description</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domestic</td>
<td>$3,000.00</td>
</tr>
<tr>
<td>Foreign Travel</td>
<td>$3,000.00</td>
</tr>
<tr>
<td>Total Travel Cost</td>
<td>$6,000.00</td>
</tr>
</tbody>
</table>

**E. Participant/Trainee Support Costs**
- 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 Medical 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”.

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

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

See the next page for sample calculations.

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

Make sure this field is completed.

- 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
- $10,000
- ($143,640 - $25,000)
- $0
- $13,734
- $12,000
- $0 = $289,736

Equipment
- Participant Support
Total Subcontract (after 1st $25K)
Renovations
Research Patient Care costs (Recruitment/retention fees are NOT eligible.)
Tuition
Lease
### R&R Budget - Cumulative Budget

**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>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$620,346.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total Number Other Personnel</th>
<th>10</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Total Salary, Wages and Fringe Benefits (A+B)</th>
<th>Total ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$620,346.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Section C, Equipment</th>
<th>Total ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$0.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Section D, Travel</th>
<th>Total ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domestic</td>
<td>$15,000.00</td>
</tr>
<tr>
<td>Foreign</td>
<td>$0.00</td>
</tr>
</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>
<td>$0.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Section F, Other Direct Costs</th>
<th>Total ($)</th>
</tr>
</thead>
<tbody>
<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/Use 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>
</tr>
<tr>
<td>9. Other</td>
<td>$0.00</td>
</tr>
<tr>
<td>10. Other</td>
<td>$0.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Section G, Direct Costs (A thru F)</th>
<th>Total ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$706,119.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Section H, Indirect Costs</th>
<th>Total ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$56,490.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Section I, Total Direct and Indirect Costs (G + H)</th>
<th>Total ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$762,609.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Section J, Fee</th>
<th>Total ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$0.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Section K, Total Costs and Fees (I+J)</th>
<th>Total ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$762,609.00</td>
</tr>
</tbody>
</table>

---

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.
### R&R Budget, Subaward - Section A & B

#### 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.

---

### RESEARCH & RELATED BUDGET – Budget Period 1

**ORGANIZATIONAL DUNS:** 259999779  
**Budget Type:** Subaward/Consortium  
**Expiry Date:** 10/31/2019

#### A. Senior/Key Person

<table>
<thead>
<tr>
<th>Prefix</th>
<th>First Name</th>
<th>Middle Name</th>
<th>Last Name</th>
<th>Salary ($)</th>
<th>Benefits ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crystal</td>
<td>Allen</td>
<td>Co-investigator</td>
<td>12</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
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<tr>
<td>3.</td>
<td></td>
<td></td>
<td></td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>4.</td>
<td></td>
<td></td>
<td></td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>5.</td>
<td></td>
<td></td>
<td></td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>6.</td>
<td></td>
<td></td>
<td></td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>7.</td>
<td></td>
<td></td>
<td></td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>8.</td>
<td></td>
<td></td>
<td></td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

#### 9. Total Funds requested for all Senior Key Persons in the attached file

| 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>12</td>
<td>12</td>
<td>$40,000.00</td>
<td>$12,000.00</td>
<td>$52,000.00</td>
</tr>
<tr>
<td>2</td>
<td>Lab Manager</td>
<td>9</td>
<td>9</td>
<td>9</td>
<td>$50,000.00</td>
<td>$15,000.00</td>
<td>$65,000.00</td>
</tr>
</tbody>
</table>

#### B. Other Personnel

<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>Total Number Other Personnel</td>
<td></td>
<td></td>
<td></td>
<td>$117,000.00</td>
<td></td>
<td>$117,000.00</td>
</tr>
</tbody>
</table>

**Total Salary, Wages and Fringe Benefits (A+B)**

| Total Other Personnel | $117,000.00 |

---
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**: 03/30/2022  
**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></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total funds requested for all equipment listed in the attached file</th>
<th>Total Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$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>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)</td>
</tr>
<tr>
<td>Foreign Travel Costs</td>
</tr>
</tbody>
</table>

**Total Travel Cost**

| $3,000.00 |

**E. Participant/Trainee Support Costs**

<table>
<thead>
<tr>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuition/Fees/Health Insurance</td>
</tr>
<tr>
<td>Stipends</td>
</tr>
<tr>
<td>Travel</td>
</tr>
<tr>
<td>Subsistence</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Number of Participants/Trainees</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
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**.
Numbers on this page are automatically calculated. If individual budgets are correct, the cumulative budget is correct.

