How to Complete an NIH Application

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International Grants Team
Research Grant and Contract Services
Research Innovation and Commercialisation
To begin with, I’d like to acknowledge that I am on the lands of the Wurundjeri people (with others joining us from other lands) who have been custodians of this land for thousands of years, and acknowledge and pay my respects to their Elders past and present.
Information Session Overview

• Key resources to know
• What’s involved in an application
  - ‘Core’ documents
  - What’s needed when working with collaborating organisations?
  - Additional application sections
  - Human subjects research sections
• The application portal
• Application tips
• Questions
<table>
<thead>
<tr>
<th>Key Resources</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH’s <em>How to Apply</em> website</td>
<td>• A complete guide on what’s needed to prepare an application (link <a href="#">here</a>)</td>
</tr>
<tr>
<td>Funding opportunity announcement</td>
<td>• May include changes needed from standard NIH application instructions</td>
</tr>
</tbody>
</table>
| NIAID’s *Apply for a Grant* website | • Overviews of how to prepare different sections (link [here](#))  
• Example applications and how they were reviewed (known as summary statements) |
| University of Melbourne Grants Library | • Successful NIH applications from the University (link [here](#)) |
| International Grants team | • Help in finding opportunities, preparing for and submitting applications  
• Recorded information sessions (link [here](#)):  
  - Introduction to the NIH  
  - Budget information session |
Format attachments:

- Documents are to be submitted as PDFs
- Page size: US letter size (8.5x11”)
- Margins: 0.5”
- Minimum font size: 11
- Reference style: Not specified
- Limit hyperlinks to only US government websites (e.g. NCBI)

### Application Form Instructions

<table>
<thead>
<tr>
<th>Application Instructions</th>
<th>Description</th>
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<tbody>
<tr>
<td>G General Instructions</td>
<td>Comprehensive guidance for research, training, fellowship, career development, multi-project, and small business applications</td>
</tr>
</tbody>
</table>

### Filtered Application Instructions

<table>
<thead>
<tr>
<th>Research Instructions</th>
<th>Guidance for research only</th>
</tr>
</thead>
</table>

- Which sections will need to be completed?
- What’s required in these?
- Links to further information

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/research-forms-g.pdf
Key Resources: Funding Opportunity Announcement

Is the Institute I’m interested in participating in this call?

NATIONAL INSTITUTES OF HEALTH (NIH)
National Eye Institute (NEI)
National Heart, Lung, and Blood Institute (NHLBI)
National Human Genome Research Institute (NHGRI)
National Institute on Aging (NIA)

Are we eligible to apply?

Foreign Institutions
Non-domestic (non-U.S.) Entities (Foreign Institutions) are eligible to apply.
Non-domestic (non-U.S.) components of U.S. Organizations are eligible to apply.
Foreign components, as defined in the NIH Grants Policy Statement, are allowed.

Can a clinical trial be supported through this call?

Clinical Trial?
Not Allowed. Only accepting applications that do not propose clinical trials. Need help determining whether you are doing a clinical trial?

When can we apply?

Application Due Date(s)
Standard dates apply.
The first application due date for this FOA is June 5, 2020.
All applications are due by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on the listed date(s).

Expiration Date
May 08, 2023
Key Resources: Funding Opportunity Announcement

Funding and project period

| Funds Available and Anticipated Number of Awards | The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications. |
| Award Budget | Application budgets are not limited but need to reflect the actual needs of the proposed project. |
| Award Project Period | The scope of the proposed project should determine the project period. The maximum project period is 5 years. |

Requests of $500,000 or more for direct costs in any year

Applicants requesting $500,000 or more in direct costs in any year (excluding consortium F&A) must contact a Scientific/Research Contact at least 5 weeks before submitting the application and follow the Policy on the Acceptance for Review of Unsolicited Applications that Request $500,000 or More in Direct Costs as described in the SF424 (R&R) Application Guide.

Who can we discuss the application with?

