NOTE: This is not a fillable form. Use the SF424 Form file downloaded from Grants.gov to complete an application and consult the scheme specific guidelines in the Funding Opportunity Announcement (FOA). These pages are meant to indicate where to fill in University ID's and administrative info.

Required materials will vary by scheme.

GRANTS.GOV™

Grant Application Package

Opportunity Title:	Methodology and Measurement in the Behavioral and Socia
Offering Agency:	National Institutes of Health
CFDA Number:	
CFDA Description:	
Opportunity Number:	PAR-18-352
Competition ID:	FORMS-E
Opportunity Open Date:	01/05/2018
Opportunity Close Date:	09/07/2019
Agency Contact:	eRA Service Desk Monday to Friday 7 am to 8 pm ET http://grants.nih.gov/support/

This information is automatically generated by Grants.gov

This opportunity is only open to organizations, applicants who are submitting grant applications on behalf of a company, state, local or tribal government, academia, or other type of organization.

Application Filing Name: This field is for reference only and does not impact the review process

Select Forms to Complete

Mandatory

- SF424 (R & R)
- PHS 398 Cover Page Supplement
- Research And Related Other Project Information
- Project/Performance Site Location(s)
- Research and Related Senior/Key Person Profile (Expanded)
- PHS 398 Research Plan
- PHS Human Subjects and Clinical Trials Information

Optional

- [x] Research & Related Budget — UoM projects will always use this type of Budget
- [x] R & R Subaward Budget Attachment(s) Form 5 YR 30 ATT — Select if there are subawardees and contact ric-international@unimelb.edu.au for assistance in coordinating mandatory documents
- [ ] PHS 398 Modular Budget
- [ ] PHS Assignment Request Form — Always recommended - helps get your application to the correct reviewers

Instructions

Show Instructions >>

This electronic grants application is intended to be used to apply for the specific Federal funding opportunity referenced here.

If the Federal funding opportunity listed is not the opportunity for which you want to apply, close this application package by clicking on the "Cancel" button at the top of this screen. You will then need to locate the correct Federal funding opportunity, download its application and then apply.

Do not use Pre-application unless specifically noted in FOA.

Use Application for first submission attempt for due date.

Use Changed/Corrected when submitting again to Grants.gov to correct eRA identified errors/ warnings.

OMB Number: 4040-0001
Expiration Date: 10/31/2019

APPLICATION FOR FEDERAL ASSISTANCE

SF 424 (R&R)

3. DATE RECEIVED BY STATE: Leave Blank

State Application Identifier: Leave Blank

1. TYPE OF SUBMISSION

[ ] Pre-application [X] Application [ ] Changed/Corrected Application

a. Federal Identifier: Leave Blank

b. Agency Routing Identifier: Leave Blank

2. DATE SUBMITTED: Leave Blank

Applicant Identifier: Leave Blank

c. Previous Grants.gov Tracking ID: Leave Blank

5. APPLICANT INFORMATION

Organizational DUNS: 753575117

Legal Name: The University of Melbourne

Department: Division:

Street1: 1-100 Grattan Street

Street2:

City: Parkville, Melbourne 3010 VIC County / Parish:

State: Province:

Country: AUS: AUSTRALIA ZIP / Postal Code: do not include Australia postcode here

Person to be contacted on matters involving this application

Prefix: Dr First Name: Adelene Middle Name:

Last Name: Auyong Suffix:

Position/Title: Senior Grants Officer, International Grants

Use the Administrative Contact information provided here to complete these sections

Street1: Level 4, 161 Barry Street

Street2:

City: Parkville, Melbourne 3010 VIC County / Parish:

State: Province:

Country: AUS: AUSTRALIA ZIP / Postal Code: leave blank

Phone Number: +613 90357362 Fax Number:

Email: ric-international@unimelb.edu.au

6. EMPLOYER IDENTIFICATION *(EIN) or (TIN):* 1900-00-2741-A1 must be typed, not copy and paste

7. TYPE OF APPLICANT: W: Non-domestic (non-US) Entity

Other (Specify):

Small Business Organization Type [ ] Women Owned [ ] Socially and Economically Disadvantaged

8. TYPE OF APPLICATION: See application guide for definitions.

[x] New [ ] Resubmission [ ] Renewal [ ] Continuation [ ] Revision

If Revision, mark appropriate box(es).

[ ] A. Increase Award [ ] B. Decrease Award [ ] C. Increase Duration [ ] D. Decrease Duration

[ ] E. Other (specify):

Is this application being submitted to other agencies? Yes [ ] No [x] What other Agencies?

9. NAME OF FEDERAL AGENCY: National Institutes of Health

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:

TITLE:

NIH will assign CFDA post-submission.

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

Full Title, limit 200 characters including spaces (must be the same title as Pre-Application, if there is one)

12. PROPOSED PROJECT:

Start Date: 07/01/2018 Ending Date: 06/30/2020

Dates must be formatted in USA style with start date: first of the month, end date: last of the month. Example shown

13. CONGRESSIONAL DISTRICT OF APPLICANT: 00-000

Foreign institutions are designated as District 00-000

Start date is an estimate; typically at least nine months after submission. Project period should not exceed what is allowed in announcement.

