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Refer to: [Grants.gov Application Guide](#) (SF 424 R&R) for more information on any of the topics below

Download the application package in response to your PA/RFA

For an R01 submission (not in response to a particular FOA); use PA announcement PA-07-070

For an R03 submission (not in response to a particular FOA); use PA-06-180

For an R21 Submission (not in response to a particular FOA); use PA-06-181

DO NOT USE HEADERS/FOOTERS ON ANY PAGES

Format; Use Arial, Helvetica, Palatino Linotype or Georgia (**black ink color**) 11 point font size

Choose the forms on the left side of the Grants.gov selector page. As you complete each form, move it to the right side.

Face Page:

1. Type is usually "Application"
2. Date – leave blank
 - a. Applicant Identifier: Use M # (not presently used by Central Departments)
3. Leave Blank
4. Federal Identifier: Use 2 letter Institute Code and six digit grant # for resubmission/renewal (i.e. GM012345) (NIH only)
5. Applicant Information is always Yale University and the address of the pertinent Grants & Contracts Office.
 - a. DUNS #: 0432075620000
 - b. Administrative Contact - Use your Reviewer's name with the following:
 - i. Med – Phone:203-785-4689 Fax: 203-785-4159 Email: ggovmd@email.med.yale.edu
 - ii. Central – Phone: 203-432-2460 Fax: 203-432-7138 Email: grants@yale.edu
6. EIN #: 06-0646973

7. Type is always O: Private Institution of Higher Education
8. Type – choose applicable
9. Autofilled
10. Most of the time this is autofilled or not used
11. Title of Project – for specific PAs, review instructions
12. As applicable – use largest political entity
13. Project Dates: Use earliest NIH suggested start date. For renewal applications start date must be after end date of current project period. **(Important – this cannot be changed on the budget pages so must be absolutely accurate to begin with).**
14. Areas – use 2 letter state codes and 3 digits Cong. Districts as applicable (i.e. CT-003)
15. PD/PI Information – fill out completely
16. a. & b. must equal total project budget and prosum/transmittal. c. should be blank unless there is program income identified.
17. b. NO
18. Check box
19. Signing Official from Grants & Contracts for Medical School and Central Campuses (i.e. Rebecca Balentine & Rita Nigri for Med and John Olender for Central)
20. Used as directed by specific agencies
21. Usually not used

R&R Senior/Key Personnel Page (Expanded):

- Complete with Institution, Division & Department for each Senior/Key Person
- Alphabetize senior/key persons by role/category. i.e. those with measureable effort are considered key personnel. They should be listed first in alphabetical order. Other significant contributors (those without measureable effort) are then listed in alphabetical order.
- Do not use the term “Co-PI” for NIH; Use “other” and “investigator” or “co-investigator”
- For multiple PI grants, all PIs are called “PD/PI”, contact PI is listed under “Profile” and other PIs are listed in Senior/Key Person 1, 2, etc. in alpha order, and you must include a multi-pi leadership plan in PHS 398 Research Plan #14
- Follow agency specific instructions or us NIH formatted bio; 4 page limit; use [this format page](#); refer to [this sample biosketch](#).
 - Max of four pages
 - List Positions/Employment/Honors in chronological order.
 - List selected publications in chronological order

- Separate ongoing and completed (last 3 years) research. Make sure completed research is not included with ongoing and that no research older than 3 years is included
- Do not include PENDING, effort, or \$\$

Research and Related – Other Project Information:

1. If yes, then Human Subjects Assurance Number should be 00002571
2. If yes, then Review must be Pending, leave date blank, Animal Welfare Assurance # is A3230-01
3. As applicable
4. As applicable
5. As applicable
6. Project summary/abstract – This is now a separate attachment; description of proposed research; no longer than 30 lines of text (formerly PHS 398 Form Page 2)
7. Project narrative – Separate attachment; relevance of the research to public health; no more than 2-3 sentences
8. Bibliography and references cited – This is now a separate attachment.
9. Facilities & other resources – Separate attachment; laboratory, animal, computer, office, clinical and other
10. Equipment – Separate attachment; major items ≥ \$5000
11. Other Attachments – Use for additional explanation of 4, 5, & 6 (above)

R&R Project/Performance Site:

Name all applicable sites including consortium sites as appropriate

Cover Page Supplement:

1. Auto-filled
 - a. Mark new investigator yes/no
 - b. Add degrees for PI (should match what is in the profile in eRA Commons)
2. Mark clinical trial and NIH Phase III if applicable
3. Complete Title and your Grants address
4. Must be checked yes or no

PHS 398 Research Plan:

1. Introduction to application – For revisions and resubmissions only; 3 page limit

Sections 2-5 (formerly sections A-D) together should not exceed 25 pages for R01s and 15 pages for R03s and R21s but review specific PA/RFA instructions for exact limits.

2. Specific aims
3. Background and significance
4. Preliminary studies/progress report

5. Research design and methods
6. Inclusion enrollment report – Include for competitive renewals as applicable
7. Progress report publication list – Include for competitive renewals only

Human Subjects

If you checked “yes” on the R&R Other Project Information page, **all** four sections (8-11) are necessary even if the section only indicates that it is n/a (i.e. targeted enrollment table for de-identified tissue can so state under # of subjects).

