SEMEL INSTITUTE
Office of Extramural Support

NIH R-SERIES CHECKLIST

📎 = **PDF Attachment** formatting requirements ▤ = **Text Box** rules for data entry **()** = **Space Limits** **NIH App Guide**

SF424 RR FORM

___ Enter proposal summary information including title, PI, NOSI Notice ID (if applicable) and Institutional details
___ 📎 **Cover Letter:** Not shared with reviewers, include applicable items per NIH guide, no assignment info **(no pg limit)**

PHS 398 COVER PAGE SUPPLEMENT FORM

___ Answer Q's re: animal studies, program income, human stem cells / fetal tissue, patents, change PI / Institution

RR OTHER PROJECT INFORMATION FORM

___ Answer Q's re: human/animal use, privileged/proprietary info, environment, use of historical site, foreign components
___ 📎 **Abstract**: Project summary, do not include proprietary info, may be made public via NIH RePORT **(30 lines)**
___ 📎 **Narrative**: Relevance of proposed research to public health, may be made public via NIH RePORT **(3 sentences)**
___ 📎 **Bibliography**: Provide PMCIDs for citations under NIH public access policy and authored by applicant **(no limits)**
___ 📎 **Facilities & Resources**: Describe scientific environment for all sites, ESI resources & support, if app **(no limits)**
___ 📎 **Major Equipment**: List equipment currently available to carry out the study **(no limits)**
___ 📎 **Other Attachments:** Leave blank unless FOA indicates otherwise AND/OR Foreign Justification is needed

RR PERFORMANCE SITE INFORMATION

___Provide address and other requested information for each performance site

RR SENIOR / KEY PERSON PROFILE FORM

___ Enter data for all Key Persons including eRA Commons ID for each PD/PI
___ 📎 **Biosketch**: Attach for each key person, including Other Significant Contributors, as described here **(5 pages)**

*RR BUDGET FORM *

Use if UCLA requests more than $250,000 in direct costs in any year of the project period

___ Request direct costs by category and indirect costs per year
___ 📎 **Budget justification**: Provide detailed justifications and cost calculations as described here **(no limits)**

**PHS 398 MODULAR BUDGET **

Use only if UCLA requesting less than $250K direct/year; FOA must state modular budget allowed

___ Request direct costs in modules of $25,000
___ 📎 **Personnel Justification**: Provide names, annual efforts and descriptions of Key and Other Personnel **(no limits)**
___ 📎 **Consortium Justification**: Justify consortium personnel only, list sub total costs rounded to nearest $1K **(no limit)**
___ 📎 **Additional Narrative Justification**: Provide justification for annual variations in total direct costs **(no limits)**

***RR SUBAWARD BUDGET FORM ***

Include if UCLA is submitting a detailed RR Budget

___ Request direct costs by category and indirect costs per year
___ 📎 **Subreceipient Budget Justification:** Sub provides detailed justification with cost calculations **(no limits)**

PHS 398 RESEARCH PLAN FORM

___ 📎 **Introduction to Application**: *Resubmission / Competitive Revision applications only* **(1 page)**
___ 📎 **Specific Aims**: List specific objectives of the proposed research **(1 page)**
___ 📎 **Research Strategy**: Describe Significance, Innovation, Approach per NIH guide **(6 or 12 pages - see FOA)**;
Human studies should not duplicate info in research strategy that is provided on HS & CT information form
___ 📎 **Progress Report Publication List:** *Renewal applications only* **(no limits)**

If applicable:

___ 📎 **Vertebrate Animals**: Complete if vertebrate animals are used **(no limits)**
___ 📎 **Select Agent Research**: Complete if proposed activities involve the use of select agents **(no limits)**
___ 📎 **Multiple PD/PI Leadership Plan:** Complete if multiple PD/PIs are proposed **(no limits)**
___ 📎 **Consortium Arrangements**: Complete if subs proposed, describe sub SOW & collaboration w UCLA **(no limits)**
___ 📎 **Support Letters:** Letters demonstrating support of sub leads, collaborators, consultants **(no limits)**
___ 📎 **Resource Sharing Plan(s)**: Address data sharing, model organism, and genomic data policy **(no limits)**
___ 📎 **Authentication of Key Biological & / or Chemical Resources**: Review NIH Rigor/Reprod Page **(Suggested 1 page)**
___ 📎 **Appendix**: Limited content review NOT-OD-17-098 **(10 PDFs)**