14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

Prefix: Prof First Name: Principal Middle Name:

Last Name: Investigator Suffix:

PD/PI first/last name should match name on file for Commons ID provided in the Credential field of the R&R Senior/Key Person Profile (Expanded) form.

Position/Title: Head of Department

Organization Name: The University of Melbourne

Department: Physiology Division:

Street1: 1-100 Grattan Street

Street2:

City: Parkville, Melbourne, 3010 County / Parish:

State: Province:

Country: AUS: AUSTRALIA ZIP / Postal Code: leave blank

Phone Number: +613 83447362 Fax Number:

Email: principal.investigator@unimelb.edu.au

Generally, there is one PI for USA projects (other researchers are considered "Co-Investigators")

15. ESTIMATED PROJECT FUNDING

Manually enter total figure (direct + indirect costs) from R&R budget in a. and c.

a. Total Federal Funds Requested

b. Total Non-Federal Funds

c. Total Federal & Non-Federal Funds

d. Estimated Program Income

The Budget must match the R&R numbers exactly. RIC will review this prior to submission

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES ☐ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE:

b. NO ☐ PROGRAM IS NOT COVERED BY E.O. 12372; OR

☐ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

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 also provide the required assurances * and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious. or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

For more information on the annual USA A133 Audit, contact ric-international@unimelb.edu.au

☒ **I agree**

See the NIH Grants Policy Statement for more information: https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1_public_policy_requirements_and_objectives.htm

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

18. SFLLL (Disclosure of Lobbying Activities) or other Explanatory Documentation

Add Attachment | Delete Attachment | View Attachment

19. Authorized Representative

Prefix: Dr First Name: David Middle Name:

Last Name: Robson Suffix:

Position/Title: Director, Major Initiatives, Contracts and Grants

Organization: The University of Melbourne

Department: Research, Innovation and Commercialisation Division:

Street1: Level 4, 161 Barry Street

Street2:

City: Parkville, Melbourne, 3010 County / Parish:

State: Province:

Country: AUS: AUSTRALIA ZIP / Postal Code:

Phone Number: +613 83442931 Fax Number:

Email: ric-international@unimelb.edu.au

Authorized Organization Representative (AOR) in Grants.gov must have signature authority for the organization. The electronic signature of the submitting AOR is recorded with submission.

In eRA Commons individuals with signature authority are called Signing Officials (SOs).

Signature of Authorized Representative Completed on submission to Grants.gov

Date Signed Completed on submission to Grants.gov

Cover letter is posted as a separate document in eRA Commons and is not part of the assembled application image. Content is only made available to select agency staff. Do not include assignment or review request information in your cover letter (use PHS Assignment Request Form for assignment and review information instead).

20. Pre-application Submit WORD document s to RIC to avoid submission errors — Add Attachment | Delete Attachment | View Attachment

21. Cover Letter Attachment Cover letter.pdf — Add Attachment | Delete Attachment | View Attachment

PHS 398 Cover Page Supplement

OMB Number: 0925-0001
Expiration Date: 3/31/2020

1. Vertebrate Animals Section

Are vertebrate animals euthanized? ☐ Yes ☐ No

Answer required if Vertebrate Animals Used is Yes on the R&R Other Project Information form.

Indicate appropriate answers

If "**Yes**" to euthanasia

Is method consistent with American Veterinary Medical Association (AVMA) guidelines? ☐ Yes ☐ No

If "**No**" to AVMA guidelines, describe method and provide scientific justification

Up to 1000 characters.

2. *Program Income Section

*Is program income anticipated during the periods for which the grant support is requested?

☐ Yes ☐ No

Indicate appropriate answers

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.

*Budget Period	*Anticipated Amount ($)	*Source(s)
		Up to 150 characters.

Form accommodates up to 10 budget periods. The number of program income budget periods must be less than or equal to the number of periods included in the budget form.

3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? ☐ Yes ☐ No

Indicate appropriate answers

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, 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):

Error if provided human embryonic stem cell lines are not listed at http://stemcells.nih.gov/research/registry/ at time of submission. Use NIH Registration Number (e.g., 0004, 0005). Provide up to 200 cell lines.

4. Inventions and Patents Section (for Renewal applications)

ONLY for renewals

*Inventions and Patents: Yes ☐ No ☐

If "**Yes**" then answer the following:

*Previously Reported: Yes ☐ No ☐

PHS 398 Cover Page Supplement

5. Change of Investigator/Change of Institution Section

ONLY for existing applications

☐ 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:

RESEARCH & RELATED Other Project Information

OMB Number: 4040-0001
Expiration Date: 10/31/2019

Indicate appropriate answers

If Human Subjects = Yes, additional attachments may be required on the PHS Human Subjects and Clinical Trials Information form.

1. Are Human Subjects Involved? ☐ Yes ☐ No

1.a. 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: [ ]

IRB Approval Date is not required at time of submission, but may be requested later in the pre-award process as Just-In-Time data. Date cannot be in the future.