Scientific/Research Contact(s)
Diane Lawrence, Ph.D.
National Institute of Allergy and Infectious Diseases (NIAID)
Telephone: 240-627-3320
Email: lawrenceci@niaid.nih.gov

Are there specific instructions for the call of interest?

R&R Subaward Budget
All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement
All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan
All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

The following modifications also apply:

- All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.
‘Core’ Documents

**Project**
- Research Strategy (6 pages for R03 or R21, 12 pages for R01)
- Specific Aims (1 page)
- Project Summary/Abstract (30 lines of text)
- Project Narrative (3 sentences)
- Bibliography & References Cited

**Project Finances**
- Budget (template provided)
- Budget Justification

**Personnel and Environment**
- Biosketches (5 page limit)
- Facilities & Other Resources
- Equipment
- Foreign Justification
Specific Aims

In one page:

- Concisely state the goals of the project
- Summarise the expected outcomes, including the impact of the work on the field
- State what the objective(s) of the research are, such as:
  - Test a stated hypothesis
  - Create a novel design
  - Solve a specific problem
  - Address a critical barrier to progress in the field
  - Develop new technology

[Image of a diagram depicting antigen presentation and MHC complexes]

https://www.niaid.nih.gov/grants-contracts/draft-specific-aims
Research Strategy

Page limit:
- 6 pages for R03 and R21 applications
- 12 pages for R01 applications

Structure using the following headings:
- Significance
- Innovation
- Approach
Biosketches

To be completed by all senior/key personnel, who are:

* Individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation

<table>
<thead>
<tr>
<th>Form Name</th>
<th>Biographical Sketch Format Page (non-fellowship) - Due Dates on or after January 25, 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>Prepare biographical sketches for applications and progress reports for all applications and awards, except fellowships.</td>
</tr>
<tr>
<td>How to Access</td>
<td>Non-fellowship Biosketch [blank format page, Word]</td>
</tr>
<tr>
<td>Instructions</td>
<td>The format page should be submitted as an attachment in grant applications and progress reports.</td>
</tr>
</tbody>
</table>

Instructions for Biographical Sketch

- Biographical Sketch topic page
- SAMPLE: Non-fellowship biosketch (Word)
- FAQs
- Learn whether a particular activity should be reported in the biosketch, other support, or annual progress reports: NIH Pre-award and Post-award Disclosures Relating to the Biographical Sketch and Other Support (PDF)
- Format Attachments (fonts, margins, page limits, etc.)
- Related Topics:
  - Other Support topic page
  - Annual Progress Reports (RPPR)

Try SciENev to help you develop your biosketch and automatically format it according to NIH requirements. Reflects removal of Section D per NOT-OD-21-073 first guide notice.

Information on who are senior/key personnel: https://grants.nih.gov/faqs#/senior-key-personnel.htm?anchor=question51335
Details on biosketches: https://grants.nih.gov/grants/forms/biosketch.htm
Biosketches

Page limit: Five pages

Sections:

General information

A. Personal Statement

Describe your scientific background
Can include ROPE information

NAME: Hunt, Morgan Casey

eRA COMMONS USER NAME (credential, e.g., agency login): huntmo!

POSITION TITLE: Associate Professor of Psychology

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

<table>
<thead>
<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE (if applicable)</th>
<th>Completion Date MM/YYYY</th>
<th>FIELD OF STUDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of California, Berkeley</td>
<td>BS</td>
<td>05/2003</td>
<td>Psychology</td>
</tr>
<tr>
<td>University of Vermont</td>
<td>PHD</td>
<td>05/2009</td>
<td>Experimental Psychology</td>
</tr>
<tr>
<td>University of California, Berkeley</td>
<td>Postdoctoral</td>
<td>08/2013</td>
<td>Public Health and Epidemiology</td>
</tr>
</tbody>
</table>

