

Preparing the Human Subjects Section

- Use Instructions for Preparing HS section
- Select one of 6 scenarios:
 - A. No Human Subjects
 - B. Non-Exempt Human Subjects Research
 - C. Exempt Human Subjects Research
 - D. Delayed-Onset of Human Subjects Research
 - E. Clinical Trial
 - F. NIH-defined Phase III Clinical Trial

Scenario A: No Human Subjects

Are Human Subjects Involved? Yes No

- Protection of Human Subjects section **NOT** required
- **MUST** provide justification if using human specimens or data; for example: “Samples are purchased from commercial vendor”
 - Include justification in Research Strategy, or
 - Create a Human Subjects section and upload



Research Involving Coded Data or Specimens

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



<http://www.hhs.gov/ohrp/policy/cdebiol.html>

Scenario B: Non-Exempt Research

Are Human Subjects Involved? X Yes ___ No
Research Exempt? ___ Yes X No
Clinical Trial? ___ Yes X No
NIH-Defined Phase III CT? ___ Yes X No

- **Human Subjects Section** – no page limitations
 - Address 4 required points: risk, protections, benefits, knowledge
([Slides 11 and 12 for more details](#))
- **Inclusion of Women, Minorities, and Children**



Scenario C: Exempt Research

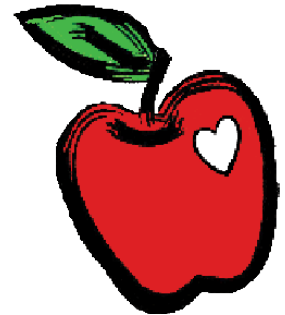
Are Human Subjects Involved? X Yes ___ No
Research Exempt? X Yes ___ No
Exemption Number X 1 ___ 2 ___ 3 ___ 4 ___ 5 ___ 6
Clinical Trial? ___ Yes X No
NIH-Defined Phase III CT? ___ Yes X No

- **Human Subjects Section**

- Justify selection of exemption(s)
- Sources of research materials

- **Inclusion of Women, Minorities, and Children ***

*Not required for Exemption 4



Scenario D: Delayed Onset HS Research

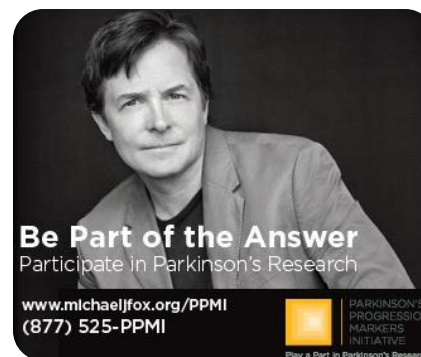
Are Human Subjects Involved? Yes No
Research Exempt? Yes No
Clinical Trial? Yes No
NIH-Defined Phase III CT? Yes No

- **Delayed Onset:** Human subjects research anticipated but specific plans cannot be described in the application
- Human Subjects Section – explain why delayed onset
- If funded, awardee must provide FWA, IRB approval, human subjects and inclusion sections to NIH before involving human subjects



Scenarios E & F: Clinical Trial

- **Recently revised Definition of Clinical Trial**: a research study in which 1 or more subjects are prospectively assigned to 1 or more interventions (including placebo) to evaluate effects on health-related biomedical or behavioral outcomes.
- **NIH Defined Phase III Trial** – broad-based, prospective trial, often to provide scientific basis for change in health policy or standard of care (Scenario F)
- All other Phases (Scenario E)



Scenario E: Clinical Trial

(not Phase III)

Are Human Subjects Involved? Yes No
Research Exempt? Yes No
Clinical Trial? Yes No
NIH-Defined Phase III CT? Yes No

- Provide information required for **Scenario B** (Non-Exempt Human Subjects Research)
- Must have a **Data and Safety Monitoring Plan**
- Register with [ClinicalTrials.gov](https://clinicaltrials.gov)

Data and Safety Monitoring Plan

- Data and Safety Monitoring Plan includes:
 - Overall framework for data and safety monitoring commensurate with risk
 - Responsible party for monitoring
 - Procedures for reporting Adverse Events/Unanticipated Problems
- Data and Safety Monitoring Board (DSMB) required for:
 - Multi-site trials > minimum risk and generally for Phase III trials
- Funding IC approval before enrollment begins

Scenario F: NIH-Defined Phase III Clinical Trial

Are Human Subjects Involved? Yes No
Research Exempt? Yes No
Clinical Trial? Yes No
NIH-Defined Phase III CT? Yes No

- Provide information required for Scenario E
- Generally requires DSMB
- Additional inclusion policy requirements to be addressed related to study design

Human Subjects Section In NIH Application

(Non-exempt Human Subjects Research)

- **Risks**

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

- **Adequacy of Protection Against Risks**

- Recruitment; consent
- Procedures to minimize risks
- Additional protections for vulnerable subjects

Human Subjects Section In NIH Application

(Non-exempt Human Subjects Research)

- **Potential Benefits of Research to Human Subjects and Others**
 - May not be direct benefit to subjects
 - Discuss risks in relation to anticipated benefits
 - Should not include monetary compensation
- **Importance of Knowledge to be Gained**
 - Discuss in relation to risks

Additional NIH Requirements

- **For Clinical Trials:**
 - Data and Safety Monitoring Plan or Board
 - Registration in [ClinicalTrials.gov](https://clinicaltrials.gov)
- **For NIH-Defined Clinical Research**
 - Inclusion of Women, Minorities, and Children

Peer Review of Human Subjects Section

- 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 Summary Statement says:
 - ❑ PROTECTION OF HUMAN SUBJECTS:
UNACCEPTABLE (Code 44)
 - ❑ *Code 44 is a bar to award*
 - ❑ Must resolve SRG concerns



Common HS Concerns Identified in Peer Review

- Human Subjects Section 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