Human Subject Assurance Number: [ ]

If Human Subjects = Yes, the Human Subject Assurance Number or the text 'None' must be provided exactly as it appears in eRA Commons institution profile.

2. Are Vertebrate Animals Used? ☐ Yes ☐ No

If Vertebrate Animals = Yes, additional attachments are required in the PHS 398 Research Plan or equivalent form.

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ☐ Yes ☐ No

IACUC Approval Date: [ ]

IACUC Approval Date is not required at time of submission, but may be requested later in the pre-award process as Just-In-Time data. Date cannot be in the future.

Animal Welfare Assurance Number: [ ]

If Vertebrate Animals = Yes, the Animal Welfare Assurance Number or the text 'None' must be provided. Type the number exactly as it appears in eRA Commons Institution Profile.

3. Is proprietary/privileged information included in the application? ☒ Yes ☐ No

4.a. Does this Project Have an Actual or Potential Impact - positive or negative - on the environment? ☐ Yes ☒ No

4.b. If yes, please explain: [ ]

If 4a is Yes, then 4b is required. Up to 55 characters.

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ☐ Yes ☐ No

4.d. If yes, please explain: [ ]

If 4c is Yes, then 4d is required. Up to 55 characters.

5. Is the research performance site designated, or eligible to be designated, as a historic place? ☐ Yes ☒ No

5.a. If yes, please explain: [ ]

If 5 is Yes, then 5a is required. Up to 55 characters.

6. Does this project involve activities outside of the United States or partnerships with international collaborators? ☒ Yes ☐ No

6.a. If yes, identify countries: Australia

If 6 is Yes, then 6a is required. Up to 55 characters.

6.b. Optional Explanation: see Foreign Justification in "Other Attachments" section 12

include Foreign Justification attachment in section 12

Up to 55 characters.

7. Project Summary/Abstract Abstract.pdf

Succinct project summary of proposed work. 30 lines or less; system will give error if over 1 page. If awarded this information becomes public. Do not include proprietary/confidential info.

8. Project Narrative Narrative.pdf

Typically 2-3 sentence statement of public health relevance; system will give error if over 1 page.

9. Bibliography & References Cited Bibliography & References Cited.pdf Add Attach

Required unless otherwise noted in opportunity.

10. Facilities & Other Resources Facilites and Other Resources.pdf Add Attachment Delete Attachment View Attachment

Required unless otherwise noted in opportunity.

11. Equipment Equipment.pdf Add Attachment Delete Attachment View Attachment

Required unless otherwise noted in opportunity.

12. Other Attachments Add Attachments Delete Attachments View Attachments ☐

Only provide Other Attachments when requested in the funding opportunity announcement text or application guide. Field accommodates multiple attachments.

NOTE: specific information for required attachments is included in the scheme specific Funding Opportunity Announcement (FOA) and may vary from one scheme to another.

Project/Performance Site Location(s)

Project/Performance Site Primary Location

☐ 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.

DO NOT check box. NIH only accepts applications from registered organizations.

Organization Name: The University of Melbou

DUNS Number: 7535751170000

DUNS required and enforced by NIH. Must be 9 or 13 digits; no letters or special characters.

* Street1:

Street2:

Include all locations including subaward(s) locations

* City: Parkville 3010

County:

* State: Victoria

Province:

* Country: AUS: AUSTRALIA

* ZIP / Postal Code: leave blank

* Project/ Performance Site Congressional District: 00-000

Project/Performance Site Location 1

☐ 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.

Organization Name:

DUNS Number:

Optional for non-primary sites. Helps facilitate application processing, so include if you have it.

* Street1:

Street2:

* City:

County:

* State:

Province:

* Country: USA: UNITED STATES

* ZIP / Postal Code:

* Project/ Performance Site Congressional District:

List all performance sites, including any foreign sites. Provide a list of resources available from each site in the Facilities and Resources attachment on the R&R Other Project Information form. Describe any consortium/contractual arrangements in the Consortium/Contractual Arrangements attachment on the PHS 398 Research Plan form or equivalent form.

Additional Location(s)

Add Attachment | Delete Attachment | View Attachment

Form accommodates up to 300 sites. Use the Additional Locations attachment to include any sites over 300. See Additional Performance Site Format page at: https://grants.nih.gov/grants/forms/additional-performance-site.htm

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

PROFILE - Project Director/Principal Investigator

Prefix: Prof * First Name: Lead Middle Name:
* Last Name: Investigator Suffix:
Position/Title: Head of Department Department: Physiology
Organization Name: The University of Melbourne
* Street1:
Street2:
* City: Parkville, Melbourne, 3010 County/ Parish: leave blank
* State: Victoria Province: leave blank
* Country: AUS: AUSTRALIA * Zip / Postal Code: leave blank
* Phone Number: +613 83440089 Fax Number:
* E-Mail: lead.investigator@unimelb.edu.au

Organization Name required by NIH for all Sr/Key entries. This information is used by NIH staff to determine potential review conflicts of interest.

VALID ERA COMMONS USERNAME MUST BE SUPPLIED. Contact PD/PI must be affiliated in Commons with applicant organization.

