Human Subjects Research

- Filling out the Human Subjects and Clinical Trials Information Form
  - Human Subjects Scenarios
- Exemptions to Federal Regulations
- Single IRB Policy
- Education and Training

Tip:
Review the new PHS Human Subjects and Clinical Trial Information Form before you start the Research Strategy as some information may be included in the new form saving you space in the Research Strategy.

For application due dates on or after January 25, 2018
Complete the Research and Related (R&R) Other Project Information Form to indicate:

- Whether your project involves Human Subjects
- If your project is exempt from Federal Regulations

Responses are auto-populated onto the PHS Human Subjects and Clinical Trials Information Form

- Study Records
Filling out the PHS Human Subjects and Clinical Trial Information Form
PHS Human Subjects and Clinical Trials Information Form

See the Application Guide for detailed information

- PHS HS/CT Information Form
- Study Record
  1. Basic information
  2. Study Population Characteristics
  3. Protection and Monitoring Plans
  4. Protocol Synopsis
  5. Other Clinical Trial-related Attachments

OEP-HS@mail.nih.gov

Search By Topic
Section 1 - Basic Information

See the Application Guide for detailed information

- PHS HS/CT Information Form
- Study Record
  1. Basic information
  2. Study Population Characteristics
  3. Protection and Monitoring Plans
  4. Protocol Synopsis
  5. Other Clinical Trial-related Attachments

Study Record: A set of data elements about a research study involving human subjects. Each proposed protocol should have its own study record.
Section 2 - Study Population Characteristics

See the Application Guide for detailed information

- PHS HS/CT Information Form
- Study Record
  1. Basic information
  2. Study Population Characteristics
  3. Protection and Monitoring Plans
  4. Protocol Synopsis
  5. Other Clinical Trial-related Attachments

Exceptions may apply for studies claiming exemption 4 or as otherwise noted in Funding Opportunity Announcement (FOA)
Section 3 - Protection and Monitoring Plans

See the Application Guide for detailed information

- **PHS HS/CT Information Form**
- **Study Record**
  1. Basic information
  2. Study Population Characteristics
  3. Protection and Monitoring Plans
  4. Protocol Synopsis
  5. Other Clinical Trial-related Attachments

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1. Protection of Human Subjects</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If yes, describe the single IRB plan</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.3. Data and Safety Monitoring Plan</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.4. Will a Data and Safety Monitoring Board be appointed for this study?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.5. Overall Structure of the Study Team</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Required for Clinical Trial studies
Required for Human Subjects studies

Search By Topic
Section 4 - Protocol Synopsis

See the Application Guide for detailed information

- **PHS HS/CT Information Form**
- **Study Record**
  1. Basic information
  2. Study Population Characteristics
  3. Protection and Monitoring Plans
  4. Protocol Synopsis
  5. Other Clinical Trial-related Attachments

Required for Clinical Trial studies

Required for Human Subjects studies
Section 5 - Other Clinical Trial-related Attachments

See the Application Guide for detailed information

- PHS HS/CT Information Form
- Study Record
  1. Basic information
  2. Study Population Characteristics
  3. Protection and Monitoring Plans
  4. Protocol Synopsis
  5. Other Clinical Trial-related Attachments

Tip: Section 5 should only be used if there are specific requirements in the FOA. Do not attach unrequested documents.
PHS Human Subjects and Clinical Trial Information Form - Human Subjects Scenarios
Human Subjects Scenarios

Scenarios:

A. No Human Subjects
B. Non-Exempt Human Subjects Research
C. Exempt Human Subjects Research
D. Delayed Onset Human Subject Study
E. Human Subjects Research Involving a Clinical Trial
F. Human Subjects Research Involving an NIH-Defined Phase III Clinical Trial
G. Human Subjects Research Involving Individual or Institutional Research Training
   G1. Career Development Award (CDA) Application - (“K” Series)
   G2. Individual Fellowship Applications - (“F” Series)

