

# *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

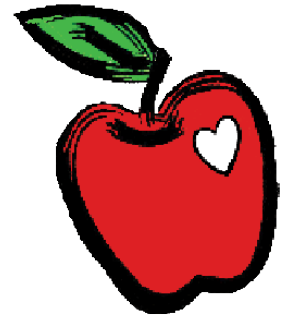
Are Human Subjects Involved?  X  Yes    \_\_\_ No  
Research Exempt?                     X  Yes    \_\_\_ No  
Exemption Number             X  1    \_\_\_ 2    \_\_\_ 3    \_\_\_ 4    \_\_\_ 5    \_\_\_ 6  
Clinical Trial?                            \_\_\_ Yes     X  No  
NIH-Defined Phase III CT?  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