Credential, e.g., agency login: contact ric-international@unimelb.edu.au to create an eRA Commons account for you , if you haven't had one

*** Project Role:** PD/PI **Other Project Role Category:**

Project Role will default to PD/PI and must remain PD/PI (do not edit).

Degree Type: PhD
Degree Year: 2007

Required. Limited to 5 pages. Format page, instructions and samples: http://grants.nih.gov/grants/forms/biosketch.htm

***Attach Biographical Sketch** Biosketch_LeadInvestigator.pdf Add Attachment Delete Attachment View Attachment
Attach Current & Pending Support Add Attachment Delete Attachment View Attachment

Only provide Current & Pending Support if specifically requested in FOA. May be requested later in pre-award process as Just-In-Time data.

PROFILE - Senior/Key Person 1

Prefix: Dr * First Name: Second Middle Name:
* Last Name: Investigator Suffix:
Position/Title: Senior Research Fellow Department: Physiology
Organization Name: The University of Melbourne Division:
* Street1:
Street2:
* City: Parkville, Melbourne, 3010 County/ Parish: leave blank
* State: Victoria Province: leave blank
* Country: AUS: AUSTRALIA * Zip / Postal Code: leave blank
* Phone Number: +613 83446677 Fax Number:
* E-Mail: second.investigator@unimelb.edu.au

Organization Name required by NIH for all Sr/Key entries. This information is used by NIH staff to determine potential review conflicts of interest.

For multiple PD/PI applications, you must use the PD/PI role and provide the eRA Commons username in the Credential field for all PD/PIs. If multiple PD/PIs are included, the Multiple PD/PI Leadership Plan on the PHS 398 Research Plan form is required.

Credential, e.g., agency login:

*** Project Role:** Co-Investigator **Other Project Role Category:**

Degree Type: PhD
Degree Year: 2012

Required. Limited to 5 pages. Format page, instructions and samples: http://grants.nih.gov/grants/forms/biosketch.htm

Attach Biographical Sketch Biosketch_SecondInvestigator.pdf Add Attachment Delete Attachment View Attachment
Attach Current ent View Attachment

Use this button to add more investigators. Can collect data for 100 Sr/Key personnel (including PD/PI). Option to provide attachment for additional Sr/Key info is available after the 100 entries are made. See Additional Senior/Key Person Profiles format page at: https://grants.nih.gov/grants/forms/additional-senior-key-person-profile.htm.

Delete Entry Next Person

To ensure proper performance of this form; after adding 20 additional Senior/ Key Persons; please save your application, close the Adobe Reader, and reopen it.

Complete human subjects section of R&R Other Project Information form prior to completing this form.

PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 03/31/2020

Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.

The following items are taken from the Research & Related Other Project Information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project Information form and may impact the data items you are required to complete on this form.

Are Human Subjects Involved? ☐ Yes ☐ No

Is the Project Exempt from Federal regulations? ☐ Yes ☐ No

Exemption number: ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8

Information populated from R&R Other Project Information form.

If No to Human Subjects

Answer required and system enforced when human subjects is No.

Does the proposed research involve human specimens and/or data? ☐ Yes ☐ No

If Yes, provide an explanation of why the application does not involve human subjects research.

Required if Yes to human specimens/data question.

Add Attachment | Delete Attachment | View Attachment

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

When human subjects is No, applicants answer a single question, provide associated attachment (as applicable), and are done with the form unless instructed in announcement to include Other Requested Information attachment.

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

Add Attachment | Delete Attachment | View Attachment

Check Application Guide and opportunity instructions to determine if attachment is needed.

Click here to extract the Human Subject Study Record Attachment

Stu

Required and system enforced for each delayed onset study. Up to 600 characters. Study title must be unique within the application. First 150 characters of title will show in application bookmark.

Atta

1) Please attach Human Subject Study 1

Add Attachment | Delete Attachment | View Attachment

Delayed Onset Study(ies)

Cannot add a Delayed Onset Study if you answer No to human subjects question on R&R Other Project Information form.

Multiple delayed onset studies can be grouped in a single record.

	Study Title	Anticipated Clinical Trial?	Justification
		☐	Add Attachment | Delete Attachment | View Attachment

Required and system enforced for each delayed onset study. Up to 600 characters. Study title must be unique within the application. First 150 characters of title will show in application bookmark.

If Anticipated Clinical Trial box is checked, funding opportunity announcement must allow clinical trials. When multiple studies are included in the same delayed onset record, select Yes if it is anticipated that any study will be a clinical trial.

Required and system enforced for each delayed onset study. In addition to justification, must include information regarding how the study will comply with the NIH single Institutional Review Board (sIRB) policy prior to initiating any multi-site study, as well as, a plan for the dissemination of NIH-funded clinical trial information.

Cannot add a Study Record if you answer No to Human Subjects question on R&R Other Project Information form.

HS = Human Subjects
CT = Clinical Trials

Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 03/31/2020

* Always required field

Section 1 - Basic Information

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

Required and system enforced. Up to 600 characters. Study title must be unique within the application. First 150 characters of title will show in application bookmark.

1.2. * Is this Study Exempt from Federal Regulations? ☐ Yes ☐ No ← Answer required and system enforced.

