

Supplemental Material

“Pre-Award Grant Preparation: Electronic Grant Submissions”

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Contents:

1. Outline of Required Material for SF 424 R&R Application
2. Directions for “Verifying and/or Updating Personal Information in NIH eRA Commons and MyColumbia”
3. Summary of NIH Statement on “Availability of Research Results: and Sharing Research Data and Resources”
4. New NIH Receipt Cycle Timeline (Application due dates; Scientific Merit Review and Advisory Council dates; Earliest Project Start Dates)
5. SF 424 R&R Detailed Human Subjects Instructions

Outline of Required Material for SF 424 R&R Application

GENERAL FORMATTING

Grant files should be formatted as follows:

- Start with plain Word document
- ½" (0.5") margins all the way around
- Font Arial size 11 (except in tables, figures, etc.)
- No headers or footers allowed
- No pagination (when referring reader to another part of the document, refer to a section rather than a page number)
- Note: a few sections still use PHS 398 form pages (e.g., biosketch, targeted enrollment)

SECTIONS OF THE SF 424 R&R ELECTRONIC APPLICATION

I. Cover Letter:

- Not mandatory, but can still be included; will be scanned in and attached separately
- Can be printed on CUSON letter head and signed

II. Project Summary (formerly "Abstract"):

- Use plain Word document (with specifications as above)
- Limited to 30 lines of text (no longer uses a box)

III. Project Narrative:

- Separate requirement (used to be part of abstract)
- Use plain Word document (with specifications as above)
- Instructions: "Using no more than two or three sentences, describe the relevance of this research to **public** health. In this section, be succinct and use plain language that can be understood by a general, lay audience"

IV. Senior/Key Personnel:

- Personnel still fall into 1 of 3 categories: Key Personnel, Other Significant Contributors (OSC), and Non-Key Personnel
- NIH biosketches are required for all Key Personnel and all OSCs
- Use PHS 398 form page for biosketches, except remove headers and footers
- New requirement: a "Profile" is required for each Key Personnel and OSC. This includes titles, addresses, phone number, fax number, e-mail address, and eRA Commons ID
- NOTE: Grants.gov is requiring ALL named personnel obtain an eRA Commons ID

V. References Cited:

- Can be kept in the Research Plan document, but will be separated into a separate document for attachment after Research Plan is finalized

VI. Facilities and Other Resources:

- Should be prepared on plain sheet of paper with specifications as above
- If a subcontract is included, the subcontract site "Resources" should be included as part of this document, after the Columbia University "Resources" section

VII. Budget Justification:

- Use plain Word document (with specifications as above)
- Use same NIH categories as previously
- If a subcontract is included, a SEPARATE document should be created for the subcontract budget justification

VIII. Research Plan:

- Should create the Research Plan as a single document (Use plain Word document with specifications as above) which will then be broken into separate attachments for uploading when finalized
- White space created by dividing the Research Plan into separate attachments will NOT be counted against page limitations
- Research Plan Sections A-D remain unchanged: Specific Aims, Background and Significance; Preliminary Studies/Progress Report; Research Design and Methods

IX. Human Subjects:

- Can be created as one document, or as part of the Research Plan document, but will be broken into 4 separate attachments:
 - Protection of Human Subjects
 - Inclusion of Women and Minorities
 - Inclusion of Children
 - Targeted / Planned Enrollment Table
- “Protection of Human Subjects” should include the following specific sections:
 1. RISKS TO THE SUBJECTS
 - a. Human Subjects Involvement and Characteristics
 - b. Sources of Materials
 - c. Potential Risks
 2. ADEQUACY OF PROTECTION AGAINST RISKS
 - a. Recruitment and Informed Consent
 - b. Protection Against Risk
 3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS
 4. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED
 5. DATA AND SAFETY MONITORING PLAN
- “Inclusion of Women and Minorities” should follow
- “Inclusion of Children” should follow (or justification for exclusion of children)
- Targeted/Planned Enrollment table uses same PHS 398 form page but remove headers and footers

