NIH FORMS-F and Other Policy Changes
Agenda

Proposal considerations

Policy changes

Review of Human Subjects/Clinical Trial Determinations and Selecting an FOA

Forms Changes
Latest on Late Application Policies

• The general NIH Late Application Policy is in effect

• NOT-OD-15-039:  

• Additional Late Application Policies
  • Mainly Institute-specific/FOA-specific
    • NIGMS, NIAID, NIA, NCI (R25 program), Parent FOA T32/T35
NIH Guide to Grants and Contracts

Track the release of new funding opportunity announcements and notices that we publish in the NIH Guide for Grants and Contracts:

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Receive weekly emails (usually on Friday afternoon) with the Current Weekly Table of Contents (TOC) from the NIH Guide to Grants and Contracts including direct links to all funding opportunities and notices published during the week.

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- Follow the instructions of your news reader

grants.nih.gov/grants/guide/newsfeed/fundingopps.xml

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Customize Saved Search Notifications

Save your search and get daily, weekly or monthly notifications when we publish a funding opportunity or notice that matches your search in the future.

https://grants.nih.gov/grants/guide/listserv_dev.htm
### Example – Related Notices in FOA

**Department of Health and Human Services**

**Part 1. Overview Information**

<table>
<thead>
<tr>
<th>Participating Organization(s)</th>
<th>National Institutes of Health (NIH)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components of Participating Organizations</td>
<td>National Institute on Aging (NIA)</td>
</tr>
</tbody>
</table>

**Funding Opportunity Title**

Mechanisms of Rejuvenation and Age-Acceleration in Heterochronic Blood Exchange (R01 Clinical Trial Not Allowed)

**Activity Code**

R01 Research Project Grant

**Announcement Type**

New

**Related Notices**

- **May 14, 2020** - NIA Late Application Policy for NIA-Specific FOAs with Application Due Dates in May, June, and July 2020. See Notice NOT-AG-20-033.
Which Forms do I use?

The **DUE DATE** drives the form selections:

- **FORMS-E** - due dates **before** May 25, 2020
  - Example, FOA due date is May 18, a late application policy allowed submission until June 30.

- **FORMS-F** - due dates **on/after** May 25, 2020
  - Example, you prepared application early, plan to submit May 20, but FOA due date is May 25.
<table>
<thead>
<tr>
<th>Due Date Range</th>
<th>Application Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>On or before May 24, 2020, including:</td>
<td>FORMS-E application forms and instructions</td>
</tr>
<tr>
<td>Applications submitted under NIH Late Policy 2-week window of consideration for intended due dates on or before May 24, 2020</td>
<td>Parent Announcements posted prior to 2020 (if applying to a parent FOA)</td>
</tr>
<tr>
<td>Applications submitted by June 1, 2020 under NIH Continuous Submission Policy for the May 7, 2020 AIDS intended due date</td>
<td></td>
</tr>
<tr>
<td>On or after May 25, 2020, including:</td>
<td>FORMS-F application forms and instructions</td>
</tr>
<tr>
<td>All application types (New, Resubmission, Renewal, Revision)</td>
<td>Parent Announcements posted in spring 2020 (if applying to a parent FOA)</td>
</tr>
<tr>
<td>Applications submitted early for intended due dates on or after May 25, 2020</td>
<td></td>
</tr>
<tr>
<td>Applications submitted after June 1, 2020 under NIH Continuous Submission Policy</td>
<td></td>
</tr>
</tbody>
</table>
Continuous Submission Policy

• Change in Submission Deadlines and End of Recent Substantial Service Option (NOT-OD-20-060):

• Discontinuing “recent substantial service”, earned for temporary or ad hoc service on a qualifying NIH study section at least 6 times in an 18 month period.

  • Reviewers who are currently eligible for continuous submission through their recent substantial service will remain eligible through the end of their term on September 30, 2020.

  • Reviewers who earn eligibility for service through June 30, 2020 will receive continuous submission eligibility from August 1, 2020 through September 30, 2021.

• Continuous submission privileges for appointed regular members of NIH committees are unchanged.