R&R Budget, Subaward - Cumulative Budget

- Check the #s against the **executed** Subrecipient Agreement form.
- Make sure these #s are correctly reflected on the PAF, 3. Budget, 3.11 Subcontracts, for the corresponding subcontract.
# PHS 398 Research Plan

**Introduction**

1. Introduction to Application (for Resubmission and Revision applications)

**Research Plan Section**

2. Specific Aims

3. Research Strategy

4. Progress Report Publication List

**Other Research Plan Sections**

5. Vertebrate Animals

6. Select Agent Research

7. Multiple PD/PI Leadership Plan

8. Consortium/Contractual Arrangements

9. Letters of Support

10. Resource Sharing Plan(s)

11. Authentication of Key Biological and/or Chemical Resources

**Appendix**

12. Appendix

---

### Not Applicable

- Required if one of the following:
  - ≥ $500K (including $500K) direct costs in any year or required by FOA → Data Sharing Plan
  - Sharing Model Organisms
  - Genome Wide Association studies

### If Applicable

- Required to implement Rigor and Transparency policy ([NOT-OD-16-011](#)). 1 page is recommended. [NIH FAQs](#).

---

### 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.
**PHS Assignment Request Form**

**Funding Opportunity Number:** PA-19-055  
**Funding Opportunity Title:** Research Project Grant (Parent R01 Clinical Trial Required)

**Awarding Component Assignment Suggestions (optional)**

If you have a suggestion for an awarding component (e.g., NIH Institute/Center) assignment, use the link below to identify the appropriate short abbreviation (e.g., "NCI" for National Cancer Institute) and enter it below in the boxes for "Suggested Awarding Components". All suggestions will be considered; however, not all assignment suggestions can be honored.

Information about Awarding Component can be found here: [https://grants.nih.gov/grants/phs_assignment_information.html#AwardingComponents](https://grants.nih.gov/grants/phs_assignment_information.html#AwardingComponents)

**Suggested Awarding Components:**
- NCI
- NIA
- NIGMS

**Study Section Assignment Suggestion**

If you have a suggestion for a “Suggested Study Section” assignment, use the short abbreviation for that study section in the boxes for "Suggested Study Sections." For example, enter "CAM" for Clinical Applications and Methods, or "ZRG1HDMR" if you wish to suggest assignment to the NIH Healthcare Delivery and Methodologies SBIR/STTR panel for informatics.

Information about Study Sections can be found here: [https://grants.nih.gov/grants/phs_assignment_information.html#StudySection]

**Suggested Study Sections:**
- QBT
- GGG

**Rationale for assignment suggestions (optional)**

For assignment suggestions, provide a short rationale. Only 1000 characters allowed.

**List Individuals who should not review your application and why (optional)**

Only 1000 characters allowed.

**Identify Scientific areas of expertise needed to review your application (optional)**

*Note: Please do not provide names of individuals.*

**Expertise:**
- Only 40 characters allowed

---

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

Delayed Onset Study: 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**

<table>
<thead>
<tr>
<th>Section 1 - Basic Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1. * Study Title (each study title must be unique)</td>
</tr>
<tr>
<td>1.2. * Is this Study Exempt from Federal Regulations?</td>
</tr>
<tr>
<td>1.3. Exemption Number</td>
</tr>
<tr>
<td>1.4. * Clinical Trial Questionnaire</td>
</tr>
</tbody>
</table>

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

- **Optional:** Provide NCT for the study, if available.

<table>
<thead>
<tr>
<th>Section 2 - Study Population Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1. Conditions or Focus</td>
</tr>
<tr>
<td>2.2. Eligibility Criteria</td>
</tr>
</tbody>
</table>

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

| 2.3.1. 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 Reports are required unless study is exemption 4.**

- **Exclusion of any specific age group should be justified here.**

- **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).