1.3. Exemption Number ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ← If Study Exempt is Yes, must provide exemption number.

1.4. * Clinical Trial Questionnaire ← Answers to questionnaire required and system enforced.

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

1.4.a. Does the study involve human participants?	☐ Yes ☐ No	If four questions are all Yes AND FOA allows clinical trials, then study will be flagged as a Clinical Trial (CT) study.*
1.4.b. Are the participants prospectively assigned to an intervention?	☐ Yes ☐ No	
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?	☐ Yes ☐ No	
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?	☐ Yes ☐ No	

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable

Optional, provide NCT# if available. Newly proposed studies do not need to be entered in ClinicalTrials.gov at time of application.

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

Required and system enforced unless study is exemption 4. Up to 20 conditions at 255 characters each.

2.2. Eligibility Criteria

Required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

Age limits are required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

2.3. Age Limits **Minimum Age** Dropdown: Years, Months **Maximum Age** Dropdown: Years, Months, Weeks, Days, Hours, Minutes, N/A (No limit)

If "N/A (No Limit)" selected, do not provide numerical min/ max age.

2.4. Inclusion of Women, Minorities, and Children Required and system enforced unless study is exemption 4.

2.5. Recruitment and Retention Plan Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

2.6. Recruitment Status Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity. Dropdown: Not yet recruiting, Recruiting, Enrolling by invitation, Active, not recruiting, Completed, Suspended, Terminated (Halted Prematurely), Withdrawn (No Participants Enrolled)

2.7. Study Timeline Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

2.8. Enrollment of First Subject Date: MM/DD/YYYY. Dropdown: Anticipated, Actual. Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

Inclusion Enrollment Report(s)

Inclusion Enrollment Reports required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

Add Inclusion Enrollment Report

Up to 20 Inclusion Enrollment Reports can be added.

* Fellowship (F) and Career Development (K) applications to FOAs that do not allow clinical trials cannot propose independent clinical trial studies led by applicant PD/PI. However, proposing studies under the leadership of a sponsor/mentor that allows for clinical trials research experience is encouraged. Such studies must include HS information, but will receive a system error if information is included in CT study fields in sections 4 or 5 of form.

Inclusion Enrollment Report

1. * Using an Existing Dataset or Resource ☐ Yes ☐ No — Answer required and system enforced.

2. * Enrollment Location Type ☐ Domestic ☐ Foreign — Answer required and system enforced. Do not mix domestic and foreign enrollment data on the same inclusion enrollment report.

3. Enrollment Country(ies)

Multi-select from list of countries.

4. Enrollment Location(s)

5. Comments

Up to 500 characters.

Planned — Planned enrollment information is required and system enforced when answer to "Using an Existing Dataset or Resource" question is No. System enforcement relaxed if Comment is provided.

Racial Categories	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
	Female	Male	Female	Male	
American Indian/ Alaska Native	0	0	0	0	0
Asian	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	0	0	0	0	0
White	0	0	0	0	0
More than One Race	0	0	0	0	0
Total	0	0	0	0	0

Cumulative (Actual) Cumulative (Actual) enrollment information is required and system enforced when answer to "Using an Existing Dataset or Resource" question is Yes. System enforcement relaxed if Comment is provided.

Racial Categories	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			**Total**
	Female	**Male**	**Unknown/ Not Reported**	**Female**	**Male**	**Unknown/ Not Reported**	**Female**	**Male**	**Unknown/ Not Reported**	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Report 1 of 1

Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects — Required and system enforced. Add Attachment | Delete Attachment | View Attachment

3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?

☐ Yes ☐ No ☐ N/A — Answer required and system enforced. "N/A" is only a valid option for fellowship, and career development applications or if exemption 4.

If yes, describe the single IRB plan — Required and system enforced if Yes. Can attach same plan (unique filenames) in multiple studies. View Attachment

3.3. Data and Safety Monitoring Plan — Required and system enforced for CT study. Optional for HS study. View Attachment

3.4. Will a Data and Safety Monitoring Board be appointed for this study?

☐ Yes ☐ No — Answer required and system enforced for CT study unless otherwise noted in opportunity. Optional for HS study.

3.5. Overall Structure of the Study Team — Optional. Add Attachment | Delete Attachment | View Attachment

Section 4 - Protocol Synopsis — You are not allowed to complete fields in Section 4 (i.e., will receive system error) if FOA does not allow clinical trials and/or you answered No to one of the Clinical Trial Questionnaire questions in Section 1.

4.1. Brief Summary

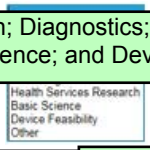
Up to 5000 characters. Required and system enforced for CT studies unless otherwise noted in opportunity.

4.2. Study Design — All Study Design fields (4.2.a thru 4.2.g) are required and system enforced for CT studies unless otherwise noted in opportunity.

4.2.a. Narrative Study Description

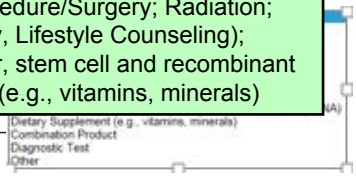
Up to 32,000 characters.