• [CSR.cont.sub.comm@mail.nih.gov](mailto:CSR.cont.sub.comm@mail.nih.gov)

• See their FAQs: [https://grants.nih.gov/faqs#/continuous-submission.htm](https://grants.nih.gov/faqs#/continuous-submission.htm)
## Continuous Submission Receipt Dates

<table>
<thead>
<tr>
<th>For the Advisory Council Round:</th>
<th>Non-AIDS Standard Application Due Dates</th>
<th>Continuous Submission Non-AIDS Application Receipt Period Ends</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>R01, R21, R34</td>
<td>R01, R21, R34</td>
</tr>
<tr>
<td><strong>May</strong></td>
<td>October 5</td>
<td>December 10</td>
</tr>
<tr>
<td></td>
<td>November 5</td>
<td></td>
</tr>
<tr>
<td><strong>October</strong></td>
<td>February 5</td>
<td>April 10</td>
</tr>
<tr>
<td></td>
<td>March 5</td>
<td></td>
</tr>
<tr>
<td><strong>January</strong></td>
<td>June 5</td>
<td>August 10</td>
</tr>
<tr>
<td></td>
<td>July 5</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>For the Advisory Council Round:</th>
<th>AIDS Application Due Dates</th>
<th>Continuous Submission AIDS Application Receipt Period Ends</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>May</strong></td>
<td>January 7</td>
<td>February 1</td>
</tr>
<tr>
<td><strong>October</strong></td>
<td>May 7</td>
<td>June 1</td>
</tr>
<tr>
<td><strong>January</strong></td>
<td>September 7</td>
<td>October 1</td>
</tr>
</tbody>
</table>

*Direct any submission issues, including Grants.gov rejection messages indicating the opportunity is closed, to the eRA Service Desk.*
Continuous Submission/Late Application Policy

- Temporary or ad hoc reviewers who are not eligible for continuous submission may be eligible to use the late submission window as described in the [NIH Late Policy](#).

**How does Continuous Submission relate to the NIH Late Policy?**

- Continuous Submission applies to R01, R21, and R34 applications submitted by continuous submission eligible PD/PIs and MPIs to FOAs with standard due dates, including standard AIDS due dates.
- The [NIH Late Policy](#) applies to
  - All other types of applications submitted by continuous submission eligible PD/PIs and MPIs.
  - All applications submitted by all other PD/PIs and MPIs.
COVID-19: Proposal Considerations

• Should I address impact of COVID-19 in my NIH/AHRQ proposal?

• Guidance for NIH Peer Reviewers:
  • “Assume that issues resulting from the coronavirus pandemic will be resolved prior to award, and not allow concerns about temporary, emergency situations to affect their scores.” [11]
Budgeting Guidance

Cost principles:
• Reasonableness (including necessity)
• Allocability
• Consistency
• Allowability/Conformance

NIH Grants Policy Statement, section 7.9, Allowability of Costs/Activities:

Develop your Budget:
Policy Change/FORMS-F
NIH/AHRQ: Career Development Awards


- Added instructions about rigor, experimental design, and quantitative approaches to the “Candidate Information and Goals for Career Development” section.

- “Describe the new or enhanced research skills and knowledge you will acquire as a result of the proposed award, including, as applicable, expertise in rigorous research design, experimental methods, quantitative approaches and data analysis and interpretation.”

Candidate Section

2. Candidate Information and Goals for Career Development

Required. This attachment and the Research Strategy attachment are limited to a combined total of 12 pages unless otherwise stated in the announcement.
• Applicants to **diversity-related** FOAs (e.g., diversity-related K01) will be required to **include an attachment** describing how the candidate’s participation would further the goals of the program.

• Added new “Description of Candidate’s Contribution to Program Goals” attachment.
• The sponsoring institution must provide a document on institutional letterhead that explains how the candidate’s participation will further the goals of the career development program to promote diversity in health-related research.

• Must be dated and signed by an institutional official. In most cases, this will be the dean or the chairman of the department.

- Applicant’s Background and Goals for Fellowship Training
- Training Goals and Objectives

Identify the skills, theories, conceptual approaches, etc., to be learned or enhanced during the award, including, as applicable, expertise in rigorous research design, experimental methods, quantitative approaches, and data analysis and interpretation, as applicable.
In the Research Strategy section, fellowship candidates will be expected to describe (a) the strengths and weaknesses in the rigor of the prior research that serves as the key support for the proposed project, (b) plans to address any weaknesses in the rigor of the prior research, (c) how the experimental objectives proposed will achieve robust and unbiased results, and (d) how relevant biological variables are factored into research designs and analyses.