X. Consortium/Contractual Arrangements:

- If application includes a subcontract, a separate document must be created and attached which addresses the Consortium/Contractual Arrangement
- Instructions: *Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee.*

XI. Sharing Research Resources:

- This is a new requirement of most NIH grant applications
- Instructions: *NIH policy expects that grant recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication. Investigators should include a sharing research resources plan addressing how unique research resources will be shared or explain why sharing is not possible.*

XII. Letters of Support:

- Are not part of the Appendix, but included as an attachment within the “Research Plan” section of the InfoEd electronic system
- Obtain electronically when possible; can be scanned in and attached separately as well
- All letters are combined into one document for attachment

XIII. Appendix:

- A maximum of 10 .pdf attachments are allowed; if more than 10 are needed, combine the remaining information into attachment #10

- A summary sheet listing all of the items included in the appendix is encouraged; when included, it should be the first appendix attachment
- Publications are no longer allowed as appendix materials except in circumstances described below. Applicants may submit up to 3 of the following types of publications:
 - Manuscripts and/or abstracts accepted for publication but not yet published: The entire article should be submitted as a .pdf attachment
 - 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
- Publications should be references by URL with the full reference in the “Bibliography and References Cited” Section and/or the “Biographical Sketch” section
- Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents are allowable attachments in the Appendix

Availability of Research Results: and Sharing Research Data and Resources

It is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public. PIs and grantee organizations are expected to make the results and accomplishments of their activities available to the research community and to the public at large. (See also “Public Policy Requirements and Objectives—Availability of Information—Access to Research Data” (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part5.htm#_Access_to_Research) for policies related to providing access to certain research data at public request.) If the outcomes of the research result in inventions, the provisions of the Bayh-Dole Act of 1980, as implemented in 37 CFR Part 401, apply.

As long as grantees abide by the provisions of the Bayh-Dole Act, as amended by the Technology Transfer Commercialization Act of 2000 (P.L. 106-404), and 37 CFR Part 401, they have the right to retain title to any invention conceived or first actually reduced to practice using NIH grant funds. The principal objectives of these laws and the implementing regulation are to promote commercialization of federally funded inventions, while ensuring that inventions are used in a manner that promotes free competition and enterprise without unduly encumbering future research and discovery.

The regulation requires the grantee to use patent and licensing processes to transfer grant-supported technology to industry for development. Alternatively, unpatented research products or resources—“research tools”—may be made available through licensing to vendors or other investigators. Sharing of copyrightable outcomes of research may be in the form of journal articles or other publications.

The importance of each of these outcomes of funded research is reflected in the specific policies pertaining to rights in data, sharing of research data and unique research resources, and inventions and patents described in the following subsections.

Sharing of Research Data

NIH believes that data sharing is essential for expedited translation of research results into knowledge, products, and procedures to improve human health. NIH endorses the sharing of final research data to serve these and other important scientific goals and expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers. “Timely release and sharing” is defined as no later than the acceptance for publication of the main findings from the final data set. Effective with the October 1, 2003 receipt date, investigators submitting an NIH application seeking \$500,000 or more in direct costs in any single budget period are expected to include a plan for data sharing or state why data sharing is not possible.

NIH recognizes that data sharing may be complicated or limited, in some cases, by organizational policies, local IRB rules, and local, State and Federal laws and regulations, including the “Privacy Rule” (See “Public Policy Requirements and Objectives—Requirements Affecting the Rights and Welfare of Individuals as Research Subjects, Patients, or Recipients of Services—Confidentiality—Standards for Privacy of Individually Identifiable Health Information”).

(http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part5.htm#_Standards_for_Privacy)

The rights and privacy of individuals who participate in NIH-sponsored research must be protected at all times. Thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

Sharing of Unique Research Resources

Investigators conducting biomedical research frequently develop unique research resources. Categories of these resources include synthetic compounds, organisms, cell lines, viruses, cell products, and cloned DNA, as well as DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data. Specific examples include specialized or genetically defined cells, including normal and diseased human cells; monoclonal antibodies; hybridoma cell lines; microbial cells and products; viruses and viral products;

recombinant nucleic acid molecules; DNA probes; nucleic acid and protein sequences; certain types of animals, such as transgenic mice; and intellectual property, such as computer programs.