A. Personal Statement

I am an Associate Professor of Psychology, and my research is focused on neuropsychological changes associated with substance use disorders. I have a broad background in psychology, with specific training and expertise in ethnographic and survey research and secondary data analysis on psychological aspects of substance use disorders. As PI or co-investigator on several university- and NIH-funded grants, I led the groundwork for the proposed research by developing effective measures of disability, depression, and other psychological factors relevant to older people with substance use disorders, and by establishing strong ties with community partners that will make it possible to recruit and track participants over time as documented in the following publications. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and procured several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work. During 2015-2016, my career was disrupted due to family obligations. However, upon returning to the field, I immediately resumed my research projects and collaborations and successfully competed for NIH support. In summary, I have the expertise, leadership, training, and motivation necessary to successfully carry out the proposed research project.

Ongoing and recently completed projects that I would like to highlight include:

R01 DA042267
Hunt (PI)
09/01/16-08/31/21
Health trajectories and behavioral interventions among older people with substance use disorders

R01 MH022721
Meryle (PI), Role: co-investigator
12/15/17-11/30/22
Physical disability, depression, and substance use among older adults
B. Positions, Scientific Appointments and Honors
Start with the most recent items

C. Contributions to Science
List up to five contributions.
Up to four publications may be referenced for each contribution.
**Project Summary/Abstract**

Limit of 30 lines of text

In this section:

- State the broad, long-term objectives and aims of the project
- Refer to the relevance of the agency’s mission
- Describe the research design and how you will achieve the goals

<table>
<thead>
<tr>
<th>SUMMARY</th>
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<tbody>
<tr>
<td>Mucosal Associated Invariant T (MAIT) cells comprise up to 10% of human peripheral blood T cells, and are enriched in the liver, lungs and gastrointestinal mucosa. This indicates that MAIT cells are key players in immunity. However, their roles in immune protection, and in immunopathology are yet to be fully established. Nevertheless, MAIT cells are implicated in chronic inflammatory diseases including tuberculosis, peptic ulceration, periodontal disease and inflammatory bowel disease. Central to the function of MAIT cells is the MAIT T cell antigen receptor (TCR). Consistent with their innate-like phenotype, MAIT cells express a very restricted T cell repertoire. Namely, human MAIT cells are characterized by an invariant TCR α-chain (TRAJ1-2-TRAJ33) paired with a limited array of TCR β-chains (TRBV6 or TRBV20). The MAIT TCR is restricted to the monomorphic Major Histocompatibility Complex class I related protein, MR1. A very high level of conservation of MR1 in mammals and the restricted MAIT TCR usage strongly indicate an important and evolutionarily conserved function for the MAIT TCR-MR1 axis in immunity. Based on our previous work and preliminary findings, we aim to: (i) Investigate novel MAIT cell antigens and their impact on MAIT TCR diversity; (ii) Define the cellular machinery involved in acquisition and presentation of MR1 antigens; (iii) Investigate the structural basis of MAIT cell antigen potency and selectivity. Our proposed studies will advance our understanding of MR1 presentation and subsequent recognition by the MAIT TCR, which is a fundamental precursor for harnessing MAIT cells for future immunotherapeutics.</td>
</tr>
</tbody>
</table>
Project Narrative

• Limit of three sentences
• Describe how the research will contribute to
  - The fundamental understanding of the nature and behaviour of living systems, and/or
  - How it may be applied to enhance health outcomes

PROJECT NARRATIVE

The increasing incidence of Alzheimer’s disease and related dementias, presents a massive global health challenge requiring a committed response from researchers, clinicians and funding entities. This application will leverage the power of five leading well characterized Alzheimer’s cohorts to clarify risk and protective factors for Alzheimer’s dementia: the Adult Children Study (ACS), the Alzheimer’s Disease Neuroimaging Initiative (ADNI), the Australian Imaging, Biomarkers and Lifestyle Flagship Study of Ageing (AIBL), the Dominantly Inherited Alzheimer Network (DIAN) and the National Alzheimer’s Coordinating Center (NACC). The study will focus on the effects that an individual’s demographic profile, genotype and comorbidities have on the risk and severity of Alzheimer’s dementia.
Bibliography & References Cited

