



= 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 for all sites, ESI resources & support, if app (**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:** Significance, Innovation, Approach per NIH guide (**Can Info + Res Strat ≤ 12p combined**)

___ Also refer to NIH Rigor & Reproducibility guidelines [found here](#) and updated K Research Policy [found here](#)

___ CTs & Human Research studies should not duplicate information collected on new 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:

___ **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, 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 (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 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 pg limits**)
- ___ **Inclusion Enrollment Report(s)**
- ___ Provide **Recruitment status** and **Date first subject enrolled** information via *dropdown selections* in form

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:** N/A for Career Development Applications
- ___ **Data Safety Monitoring Plan:** •CT required, •CTRE required (reduced), •HS Research optional (**no limits**)
Data Safety board appointed for study? •CT required, •CTRE required, •HS Research optional
- ___ **Overall Structure of Study Team:** •CT required, •CTRE required (reduced), •HS Research optional (**no limits**)

CT STUDY RECORD SECTION 4: PROTOCOL SYNOPSIS

- ___ **Brief Summary:** Brief description of protocol objectives (**5,000 characters**)
- ___ **Narrative Study Description:** Describe intervention delivery / assignment plans (**32,000 characters**)
- ___ **Interventions:** Provide type, name (**200 characters**), description (**1K characters**) for each intervention (**up to 20**)
- ___ **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**)
- ___ **Dissemination Plan:** A plan is required for each study within your application [per NIH and or FDA policy](#)
Provide **Primary purpose**, **Study phase**, **Interventional model**, **Masking**, and **Allocation** information via *dropdown selections* in form. Dropdown options not defined in NIH guide, available via [Section 7 clinicaltrials.gov](#)

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!**