If applicable, fellowship candidates will be required to include an attachment describing how they will authenticate key biological and/or chemical resources.
Let’s Talk About Rigor and Reproducibility!

This discussion guide is intended for fellows and early-career researchers initiating conversations with mentors and others on addressing NIH’s Rigor and Reproducibility requirements for career development and training goals. For more information on NIH’s Rigor and Reproducibility including webinars and presentations, see the ReDI Program’s Reproducibility webpage.

Applicants are expected to address any new research skills planned to acquire in areas of rigorous research design, experimental methods, quantitative approaches, and data analysis and interpretation. For each of the areas below, list what research skills you will require to learn and further develop to carry-out the research project?

<table>
<thead>
<tr>
<th>Rigorous Research Design</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>(Review Planning a Rigorous Experiment checklist)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Experimental Methods</th>
<th></th>
</tr>
</thead>
</table>
ReaDI Program

Reproducibility Resources and Guidelines by Topic

The following resources have been identified to aid researchers meet Rigor and Reproducibility Requirements from NIH as well as provide tools to researchers to ensure research is verifiable and reproducible.

RESOURCES FOR COLUMBIA NIH INVESTIGATORS

- Rigor and Reproducibility Presentation Slides (last updated 1/6/2020)
- Rigor and Reproducibility Webinar

Contact
ReaDI Program
Office of Research Compliance and Training

Stay Informed!
Join ReaDI Program's Email listserv
Follow on Twitter - @ReaDI_Columbia
Like on Facebook

Home
ReaDI Program
Office of Research Compliance and Training

Related Links
Resources
Outreach
Consultations

https://research.columbia.edu/ReaDI-Program
 NIH/AHRQ: Individual Fellowships (F’s)

- The sponsoring institution must provide a document on institutional letterhead that explains how the candidate’s participation will further the goals of the fellowship program to promote diversity in health-related research.

- Must be dated and signed by an institutional official. In most cases, this will be the dean or the chairman of the department.
• **For NIH applicants, the single IRB plan is no longer required.** Do not provide an attachment. The applicant must provide a statement naming the sIRB of record in the Just-in-Time submission prior to award.

• Still required for AHRQ

• Career Development and Fellowship Applications are now subject to Single IRB Policy. – must select Yes or No in section 3.2 of Study Record

• Still need to budget for Single IRB costs
Single IRB

- See HRPO site: [https://research.columbia.edu/single-irb-review-multi-site-research](https://research.columbia.edu/single-irb-review-multi-site-research)

- If you are conducting **non-exempt** human subjects research and research will be conducted at multiple domestic sites:
  - Immediately complete the [CU sIRB Request Form](https://research.columbia.edu/single-irb-review-multi-site-research)
  - Email it to [irboffice@columbia.edu](mailto:irboffice@columbia.edu)

- Process the same for when Columbia is the PTE, or when Columbia is the subrecipient.

- **Single IRB is mandatory for all federal agencies** (with the exception of FDA)
Am I doing Human Subjects (HS) Research?

Use the Human Subjects Decision Tree:
https://grants.nih.gov/policy/humansubjects/hs-decision.htm
Human Subjects Research

Research involving a living individual about whom data or biospecimens are obtained/used/studied/analyzed through interaction/intervention, or identifiable, private information is used/studied/analyzed/generated

Examples of human subjects research include:

- Collecting blood
- Administering medicine
- Collecting data
- Conducting a survey
- Interviewing
- Administering a psychological test
- Changing participants’ environment
- Conducting a focus group
- Testing a new educational technique

Included in the NIH application:

✓ Protection of Human Subjects attachment

If funded, grantees will need:

✓ An Institutional Federal-Wide Assurance (FWA) with OHRP
✓ IRB approval or determination of exemption
✓ Human Subjects education* even for exemptions

If research meets the criteria for one of the eight categories of activities that are exempt from the federal regulations, not all of the above may apply. Some of the exemptions require a limited IRB review (7 and 8, and some designs under 2 and 3).