NIH considers the sharing of such unique research resources (also called research tools) an important means to enhance the value of NIH-sponsored research. Restricting the availability of unique resources can impede the advancement of further research. Therefore, when these resources developed with NIH funds and the associated research findings have been published or after they have been provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community.

To provide further clarification of the NIH policy on disseminating unique research resources, NIH published *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources* (64 FR 72090, December 23, 1999), which is available on the NIH website (http://www.ott.nih.gov/policy/rt_guide_final.html). This document will assist grantees in determining reasonable terms and conditions for disseminating and acquiring research tools.

The terms of those agreements also must reflect the objectives of the Bayh-Dole Act and the Technology Transfer Commercialization Act of 2000 to ensure that inventions made are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery.

In addition to sharing research resources with the research community, upon request of the NIH awarding office, the grantee also must provide a copy of documents or a sample of any material developed under an NIH grant award. The grantee may charge a nominal fee to cover shipping costs for providing this material. Income earned from these charges must be treated as program income (see “Administrative Requirements—Management Systems and Procedures—Program Income”) (http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part8.htm#_Program_Income).

To facilitate the availability of unique or novel biological materials and resources developed with NIH funds, investigators may distribute the materials through their own laboratory or organization or submit them, if appropriate, to entities such as the American Type Culture Collection or other repositories. Investigators are expected to submit unique biological information, such as DNA sequences or crystallographic coordinates, to the appropriate data banks so that they can be made available to the broad scientific community. When distributing unique resources, investigators are to include pertinent information on the nature, quality, or characterization of the materials.

Investigators must exercise great care to ensure that resources involving human cells or tissues do not identify original donors or subjects, directly or through identifiers such as codes linked to the donors or subjects.

Organizations that believe they will be unable to comply with these requirements should promptly contact the GMO to discuss the circumstances, obtain information that might enable compliance, and reach an understanding in advance of an award.

	RECEIPT CYCLE I	RECEIPT CYCLE II	RECEIPT CYCLE III
Program Project Grants and Center Grants – all P Series <i>new, renewal, resubmission, revision*</i>	January 25 (old date Feb. 1)	May 25 (old date June 1)	September 25 (old date Oct. 1)
Research Grants – R10, R18, R24, R25 <i>new, renewal, resubmission, revision*</i>	January 25 (old date Feb 1, March 1)	May 25 (old date June1, July 1)	September 25 (old date Oct. 1, Nov. 1)
Research-Related and Other Programs – all S and G Series, C06, M01 <i>new, renewal, resubmission, revision*</i>	January 25 (old date Feb. 1)	May 25 (old date June 1)	September 25 (old date Oct. 1)
Institutional Ruth L. Kirschstein National Research Service Awards - T Series (Training)** <i>new, renewal, resubmission, revision*</i>	January 25 (old date Jan. 10)	May 25 (old date May 10)	September 25 (old date Sept. 10)
Research Grants - R01 <i>new</i>	February 5 (old date Feb. 1)	June 5 (old date June 1)	October 5 (old date Oct. 1)
Research Career Development – all K series <i>new</i>	February 12 (old date Feb. 1)	June 12 (old date June 1)	October 12 (old date Oct. 1)
Research Grants - R03, R21, R33, R21/R33, R34, R36 <i>new</i>	February 16 (old date Feb. 1)	June 16 (old date June 1)	October 16 (old date Oct. 1)
Academic Research Enhancement Award (AREA) - R15 <i>new, renewal, resubmission, revision*</i>	February 25 (no change)	June 25 (no change)	October 25 (no change)
Research Grants - R01 <i>renewal, resubmission, revision*</i>	March 5 (old date March 1)	July 5 (old date July 1)	November 5 (old date Nov. 1)
Research Career Development – all K series <i>renewal, resubmission, revision*</i>	March 12 (Old date March 1)	July 12 (old date July 1)	November 12 (old date Nov. 1)
Research Grants - R03, R21, R33, R21/R33, R34, R36 <i>renewal, resubmission, revision*</i>	March 16 (old date March 1)	July 16 (old date July 1)	November 16 (Old date Nov. 1)
<u>New Investigator</u> – R01 <i>resubmission* for those applications involved in pilot ONLY NOT-OD-06-060.html</i>	March 20 (no change)	July 20 (no change)	November 20 (no change)
Small Business Innovation Research (SBIR), Small Business Technology Transfer (STTR) Grants - R43, R44, R41 and R42 <i>new, renewal, resubmission, revision*</i>	April 5 (old date April 1)	August 5 (old date Aug. 1)	December 5 (old date Dec. 1)
Individual Ruth L. Kirschstein National Research Service Awards (Standard) – all F series Fellowships. <i>new, renewal, resubmission*</i>	April 8 (old date April 5)	August 8 (old date Aug. 5)	December 8 (old date Dec. 5)
Conference Grants and Conference Cooperative Agreements - R13, U13 <i>new, renewal, resubmission, revision*</i>	April 12 (old date April 15)	August 12 (old date Aug. 15)	December 12 (old date Dec. 15)
AIDS and AIDS-Related Grants ALL of the mechanisms cited above <i>new, renewal, resubmission, revision*</i>	May 1 (no change)	September 1 (no change)	January 2 (no change)
	CYCLE I	CYCLE II	CYCLE III
Scientific Merit Review	June-July	October-November	February-March
Advisory Council Review	September-October	January-February	May-June
Earliest Project Start Date	December	April	July

