SEMEL INSTITUTE
Office of Extramural Support

NIH F-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, include referee list with names, affiliations **(no pg limit)**

RR PERFORMANCE SITE INFORMATION

___Provide address and other requested information for each performance site

RR OTHER PROJECT INFORMATION FORM

___ Answer Q's re: human/animal use, privileged/proprietary info, environment, use of historical site, foreign components
___ 📎 **Abstract**: Project/Training Plan Summary, no 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 fellow **(no limits)**
___ 📎 **Major Equipment**: List project equipment **(no limits)**
___ 📎 **Other Attachments:** Leave blank unless FOA indicates otherwise AND/OR Diversity Certification or Foreign Justification is needed **(no limits)**

RR SENIOR / KEY PERSON PROFILE FORM

___ Enter data for all Key Persons including eRA Commons ID for PD/PI, sponsor and co-sponsors
___ PD/PI must have an ORCID iD linked to their eRA Commons Personal Profile see NOT-OD-19-109
___ 📎 **Biosketch**: Attach for PD/PI*, sponsor, co-sponsors and others identified as Key Personnel **(5 pages each bio)**
*PD/PI provides biosketch in fellowship format, other key persons use the non-fellowship format found here

PHS 398 FELLOWSHIP SUPPLEMENTAL FORM

ALL APPLICANTS:

___ 📎 **Introduction to Application**: *Resubmission applications only* **(1 page)**
___ 📎 **Applicant Background & Goals**: Dissertation/Research Experience, Goals/Objectives, Activities Plan **(6 pages)**
___ 📎 **Specific Aims**: List specific objectives of the proposed research **(1 page)**
___ 📎 **Research Strategy**: Include relevant sections per NIH guide **(6 pages)**
CTs & Human Research studies should not duplicate information collected on new HS & CT information form
___ 📎 **Respective Contributions:** Describe collaborative process (PD/PI and sponsors) to achieve training plan **(1 page)**
___ 📎 **Selection of Sponsor and Institution:** Justify PD/PI's selection of sponsor (s) and institution **(1 page)**
___ 📎 **Training in the Responsible Conduct of Research:** Address NIH application guide bulleted items 1-5 **(1 page)**
___ 📎 **Sponsor and Co-Sponsor Statements**: *Must* include sections A-E & sponsor Clin Trial info if applicable **(6 pages)**
___ 📎 **LOS from Collaborators, Contributors and Consultants:** One letter provided by each non-sponsor **(6 pages)**
___ 📎 **Description of Institutional Environ & Commitment to Training:** F30/F31 include grad program info **(2 pages)**

IF APPLICABLE:

___ Provide information regarding **Vertebrate animal Euthanasia**
___ 📎 **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)**: If applicable, include data sharing, model organism, and genomic data plan **(no limits)**
___ 📎 **Authentication of Key Biological & / or Chemical Resources**: Do not submit unless requested in FOA **(no limits)**
___ Provide information regarding **Human Embryonic Stem Cells**
___ Provide PD/PI Info: **Alternative telephone, Current degree**, **Field of Training Code, Previous NRSA support**
___ 📎 **Applications for Concurrent Support:** If applicable, provide a description/type/dates/ source of support **(no limits)**
___ US or Non-Citizen National? If no, check box that you expect to be granted a permanent resident visa by start date
___ 📎 **Appendix**: Limited content review NOT-OD-17-098 **(10 PDFs)**

BUDGET:

At the time of the application, do not apply the 60% formula to your tuition request. Tuition will be calculated at the time of the award by NIH using the most current tuition rate.

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**
4 **See guide for Human Research, Exemption 4 instructions**

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

*If **NO*** human subjects involved:
___ Confirm if data/specimens are considered HS research, refer to NIH Decision Tool and specimen/cell line FAQ
___ 🖇 **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 (max 150 records) & complete sections below 1-3 as required
___ Create Delayed Onset HS Study Record for each DO study, do not mark anticipated clinical trial (F-series not allowed)
___ 🖇 **Delayed Onset Study Justification**: Provide for DO studies only **(no limits)**
___ 🖇 **Other Requested Information**: Upload file only if requested by FOA

HS RE 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; even if "yes" to all, fellowship FOAs do not allow independent CTs
___ Clinicaltrials.gov identifier: optional, likely leave blank

HS RE 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 of Women, Minorities & Children**: Address NIH Inclusion Across the Lifespan Policy **(no limits)**
___ 🖇 **Recruitment & Retention Plan**: Describe planned recruitment activities & retention strategies **(no limits)**
___ 🖇 **Study Timeline:** Description / diagram using general timeframes, do not use specific dates **(no limits)**
___ 🖇 **Inclusion Enrollment Report(s)**
___ Provide **Recruitment status** and **Date first subject enrolled** information via *dropdown selections* in form

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

___ 🖇 **Protection of Human Subjects**: Address NIH instruction bullets 1-4 **(no limits)** ● *HS Exemption 4 refer to guide*
___ 🖇 **Single IRB Plan:** N/A for Fellowship Applications
___ 🖇 **Data Safety Monitoring Plan:** ●CTRE required (follow instructions), ●HS Research optional **(no limits)**
___ Data Safety board appointed for study? ●CTRE required (follow instructions), ●HS Research optional
___ 🖇 **Overall Structure of Study Team:** ●CTRE required (follow reduced), ●HS Research optional **(no limits)**

STUDY RECORD SECTION 4: PROTOCOL SYNOPSIS: F-series applications do not complete

STUDY RECORD SECTION 5: OTHER CLINICAL TRIAL RELATED ATTACHMENTS: F-series do not complete

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!**