Exemptions:

- Exemption 1
  Conducted in an educational setting involving normal education practices
- Exemption 2
  Use of educational tests, surveys, interviews, or observations of public behavior
- Exemption 3
  Use of design behavioral interventions in adults
- Exemption 4
  Collection/study of data or specimens if publicly available or recorded such that subjects cannot be identified* *May be identifiable in limited exams. See 45 CFR 46(102) and (113)
- Exemption 5
  Public service program research or demonstration projects
- Exemption 6
  Taste and food quality evaluations
- Exemption 7
  Storage of identifiable information or biospecimens for secondary research use. Broad consent and limited IRB review are required.
- Exemption 8
  Secondary research use of identifiable information or biospecimens. Broad consent and limited IRB review are required.

Research Involving Private Information or Biospecimens may also be considered Human Subjects Research. See flowchart:


We come back to this later on in this presentation:
If YES, is it Exempt of Non-Exempt?

• Contact the IRB to discuss and clarify.

• Has an impact on the sections you complete in the PHS Human Subjects/Clinical Trial form and study records.

• Impact on Single IRB if multiple sites are involved.

• IRB doesn’t designate Exemptions 7 and 8.

• The IRB makes the final determination when a protocol is submitted during JIT.
Exempt Human Subjects Research

1. Meets the definition of human subjects research.
   Exempt studies involve human subjects research: research involving a living individual about whom data or biospecimens are obtained/used/studied/analyzed through interaction/intervention, or identifiable, private information is used/studied/analyzed/generated.

2. Meets the criteria of one or more of the following exemptions:
   - Exemption 1: conducted in an educational setting using normal educational practices*
     *Cannot include any other procedures, such as collection of clinical data or biospecimens
   - Exemption 2: uses educational tests, surveys, interviews, or observations of public behavior*
     *Limited IRB review may be required.
   - Exemption 3: benign behavioral interventions in adults*
     *Limited IRB review may be required.
   - Exemption 4: secondary research using identifiable information or biospecimens if publicly available, or recorded such that subjects cannot be re-identified*
     *See 46.104(d)(4)(i), (ii), and (iv) for all criteria
   - Exemption 5: public service program research or demonstration projects
   - Exemption 6: taste and food quality evaluations
   - Exemption 7: storage or maintenance of identifiable information or biospecimens for secondary research use. Broad consent and limited IRB review are required.
   - Exemption 8: secondary research using identifiable information or biospecimens. Broad consent and limited IRB review are required.

For more information see the NIH OER Human Subjects Research website. Send questions/comments to OER-HS@nih.gov

NIH Requirements:
- Human Subjects education.
- Inclusion tracking for all except exemption 4.

45 CFR 46 Requirements:
- Limited IRB review for exemptions 7 & 8, and some study designs under 2 & 3.
- Broad consent for exemptions 7 & 8.

Consider

Cannot involve prisoners, unless research includes a broader population that happens to include prisoners.

Cannot involve children in:
- Exemption 2 research if data is recorded with identifiers, for survey or interview procedures, or for observations of public behavior if investigators participate in the activity being observed.
- Exemption 3 research.

If non-exempt, is it an NIH-defined Clinical Trial?

Use the Clinical Trial Decision Tool:

The four questions:
• Does the study involve human participants?
• Are the participants prospectively assigned to an intervention?
• Is the study designed to evaluate the effect of the intervention on the participants?
• Is the effect being evaluated a health-related biomedical or behavioral outcome?

Also see NIH Protocol Templates and e-Protocol Writing Tool:
• Phase 2 or 3 clinical trials that require Investigational New Drug applications (IND) or Investigational Device Exemption (IDE) applications
• Behavioral and social sciences research involving humans

ReaDi Program Resources: [https://research.columbia.edu/clinical-and-health-sciences](https://research.columbia.edu/clinical-and-health-sciences)
Select the Appropriate FOA

Understanding FOAs:


• Applications that include **clinical trials** must be submitted in response to an FOA that allows clinical trials (even if other studies on the same application are not clinical trials).

• Make sure that the NIH Institute or Center that might be interested in your research is listed as a participating organization in the FOA.

• Notices of special interest (NOSIs) may identify NIH Institutes or Centers participating in the notice initiative that are not listed in the FOA used for submission.