Study Record: Each proposed protocol should have its own study record. Because information is collected at the study record, an application may be composed of any combination of “scenarios” discussed.
Determine Whether NIH Would Consider the Research Study ‘Not Human Subjects Research’

• Studies involving coded data or biospecimens:
  ▫ If research involves only secondary analysis of coded biospecimens or data, it is **NOT human subjects research** if:
    • Collected for other reason, **AND**
    • None of the investigators can readily ascertain the identity of subjects (Provider has no other role in research)

For more information, visit: [http://www.hhs.gov/ohrp/policy/cdebiol.html](http://www.hhs.gov/ohrp/policy/cdebiol.html)
Scenario A: No Human Subjects

Answered “No” on the R&R Other Project Information form

- “No” is Auto-populated on PHS HS/CT Information form
  - Must answer: “Does the proposed research involve human specimens and/or data?”
In the PHS HS/CT Information Form, complete the following:

- Under the “If No to Human Subjects” heading, complete the question “Does the proposed research involve human specimens and/or data?”:
  - “Yes” was answered, upload an explanation of why the study does not involve human subjects research. Include the following:
    - Information on source or provider of the data/biospecimens and their role
    - Description of the identifiers associated with the data/biospecimens
    - Who has access to subject identifiers
    - Information on protecting subject’s privacy, and data confidentiality

If “No” was answered, skip the rest of the questions on this form.
**Scenario B: Non-Exempt Human Subjects Research**  
*(Not a Clinical Trial)*

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Subjects Involved?</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Research Exempt?</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Clinical Trial</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

Complete the PHS HS/CT Information Form  
- ‘Add New Study’ record for each individual study or protocol

**Note:** Apply to a FOA in which Clinical Trials are either ‘Not Allowed’ or ‘Optional’

**PHS HS/CT Information Form Section** | **Complete for HS Studies**
--- | ---
Section 1 Basic Information | Yes
Section 2 Study Population Characteristics | Yes
Section 3 Protection and Monitoring Plans | Yes
Section 4 Protocol Synopsis | No
Section 5 Other CT-related Attachments | No
**Scenario C: Exempt Human Subjects Research**

Complete the PHS HS/CT Information Form

- ‘Add New Study’ record for each individual study or protocol

**Note: May not** involve a Clinical Trial if one or more questions of 1.4 CT Questionnaire was answered “No”

(See slides 36-41 for more information on Exempt HS Research)

<table>
<thead>
<tr>
<th>PHS HS/CT Information Form Section</th>
<th>Complete for HS Studies</th>
<th>Complete for CT Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 1 Basic Information</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Section 2 Study Population Characteristics</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Section 3 Protection and Monitoring Plans</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Section 4 Protocol Synopsis</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Section 5 Other CT-related Attachments</td>
<td>No</td>
<td>Yes (per FOA instructions)</td>
</tr>
</tbody>
</table>

*Exemption 4 is not required to complete Section 2*

Tip: While infrequent, some studies considered to be exempt human subjects research can also be considered clinical trials. Check out the Clinical Trial Case Studies for examples: [https://grants.nih.gov/policy/clinical-trials/case-studies.htm](https://grants.nih.gov/policy/clinical-trials/case-studies.htm)
Scenario D: Delayed Onset Human Subjects Study

Complete the “Delayed Onset Study(ies)” section in the PHS HS/CT Information Form

- ‘Add New Delayed Onset Study’ record for each individual study or protocol
- Multiple delayed onset studies may be included in one entry

In summary, the “Delayed Onset Study(ies)” section should include (see the Application Guide for a complete list of requirements):

- The ‘Study Title’ and whether the study is anticipated to be a clinical trial.
- In the “Delayed Onset Study(ies)” entry add an attachment for the delayed onset study. Upload a justification document explaining why the human subjects study information is not available at the time of application, as well as the single IRB plan and dissemination plan, if applicable.
- If funded, awardee must provide FWA, IRB approval, human subjects and inclusion information to NIH before involving human subjects.