- 8-11. Refer to [instructions](#) and note above

Other Research Plan Sections

Leave blank if not applicable

12. Vertebrate Animals – if you checked “yes” on the R&R Other Project Information page, this section is necessary. Do not reference an approved protocol as each research plan must be separately reviewed for congruency against your approved protocols. Since this is a new/renewal proposal the description of your proposed research should be written in future tense.
13. Select Agent Research – explain as applicable
14. Multi-PI Leadership Plan – Required for Multi-PI applications as included in the R&R Key Person page.
15. Consortium/Contractual Arrangements
Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). See [instructions](#).
16. Letters of Support – Attache one pdf file with letters from all collaborators/other significant contributors
17. Unique Research Resource Sharing Plan – now usually required for all applications, including Parent FOAs (PA-07-070, PA-06-180, PA-06-181) – read the terms of each specific PA to which you plan to apply.

Sample: Research Resources generated with funds from this grant will be freely distributed, as available, to qualified academic investigators for non-commercial research. My institution and I will adhere to the NIH Grants Policy on Sharing of Unique Research Resources including the [“Sharing of Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Grants and Contracts”](#) issued in December, 1999. Specifically, material transfers would be made with no more restrictive terms than in the Simple Letter Agreement or the UBMTA and without reach through requirements. Should any intellectual property arise which requires a patent, we would ensure that the technology remains widely available to the research community in accordance with the NIH Principles and Guidelines document.

18. Appendix – Use if applicable. This is sent only to primary reviewers. Refer to: <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-07-018.html>

- a. If you have multiple items, include a summary sheet listing all of the items as the first appendix attachment. You can also include a list of publications with URLs or PMCs.
- b. A maximum of 10 PDF attachments is allowed. If more than 10 are needed, combine the remaining information into attachment #10.
- c. **Publications – No longer allowed as appendix materials except in the circumstances noted below**
 - i. **Manuscripts and/or abstracts accepted for publication but not yet published:** The entire article should be submitted as a PDF attachment.
 - ii. **Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available:** The entire article should be submitted as a PDF attachment.
 - iii. **Patents directly relevant to the project:** *The entire document should be submitted as a PDF attachment.*
 - iv. Photographs or color images of gels, micrographs, etc., **are no longer accepted as Appendix material.** These images must be included in the Research Plan PDF. However, images embedded in publications are allowed.

PHS 398 Checklist:

- Application Type. For resubmissions of renewals, type is resubmission. Include Federal Identifier (IC + 6 digits, i.e. GM012345). Revision is used for supplemental funding requests such as Administrative or Minority Supplements.
- Change of Investigator/Grantee Institution – not presently used but consult with your Grants Reviewer.
- Inventions and Patents – required for renewal applications and resubmissions of renewal applications.
- Program Income – Usually NO.
- Assurances & Certifications – leave blank – grants office use only.

Optional Documents:

You must include either a Modular Budget (under \$250K/ annual Direct Costs) or a detailed Research & Related Budget (over \$250K/annual Direct Costs)

Cover Letter File

GCA – Central
Campus Mail: 155 Whitney Ave, Room 214
Phone: 203-432-2460
Fax: 203-432-7138
Email: grants@yale.edu

GCA – Medical School
Campus Mail: 47 College St, Suite 203
Phone: 203-785-4689
Fax: 203-785-4159 (Grants)
Fax: 203-785-4169 (Contracts)
Email: contract.med@email.med.yale.edu

Attach as necessary. This must be included for applications over \$500K, late applications (PI was on study section), or changed/correct application after deadline.

Modular Budget – under \$250K, annual Direct Costs

Enter dates – must be the same as face page dates.

- A. Complete as required for Direct Costs (see http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_Ver2.pdf)
- B. Indirect Costs:
 - a. Type of Direct Costs; Modified Total Direct Costs (MTDC)
 - b. Cognizant Agency Info: DHHS, Michael Stanco, 212-264-2069
 - c. Use latest DHHS Agreement Date: http://grants.med.yale.edu/proposal_development/facts.html
 - d. Complete for EACH budget period.
- C. Total Direct & Indirect Costs – must equal face page and Proposal Data Collection (PDC) sheet totals exactly.

Cumulative Budget Information:

- a. Attach Personnel Justification PDF file
 - i. Begin with PI, list and justify all personnel including OSCs. Include effort in calendar months, OR academic and summer months. Do not use % for effort.
 - ii. Do NOT justify any other expenses.
- b. Attach Consortium justification PDF file – use only if necessary
 - i. Include annual direct costs for each year.
- c. Attach Additional Narrative Justification PDF file only IF you have a variation in the number of modules you are requesting.

Research & Related Budget – over \$250K, Total Direct Costs

Follow instructions carefully in Section 4.7 at:

http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_Ver2.pdf

Additional Notes:

1. Do not use 0.0 effort – effort must be a minimum of .12 months for Key Personnel. Do not include Other Significant Contributors on budget pages but DO include them in the Budget Justification.
2. Attach budget justification in year 01 (you will not be able to proceed to next period without this step).
3. Do NOT change PD/PI role to anything else – this will cause error
4. Do not forget to include effort for Senior/Key Persons in each year.
5. Remember dates for each year.
6. Include Cognizant Agency info in each year.
7. Do not use Participant Support Costs for anything other than Conference Grants.

R & R Subaward Budget:

1. Extract a budget and email it to each of your subawardee contacts to complete.
2. When returned check carefully for the following:
 - a. Dates match prime proposal dates
 - b. DUNS number of each institution has been completed (ending with four zeros).
 - c. Format is in .xfd format.
 - d. Budget Justification is attached in .pdf format.
3. Attach .xfd file for each consortium using name of institution as filename in Attachment 1, 2, etc. (i.e. Baylor.xfd, Columbia.xfd)