• Return to the FOA to check the **Related Notices** section before submission to ensure you are in line with the most recent guidance.
  • Don’t turn the FOAs into PDFs! Updated in real-time.
Research Project Grant (Parent R01 Clinical Trial Required) (PA-20-183)

Contacts and Special Interests

Release Date: May 05, 2020
Expiration Date: May 8, 2023

R01 Clinical Trial Required Participating Institutes and Centers:

- NIH Institutes and Centers that **accept** Investigator-Initiated R01 applications in response to the Parent R01 Clinical Trial Required Announcement - (PA-20-NNN): NHGRI, NEI, NIA, NIAAA, NIAID, NIDA, NIDCD, NIEHS, NIGMS, NIMHD, NINR
- NIH Institutes and Centers that only accept Investigator-Initiated R01 applications proposing **mechanistic clinical trials** in response to the Parent R01 Clinical Trial Required Announcement (PA-20-NNN): NCCIH, NHLBI, NIAMS, NIMH, NINDS
- NIH Institutes and Centers that **DO NOT ACCEPT** applications in response to the Parent R01 Clinical Trial Required Announcement but ONLY accept R01 applications proposing clinical trial(s) in response to their specific funding opportunity announcements: NCI, NIBIB, NICHHD, NIDCR, NIDDK (PA-18-330), NLM, FIC, NCATS

When in doubt, talk to the Scientific/Research Contact at the specific Institute named in the FOA.
Notices of Special Interest (NOSIs)

• Video on NOSIs: [https://youtu.be/LhXW67LNblc](https://youtu.be/LhXW67LNblc)

• NOSI, you **must** include the NOSI number in Box 4B (the Applicant Routing Identifier) on the proposal SF 424 cover page.
FORMS-F Proposal Checklists

•Courtesy of VP&S Office for Research:
  •https://research.ps.columbia.edu/content/checklists

•Grant Starter Kit:
  •https://research.ps.columbia.edu/content/grant-starter-kit
Resubmission?

- Careful to switch to FORMS-F
- Make sure to use the latest Biosketch format, new expiration date: https://grants.nih.gov/grants/forms/biosketch.htm
New Expiration Dates

Expiration Date: old (FORMS-E) 03/31/2020;

New (FORMS-F) date 02/28/2023
New Question: Human Fetal Tissue (HFT)

**New on Cover Page Supplement**

4. Human Fetal Tissue Section

* Does the proposed project involve human fetal tissue obtained from elective abortions?
  - [ ] Yes
  - [ ] No

If "Yes" then provide the HFT Compliance Assurance

If "Yes" then provide the HFT Sample IRB Consent Form

- Add Attachment
- Delete Attachment
- View Attachment

• If Yes, go to application instructions for specific information about these two attachments:
PHS Human Subjects/Clinical Trial Information Form and Study Records

- Updated Expiration Date
- Reworked landing page to require an answer and supporting explanation (if applicable) for the question “Does any of the proposed research in the application involve human specimens and/or data?” for all applications

Study record changes
- Defaulted Clinical Trial Questionnaire question “1.4.a Does the study involve human participants?” to Yes, since study records are only available when the answer to the “Are Human Subjects Involved?” question on the R&R Other Project Information form is Yes
- Separated “Inclusion of Women, Minorities, and Children” attachment into two attachments – “Inclusion of Individuals Across the Lifespan” and “Inclusion of Women and Minorities”
- Renamed “Enrollment of First Subject” field to “Enrollment of First Participant”
- Added “Inclusion Enrollment Report Title” field to the Inclusion Enrollment Report
- Removed “Brief Summary” attachment
- Renamed “Narrative Study Description” attachment to “Detailed Description”
- Added new question and checkbox – “Is this an applicable clinical trial under FDAAA?”
- Renumbered form fields, as needed
All applicants are required to answer this question. The explanation attachment is now always available. Previously, the question and attachment were only available when Human Subjects was NO, which didn’t allow for scenarios where an application involved both human subjects and human specimens and/or data.
Remember that flowchart? Slide 25: **Research Involving Private Information or Biological Specimens.**

- You must provide an explanation for any use of human specimens and/or data **not** considered to be **human subjects research**.