Delayed Onset Human Subjects Study: Human subjects research anticipated but specific plans cannot be described at the time of application. For example, results from pre-clinical research are needed before planning human subjects work; for networks protocols will be determined after award; or awards that fund small projects selected after funding.

Some Training programs (D43 or K12) may submit delayed onset studies.
Clinical Trial Definitions

- **Clinical Trial**: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

- **NIH Defined Phase III Clinical Trial**: a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or controlled intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.
Determine Whether NIH Would Consider the Human Subjects Research Study a Clinical Trial

The following four questions are used to determine if the research study is a clinical trial (see section 1.4 of the PHS HS/CT Information form for Clinical Trial Questionnaire):

- 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 that will be evaluated a health-related biomedical or behavioral outcome?

If ‘Yes’ to all 4 questions – study is considered a Clinical Trial.

If you are proposing a clinical trial, you MUST apply to a FOA that either accepts Clinical Trials (CT Optional) or requires Clinical Trials (CT Required).

If you apply to a FOA that does not accept clinical trials, you may not be able to submit your application.

See case studies to determine if your study meets the NIH definition of a clinical trial: https://grants.nih.gov/policy/clinical-trials/case-studies.htm

See slides 25-29 regarding applications that propose clinical trials research experience.

Tip: Check out the Clinical Trial Case Studies for examples: https://grants.nih.gov/policy/clinical-trials/case-studies.htm
**Scenario E: Human Subjects Research Involving a Clinical Trial**

Complete the PHS HS/CT Information Form

- ‘Add New Study’ record **for each individual study or protocol**
- A study will be considered a Clinical Trial if all 4 questions on the 1.4 CT Questionnaire are answered “Yes”

**Note:** Clinical trial may also be a NIH-Defined Phase III CT

<table>
<thead>
<tr>
<th>PHS HS/CT Information Form Section</th>
<th>Complete for CT Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 1 Basic Information</td>
<td>Yes</td>
</tr>
<tr>
<td>Section 2 Study Population Characteristics</td>
<td>Yes</td>
</tr>
<tr>
<td>Section 3 Protection and Monitoring Plans</td>
<td>Yes</td>
</tr>
<tr>
<td>Section 4 Protocol Synopsis</td>
<td>Yes</td>
</tr>
<tr>
<td>Section 5 Other CT-related Attachments</td>
<td>Yes (per FOA instructions)</td>
</tr>
</tbody>
</table>

*Exemption 4 cannot be a clinical trial*

**Must apply to a FOA that allows Clinical Trials**

**Must have a Data and Safety Monitoring Plan**

After award, **register and report results** in ClinicalTrials.gov
Scenario F: Human Subjects Research Involving an NIH-Defined Phase III Clinical Trial

Complete the PHS HS/CT Information Form

- ‘Add New Study’ record **for each individual study or protocol**
- A study will be considered a Clinical Trial if all 4 questions on the 1.4 CT Questionnaire are answered “Yes”

<table>
<thead>
<tr>
<th>PHS HS/CT Information Form Section</th>
<th>Complete for CT Studies</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 1 Basic Information</td>
<td>Yes</td>
<td>Must apply to a FOA that allows Clinical Trials</td>
</tr>
<tr>
<td>Section 2 Study Population Characteristics</td>
<td>Yes</td>
<td>Must have a <strong>Data and Safety Monitoring Plan</strong></td>
</tr>
<tr>
<td>Section 3 Protection and Monitoring Plans</td>
<td>Yes</td>
<td>Additional inclusion policy requirements related to study design</td>
</tr>
<tr>
<td>Section 4 Protocol Synopsis</td>
<td>Yes</td>
<td>After award, <strong>register and report results</strong> in ClinicalTrials.gov</td>
</tr>
<tr>
<td>Section 5 Other CT-related Attachments</td>
<td>Yes (per FOA instructions)</td>
<td></td>
</tr>
</tbody>
</table>

Human Subjects Involved? | Yes | No
Clinical Trial | X
NIH-Defined Phase III CT | X

Search By Topic  
OEP-HS@mail.nih.gov  
Back Home
Scenario G: Human Subjects Research Involving Individual or Institutional Training

- **G1. Individual Research Career Development Award (CDA) Application (“K” Series):** A program that provides opportunities to build research training through individual or institutional awards.