- Provide a concise list of publications cited in the application
- Note that there isn’t a preferred referencing style
Facilities and Other Resources

• No page limit

• Describe how the scientific environment where the research will be done contributes to the probability of success of the project

• This could include institutional support, physical resources etc.
Equipment

- No page limit
- List major items of equipment already available for the project and identify their capabilities in performing the research

- Flow Cytometry: Flow cytometry is routinely used in the diagnosis of health disorders, especially blood cancers, but has many other applications in basic research, clinical practice and clinical trials. A common variation is to physically sort particles based on their properties, so as to purify populations of interest. The Doherty Institute houses the ImmunolD facility, a purpose-built facility that provides researchers with a world-class Flow Cytometry resource. Equipped with the latest high-end instrumentation it also forms part of the Melbourne Cytometry Platform, providing a resource for the University of Melbourne and broader scientific community in and around Melbourne. The flow Cytometry Platform houses one PC3 high-speed sorter (Aria Fusion), two PC2 sorters (FACS Aria III and MoFlo Astrios) and five analysers (3 x Cytek Aurora, 4x LSR Fortessa, 2x FACS Calibur, 2x FACS Canto II and LSR II). FACs Calibur for cell analysis and a MoFlo Astrios for cell sorting.

- Electron Microscopy: The Doherty Institute houses a Tecnai G2 Spirit Transmission Electron Microscope (TEM), specifically designed for life sciences, allowing atomic-level investigations in cell biology, structural biology, soft matter, (bio)-nanotechnology, and high resolution imaging of microbes such as bacteria and viruses. The Doherty's TEM is part of an Electron Microscopy platform within the Parkville precinct that combines instrumentation of the Doherty Institute, Bio21 Molecular Science and Biotechnology Institute, and the School of Botany and operates under the umbrella of the University of Melbourne's Advanced Microscopy Facility.

- Imaging: The Doherty Institute is equipped with state-of-the-art imaging equipment for PC2 and PC3 applications and is part of the Biological Optical Microscopy Platform (BOMP). The BOMP is a 3-microscope lab capable of epifluorescent & light microscopy with two cameras available for image acquisition, two Zeiss confocal microscopes, one of which has an incubation chamber for live cell imaging. The institute also houses a Zeiss 710 2-photon/confocal microscope within the multiphoton facility, which is designed to facilitate intravital imaging of mouse tissues and organs and have significantly expanded the possibilities for research in microbiology and the immune system. Also available to all Doherty Institute staff via the BOMP network, and located in the Bio21 Institute, is super resolution imaging platforms including 3D-Structured Illumination Microscopy (3D-SIM) and Localization microscopy (PALM, STORM). Three high-performance imaging computers are available for image analysis on your images, as well as facilities for sectioning of both fresh and frozen tissue for imaging.

- Mass Spectrometry: The Mass Spectrometry and Proteomics Facility is housed at the Bio21 Molecular Science and Biotechnology Institute, which is located less than 1 mile from the Doherty Institute and are accessed through Departmental access agreement. The Facility has 2 x Thermo NanoLC/Orbitrap Fusion Lumos, 2 x Thermo Q Exactive Plus Mass spectrometers, Thermo NanoLC/Orbitrap Elite ETD mass spectrometer, Thermo Orbitrap Fusion, 2 x Agilent 6220 LC/ESI-TOF mass spectrometers, AB SCIEX 5500 NanoLC/QTAP Mass spectrometer, Bruker Microflex MALDI-TOF Mass spectrometer, Shimadzu UHPLC 8060 QQQ, Four Agilent HPLC systems for sample preparation, as well as a range of general equipment for use.

- Metabolomics Australia: Metabolomics Australia (MA) provides researchers with access to world-class expertise, analytical technologies and bioinformatics for metabolomics analyses. Based within the Bio21 Institute, MA uses cutting-edge technologies and high-throughput analytics for the detection and quantification of metabolites in biological systems.
Foreign Justification

• No page limit

• Outline special resources or characteristics of the project, highlighting why the University will be better placed to carry out this research than a US organisation.

