BMRA Proposal Preparation Checklist – NIH R01 Forms E

Before you begin:

- **READ THE PA/RFA Solicitation.** Pay attention to the "Application and Submission Information" section
- Individual NIH PA/RFA take precedence over *NIH SF424 General Guidelines;* the *NIH SF424 Application Guide* takes precedence over this document
- Proposals MUST be submitted on or before 5:00pm Local time on the Deadline Date. If an NIH "standard deadline" falls on a weekend or **Federal** Holiday, the deadline is extended to the following business day. For RFAs with specific deadline dates the deadline is fixed and does NOT change.

☐ Cover Letter *(generally 1 – 2 pages)*

☐ Project Summary/Abstract *(30 lines of text)*

☐ Project Narrative *(2 or 3 sentences)*

☐ Bibliography & References Cited

☐ Facilities & Other Resources

☐ Equipment

☐ Biographical Sketch *(5 page limit)*

☐ Budget Justification

☐ Introduction to Application *(resubmission and revision applications, 1 page limit)*

☐ Specific Aims *(1 page limit)*

☐ Research Strategy *(12 page limit)*

☐ Progress Report Publication List *(renewal applications only)*

☐ Vertebrate Animals

☐ Select Agent Research

☐ Multiple PD/PI Leadership Plan

☐ Consortium/Contractual Arrangements

☐ Letters of Support

☐ Resource Sharing Plan

☐ Authentication of Key Biological and/or Chemical Resources *(1 page suggested)*

☐ Appendix

☐ Assignment Request Form

Cover Letter Attachment *(no page limit but generally 1 – 2 pages)*
Attach the cover letter, addressed to the Division of Receipt and Referral, in accordance with the FOA and/or instructions on page R-26. Usually optional and used for NIH internal purposes. May be required if direct cost budget exceeds $500,000 in any one year, application included a video or large scale genomic data. Refer to the program announcement. Note: No longer used to request application assignment or review, that is now done by the optional PHS Assignment Request Form.

Project Summary/Abstract *(30 lines of text)*
State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the agency). Describe the research design and methods for achieving the stated goals. Full instructions pages R-37 and R-38.

Project Narrative *(2 or 3 sentences)*
Describe the relevance of this research to public health in, at most, three sentences. Full instructions page R-38.

Bibliography & References Cited
When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant, and arose from NIH support, provide the NIH Manuscript Submission reference number or the PubMed Central (PMC) reference number for each article. Full instructions pages R-38 and R-39.

Facilities & Other Resources
Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). If there are multiple performance sites, describe the resources available at each site. Describe any special facilities used for working with biohazards and any other potentially dangerous substances. Full instructions page R-39.

Equipment
List major items of equipment already available for this project and, if appropriate, identify the equipment's location and pertinent capabilities. Full instructions page R-40.

Other Attachments
Attach a file to provide additional information only in accordance with the FOA and/or agency-specific instructions.

Biographical Sketch
All senior/key personnel and other significant contributors (OSCs) must include biographical sketches. Unless otherwise specified in a FOA, senior/key personnel are defined as all individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project, whether or not salaries are requested. Full instructions begin on page R-45. An NIH Biosketch Reference Sheet can be found here. A sample NIH biosketch can be found here. An NIH biosketch FAQ can be found here.

Budget Justification
There are two primary types of Budget Forms: detailed R&R and PHS 398 modular. Generally, you must use the R&R Budget Form if you are applying for more than $250,000 per budget period in direct costs, and you must use the Modular Budget Form if you are applying for $250,000 or less. Full instructions begin on page R-56. See here for budget justification best practices.

Introduction to Application *(resubmission and revision applications, 1 page limit)*
Resubmission Applications: See specific instructions on the content of the introduction on the NIH's
Resubmission Application page.
Competing Revisions: See specific instructions on the content of the introduction on the NIH's Competing
Revisions page.

Specific Aims *(1 page limit)*
State concisely the goals of the proposed research and summarize the expected outcome(s), including the
impact that the results of the proposed research will have on the research field(s) involved. Full instructions
pages R-78 and R-79.

Research Strategy *(12 page limit)*
Start each section with the appropriate heading – Significance, Innovation, Approach. Full instructions pages
R-79 – R81. Note: new proposals should include preliminary studies; Renewal/Revisions should include
progress report.

Progress Report Publication List *(renewal applications only)*
List the titles and complete references to all appropriate publications, manuscripts accepted for publication,
patents, and other printed materials that have resulted from the project since it was last reviewed competitively.
Full instructions pages R-81 and R-82.

Vertebrate Animals
If live vertebrate animals are involved in the project, address each of the following criteria: 1) Description of
Procedures; 2) Justifications; 3) Minimization of Pain and Distress. Full instructions pages R-82 and R-83.

Select Agent Research
Include a Select Agent Research attachment if your proposed activities involve the use of select agents at any
time during the proposed project period, either at the applicant organization or at any performance site. Full
instructions pages R-83 and R-84.