- **G2. Individual Fellowship Applications (“F” Series):** An individual fellowship that provides research training to fellows at the graduate and postdoctoral levels.

- **G3. Individual Research Training and Career Development Program Applications (“T” Series):** A program that provides institutional research training to trainees at the undergraduate, graduate and postdoctoral levels.
Independent Clinical Trial

- For the purposes of research career development programs, a clinical trial for which the researcher proposing the study has primary responsibility. An independent clinical trial differs from a clinical trial research experience in that the clinical trial is led by the career development candidate rather than a mentor or other investigator. An ancillary study proposed by the candidate to a larger clinical trial may be considered an independent clinical trial.

- Some K awards allow for the inclusion of Independent Clinical Trials.

- Fellowship awards do not allow Independent Clinical Trials; instead awardees can participate in a clinical trial research experience.
Clinical Trial Research Experience

• The involvement of a Fellowship (F) or Career Development (K) applicant or awardee in a clinical trial led by another investigator which provides experience relevant to their research project and/or career development goals.

• The Career Development (K) applicant or Fellowship (F) applicant must be working under a mentor’s supervision.

• Applicant cannot apply to an independent clinical trial FOA.

• Some K awards can involve an Independent Clinical Trial (see previous slide).
### Scenario G1: Human Subjects Research Involving “K” Series Applications

**Complete the PHS HS/CT Information Form**

- ‘Add New Study’ record for each individual study or protocol
- If proposing a study involving human subjects or a clinical trial research experience, complete only the HS studies sections
- If proposing an *Independent Clinical Trial*, complete the CT studies sections

<table>
<thead>
<tr>
<th>PHS HS/CT Information Form Section</th>
<th>Complete for HS Studies</th>
<th>Complete for CT Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 1 Basic Information</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Section 2 Study Population Characteristics</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Section 3 Protection and Monitoring Plans</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Section 4 Protocol Synopsis</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Section 5 Other CT-related Attachments</td>
<td>No</td>
<td>Yes (per FOA instructions)</td>
</tr>
</tbody>
</table>

- Human Subjects Involved? X
- Research Exempt? Maybe
- Clinical Trial (Independent) Maybe
- Clinical Trial Research Experience Maybe

*CT research experience* awardee must be under a mentor’s supervision

If proposing an *Independent Clinical Trial*, must apply to a FOA that allows CT.
Scenario G2: Human Subjects Research Involving “F” Series Applications

- Fellowship applicants are permitted to conduct research involving human subjects but not to lead an independent clinical trial.
  - Even if all four questions in the 1.4 Clinical Trial Questionnaire were answered “Yes”, the study is not an independent clinical trial, and only certain fields in the PHS HS/CT Information form are required, applicant should follow relevant Fellowship instructions in the Application Guide.

- Fellowship applicants can propose to gain clinical trial research experience under a mentor’s supervision, but will not be leading an independent clinical trial.
### Scenario G2: Human Subjects Research Involving “F” Series Applications

#### Complete the PHS HS/CT Information Form
- ‘Add New Study’ record **for each individual study or protocol**
- Only Human Subjects studies without a clinical trial are permitted
- Applicant may answer “Yes” to all CT questions but independent CTs are not allowed for F awards
- The CT-specific sections of the HS/CT Form may not be available