• This could include unique:
  - Expertise
  - Collaborations
  - Human subjects/specimens
  - Animals
  - Disease
  - Equipment
  - Techniques

FOREIGN JUSTIFICATION

The major part of this program of research will be conducted in Australia for a number of key reasons:

1. The Australian investigators have unique expertise and track record in this field. The concept of pre-psychotic intervention for young people in the earliest clinical stages of disorder was originally formulated in Australia by our group in the early 1990s, along with the criteria and related assessment tools to define and measure the syndrome which was associated with a substantial increase in risk for progression to full threshold psychosis. We have been the innovation drivers conceptually and in terms of instrument development and predictive modelling. We have provided care for thousands of patients meeting these Clinical High Risk criteria over two and a half decades and have conducted long term cohort studies, neurobiological research and 5 clinical trials in this population, including a large (n=304) international multicenter trial of omega-3 polyunsaturated fatty acids (PUFA) and a recent NIH-funded sequential multiple assignment randomized trial (SMART) of psychosocial and pharmacological interventions, the largest in the field to date (n=342).

2. Since 2006, Australia has invested heavily in a new model of youth mental care for young people aged 12 – 25 years, developed and implemented by our group of investigators and clinical leaders, which allows us to recruit large numbers of CHR youth. Branded as “headspace”, this is a one stop shop, enhanced primary care model which has already provided stigma-free multidisciplinary care to over 524,000 young Australians through 110 centers. Headspace, the home base for the headspace Clinical Trial Network (CTN) which conducted the CHR concept and has led Australian research in this field, directly operates 5 headspace services in its local region of Northwestern Melbourne, and these services, which are fully integrated with Orygen’s specialist early intervention services, collectively provide access to care for over 5000 young people and their families annually. We know from recent studies (see Research Plan) that ~30% of the patients attending headspace clinics meet CHR criteria. In addition, Australia has a national platform of early psychosis clinics, the government funded headspace Youth Early Psychosis Program (n=342). The research team advocated for and designed these services and have a role mandated by the Federal Government in overseeing their work as well as ensuring they deliver services with high fidelity to the model developed by Orygen. In 2015, Orygen established the Australian Early Psychosis Research Network as a collaborative venture linked to the development of the nYEPF services. In 2019, the Australian Early Psychosis Collaborative Consortium (AEPCC) was established, with funding support from the Wellcome Trust, introducing a national platform for a Clinical Registry (CR) and Clinical Trial and Translation Network (CTTN) across early psychosis clinics. The research team has access to this entire clinical infrastructure for the current program of work (see Research Plan). Orygen, through Orygen, the nation’s largest mental health research institute and National Centre for Excellence in Youth Mental Health, is therefore uniquely placed and experienced to rapidly recruit and reliably conduct large scale cohort studies in this clinical population and translate resulting knowledge into frontline real-world settings. Notably, the clinical infrastructure spans both primary and specialist service settings so risk calculators that emerge from the program of work can be calibrated for service setting, which would not be possible in many other jurisdictions. For example, US CHR research is based primarily on studies in specialist research clinics with small, highly selected samples and may therefore be less representative of the CHR phenotype, limiting generalizability, external validity and the potential for clinical translation. Although different CHR identification instruments are commonly used in Australia compared to the US (CAARMS vs SIPS) these instruments have been found to be highly comparable in identification of CHR patients (see Research Plan).

3. We are able to recruit larger numbers of CHR participants and more rapidly than any existing US research group or network. While other centers in North America, Europe and Asia have conducted important research in the same CHR population, including multicenter studies, it has proven and will continue to be difficult to recruit large sample sizes which are essential for the type of research intended for support under the current RFA for extensive networks of sites for rapid recruitment of large CHR samples. We have the strongest international track record of CHR recruitment and coordination and have the strongest and proven international collaborative relationships already in place.