**This explanation should include:**

- information on who is providing the data/biological specimens and their role in the proposed research;
- a description of the identifiers that will be associated with the human specimens and data;
- a list of who has access to subjects’ identities; and
- information about the manner in which the privacy of research participants and confidentiality of data will be protected.
1.4. Clinical Trial Questionnaire

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]
If you answered “Yes” to all the questions in the Clinical Trial Questionnaire, this study meets the definition of a clinical trial.

Refer to the table below for information about what sections of this form are required, based on your answers to Question 1.4 "Clinical Trial Questionnaire."

<table>
<thead>
<tr>
<th>Form Section</th>
<th>If you answered &quot;yes&quot; to all the questions in the Clinical Trial Questionnaire</th>
<th>If you answered &quot;no&quot; to any of the questions in the Clinical Trial Questionnaire</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 2 - Study Population Characteristics</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Section 3 - Protection and Monitoring Plans</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Section 4 - Protocol Synopsis</td>
<td>Required</td>
<td>Do not complete</td>
</tr>
<tr>
<td>Section 5 - Other Clinical Trial-related Attachments</td>
<td>Required if specified in the FOA</td>
<td>Do not complete</td>
</tr>
</tbody>
</table>
Section 2 – Study Population Characteristics

• Separated “Inclusion of Women, Minorities, and Children” attachment into two attachments
• “Inclusion of Individuals Across the Lifespan”
• “Inclusion of Women and Minorities”
• Renamed “Enrollment of First Subject” field to “Enrollment of First Participant”
Inclusion Enrollment Reports (IERs)

2.9. **Inclusion Enrollment Reports(s)**

<table>
<thead>
<tr>
<th>Entry #</th>
<th>Enrollment Location Type</th>
<th>Enrollment Location</th>
<th>Action</th>
</tr>
</thead>
</table>

Nothing found to display.

Added a field number.
IERs continued

• Added a TITLE field in the IER.

![Inclusion Enrollment Report](image)
Let’s Talk IERs

• Each proposed study, unless it falls under Exemption 4, must contain at least one IER.
• Max. 20 IERs per Study Record
• More than one site?
  • May create one IER or separate, multiple IERs to enable reporting by study or by site, depending on the scientific goals of the study and whether monitoring of inclusion enrollment would benefit from being combined or separated.
  • Non-U.S. sites must be reported separately from participants enrolled at U.S. sites, even if they are part of the same study.
• Please review the FOA to determine whether there are any other specific requirements about how to complete the IER.
Human Subjects System (HSS)

• The HSS system is a shared system that enables grant recipients to electronically report and update their data on human subjects and clinical trials to NIH; and for NIH agency staff to monitor and manage the data.

• The HSS is automatically populated by human subjects and clinical trial data entered by the principal investigator (PI) on the Human Subjects and Clinical Trial Information form.

• This data is then made available to PIs and signing officials (SO) through a link that will be available on the eRA Commons Status screen and the Research Performance Progress Report (RPPR).
Section 3.2 - Single IRB

• Must answer Yes or No.
• N/A not an option
• AHRQ, must upload the Single IRB Plan
• NIH applications – nothing to upload

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

Add Attachment  Delete Attachment  View Attachment
Section 4 – Protocol Synopsis (Clinical Trials only)

• Removed “Brief Summary” attachment.
• Renamed “Narrative Study Description” attachment to “Detailed Description”
  • To reduce overlap of requested information, and align with clinicaltrials.gov.

4.1. Study Design

4.1.a. Detailed Description

[ Enter up to 32000 Characters ]
Section 4 continued

• Added new question and checkbox – “Is this an applicable clinical trial under the Food and Drug Administration Amendments Act (FDAAA)?”

• For more information, see https://clinicaltrials.gov/ct2/manage-recs/faq#act
Optional PHS Assignment Request Form

• The PHS Assignment Request Form was reworked to improve usability.
  • Clarified instructional text
  • Improved field labels
  • And a new “Rationale for assignment suggestions” text box.

• Removed fields
  • Do Not Assign to Awarding Components
  • Do Not Assign to Study Sections
In order to prepare the application:

• Parent Announcements

• Application Instructions

• FORMS-F Annotated Form Sets

• Biosketch Format Pages
Questions?

• Contact your SPA Project Officer

• We’re here to help!