* The move to electronic applications also has brought a change in terminology. The new Grants.gov terminology (included in the table above) corresponds to traditional NIH terms as follows:

- New = new
- Resubmission = a revised or amended application
- Renewal = Competing Continuation
- Continuation = Progress Report
- Revision = Competing Supplement

** **Institutional Research Training Grants (T32)** are accepted by many NIH Institutes and Centers (IC) for only one or two of the dates. Applicants should contact the relevant IC for specific dates.

INSTRUCTIONS PERTAINING TO NON-EXEMPT HUMAN SUBJECTS RESEARCH

In your PHS398 Research Plan Component, include attachments for Items 8 through 11, if required. Although no specific page limitation applies to this section of the application, be succinct. Scientific Review Groups will assess each application as being “acceptable” or “unacceptable” with regard to the protection of human subjects.

In the attachment for Item 8, include a heading entitled “Protection of Human Subjects.” Use subheadings to address the issues listed under items 1- 5 below.

Protection of Human Subjects

1. RISKS TO THE SUBJECTS

a. Human Subjects Involvement and Characteristics

- Describe the proposed involvement of human subjects in the work outlined in the Research Design and Methods section.
- Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
- Identify the criteria for inclusion or exclusion of any subpopulation.
- Explain the rationale for the involvement of special classes of subjects, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. Note that ‘prisoners’ includes all subjects involuntarily incarcerated (for example, in detention centers) as well as subjects who become incarcerated after the study begins.
- List any collaborating sites where human subjects research will be performed, and describe the role of those sites in performing the proposed research.

b. Sources of Materials

- Describe the research material obtained from living human subjects in the form of specimens, records, or data.
- Describe any data that will be recorded on the human subjects involved in the project.
- Describe the linkages to subjects, and indicate who will have access to subject identities.
- Provide information about how the specimens, records, or data are collected and whether material or data will be collected specifically for your proposed research project.

c. Potential Risks

- Describe the potential risks to subjects (physical, psychological, social, legal, or other), and assess their likelihood and seriousness to the subjects.
- Where appropriate, describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures to participants in the proposed research.

2. ADEQUACY OF PROTECTION AGAINST RISKS

a. Recruitment and Informed Consent

- Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include children, describe the process for meeting requirements for parental permission and child assent.
- Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. Informed consent document(s) need not be submitted to the PHS agencies unless requested.

b. **Protection Against Risk**

- Describe planned procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
- Where appropriate, discuss plans for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Studies that involve clinical trials (biomedical and behavioral intervention studies) must include a description of the plan for data and safety monitoring of the research and adverse event reporting to ensure the safety of subjects.