Multiple PD/PI Leadership Plan
Any applicant who designates multiple PD/PIs must include a Multiple PD/PI Leadership Plan. Full instructions
pages R-84 and R-85. Sample leadership plans can be found here.

Consortium/Contractual Arrangements
Include a Consortium/Contractual Arrangements attachment if you have consortiums/contracts in your budget.
Full instructions page R-85.

Letters of Support
Attach a file with all letters of support, including any letters necessary to demonstrate the support of consortium
participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the
grant application. Full instructions pages R-85 and R-86.

Resource Sharing Plan
See the NIH Data Sharing Policy. An NIH Data Sharing Plan template can be found here. Full instructions
pages R-86 and R-87.

Authentication of Key Biological and/or Chemical Resources *(1 page suggested)*
If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key
biological and/or chemical resources used in the proposed studies. See NIH's page on Rigor and
Reproducibility. Full instructions page R-87.

Appendix
Refer to the FOA to determine whether there are any special appendix instructions for your application. See the NIH Guide Notice on the [Appendix Policy](). [Full instructions pages R-88 and R-89]().

Assignment Request Form
The Assignment Request Form may be used to communicate specific application assignment and review requests to the Division of Receipt and Referral. [Full instructions pages R-121 - R123.]()

Human Subjects and Clinical Trial Information <mark>see Human Subjects checklist here</mark>

- New Form included in all Applications (whether or not human subjects or clinical trials are involved)
- Required form fields vary based on a number of factors, including:
    - If proposed research does not involve human subjects BUT involves use of Human Specimens or Data (see [here]() for Research Involving Private Information or Biological Specimens flowchart)
    - Whether study is Delayed Onset , defined as human subjects research is anticipated within the period of award but definite plans cannot be described in the application.
    - Announcement specific instructions
    - Human Subjects Exemptions
    - Whether study involves a clinical trial
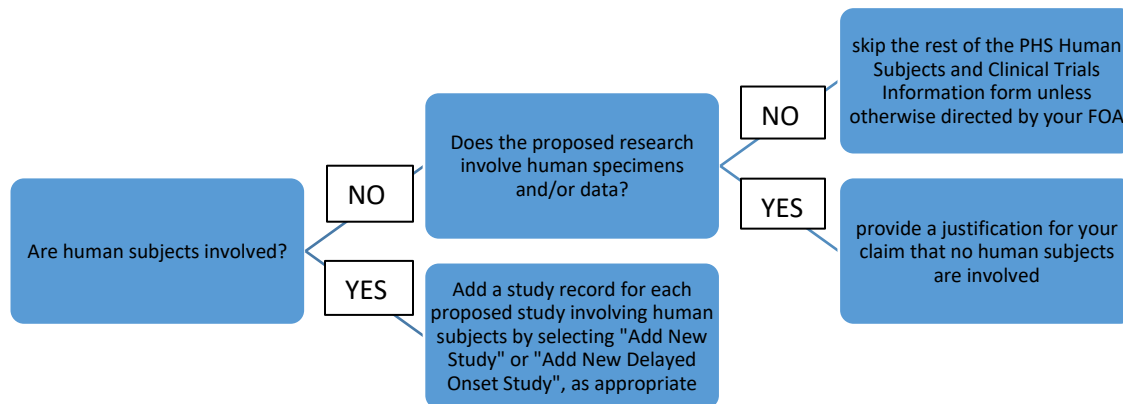
Additional NIH Information

- After submission of an application, there is a two-day application viewing window. Prior to the due date, you may submit a change/corrected application. Submitting a change/corrected application will replace the previous submission and remove the previous submission from consideration.
- Descriptive Title of Applicant's Project: The descriptive title is limited to 200 characters, including spaces and punctuation. For resubmission and renewal applications you should normally have the same title as the previous grant or application. However, if the specific aims of the project have significantly changed, choose a new title.
- If you are requesting a budget with $500,000 or more in direct costs for any budget period, contact the awarding component to determine whether you must obtain prior approval before submitting the application. Some NIH Institutes/Centers do not require prior approval.

Additional NIH Links

How To Apply - Application Guide

Selecting the Correct Application Instructions

Parent Announcements (for unsolicited or investigator-initiated applications)

Understand Funding Opportunities

Types of Applications

Submission Policies

Write Your Application

Guide to Grants and Contracts

Format Attachments

Page Limits

Application Due Dates

Frequently Asked Questions (FAQs)

Frequently Asked Questions - Applying Electronically

Frequently Asked Questions - Resubmissions

Glossary & Acronym List

Rigor and Reproducibility

Authentication of Key Biological and/or Chemical Resources in NIH Applications

Develop Your Budget

Additional BMRA Links

Brown Proposal Submission (5 Day Rule) Policy

BMRA Proposal Deadline Exception Request Form

Pre-Award Frequently Asked Questions

Institutional Facts and Reference Documents

Request a User ID for NIH eRA Commons