<table>
<thead>
<tr>
<th>PHS HS/CT Information Form Section</th>
<th>Complete for HS Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 1 Basic Information</td>
<td>Yes</td>
</tr>
<tr>
<td>Section 2 Study Population Characteristics</td>
<td>*Yes</td>
</tr>
<tr>
<td>Section 3 Protection and Monitoring Plans</td>
<td>Yes</td>
</tr>
<tr>
<td>Section 4 Protocol Synopsis</td>
<td>No</td>
</tr>
<tr>
<td>Section 5 Other CT-related Attachments</td>
<td>No</td>
</tr>
</tbody>
</table>

*Exemption 4 is not required to complete Section 2

---

**CT research experience** awardee must be under a mentor’s supervision

May apply to a FOA that encourages CT research experience led by a sponsor/co-sponsor.
**Scenario G3: Human Subjects Research Involving “T” Series Applications**

- Institutional Research Training program applications (“T” Series) generally do not provide research support for conducting human subjects research or clinical trials.

- After award, if funds from a Training award are used to directly support human subjects research, the FWA, IRB approval, human subjects information, and inclusion sections must be submitted to NIH before beginning research involving human subjects.
Scenario G3: Human Subjects Research Involving “T” Series Applications

- PHS HS/CT Information Form is not applicable and will not be available to training award applicants

### PHS HS/CT Information Form Section | Complete for HS Studies
---|---
Section 1 Basic Information | Not Allowed
Section 2 Study Population Characteristics | Not Allowed
Section 3 Protection and Monitoring Plans | Not Allowed
Section 4 Protocol Synopsis | Not Allowed
Section 5 Other CT-related Attachments | Not Allowed

If trainees are proposing to gain human subjects or **CT research experience** under a mentor’s supervision, funded by the T award, communicate plans with funding-IC Program Staff.
PHS Human Subjects and Clinical Trial Information Form – Section 3 – Protection and Monitoring Plans
3.1 Protection of Human Subjects

The “Protection of Human Subjects” attachment, in section 3.1, is required for all human subjects studies and clinical trials. In summary, the “Protection of Human Subjects” attachment should include the following (for a complete list see the Application Guide):

1. **Risks to Human Subjects**
   - Human subjects involvement and characteristics; vulnerable populations
   - Sources of materials – what, how, access to identifiers
   - Potential Risks – physical, psychological, social, etc.

2. **Adequacy of Protection Against Risks**
   - The consent process
   - Procedures to minimize risks
   - Additional protections for vulnerable subjects

3. **Potential Benefits of Proposed Research to Research Participants and Others**
   - May not be direct benefit to subjects
   - Discuss risks in relation to anticipated benefits
   - Should not include monetary compensation

4. **Importance of the Knowledge to be Gained**
   - Discuss knowledge in relation to risks

Tip: The instructions have changed. Make sure you are using the instructions for the appropriate Form.
3.3 Data and Safety Monitoring Plan

The “Data and Safety Monitoring Plan”, in section 3.3, is required for clinical trials and optional for human subjects studies. In summary, the “Data and Safety Monitoring Plan” should include the following (for a complete list see the Application Guide):

- Overall framework for data and safety monitoring commensurate with risk
- Responsible party for monitoring
- Procedures for reporting Adverse Events/Unanticipated Problems
- Trial monitoring by individual(s) or group:
  - Data and Safety Monitoring Board (DSMB) required for:
    - Multi-site trials with greater than minimal risk, and generally, for all Phase III trials

**Note:** Funding IC approval is required before enrollment begins.
Additional NIH Requirements

- For Clinical Trials:
  - Registration and Results Reporting in ClinicalTrials.gov

- For NIH-Defined Phase III Clinical Trials:
  - Inclusion of Women, Minorities, and Children

See the NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research
https://grants.nih.gov/grants/funding/women_min/guidelines.htm
Peer Review of PHS HS/CT Information Form

- Each reviewer will assess human subjects protections
  - Actual or potential unacceptable risks, or inadequate protections, or insufficient information

- Peer review group will determine overall rating of “acceptable” or “unacceptable”
  - If the Summary Statement says: “PROTECTION OF HUMAN SUBJECTS: UNACCEPTABLE”, resolve SRG concerns with funding-IC
Common Human Subjects Concerns Identified in Peer Review