3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

- Discuss the potential benefits of the research to the subjects and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

4. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

NOTE: Test articles (investigational new drugs, devices, or biologicals) including test articles that will be used for purposes or administered by routes that have not been approved for general use by the Food and Drug Administration (FDA) must be named. State whether the 30-day interval between submission of applicant certification to the FDA and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the Food and Drug Administration, and/or the status of requests for an IND or IDE covering the proposed use of the test article in the Research Plan.

5. DATA AND SAFETY MONITORING PLAN

- If your research includes a clinical trial, create a subheading entitled “Data and Safety Monitoring Plan.”
- Provide a general description of a monitoring plan that you plan to establish as the overall framework for data and safety monitoring. Describe the entity that will be responsible for monitoring and the process by which Adverse Events (AEs) will be reported to the Institutional Review Board (IRB), the funding I/C, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA) in accordance with Investigational New Drug (IND) or Investigational Device Exemption (IDE) regulations. Be succinct. Contact the FDA (<http://www.fda.gov/>) and also see the following websites for more information related to IND and IDE requirements:

http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr312_01.html (IND)

http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr812_01.html (IDE)

- The frequency of monitoring will depend on potential risks, complexity, and the nature of the trial; therefore, a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:
 - a. PD/PI (required)
 - b. Independent individual/Safety Officer
 - c. Designated medical monitor
 - d. Internal Committee or Board with explicit guidelines
 - e. Data and Safety Monitoring Board (DSMB). NIH specifically requires the establishment of Data and Safety Monitoring Boards (DSMBs) for *multi-site* clinical trials involving interventions that entail potential *risk* to the participants, and generally for Phase III clinical trials. Although Phase I and Phase II clinical trials may also use DSMBs, smaller clinical trials may not require this oversight format, and alternative monitoring plans may be appropriate.
 - f. Institutional Review Board (IRB - required)
- A detailed Data and Safety Monitoring Plan must be submitted to the applicant's IRB and subsequently to the funding IC for approval prior to the accrual of human subjects (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>). For additional guidance on creating this Plan, see the above reference.

Guidance and Additional Instructions

Proceed to [Inclusion of Women and Minorities](#).

INCLUSION OF WOMEN AND MINORITIES

In the attachment for Item 9, include a heading entitled “Inclusion of Women and Minorities.” Although no specific page limitation applies to this section of the application, be succinct.

Scientific Review Groups will assess each application as being “acceptable” or “unacceptable” with regard to the protection of human subjects.

In this section of the Research Plan, address, at a minimum, the following four points:

1. The targeted/planned distribution of subjects by sex/gender and racial/ethnic groups for each proposed study or protocol using the format in the Targeted/Planned Enrollment Table. (Instructions for completing this table are provided below.) If you are using existing specimens and/or data that does not meet the criteria for Exemption 4 and you do not have access to information on the distribution of women and minorities, so state and explain the impact on the goals of the research as part of the rationale that inclusion is inappropriate (item 3 below). Alternatively, you may describe the women and minority composition of the population base from whom the specimens and/or data will be obtained. Include the Targeted/Planned Enrollment Table in **Item 10**.
2. A description of the subject selection criteria and rationale for selection of sex/gender and racial/ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.
3. A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group (see examples below).
4. A description of proposed outreach programs for recruiting sex/gender and racial/ethnic group members as subjects.

Examples of acceptable justifications for exclusion of:

A. **One gender:**

1. One gender is excluded from the study because:
 - inclusion of these individuals would be inappropriate with respect to their health;
 - the research question addressed is relevant to only one gender;
 - evidence from prior research strongly demonstrates no difference between genders;
 - sufficient data already exist with regard to the outcome of comparable studies in the excluded gender, and duplication is not needed in this study.
2. One gender is excluded or severely limited because the purpose of the research constrains the applicant’s selection of study subjects by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or overriding factors dictate selection of subjects, such as matching of transplant recipients, or availability of rare surgical specimens).
3. Gender representation of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens, or data-sets with incomplete gender documentation are used), and this does not compromise the scientific objectives of the research.

