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)

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

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?  **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

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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?  **No**
- Clinical Trial?  **Yes**  **No**
- NIH-Defined Phase III CT?  **No**

**National Institutes of Health**

- 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?  **X** 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

• 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