4. Drug naïveté, standardized treatment and epidemiological representativeness:
   a) Current US clinical practices in many communities result in CHR youth being exposed to multiple treatments prior to enrolling in cohort studies and clinical trials. The NIMH-funded NAPLS project, for example, which has successfully studied cohorts of CHR patients from a predictive standpoint and has conducted one clinical trial of
Please note that detailed budget information is available on the recorded US budgets information session on the Research Gateway.
Budget Justification

• No page limit

• Provide a justification for each budget category where funds are being requested.

• Address multiple years under each category
What if I have collaborators from other organisations?

Discuss with the International Grants team as early as possible

Documents to include in the application

- Biosketches
- Facilities & Other Resources
- Equipment
- Budget and Budget Justification
- Foreign Justification
- Consortium/Contractual Arrangements
- Letters of Support

Compliance document (not for submission in the application)

- Subrecipient commitment form
Example text is shown below:

Should the proposed research be funded, consortium arrangements will be executed between the University of Melbourne and [insert the name(s) of collaborating organization(s) here].

The appropriate programmatic and administrative personnel at each site are aware of the agency’s consortium agreement policy and are prepared to establish the necessary inter-organizational agreements consistent with that policy.
Letters of Support

Letters can be included to demonstrate support for the project from participants such as senior/key personnel, other significant contributors and consultants.

Letters of support can be used to outline:

• How the researcher will contribute to the project
• If there are any samples, cell lines or data that the researcher will contribute
• In the case of a consultant provide the rate/charge for their service
Additional Application Sections

Sections which may/may not be required

- Cover Letter
- Introduction to Application (for resubmission and revision applications)
- Select Agent Research
- Vertebrate Animals
- Multiple PD/PI Leadership Plan
- Resource Sharing Plan
- Authentication of Key Biological and/or Chemical Resources
A cover letter can be included, however this won’t be seen by reviewers. A cover letter is used in cases such as:

- Late applications
- Changed/corrected applications
- Noting that you have received permission from the NIH to request >$500,000 USD in any particular year (if approval is required)
- When submitting a video as part of the application
- If your proposed project:
  - Will generate large-scale genomic data
  - Involves human fetal tissue from elective abortions
Introduction to Application

Only applicable for resubmission or revision applications.

If an earlier application isn’t successful, this section allows you to:

• Summarise substantial changes to the application
• Respond to the reviewers’ comments
• Limit: 1 page
Select Agent Research

This section only needs to be completed if your research includes the use of select agents, which are:

Hazardous biological agents and toxins which have been defined by the HHS and the USDA as having the potential to pose a severe threat to:

- Public health and safety
- Animal and plant health, or to
- Animal and plant products

A list of select agents is available at selectagents.gov, and also the NIH Grants Policy Statement (Section 4.1.24.1.1).

If applicable this section is used to outline what the select agent is, where it will be used and how it will be handled.
Vertebrate Animals

If the project involves vertebrate animals:

- Describe the procedures to be performed, and where the research will be undertaken
- Outline why these procedures are necessary
- Address how pain and distress will be minimised for the animals
Multiple PD/PI Leadership Plan

Only required if the application includes multiple program director/principal investigators (PD/PIs)

This section will address:

• Rationale for this approach
• How the PD/PIs will work together, such as plans on how best to communicate, make decision on scientific direction and how to resolve disagreements
• The roles that the PD/PIs will each take, and outline at a high level how the budget will be allocated between the different parties
Resource Sharing Plan(s)

Data Sharing Plan

This section only needs to be completed if you are requesting more than $500,000 USD direct costs in any particular budget year, or if the funding opportunity announcement specifically asks for it.

If applicable, include a 1-paragraph description of how the final research data will be shared.

Sharing Model Organisms

If your project includes the development of model organisms, outline how these will be shared with the scientific community (or why it isn’t possible).