B. **Minority groups or subgroups:**

1. Some or all minority groups or subgroups are excluded from the study because:

- Inclusion of these individuals would be inappropriate with respect to their health;
 - The research question addressed is relevant to only one racial or ethnic group;
 - Evidence from prior research strongly demonstrates no differences between racial or ethnic groups on the outcome variables;
 - A single minority group study is proposed to fill a research gap;
 - Sufficient data already exists with regard to the outcome of comparable studies in the excluded racial or ethnic groups and duplication is not needed in this study.
2. Some minority groups or subgroups are excluded or poorly represented because the geographical location of the study has only limited numbers of these minority groups who would be eligible for the study, and the investigator has satisfactorily addressed this issue in terms of:
- The size of the study;
 - The relevant characteristics of the disease, disorder or condition;
 - The feasibility of making a collaboration or consortium or other arrangements to include representation.
- Some minority groups or subgroups are excluded or poorly represented because the purpose of the research constrains the applicant's selection of study subjects by race or ethnicity (e.g., uniquely valuable cohorts, stored specimens or existing datasets are of limited minority representation, very small numbers of subjects are involved, or overriding factors dictate selection of subjects, such as matching of transplant recipients or availability of rare surgical specimens).
3. Racial or ethnic origin of specimens or existing datasets cannot be accurately determined (e.g., pooled blood samples, stored specimens or data sets with incomplete racial or ethnic documentation are used) and this does not compromise the scientific objectives of the research.

Additional Instructions and Requirements When NIH-Defined Phase III Clinical Trials Are Proposed

If your proposed research includes an [NIH-Defined Phase III Clinical Trial](#), the section on Inclusion of Women and Minorities also must address whether you expect to find clinically important sex/gender and/or race/ethnicity differences in the intervention effect. The discussion may include supporting evidence and/or data derived from prior animal studies, clinical observations, metabolic studies, genetic studies, pharmacology studies, and observational, natural history, epidemiology and other relevant studies. Your discussion of expected sex/gender and/or race/ethnicity differences in intervention effect must include selection and discussion of one of the following analysis plans:

- Plans to conduct valid analyses to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, *or*
- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups. (Representation of sex/gender and racial/ethnic groups is not required as subject selection criteria, but inclusion is encouraged.), *or*
- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Instructions for Completing the Targeted/Planned Enrollment Tables for Reporting Race and Ethnicity Data for Subjects in Clinical Research

If your application includes Targeted/Planned Enrollment tables, save all as a single PDF file and attach them using section 10. Targeted/Planned Enrollment of the PHS 398 Research Plan Component.

A. New Applications and Clinical Research Studies begun after January 10, 2002:

All new clinical research studies should collect and report information on participants with respect to two categories of ethnicity and five categories of race. The new [Inclusion Enrollment Report](http://grants.nih.gov/grants/funding/424/SF424R-R_enrollmentreport.doc) Table (http://grants.nih.gov/grants/funding/424/SF424R-R_enrollmentreport.doc) for reporting summary data on participants to NIH includes two categories of ethnicity and five categories of race and is based on recent changes by the Office of Management and Budget (OMB) regarding standards for data on race and ethnicity. Investigators should review the instructions and Frequently Asked Questions about using the new Enrollment Table format at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html>.

When reporting these data in the aggregate, investigators should report: (a) the number of respondents in each ethnic category; (b) the number of respondents who selected only one category for each of the five racial categories; (c) the total number of respondents who selected multiple racial categories reported as the “number selecting more than one race,” and (d) the number of respondents in each racial category who are Hispanic or Latino. Investigators may provide the detailed distributions, including all possible combinations, of multiple responses to the racial designations as additional information. However, more detailed items should be designed in a way that they can be aggregated into the required categories for reporting purposes.

For new applications and clinical research studies begun after January 10, 2002, complete the [Targeted/Planned Enrollment Table](http://grants.nih.gov/grants/funding/424/SF424R-R_enrollment.doc) (http://grants.nih.gov/grants/funding/424/SF424R-R_enrollment.doc) and attach as Item 10.

