

WORKSHEET FOR PREPARATION OF COMMENTS ON HUMAN SUBJECTS

Revised 12/16/04

PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISK:

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

Give number of exemption(s) that applies (E1-E6):

o **If exemption 1, 2, 3, 5, or 6 is Acceptable, so state and skip to Inclusion of Women Plan.**

o **If exemption 4 is Acceptable, so state.**

o **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?

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

(C) If research involves a Clinical Trial, also evaluate whether the Data and Safety Monitoring Plan includes plans for **1) adverse event reporting and 2) monitoring entities.**

Is the Data and Safety Monitoring Plan Acceptable or Unacceptable?

o **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?

o **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?

o **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?

o **State why plan is Acceptable or Unacceptable:**

EXAMPLES OF PROTECTION OF HUMAN SUBJECT COMMENTS:

o **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:

- o Only women will participate in the study because the disease under study affects only women.
- o Minority representation is adequate (75% Caucasian; 7% Hispanic; 15% African American; 3% Asian) for the research proposed.
- o 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.