WORKSHEET FOR PREPARATION OF COMMENTS ON HUMAN SUBJECTS

Revised 05/17/2007

(Please note that existing, unidentified human specimens and data are no longer necessarily considered human subjects research. Visit http://grants.nih.gov/grants/policy/hs/coded_synopsis.htm for the current policy).

PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISK:

(A) If exemption is claimed, is exemption Acceptable or Unacceptable?

Give number of exemption(s) that appl(ies/y) (E1-E3, E5 or E6); please note that a study that qualifies for E4 is not considered clinical research and does not need to be coded for gender, minorities or children inclusion. All other exemptions still require inclusion coding.

- **If exemption is Acceptable, so state and skip to inclusion coding for exemptions other than exemption 4.**
- **If exemption is Unacceptable, state why and proceed to Part B below.**

(B) If no exemption is claimed, evaluate investigator's description of: **1)** Risks to Subjects, **2)** Adequacy of Protection Against Risks, **3)** Potential Benefits of Proposed Research to Subjects & Others, and **4)** Importance of the Knowledge to be Gained.

Is investigator's plan for Protecting Human Subjects from Research Risk Acceptable or Unacceptable?

- **If plan is Acceptable state "acceptable risks or adequate protections", if Unacceptable, state why.**

(C) If research involves a clinical trial, also evaluate whether a Data and Safety Monitoring Plan exists and provides a framework for data and safety monitoring as well as plans for 1) adverse event monitoring and 2) monitoring entities. The frequency of adverse event monitoring and the nature of the monitoring entity will depend upon the risks, complexity and nature of the trial. Monitoring entities may be only the Principal Investigator or a designated safety or medical officer or may extend to a Data and Safety Monitoring Board or an IRB. **If plan is Acceptable, so state; if Unacceptable, state why.**

INCLUSION OF WOMEN PLAN:

Which applies: **1)** both genders, **2)** women only, **3)** men only, or **4)** unknown composition?

Is inclusion/exclusion plan Acceptable or Unacceptable?

- **State why plan is Acceptable or Unacceptable.**

INCLUSION OF MINORITIES PLAN:

Which applies: **1)** minorities & non-minorities, **2)** minorities only, **3)** non-minorities only, **4)** composition not known, or **5)** foreign?

Is inclusion/exclusion plan Acceptable or Unacceptable?

- **State why plan is Acceptable or Unacceptable.**

INCLUSION OF CHILDREN PLAN:

Which applies: **1)** children & adults, **2)** children only, **3)** adults only, or **4)** composition not known?

Is inclusion/exclusion plan Acceptable or Unacceptable?

- **State why plan is Acceptable or Unacceptable.**

EXAMPLES OF PROTECTION OF HUMAN SUBJECT COMMENTS:

- Unacceptable Risks and/or Inadequate Protections: The applicant states that the proposed research involves minimal physical risk; however, genetics research is considered of moderate risk due to the possibility of breaches in confidentiality. Insufficient detail is provided regarding measures to protect against such risk.

EXAMPLES OF INCLUSION COMMENTS:

- Only women will participate in the study because the disease under study affects only women.
- Minority representation is adequate (75% Caucasian; 7% Hispanic; 15% African American; 3% Asian) for the research proposed.
- Children between the ages of 18 and 21 are included, but children under the age of 18 are excluded because it is inappropriate to expose such children to drugs of abuse, such as methamphetamine.