Provide the study title.

The “Total Planned Enrollment” means the number of subjects that are expected to be enrolled during the entire period of the study and are needed to evaluate the research question. The “Total Planned Enrollment” will be reported in two ways in the table: by “Ethnic Category” and by “Racial Categories.”

“Ethnic Category”: Provide the numeric distribution of the Total Planned Enrollment according to ethnicity and sex/gender in the top part of the table.

“Racial Categories”: Provide the numeric distribution of the Total Planned Enrollment, this time by racial categories and sex/gender, in the bottom part of the table. Note that Hispanic is not a racial category.

If there is more than one study/protocol, provide a separate table for each.

List any proposed racial/ethnic subpopulations below the table.

How should I report race and ethnicity data when my research involves a foreign population?

Investigators are encouraged to design their data collection instruments in ways that allow respondent self-identification of their racial and ethnic affiliation. However, these items should be designed in a way that they can be aggregated into the required categories. Also, the investigator can report on any racial/ethnic subpopulations by listing this information in an attachment to the required table. This may be particularly useful when distinctive subpopulations are relevant to the scientific hypotheses being studied.

When completing the tables, investigators should asterisk and footnote the table indicating that data includes foreign participants. If the aggregated data only includes foreign participants, the investigator should provide information in one table with an asterisk and footnote. However, if the study includes both

domestic and foreign participants, the investigator should complete two separate tables – one for domestic data and one for foreign data, with an asterisk and footnote accompanying the table with foreign data.

B. Clinical Research Studies begun before January 10, 2002:

If the proposed research uses existing data, then use the formats below for competing continuations (now known as “Renewals”) and competing supplements (now known as “Revisions”). Investigators should review the instructions and Frequently Asked Questions about using the new Enrollment Table format at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html>.

Competing Continuations (now known as “Renewals”):

For renewal applications involving the collection of new/additional clinical data, use the “[Targeted/Planned Enrollment Table](#)” and the instructions above. *Note:* If you choose to report information with the new Targeted/Planned Enrollment Table, you must continue to use this format for the remaining years of the project.

For renewal applications involving studies begun before January 10, 2002 that do not involve the collection of new/additional clinical data, the data on ethnicity/race and sex/gender may be presented in EITHER the [Targeted/Planned Enrollment Table](#) OR the [4/98 Version of the Inclusion Table](#). If data were originally collected from study subjects using two questions (one about ethnicity and one about race) and subjects were given the option of selecting more than one race, then use the Targeted/Planned Enrollment Table. Otherwise, use the 4/98 Version of the Inclusion Table, which uses a combined race/ethnicity format with five categories.

Competing Supplements (now known as “Revisions”):

For revision applications involving studies begun before January 10, 2002, investigators may report ethnicity/race and sex/gender composition using EITHER the [Inclusion Enrollment Report](#) OR the [4/98 Version of the Inclusion Table](#). If data are being collected using two questions (one about ethnicity and one about race) and subjects were given the option of selecting more than one race, then use the Targeted/Planned Enrollment Table. *Note:* If you choose to report information with the new Targeted/Planned Enrollment Table, you must continue to use this format for the remaining years of the project.

If data are being collected using one question that combines ethnicity and race, use the 4/98 Version of the Inclusion Table. For previously funded studies that used the 4/98 Version of the Inclusion Table the earlier reporting format is NOT directly transferable to the format.

C. What Inclusion/Enrollment Table Should PDs/PIs Use for Reporting Accrual Data to NIH? (New versus Old Table)

The following instructions apply to progress reports, whether submitted as part of a non-competing or competing application.

Guidelines for choosing the new Inclusion Enrollment Report Table versus the old Inclusion Table are as follows:

New Inclusion Enrollment Report (http://grants.nih.gov/grants/funding/424/SF424R-R_enrollmentreport.doc)

- Studies begun after January 10, 2002, must be designed to ask participants two questions, one about their ethnicity and one about their race, and investigators must use the new Inclusion Enrollment Report table format for reporting summary data to NIH.
- Project Directors/Principal Investigators (PDs/PIs) who started a study prior to January 10, 2002 using the old Inclusion Table format for reporting summary data to NIH may switch to the new

Inclusion Enrollment Report format if they choose to do so, but they must also change their data collection methods to ask two questions (one about ethnicity and another about race) rather than one question (that combined race and ethnicity) for all participants enrolled in the study from that point on.