- ‘Protection of Human Subjects’ attachment inadequate
- Missing/inadequate DSMP/B
- Source of specimens/data inadequately described
- Physical/psychological risks not adequately addressed
- Informed consent issues
- Confidentiality of data
- Incidental findings not addressed
Exemptions to Federal Regulations
Determine if Your Research Qualifies for an Exemption

- The majority of human subjects research funded by NIH is non-exempt.
- Research that meets criteria for one or more of the exemptions below is categorized as exempt (see 45 CFR 46 for more information).

<table>
<thead>
<tr>
<th>Exemption</th>
<th>Summary Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Research involving educational practices</td>
</tr>
<tr>
<td>2</td>
<td>Educational tests, surveys, interviews, and observations of public behavior</td>
</tr>
<tr>
<td>3</td>
<td>Similar to Exemption 2 if the subjects are public officials or candidates or the law requires confidentiality</td>
</tr>
<tr>
<td>4</td>
<td>Secondary use of unidentifiable data or biospecimens</td>
</tr>
<tr>
<td>5</td>
<td>Research or demonstration projects of public benefit or service program</td>
</tr>
<tr>
<td>6</td>
<td>Taste and food quality</td>
</tr>
</tbody>
</table>

Tip: We are still using the original 6 exemptions in the 1991 Common Rule.
Determining if Your Research Qualifies for an Exemption

• **Step 1:** Determine if your study involves human subjects.

  ▫ Does it meet the definition of human subjects research?
    
    A. Are you collecting data from a living individual through intervention or interaction?
    
    OR
    
    B. Do you or a collaborator have access to identifiable private information?
    
  If yes to either A or B, you are conducting human subjects research.

Tip: Exempt studies are human subjects research! Therefore, it must meet the definition of human subjects first.
Determine if Your Research Qualifies for an Exemption

**Step 2:** Determine if your study qualifies for any of the exemptions

- If yes, determine the exemption. You will select this on either the R&R Other Project Information form or a Study Record.

- If no exemptions apply and you are doing research that involves human subjects, then the study is non-exempt human subjects research.
Exemptions for Studies Involving Vulnerable Populations

• **Prisoners**: Exemptions to the Common Rule do not apply to research involving prisoners.

• **Children**: Most exemptions to the Common Rule may apply to research involving children, except Exemption 2:
  - **Exemption 2** (tests, surveys, interviews of observation of public behavior) only applies to children when conducting educational tests and research involving observation of public behavior **when** the investigator does not participate in the activities being observed.
Completing the PHS HS/CT Information Form – Exempt HS Research

<table>
<thead>
<tr>
<th>Exemption</th>
<th>Section 1 Basic Information</th>
<th>Section 2 Study Population Characteristics</th>
<th>Section 3 Protection and Monitoring Plan</th>
<th>Section 4 Protocol Synopsis (Clinical Trials only)</th>
<th>Section 5 Other Clinical Trial Related Attachments (Clinical Trials only)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exemption 1</td>
<td>Complete</td>
<td>Complete</td>
<td>Complete</td>
<td>Complete, if clinical trial</td>
<td>Complete, if clinical trial</td>
</tr>
<tr>
<td>Exemption 2</td>
<td>Complete</td>
<td>Complete</td>
<td>Complete</td>
<td>Complete, if clinical trial</td>
<td>Complete, if clinical trial</td>
</tr>
<tr>
<td>Exemption 3</td>
<td>Complete</td>
<td>Complete</td>
<td>Complete</td>
<td>Complete, if clinical trial</td>
<td>Complete, if clinical trial</td>
</tr>
<tr>
<td>Exemption 4</td>
<td>Complete</td>
<td>No</td>
<td>Complete</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Exemption 5</td>
<td>Complete</td>
<td>Complete</td>
<td>Complete</td>
<td>Complete, if clinical trial</td>
<td>Complete, if clinical trial</td>
</tr>
<tr>
<td>Exemption 6</td>
<td>Complete</td>
<td>Complete</td>
<td>Complete</td>
<td>Complete, if clinical trial</td>
<td>Complete, if clinical trial</td>
</tr>
</tbody>
</table>
Single IRB Policy

• NIH issued a **Policy** on the use of a Single Institutional Review Board (Single IRB) for Multi-Site Research. The policy applies to domestic sites of multi-site studies conducting the **same non-exempt human subjects research** protocol.