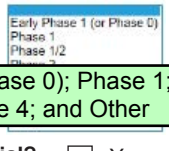
4.2.b. Primary Purpose — Dropdown list: Treatment; Prevention; Diagnostics; Supportive Care; Screening; Health Services Research; Basic Science; and Device Feasibility



4.2.c. Interventions — Up to 20 Interventions allowed.

Intervention Type	Dropdown list: Drug (including placebo); Device (including sham); Biological/Vaccine; Procedure/Surgery; Radiation; Behavioral (e.g., Psychotherapy, Lifestyle Counseling); Genetic (including gene transfer, stem cell and recombinant DNA); and Dietary Supplement (e.g., vitamins, minerals)
Name	Up to 200 characters.
Description	Up to 1,000 characters.





4.2.d. Study Phase — Dropdown list: Early Phase 1 (or Phase 0); Phase 1; Phase 1/2; Phase 2; Phase 2/3; Phase 3; Phase 4; and Other

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

4.2.e. Intervention Model — Dropdown list: Single Group; Parallel; Cross-Over; Factorial; Sequential; and Other.

4.2.f. Masking ☐ Yes ☐ No

☐ Participant ☐ Care Provider ☐ Investigator ☐ Outcomes Assessor

If Masking is Yes, you must select at least 1 of the Participant/Care Provider/Investigator/ Outcomes Assessor check boxes.

4.2.g. Allocation

Dropdown list: N/A; Randomized; and Non-randomized

Randomized
Non-randomized

4.3. Outcome Measures

At least one Outcome Measure required and system enforced for CT studies unless otherwise noted in opportunity. Up to 50 Outcome Measures allowed.

Name	Up to 255 characters.
Type	Dropdown list: Primary; Secondary; and Other
Time Frame	Up to 255 characters.
Brief Description	Up to 999 characters.

Other

4.4. Statistical Design and Power

Required and system enforced for CT study unless otherwise noted in opportunity.

dd Attachment | Delete Attachment | View Attachment

4.5. Subject Participation Duration

Up to 255 characters. Required and system enforced for CT studies unless otherwise noted in opportunity.

4.6. Will the study use an FDA-regulated intervention? ☐ Yes ☐ No

Answer required and system enforced for CT study unless otherwise noted in opportunity.

4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status

Required and system enforced if Yes.

Add Attachment | Delete Attachment | View Attachment

4.7. Dissemination Plan

Required and system enforced for CT study. Generally one Dissemination Plan per application is sufficient. Can attach same plan (unique filenames) in multiple studies.

ent

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments

Add Attachments | Delete Attachments | View Attachments

Form supports up to 10 attachments. Attachments only allowed for CT studies. Only include attachments requested in opportunity.

Optional form in most grant application packages.

PHS Assignment Request Form

OMB Number: 0925-0001
Expiration Date: 3/31/2020

The PHS Assignment Request Form will be posted as a separate document in eRA Commons and is not part of the assembled application image. Content is only made available to select agency staff.

Funding Opportunity Number:

Pre-populated from announcement information.

Funding Opportunity Title:

Awarding Component Assignment Request *(optional)*

If you have a preference for an awarding component (e.g., NIH Institute/Center) assignment, use the link below to identify the appropriate short abbreviation and enter it below. All requests will be considered; however, assignment requests cannot always be honored.

Awarding Components: https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents

	First Choice	Second Choice	Third Choice
Assign to Awarding Component:			
Do Not Assign to Awarding Component:			

Study Section Assignment Request *(optional)*

If you have a preference for study section assignment, use the link below to identify the appropriate study section (e.g., NIH Scientific Review Group or Special Emphasis Panel) and enter it below. Remove all hyphens, parentheses, and spaces. All requests will be considered; however, assignment requests cannot always be honored.

Study Sections: https://grants.nih.gov/grants/phs_assignment_information.htm#StudySection

	First Choice	Second Choice	Third Choice
Assign to Study Section: *Only 20 characters allowed*			
Do Not Assign to Study Section: *Only 20 characters allowed*			

PHS Assignment Request Form

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

	1	2	3	4	5
Expertise: *Only 40 characters allowed*					

Use the budget workbook provided by RIC to assist with calculating R&R Budget

Provide DUNS for the organization whose budget is reflected on this form.

RESEARCH & RELATED BUDGET - Budget Period 1

OMB Number: 4040-0001
Expiration Date: 10/31/2019

ORGANIZATIONAL DUNS: 7535751170000 **Enter name of Organization:** The University of Melbourne

Budget Type: [X] Project [ ] Subaward/Consortium **Budget Period: 1** **Start Date:** 09/01/2018 **End Date:** 08/30/2021

date must be the same as on page 1

Only the primary applicant organization should use Budget Type of Project.

A. Senior/Key Person

PD/PI must be listed as a Sr/Key with measurable effort in every budget period.

Every Sr/Key listed must have measurable effort in either Calendar Months

Prefix	First	Middle	Last	Suffix	Base Salary ($)	Months Cal.	Months Acad.	Months Sum.	Requested Salary ($)	Fringe Benefits ($)	Funds Requested ($)
Prof	Lead		Investigator		183,300.00	2.40			36,660.00	5,316.00	41,976.00

this is just an example for your reference

Project Role: PD/PI

Role must be PD/PI for the PD/PI (enter carefully eRA will look for exact string match to PD/PI).