Genomic Data Sharing

For a project which will generate large-scale genomic data, include a plan for how this data will be shared. Further details are available here.
Authentication of Key Biological and/or Chemical Resources

If you are working with biological/chemical resources which:

• May differ from lab to lab, or over time
• Have particular qualities which could influence the studies, and
• Are integral to the research,

briefly describe how you will ensure the identity/validity of the species

Decision Tool: Am I Doing Human Subjects Research?

The Office of Extramural Research (OER) has developed a quick decision tool that should assist you with determining if your research involves human subjects, may be considered exempt from Federal regulations, or is not considered human subjects research. This tool should not be used as the sole determination of exemption.

**Note:** This tool uses the 2018 Revised Common Rule requirements. For more information, please visit OHRP’s page [here](https://grants.nih.gov/policy/humansubjects.htm).

### Question 1

Please check which best describes your research:

- For the purpose of this study, at some point there will be an intervention or interaction with subjects for the collection of biospecimens or data (including health or clinical data, surveys, focus groups or observation of behavior). Or identifiable private information or identifiable biospecimens will be obtained, used, studied, analyzed, or generated for the purpose of this study.
- The study will involve only secondary research using data or biospecimens not collected specifically for this study.
- This study will involve only materials/specimens or data from deceased individuals.
- My study will involve only the storage or maintenance of identifiable private information or identifiable biospecimens for secondary research.
- This study does not fit any of these categories, or I am unsure if my study fits any of these categories.

[Next](https://grants.nih.gov/policy/humansubjects.htm)
If your research is classified as human subjects research, in separate attachments provide information on:

- Inclusion of Individuals Across the Lifespan
- Inclusion of Women and Minorities
- Recruitment and Retention Plan
- Study Timeline
- Protection of Human Subjects
- Data and Safety Monitoring Plan
- Overall Structure of the Study Team
- Statistical Design and Power
- Dissemination Plan
- Other Clinical Trial-Related Attachments (if applicable)
• Register here, and when asked for a Unique Entity Identifier (UEI) number, enter: P8JJC89CWNK5

• Once registered the International Grants team will be able to update your account to allow you to start an application
Two-factor authentication

Common authentication options:
- An app, such as Google Authenticator or Okta Verify
- Text message
- A list of codes
1. Login to grants.gov

2. Search for the funding opportunity (e.g. PA-20-185)

3. Click on the opportunity hyperlink

4. Click on apply

5. Enter an application filing name (e.g. the project title, or a brief description such as IntGrants NIH 2022)
Welcome to Grants.gov!

Manage access to the application

Download a PDF copy of the application

Check your application is compliant

Download/upload application sections

Add extra application sections

Lock/unlock application sections

Application sections
SF424 (The application header)

Much of this section will be completed by the International Grants team

Details for the applicant:

• 4b. Applicant Routing Identifier: If you are applying through a Notice of Special Interest, enter this here

• 11. Application title

• 12. Proposed dates

• 14. Lead investigator’s (Program Director/Principal Investigator, or PD/PI) contact details

• 15. a) and c) How much funding is being requested
Will the project be making a profit (known as program income)?

Does the project involve:
- The euthanization of vertebrate animals?
- Embryonic human stem cells?
- Human fetal tissue from elective abortions?
Other Project Information

• Are human subjects involved?
• Are vertebrate animals used?
• Is proprietary/privileged information included in the application?
• Does the project have an impact on the environment?
• Is the work being performed at a historic site?
• Does the project involve activities outside of the US or partnerships with international collaborators?
Enter the location information for the different sites included in the project

Notes:
- The check box at the top shouldn’t be checked
- UEI numbers can be provided by sites, or found online
- Add the state on the same line as the city
- The congressional district for any non-US site will be 00-000
Senior/Key Person Profile

- Enter contact details for the lead applicant (PD/PI), as well as any other senior/key people.
- Note that eRA Commons accounts will be needed for all senior/key personnel. These accounts are created by their central research office.
Tips from the NIH

The NIH Center for Scientific Review identify the following as the most common issues with applications:

- Lack of new or original ideas
- Absence of an acceptable scientific rationale
- Lack of experience in the essential methodology
- Questionable reasoning in experimental approach
- Uncritical approach
- Diffuse, superficial, or unfocused research plan
- Lack of sufficient experimental detail
- Lack of knowledge of published relevant work
- Unrealistically large amount of work proposed
- Uncertainty concerning future directions

https://nexus.od.nih.gov/all/2022/04/01/top-10-problems-reviewers-cite-in-applications/
Questions?

