NO headers, footers or page numbers

SF424 Research Plan – E-forms
OUTLINE for grants (effective 1-25-18)

If you do not use that section—skip that number, no blank page needed. For example for a new grant start with #2.

Research Plan Section

1. Introduction to Application (1 page for resubmissions or revisions only)

2**. Specific Aims (page limit=1)**

3. ****Research Strategy (R01=12 pages; R21 = 6) *Be sure to include Rigor and Reproducibility here!***

4. Progress Report Publication List—NOT USED

Human Subjects Sections –ALL MOVED to HS/CT form….*new (see next page)!*

Other Research Plan Sections

5. Vertebrate Animals

6. Select Agent Research

7. Multiple PI Leadership Plan

8. Consortium/Contractual Arrangements

9**. Letters of Support (external letters) – In one long PDF**

10. Resource Sharing Plan(s) - *All investigator-initiated applications with direct costs of $500,000 or greater (exclusive of consortium F&A) in any single year are expected to address data-sharing in their application.*

11. Authentication of Key Biological and/or Chemical Resources**** *(optional—only attach if needed)***

Appendix (if applicable)

16. Appendix –VERY limited review instructions!

OTHER PROJECT INFORMATION (No numbering for these!)

Cover Letter-optional –CANNOT include institute or study section requests—must go on PHS assignment for an end of grant!
Abstract (no more than 30 lines)
Narrative (3 sentences)
Bibliography & References Cited (no page limit)
Facilities and other resources (no page limit)
Equipment (no page limit)
Budget justification-No page limit—But check your RFA!

New-Targeted enrollment form (online)

NOTE: Also change in **Biosketches from D forms** –In Contribution to Science: limit 4 references per section limit =5 pages.

2016-added—new form PHS Assignment Request—use to select Institutes or study sections or list places you don't want the grant sent to!

NO headers, footers or page numbers

New 2018- Human Subjects section:

SECTION 1

1,1 * Study Title **(limited to 30 characters)**

1.2. * Is this Study Exempt from Federal Regulations? ○ Yes ○ No

1.3. Exemption Number ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

1.4. * Clinical Trial Questionaire

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

1.4.a. Does the study involve human participants? ◉ Yes ○ No

1.4.b. Are the participants prospectively assigned to an intervention? ○ Yes ○ No

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants? ○ Yes ○ No

1.4.d. Is the effect that will be evaluated a health-related, biomedical, or behavioral outcome? ○ Yes ○ No

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable optional

SECTION 2

2.1. Conditions or Focus of Study---*Provide as WORD doc to cut and paste*

2.2. Eligibility Criteria---*Provide as WORD doc to cut and paste*

2.3 Age Limits—*need to fill in boxes*

2.4. Inclusion of Women, Minorities, and Children—*provide as a PDF*

2.5. Recruitment and Retention Plan—*provide as a PDF*

2.6. Recruitment Status: pull down menu

- Not yet recruiting
- Recruiting
- Enrolling by invitation
- Active, not recruiting
- Completed
- Suspended
- Terminated (Halted prematurely)
- Withdrawn (No participants enrolled)

2.7. Study Timeline—*provide as a PDF*

2.8. Enrollment of First Subject Date Anticipated or Actual

Inclusion Enrollment Reports—planned or actual. ---These will need to be filled in on a PDF and then retyped into Cayuse

SECTION 3

3.1. Protection of Human Subjects- provide as a PDF

IF Clinical Research—that's all that is needed
IF Clinical Trial…..continue!

NO headers, footers or page numbers

For Clinical Trials only:

3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site? ○ Yes ○ No ○ N/A

If yes, describe the single IRB Plan --*provide as a PDF*

3.3. Data and Safety Monitoring Plan --*provide as a PDF*

3.4. Will a Data and Safety Monitoring Board be appointed for this study? ○ Yes ○ No

3.5. Overall Structure of the Study Team -- *provide as a PDF*

SECTION 4

4.1. Brief Summary—*In Word doc to cut and paste*

4.2. Study Design

4.2.a. Narrative Study Description

4.2.b. Primary Purpose :

- Treatment
- Prevention
- Diagnostics
- Supportive Care
- Screening
- Health Services Research
- Basic Science
- Device Feasibility
- Other

4.2.c. Interventions

NAME-—*In Word doc to cut and paste*

DESCRIPTION—*In Word doc to cut and paste*

4.2.d. Study Phase [fill in]

Is this an NIH-defined Phase III clinical trial? ○ Yes ○ No

4.2.e. Intervention Model [fill in] SINGLE GROUP, PARELLEL, CROSS-OVER, FACTORIAL, SEQUENTIAL, OTHER

4.2.f. Masking ○ Yes ○ No

☐ Participant ☐ Care Provider ☐ Investigator ☐ Outcomes Assessor

4.2.g. Allocation: N/A, Randomized or non-randomized

4.3. Outcome Measures: Select Primary, Secondary or Other

TIME FRAME -- *In Word doc to cut and paste*

BRIEF DESCRIPTION --*In Word doc to cut and paste*

4.4. Statistical Design and Power -- *provide as a PDF*

4.5. Subject Participation Duration—fill in box

4.6. Will the study use an FDA-regulated intervention? ○ Yes ○ No

4.6.a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status -- *provide as a PDF*

4.7. Dissemination Plan -- *provide as a PDF*