Additional Senior Key Persons: Add Attachment | Delete Attachment | View Attachment

If more than 8 Sr/Key, use attachment and enter total funds requested for additional Sr/Key persons.

Total Funds requested for all Senior Key Persons in the attached file:

Total Senior/Key Person: 41,976.00

B. Other Personnel

Aggregate information should be provided in section B and explained in Budget Justification.

This is just an example for your reference

Number of Personnel	Project Role	Months Cal.	Months Acad.	Months Sum.	Requested Salary ($)	Fringe Benefits ($)	Funds Requested ($)
1	Post Doctoral Associates	6.00			44,139.00	6,400.00	50,539.00
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						

You can name up to 6 additional Project Role categories. Once data for the first user-defined Project Role is entered, you will have the option to add another. If you run out of additional categories combine categories in a single row and explain what was included in the Budget Justification.

Total Number Other Personnel

Total Other Personnel

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

C. Equipment Description

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

Equipment item		Funds Requested ($)

Once equipment data is entered, you will be able to add up to 9 more rows to this section for a total of 10 equipment items.

Items with unit price over $5,000; everything else is listed under "Materials and Supplies"

Ensure that each piece of equipment is explained in Budget Justification document

Additional Equipment: Add Attachment | Delete Attachment | View Attachment

Total funds requested for all equipment listed in the attached file

Total Equipment

D. Travel

		Funds Requested ($)
1.	Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	
2.	Foreign Travel Costs	
	Total Travel Cost	

E. Participant/Trainee Support Costs

Only complete this section if requested to do so in the funding opportunity announcement.

		Funds Requested ($)
1.	Tuition/Fees/Health Insurance	
2.	Stipends	
3.	Travel	
4.	Subsistence	
5.	Other	
	Number of Participants/Trainees / **Total Participant/Trainee Support Costs**	

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 Expenses" is a common description for minor costs that do not justify a line item	
9.		
10.		
	Total Other Direct Costs	

Subaward/Consortium/Contractual Costs are not pre-populated. Include both Direct and Indirect costs.

The *de minimis* indirect cost rate is applied to Modified Total Direct Costs (MTDC). MTDC means all direct salaries and wages, applicable fringe benefits, materials and supplies, services, travel, and up to the first $25,000 of each subaward (regardless of the period of performance of the subawards under the award).
MTDC excludes equipment, capital expenditures, charges for patient care, rental costs, tuition remission, scholarships and fellowships, participant support costs and the portion of each subaward in excess of $25,000.

Summary:
Direct cost minus Equipment, minus Subawards total & add $25,000 from each subaward (value is added manually)

G. Direct Costs

	Funds Requested ($)
Total Direct Costs (A thru F)	

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	Funds Requested ($)
F&A rate allowable to Foreign Institutions	8.00		

Department and RIC offices will review this section H

Indirect cost for foreign entity without negotiated indirect cost research agreement (NICRA) is:
8% for NIH
10% for DoD and all other agencies

Total Indirect Costs	

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

Entities with negotiated rate agreement (NICRA) will need to complete this section on their budget form

I. Total Direct and Indirect Costs

	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	

J. Fee

	Funds Requested ($)

K. Total Costs and Fee

	Funds Requested ($)
Total Costs and Fee (I + J)	

L. Budget Justification

(Only attach one file.) Budget Justification.pdf [Add Attachment] [Delete Attachment] [View Attachment]

Budget Justification is required and must cover all budget periods.

Subawards submit separate Budget Justfications and attach to the respective Budget Period 1 document

Click "Add Period" button to enter budget costs for Budget Period 2,3 and so forth. Enter the appropriate "start/end date" for the respective Budget Periods

RESEARCH & RELATED BUDGET - Cumulative Budget

Cumulative Budget is system generated based on budget period data provided.

		Totals ($)
Section A, Senior/Key Person		
Section B, Other Personnel		
Total Number Other Personnel		
Total Salary, Wages and Fringe Benefits (A+B)		
Section C, Equipment		
Section D, Travel		
1. Domestic		
2. Foreign		
Section E, Participant/Trainee Support Costs		
1. Tuition/Fees/Health Insurance		
2. Stipends		
3. Travel		
4. Subsistence		
5. Other		
6. Number of Participants/Trainees		
Section F, Other Direct Costs		
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 1		
9. Other 2		
10. Other 3		
Section G, Direct Costs (A thru F)		
Section H, Indirect Costs		
Section I, Total Direct and Indirect Costs (G + H)		
Section J, Fee		
Section K, Total Costs and Fee (I + J)		

The actual look of this form will vary based on your submission method. The Grants.gov downloadable form version is shown here. In ASSIST, use the Add Optional Form option to add the R&R Subaward Budget tab to your application.

OMB Number: 4040-0001
Expiration Date: 10/31/2019

R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

Instructions: On this form, you will attach the R&R Subaward Budget files for your grant application. Complete the subawardee budget(s) in accordance with the R&R budget instructions. Please remember that any files you attach must be a PDF document.