- **NEW: Defaulted to Yes, since study records are only available when the answer to the “Are Human Subjects Involved?” question on the R&R Other Project Information form is Yes **

- **Inclusion Narrative:** Separated “Inclusion of Women, Minorities, and Children” attachment into two attachments – “Inclusion of Individuals Across the Lifespan” and “Inclusion of Women and Minorities”

Each **Study Title** must be unique; identical titles will cause submission errors.
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).

**STOP**

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

Name: Brain imaging
Type: Primary
Time Frame: One week before the book club to 2 months after the book club. The book club will last six months.
Brief Description: Brain study

Outcome Type
- Primary & Secondary: The results will be required to be reported to ClinicalTrials.gov.
- Other & Exploratory: The results are not required for reporting.

4.3. Statistical Design and

4.4. Subject Participation Duration

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

4.6. 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).

New question and checkbox

The word “use” is approximately equivalent to “evaluate” as defined at ClinicalTrials.gov.
## PHS Human Subjects and Clinical Trials Information
### Study Record, Section 5

### Section 5 - Other Clinical Trial-related Attachments

### 5.1. Other Clinical Trial-related Attachments

Refer to the FOA for specific instructions.

### 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>2.3.a Inclusion of Individuals Across the Lifespan</td>
<td>Optional</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<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>2.9 Inclusion Enrollment Reports</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>NIH: Not required</td>
<td>NIH: Not required</td>
</tr>
<tr>
<td></td>
<td></td>
<td>AHRQ: Required</td>
<td>AHRQ: Required</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>Optional</td>
</tr>
<tr>
<td>4.3 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>
<tr>
<td>5.1 Other Clinical Trial-related Attachments</td>
<td>N/A</td>
<td>N/A</td>
<td>Only include attachments requested in opportunity.</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 (dlehan@med.umich.edu) at Regulatory Affairs for questions on ClinicalTrials.gov.
### PAF Summary - Print Version

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

<table>
<thead>
<tr>
<th>Project Title:</th>
<th>Project Long Title:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>R01 - Research Training Grant: Predoctoral Training (Predoctoral Appointee, R&amp;R Budget, Subj, Vertebrate Animals, Human Fetal Tissue</td>
</tr>
</tbody>
</table>

**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.**
- 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**.

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

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

If “No”, provide the IBCA approval information in the next line.

<table>
<thead>
<tr>
<th>Related IBC Applications:</th>
</tr>
</thead>
<tbody>
<tr>
<td>LEGACY - Related IBC Registrations:</td>
</tr>
<tr>
<td>There are no items to display</td>
</tr>
</tbody>
</table>

| 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 |
| Please 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 |

<table>
<thead>
<tr>
<th>Related UFAs</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID</td>
</tr>
<tr>
<td>15-UFAM0482</td>
</tr>
</tbody>
</table>

Use of controlled substances (as defined by the federal Controlled Substances Act) or Propofol in a UM research laboratory? | No |
<p>| Is a disclosure (e.g., technology, software, or research tool) related to this proposal on file in the Office of Technology Transfer? | No |</p>
<table>
<thead>
<tr>
<th>Name</th>
<th>U-M Role</th>
<th>Space Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heather Offhaus</td>
<td>UM Principal Investigator</td>
<td>Adequate space, no add'l space 230037 Grant Services &amp; Analysis Medical School Space</td>
</tr>
<tr>
<td>Jane Sierra</td>
<td>UM Principal Investigator</td>
<td>Adequate space, no add'l space 230037 Grant Services &amp; Analysis Hospital Clinic Space</td>
</tr>
</tbody>
</table>

**REOUIRED SPACE NOT ASSOCIATED WITH AN INDIVIDUAL**

**Space Needed**

Or Square Feet Required: 

Comments: 

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.
• **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.

---

All institutionally signed **Subrecipient Statement of Collaborative Intent** forms are required prior to routing the PAF for review.
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.