

NIH U01 Application Checklist

Submission Deadline:

- ☐ Grant ASSIST access to Research Office (RoPH)
- ☐ Document Upload Responsibility: ☐ PI ☐ RoPH
- ☐ Document Sharing Method: ☐ Email ☐ SharePoint folder
- ☐ NIH Research Security Training Requirement
 - Complete **OCP-Research Security Training Requirements for NIH** through **CATS**. Email the **certification** to Ann Clesi (aclesi@lsuhsc.edu) or Jessica Raymond (jraym2@lsuhsc.edu).
- ☐ Review the **Preview Application document**. The PI is responsible for ensuring the accuracy and completeness of the application.

A. Internal Routing Checklist (at least 10 business days prior to the sponsor deadline).

Due Date:

Item	PI	Research Office OR Business Office
☐ Project Summary/Abstract (30 lines of text)	☐	
☐ Budget	☐	☐
☐ Budget Justification	☐	
☐ Indirect Cost Waiver Request Form (if applicable)		☐
☐ Cost Sharing Approval Form (if applicable)		☐
☐ Consortium/Subaward Documents (if applicable)	☐	☐
☐ Data Management & Sharing Plan	☐	

B. Final Submission Package (at least 5 business days prior to the sponsor deadline).

Due Date:

ASSIST Forms:

Item	PI	RoPH
☐ SF424 (R&R) Cover		☐
☐ PHS398 Cover Page Supplement	☐	☐
☐ R&R Other Project Information	☐	☐
☐ Project/Performance Site Location(s)	☐	☐
☐ Senior/Key Person Profile	☐	☐
☐ R&R Budget or PHS398 Modular Budget	☐	☐
☐ R&R Subaward Budget Attachment(s) when applicable	☐	☐
☐ PHS398 Research Plan	☐	☐
☐ PHS Human Subjects & Clinical Trials Information	☐	☐

Attachments:

Item

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

☐ **Project Narrative (3 sentences)**

☐ **Bibliography & References Cited**

☐ **Facilities & Other Resources ([SoPH template](#))**

☐ **Equipment**

☐ **Other Attachments (if applicable)**

- Only attach a file to provide additional information in accordance with the NOFO and/or agency-specific instructions.

- **Foreign Justification** (if applicable)

☐ **NIH Biosketch (all key personnel)**

☐ **Other Support (if requested)**

For Detailed Budget

☐ **Budget Justification**

☐ **Consortium Justification (if applicable)**

For Modular Budget

☐ **Personnel Justification**

☐ **Consortium Justification (if applicable)**

Provide an estimate of total consortium costs (direct plus indirect costs) for each budget period, rounded to the **nearest \$1,000**.

☐ **Additional Narrative Justification**

☐ **Introduction to Application (if applicable, 1 page)**

Required only if the type of application is **Resubmission** or **Revision**

☐ **Specific Aims (1 page)**

☐ **Research Strategy (12 pages)**

☐ **Progress Report Publication List (if applicable)**

Required only if the type of application is **renewal**

☐ **Vertebrate Animals (if applicable)**

☐ **Select Agent Research (if applicable)**

☐ **Multiple PD/PI Leadership Plan (if applicable)**

☐ **Consortium/Contractual Arrangements (if applicable)**

☐ **Letters of Support**

☐ **Resource Sharing Plan (if applicable)**

☐ **Other Plan(s) – Data Management & Sharing Plan**

☐ **Authentication of Key Biological and/or Chemical Resource (if applicable, 1 page)**

☐ **Appendix (if applicable, a maximum of 10 PDF attachments)**

Only attach file(s) if they are specified in the NOFO as allowable Appendix materials.

Simply relocating disallowed materials to other parts of the application will result in a **noncompliant application**. Application will be withdrawn.

Human Subjects and Clinical Trials Requirements

Complete only when the proposed project involves human subjects, human specimens, and/or human data, as applicable. Detailed instructions refer to [Research Instructions for NIH and Other PHS Agencies](#) Page 96 – 132.

1. Use of Human Specimens and/or Data

Item
☐ Use of Human Specimens and/or Data
☐ Explanation of Why Human Specimens and/or Data Do Not Constitute Human Subjects Research
<i>If the answer of the previous question is “Yes” and the proposed project is not considered human subject research, please attach an explanation.</i>

2. Study Record: PHS Human Subjects and Clinical Trials Information

Complete one Study Record for each proposed human subjects study.

Item
☐ Section 1 – Basic Information
☐ Section 2 – Study Population Characteristics
<i>Not required if only Exemption 4 is selected on the “1.3 Exemption Number” question.</i>
☐ Section 3 – Protection And Monitoring Plans
☐ Section 4 – Protocol Synopsis
<i>Complete only if all Clinical Trial Questionnaire responses are “Yes”.</i>
☐ Section 5 – Other Clinical Trial-related Attachments
<i>Complete only if all Clinical Trial Questionnaire responses are “Yes”.</i>

Helpful links:

NIH R-Series Application Instructions: [Research Instructions for NIH and Other PHS Agencies](#)

Page Limits: [Page Limits | Grants & Funding](#)

Format Attachments: [Format Attachments | Grants & Funding](#)

DMS Plan: [Data Management and Sharing Plan Format Page | Grants & Funding](#)