SEMEL INSTITUTE
Office of Extramural Support

NIH K-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, NOSI Notice ID (if applicable), PI and Institutional details
___ 📎 **Cover Letter:** Not shared with reviewers, if mentored CDA include referee list with names, affiliations **(no pg limit)**

PHS 398 COVER PAGE SUPPLEMENT FORM

___ Answer Q's re: animal studies, program income, human embryonic stem cells, 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 acknowledging NIH funding and authored by applicant **(no limits)**
___ 📎 **Facilities & Resources**: Describe scientific environment & institutional resources available to the PI **(no limits)**
___ 📎 **Major Equipment**: List project equipment **(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 PD/PI, primary mentor and co-mentors.
___ PD/PI must have an ORCID iD linked to their eRA Commons Personal Profile see NOT-OD-19-109.
___ 📎 **Biosketch**: Attach for PD/PI, primary mentor, co-mentors and others identified as Key Personnel **(5 pages each)**
___ 📎 **Current & Pending Support**: Provide for mentor, co-mentors only. Do not include efforts or overlap **(3 pages)**

RR BUDGET FORM

___ Annual direct costs for salary and research support dictated by Institute; refer to link in Section II of FOA
___ Complete RR Budget Section A for PI only (effort, salary, fringe) and Section F.1 lump sum for Research Support
___ 📎 **Budget justification:** Provide detailed justification of salary and research support line items **(no limits)**

PHS 398 CAREER DEVELOPMENT AWARD SUPPLEMENT FORM

___ 📎 **Introduction to Application**: *Resubmission applications only* **(1 page)**
___ 📎 **Candidate Information**: Background, goals/objectives, dev/training plan **(Can Info + Res Strat ≤ 12p combined)**
___ 📎 **Specific Aims**: List specific objectives of the proposed research **(1 page)**
___ 📎 **Research Strategy**: Include relevant sections per NIH guide **(Can Info + Res Strat ≤ 12p combined)**
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)**
___ 📎 **Training in the Responsible Conduct of Research:** Address NIH application guide bulleted items 1-5 **(1 page)**
___ 📎 **Candidate's Plan to Provide Mentoring:** Include when required by FOA *mentoring proposals only* **(6 pages)**
___ 📎 **Plans and Statements of Mentor / Co-mentors**: Generated by each mentor, *mentored proposals only* **(6 pages)**
___ 📎 **LOS from Collaborators, Contributors and Consultants:** One letter provided by each non-mentor **(6 pages)**
___ 📎 **Description of Institutional Environment:** Names of faculty, necessary facilities and resources **(1 page)**
___ 📎 **Institutional Commitment to Candidate:** Provide on Institutional letterhead with Chair signature **(1 page)**

If applicable:

___ 📎 **Description of Candidate Contribution to Program Goals***: Diversity FOAs only,* Diversity letter from chair/dean
___ 📎 **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)**
___ 📎 **Consortium Arrangements**: Complete if subs proposed, describe sub SOW & collaboration w UCLA **(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)**

___US or Non-Citizen National? If no, check box that you expect to be granted a permanent resident visa by start date

PHS HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION FORM

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

NH HS RE 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 RE 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 RE 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 and ●CTRE required (follow instructions) ●HS Research optional **(no limits)**
___ Provide **Recruitment status** and **Date first subject enrolled** information via *dropdown selections* in form
___ **Inclusion Enrollment Report(s)**

HS RE 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, ●CTRE required (follow instructions) ● HS Research optional **(no limits)**
___ Data Safety board appointed for study? ●CT and ●CTRE required, ● 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. Do not complete if CT Research Experience

PHS ASSIGNMENT REQUEST FORM

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

REMINDER: Applicant must login to eRA commons and confirm receipt of reference letters (must be received by 5pm local time on application due date) Review guidelines here. **Resubmission applications require new letters!**