Click here to extract the R&R Subaward Budget Attachment

Always retrieve and circulate subaward budget template from the respective FOA provided.
Completed Subaward R&R Budget and Budget Justification provided by subawardee is to be attached separately for each Subawardee.

Important: Please attach your subawardee budget file(s) with the file name of the subawardee organization. Each file name must be unique.

The sum of all subaward budgets (e.g., those attached separately on this form and those provided as part of the budget justification), must be included in Line F.5 Subawards/Consortium/ Contractual Costs of the parent budget.

If submitting an application with >30 subaward budgets, budgets 31 and above should be converted to PDF and included as part of the Budget Justification of the parent budget in Section K of the R&R Budget form. This form should only be used in conjunction with the R&R Budget form.

Do not include the Subaward Budget Attachment form with applications that use the PHS 398 Modular Budget form.

1) Please attach Attachment 1	SubawardName1.pdf	Add Attachment	Delete Attachment	View Attachment
2) Please attach Attachment 2	SubawardName2.pdf	Add Attachment	Delete Attachment	View Attachment
3) Please attach Attachment 3		Add Attachment	Delete Attachment	View Attachment
4) Please attach Atta				Attachment
5) Please attach Atta				Attachment
6) Please attach Atta				Attachment
7) Please attach Atta				Attachment
8) Please attach Atta				Attachment
9) Please attach Atta				Attachment
10) Please attach Att				Attachment
11) Please attach Attachment 11		Add Attachment	Delete Attachment	View Attachment
12) Please attach Attachment 12		Add Attachment	Delete Attachment	View Attachment
13) Please attach Attachment 13		Add Attachment	Delete Attachment	View Attachment
14) Please attach Attachment 14		Add Attachment	Delete Attachment	View Attachment
15) Please attach Attachment 15		Add Attachment	Delete Attachment	View Attachment
16) Please attach Attachment 16		Add Attachment	Delete Attachment	View Attachment
17) Please attach Attachment 17		Add Attachment	Delete Attachment	View Attachment
18) Please attach Attachment 18		Add Attachment	Delete Attachment	View Attachment
19) Please attach Attachment 19		Add Attachment	Delete Attachment	View Attachment
20) Please attach Attachment 20		Add Attachment	Delete Attachment	View Attachment
21) Please attach Attachment 21		Add Attachment	Delete Attachment	View Attachment
22) Please attach Attachment 22		Add Attachment	Delete Attachment	View Attachment
23) Please attach Attachment 23		Add Attachment	Delete Attachment	View Attachment
24) Please attach Attachment 24		Add Attachment	Delete Attachment	View Attachment
25) Please attach Attachment 25		Add Attachment	Delete Attachment	View Attachment
26) Please attach Attachment 26		Add Attachment	Delete Attachment	View Attachment
27) Please attach Attachment 27		Add Attachment	Delete Attachment	View Attachment
28) Please attach Attachment 28		Add Attachment	Delete Attachment	View Attachment
29) Please attach Attachment 29		Add Attachment	Delete Attachment	View Attachment
30) Please attach Attachment 30		Add Attachment	Delete Attachment	View Attachment

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 3/31/2020

Introduction

1. Introduction to Application (for Resubmission and Revision applications)		Limited to 1 page (except R25 Resubmission can be 3 pages).

Research Plan Section

2. Specific Aims	Specific Aims.pdf	Required attachment. Limited to 1 page.
3. *Research Strategy	Research Strategy.pdf	Adhere to page limits specified in Application Guide and/or FOA. Typically 6 or 12 pages; a small number of FOAs will specify 30 pages.
4. Progress Report Publication List		

Other Research Plan Section

5. Vertebrate Animals	Verterbrate Animals.pdf	Required for all apps. (except S10), if Vertebrate Animals is Yes on the Other Project Information form.
6. Select Agent Research		Add Attachment / Delete Attachment / View Attachment
7. Multiple PD/PI Leadership Plan	Multiple PD/PI Plan.pdf	Required if more than one PD/PI is specified on R&R Sr/Key Person Profile form.
8. Consortium/Contractual Arrangements		Add Attachment / Delete Attachment / View Attachment
9. Letters of Support	Letters of Support.pdf	Required for applications.
10. Resource Sharing Plan(s)	Resource Sharing Plans.pdf	Add Attachment / Delete Attachment / View Attachment
11. Authentication of Key Biological and/or Chemical Resources	Biological Resources.pdf	Required if project involves key biological and/or chemical resources. Recommend 1 page.

Appendix

12. Appendix — Add Attachments / Delete Attachments / View Attachments

DO NOT use Appendix attachments to circumvent page limits in other sections of the application. Applications will be withdrawn and not reviewed if they are submitted with appendix material that are not specifically listed in notice NOT-OD-17-098 or the FOA as allowed or required.

Allows for up to 10 appendices. See Application Guide and announcement for restrictions.

Appendices are stored separately in the eRA Commons (not as part of the application image) and are accessible to appropriate agency staff and peer reviewers.