- For studies that began prior to January 10, 2002: When the study is submitted for renewal and plans to collect new/additional data, the PD/PI is required to change to the new standards for collecting data and use the new Inclusion Enrollment Report format for reporting data to NIH. In some cases, this will mean that PDs/PIs will need to re-ask study participants about their race and ethnicity using the new two-question format. Note: PDs/PIs should not ask again about race and ethnicity if the subjects are no longer participating in the study.

Old Inclusion Table (4/98 Version) (http://grants.nih.gov/grants/funding/424/SF424R-R_Inclusion498version.doc)

- Studies begun prior to January 10, 2002 (and now in their non-competing Type 5 period) that were structured with one question about race and ethnicity may continue to report enrollment/accrual data to NIH based on the old form, i.e., using five categories of race/ethnicity. However, when they come in for competitive renewal (Type 2), they will need to change to the new standards/new form for any additional data collection.
- PDs/PIs should not switch to the new form if only one question about race and ethnicity is used in data collection.

Investigators who have questions about these choices should contact NIH program staff for advice.

Guidance and Additional Instructions

After you have completed the Inclusion of Women and Minorities section, proceed to [Inclusion of Children](#).

INCLUSION OF CHILDREN

- In the attachment for Item 11, include a heading entitled “Inclusion of Children.”
- For the purpose of implementing these guidelines, a *child* is defined as an individual under the age of 21 years (for additional information see <http://grants.nih.gov/grants/funding/children/children.htm> and <http://grants.nih.gov/grants/guide/notice-files/not98-024.html>).
- Provide either a description of the plans to include children or, if children will be excluded from the proposed research, application, or proposal, then you must present an acceptable justification (see below) for the exclusion.
- If children are included, the description of the plan should include a rationale for selecting a specific age range of children. The plan also must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.
- Scientific Review Groups will assess each application as being “acceptable” or “unacceptable” with regard to the age-appropriate inclusion or exclusion of children in the research project.
- When children are involved in research, the Additional Protections for Children Involved as Subjects in Research ([45 CFR Part 46 Subpart D](#)) apply and must be addressed in the “Human Subjects Research and Protection from Risks” subheading.

Justifications for Exclusion of Children

For the purposes of this policy, all individuals under 21 are considered children; however, exclusion of any specific age group, such as individuals under 18, should be justified in this section.

It is expected that children will be included in all clinical research unless one or more of the following exclusionary circumstances can be fully justified:

1. The research topic to be studied is not relevant to children.
2. There are laws or regulations barring the inclusion of children in the research.
3. The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be needlessly redundant. Documentation of other studies justifying the exclusions should be provided. NIH program staff can be contacted for guidance on this issue if the information is not readily available.
4. A separate, age-specific study in children is warranted and preferable. Examples include:
 - a. The condition is relatively rare in children, as compared to adults (in that extraordinary effort would be needed to include children, although in rare diseases or disorders where the applicant has made a particular effort to assemble an adult population, the same effort would be expected to assemble a similar child population with the rare condition); or
 - b. The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
 - c. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages or different age-related metabolic processes). While this situation may represent a justification for excluding children in some instances, consideration should be given to

taking these differences into account in the study design and expanding the hypotheses tested, or the interventions planned, to allow inclusion of children rather than excluding them.

5. Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). Although children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis.
6. Study designs are aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children).
7. Other special cases can be justified by the investigator and found acceptable to the review group and the Institute Director.

Guidance and Additional Instructions

After you have completed this section of the application, proceed to Vertebrate Animals.

See Policy on [Inclusion of Children](#).

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title:

Total Planned Enrollment:

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino			
Not Hispanic or Latino			
Ethnic Category: Total of All Subjects *			
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
Racial Categories: Total of All Subjects *			

* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."