PHS HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION FORM

Key: NH **Section required for Non-Human subjects studies**
HS **Section required for Human Subjects studies**
CT **Section required for Clinical trial studies**
4 **See guide for Human Research, Exemption 4 instructions**

NH HS CT OVERVIEW SECTION *Responses populated from PHS Other Project Info Form*

*If **NO*** human subjects involved:
___ Confirm if data/specimens are considered HS research, for help, refer to NIH Decision Tools, Infographs & Charts
___ **Justification Non-HS Research**: Attach if study involves human specimens/data but is not HS research **(no limits)**

*If **YES*** human subjects research involved:
___ Create HS Study Record for each HS research study (150 records) & complete sections below 1-5 as required
___ Create Delayed Onset HS Study Record for each DO study and "check box" if CT is anticipated
___ **Delayed Onset Study Justification**: Provide for DO studies only **(no limits)**
___ **Other Requested Information**: Upload file only if requested by FOA

HS CT 4 STUDY RECORD SECTION 1: BASIC INFORMATION

___ **Study Title: (600 characters)**
___ Exempt from Federal Regulations? If exempt study, review NIH Exemption Infographic & select appropriate number
___ Complete Clinical Trial Questionnaire Items 1-4; Review NIH CT definition, Case Studies, FAQ prior to responding
___ Clinicaltrials.gov identifier: optional, likely leave blank

HS CT STUDY RECORD SECTION 2: STUDY POPULATION CHARACTERISTICS

___ **Conditions or focus of study**: Identify the disease(s) or condition(s) you are studying, or the focus of the study Use MeSH headings, if available **(20 conditions, 255 characters per condition)**
___ **Eligibility Criteria**: Provide bulleted list – View PDF to check formatting **(15,000 characters)**
___ **Specify Min and Max Age**
___ **Inclusion Across the Lifespan:** Address all applicable bullets described in HSCTI form section 2.3a **(no limits)**
___ **Inclusion of Women & Minorities:** Address all applicable bullets described in HSCTI form section 2.4 **(no limits)**
___ **Recruitment & Retention Plan**: Describe planned recruitment activities & retention strategies **(no limits)**
___ **Study Timeline:** ●CT required ●HS Research optional; Description / diagram using general timeframes **(no pg limits)**
___ Provide **Recruitment status** and **Date first subject enrolled** information via *dropdown selections* in form
___ **Inclusion Enrollment Report(s)**

HS CT 4 STUDY RECORD SECTION 3: PROTECTION AND MONITORING PLANS

___ **Protection of Human Subjects**: Address NIH instruction requirements bullets 1-4 ● *HS Exemption 4 refer to guide*
___ **Single IRB Plan:** NIH no longer requires this plan at the application stage. Do not include.
___ **Data Safety Monitoring Plan:** ● CT required, ● Other HS Research optional **(no limits)**
___ Data Safety board appointed for study? ● CT required, ● Other HS Research optional
___ **Overall Structure of Study Team:** Optional, include only if required by FOA **(no limits)**

CT STUDY RECORD SECTION 4: PROTOCOL SYNOPSIS

___ **Provide Detailed Description, Primary purpose, Interventions, Study phase, Interventional model, Masking,** and **Allocation** info via direct entry or *dropdown selections*. Dropdown definitions available via clinicaltrials.gov
___ **Outcome Measures (OM)**: Provide name, type, timeframe, description **(200 characters)** for each OM **(up to 50)**
___ **Statistical Design and Power:** In addition to NIH guide, review Research Methods Resources **(no limits)**
___ **Subject Participation Duration**: Time length for participant to complete all visits **(255 characters)**
___ **Study use of an FDA-regulated intervention?** If yes, attachment required **(no limits)**
___ **Applicable Clinical Trial per FDAAA?**: Determine if your CT is an applicable clinical trial
___ **Dissemination Plan:** A plan is required for each study within your application per NIH and or FDA policy

CT STUDY RECORD SECTION 5: OTHER CLINICAL TRIAL-RELATED ATTACHMENTS

___ **Other attachment (s)** Include only if requested by FOA

PHS ASSIGNMENT REQUEST FORM

___Must include if requesting institute/study section assignment, naming individuals who should/not review, etc.