Blake Plowman
Research Partnerships Leader (USA)
International Grants Team
Research Grants and Contracts Services
Research, Innovation and Commercialisation

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COMMONWEALTH OF AUSTRALIA

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## Where to Attach the Files?

### SF424
- Cover letter

### Other Project Information
- Project Summary/Abstract
- Project Narrative
- Bibliography & References Cited
- Facilities & Other Resources
- Equipment
- Foreign Justification (attachment 12)

### Project/Performance Site Locations
- Biosketches
Where to Attach the Files?

**Research Plan**
- Introduction to Application (for resubmission and revision applications)
- Specific Aims
- Research Strategy
- Vertebrate Animals
- Select Agent Research
- Multiple PD/PI Leadership Plan
- Consortium/Contractual Arrangements
- Letters of Support
- Resource Sharing Plan(s)
- Authentication of Key Biological and/or Chemical Resources
- Appendix (we don’t use this unless the FOA says, or to give participant recruitment details)

**Research and Related Budget**
- University of Melbourne budget justification

**Subaward Budget Justification**
- Budget justifications from each of the subaward sites

**Human Subjects and Clinical Trials**
- All attachments outlined human subjects/clinical trials attachments
Example Summary Statement

**PROGRAM CONTACT:** (Privileged Communication)

**Principal Investigator**
GORDON, VERNITA

**Applicant Organization:** UNIVERSITY OF TEXAS, AUSTIN

**Review Group:** Biomaterials and Biointerfaces Study Section

**Meeting Date:** 02/15/2017  
**Council:** MAY 2017  
**Requested Start:** 05/01/2017

**Project Title:** Assessing the roles of biofilm structure and mechanics in pathogenic, persistent infections

**SRG Action:** Impact Score:15  
**Percentile:**1  
**Next Steps:** Visit [http://grants.nih.gov/grants/next_steps.htm](http://grants.nih.gov/grants/next_steps.htm)

**Human Subjects:** 10-No human subjects involved  
**Animal Subjects:** 30-Vertebrate animals involved - no SRG concerns noted

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**ADMINISTRATIVE BUDGET NOTE:** The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

NEW INVESTIGATOR
Example Summary Statement

CRITIQUE 1:

Significance: 2
Investigator(s): 1
Innovation: 1
Approach: 2
Environmnt: 1

Overall Impact: This application is to investigate the structural and physical properties of biofilms using a wide range of novel techniques developed by the team and how these properties affect infections, antibiotic resistance, resistance to immune invasion and virulence. The proposed study is very novel in several aspects including novel techniques used, different properties to be studied, new insights into biofilm development, etc. This application has been improved substantially from the previous applications and the team has made several progress with published records to support the current study. A few concerns still exist including coordination of the research activities, unclear description of budgets, inconsistence in description of research activities and justification of animal to be used.

1. Significance:
Strengths
- It is novel to investigate the structural and physical properties of biofilms.
- Better understanding of such properties will likely lead to develop novel control strategies.
Weaknesses

2. Investigator(s):
Strengths
- All investigators have published extensively in the areas of proposed research.
Weaknesses
- It is not well defined specific tasks for each investigator.

3. Innovation:
Strengths
- Novel techniques will be developed to study biofilms.
- The application focus on the structural and mechanical properties of biofilms.
- The application will also study interaction of immune cells with biofilms.
Weaknesses

4. Approach:
Strengths
- The application will use both in vivo and in vitro models for characterization of biofilm.
How long does it take to get funded?

- Application to award takes ~9-10 months