The policy **does not** apply to:

• Foreign sites
• Career Development (K), Institutional Training (T), and Fellowship awards (F)

**Exceptions** will be made to allow for local IRB review when:

• Federal, state, and tribal **laws, regulations or policies** require local IRB review. This exception does not require NIH approval.

• For ancillary studies, **time limited exceptions** will be made for ancillary studies to other ongoing or parent studies. This exception does not require NIH approval.

• **Other exceptions** will may be considered if there is a compelling justification for local review. This exception requires NIH approval.

Tip: Unless instructed to do otherwise, the applicant should select the single IRB of record. The applicant should pick the most appropriate IRB for study.
Provide a Single IRB Plan

Applicants proposing multi-site research must submit a plan for implementing a single IRB and should:

- Answer “Yes” to Section 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?”, then:
  - Describe the single IRB plan and upload it in the PHS HS/CT Information form under Protection and Monitoring Plans, Section 3.2.

Additional resources on the Single IRB Policy, plan and request for exceptions can be found here: https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm

K and F applicants should mark N/A to question 3.2
Elements of a Single IRB Plan

The single IRB plan should include the following:

- The name of the IRB of record
- Compliance with the NIH policy on single IRBs
- Statement that all sites have agreed to use the single IRB, will sign a reliance agreement that includes a communication plan
- Name of institution that will maintain records
- Policy-based, time-limited ancillary study or other exceptions with compelling justification

When creating a budget, consider all sites, including those requested for an other exception with a compelling justification – as they have not been granted at the time of application. DO NOT budget as if other exceptions have been granted. Include these sites in the total budget for single IRB review. Budget can be adjusted down if an exception is granted.

Additional resources can be found here: https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm

See the Application Guide for all required information.
Education and Training

• Education and training for NIH-funded studies is a requirement for all investigators and key personnel involved in either human subjects research studies or clinical trials.

Investigators and key personnel involved only in human subjects research studies must fulfill the following requirement:

• Education in the Protection of Human Research Participants

If involved in clinical trials, both trainings below are required:

• Education in the Protection of Human Research Participants, and
• Good Clinical Practice (GCP) Training for Clinical Trials

Note: NIH does not endorse any specific educational programs. Institutions should determine what programs are appropriate for fulfilling this requirement.
The NIH policy was issued in 2000 (NOT-OD-00-039) and requires education on the protection of human research participants for all investigators applying to NIH grants or proposals that involve human subjects. Not just the investigators but also all key personnel involved in the design and conduct of the study must fulfill the education requirement. It applies to all human subjects research, including research exempt from IRB review and approval.
Good Clinical Practice (GCP) Training for Clinical Trials

- Effective as of January 1, 2017, all NIH-funded investigators and staff involved in clinical trials are expected to receive training in Good Clinical Practice (GCP) (NOT-OD-16-148).

  - GCP training consists of:
    - Principles of the International Conference on Harmonisation (ICH) GCP, found in Section 2 of ICH E6

GCP training may be obtained through a class or course, academic training program, or certification from a recognized clinical research professional organization.

GCP training should be refreshed at least every three years and investigators and staff are expected to retain documentation of their training.
Educational Resources

Suggested educational resources on the protection of human subjects and clinical trials:

- Acceptable GCP courses include:
  - NIAID GCP Learning Center website ([http://gcplearningcenter.niaid.nih.gov](http://gcplearningcenter.niaid.nih.gov))