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

OEP-HS@mail.nih.gov
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)

Scenario B: Non-Exempt Research

Are Human Subjects Involved?  ___ 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

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<td>NIH-Defined Phase III CT?</td>
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#### 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?  __x__ 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
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     X No
Clinical Trial?     X 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
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

- **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