INFORMATION FOR DEVELOPING A FREE-STANDING HUMAN PARTICIPANTS SECTION

The Department of Health and Human Services (DHHS) regulations define "human participant" as a living individual about whom an investigator (whether a professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. The regulations extend to the use of human organs, tissues, and body fluids as well as to graphic, written or recorded information derived from individually identifiable human participants. The use of autopsy materials is governed by applicable state and local law and is not directly regulated by the code of federal regulations (45 CFR 46). The regulations also specify additional protections for certain classes of human research involving fetuses, pregnant women, in vitro fertilization, children or prisoners. The regulations require that all **non-exempt** research activities involving human participants be reviewed and approved by the HU Institutional Review Board.

POPULATION: Describe the characteristics of the participant population, including their anticipated number, age range, and health status. Identify the criteria for inclusion and exclusion of any subpopulation. Explain the rationale for the use of special classes of participants, such as fetuses, pregnant women, children, institutionalized individuals or others who are likely to be vulnerable.

RESEARCH MATERIAL: Identify the sources of research material obtained from individually identifiable **LIVING** human participants in the form of specimens, records or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records or data.

RECRUITMENT INFORMATION: Describe plans for the recruitment of participants and the informed consent procedures to be followed, including the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective participants, and the method of documenting informed consent. State if the Institutional Review Board has authorized a modification or waiver of the elements of informed consent or the requirement for documentation of informed consent.

INCLUSION/EXCLUSION CRITERIA: Describe any potential risks – (physical, psychological, social, legal or other) – and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the participants.

RISKS STATEMENT: Describe the procedures for protection against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for insuring necessary medical or professional intervention in the event of adverse effects to the participants. Also, where appropriate, describe the provisions for monitoring the data collected to insure the safety of participants.

BENEFITS STATEMENT: Discuss why the risks to participants are reasonable in relation to the anticipated benefits to them and in relation to the importance of the knowledge that may reasonably be expected to be obtained. Identify what individual benefit the participant can expect as a result of their participation and if there are none, it must be so stated.

GENDER AND MINORITY INCLUSION: Since HU's participant population is predominantly ethnic minority, its investigators should discuss the inclusion of women and members of <u>non-minority</u> groups in developing a research design appropriate to the scientific objectives of the study. Describe the composition of the proposed study population in

terms of gender and racial/ethnic group, and provide a rationale for section of such participants:

	American Indian or Alaskan Native	Asian or Pacific Islander	Black not of Hispanic Origin	Hispanic	White not of Hispanic Origin	Other or Unknown	Total
Female							
Male							
Unknown							
Total							

Include a description of proposed outreach programs for recruiting women and non-minorities as participants, and provide a compelling rationale and justification for requesting any exclusions. When proposing Phase III clinical trials, show whether clinically important gender or race/ethnicity differences are to be expected, and design the trials to accommodate such differences.

The following definitions apply for the racial and ethnic categories.

A. **Minority Groups**: A minority group is a readily identifiable subset of the U.S. population which is distinguished by either racial, ethnic, and/or cultural heritage.

   a. **American Indian or Alaskan Native:** A person having origins in any of the original people of North America, and who maintains cultural identification through tribal affiliation or community recognition.

   b. **Asian or Pacific Islander:** A person having origins in any of the original peoples of the Far East, Southeast Asia, the Indian subcontinent, or the Pacific Islands. This area includes, for example, China, India, Japan Korea, the Philippine Islands, and Samoa.

c. **Black not of Hispanic Origin:** A person having origins in any of the black racial groups of Africa.

d. **Hispanic:** A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.

B. **Majority Group:**

a. **White not of Hispanic Origin:** A person having origins in any of the original peoples of Europe, North Africa, or the Middle East.

C. **Subpopulations:** Each minority group contains subpopulations, which are delimited by geographic origins, national origins and/or cultural differences. It is recognized that there are different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting of special racial and ethnic origin. Attention to subpopulations also applies to individuals of mixed racial and/or ethnic parentage. Researchers should be cognizant of the possibility that these racial/ethnic combinations may have biomedical and/or cultural implications related to the scientific question under study.

INCLUSION OF CHILDREN IN RESERCH:

Definition of a Child: For the purpose of implementing these instructions, a child is defined as an individual under the age of 17 years by this IRB. If children are included, the description of the plan should include a rationale for selecting or excluding a specific age range of children.

When children are included, the plan also must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate

the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

Justification for Exclusion of Children: It is expected that children will be included in all research involving human participants unless one or more of the following exclusionary circumstances can be fully justified:

a. The research topic to be studied is not relevant to children.

b. There are laws or regulations barring the inclusion of children in research.

c. The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. Documentation of other studies justifying the exclusions should be provided.

d. A separate, age-specific study in children is warranted and preferable. Examples include:

◇ The relative rarity of the condition in children, as compared to adults (in that extraordinary effort would be needed to include children, although in rare diseases or disorders where the applicant has made a particular effort to assemble an adult population, the same effort would be expected to assemble a similar child population with the rare condition); or

◇ The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or

◇ Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different

cognitive, developmental, or different age-related metabolic processes). While this situation may represent a justification for excluding children in some instances, consideration should be given to taking these differences into account in the study design and expanding the hypotheses tested, or the interventions, to allow children to be included rather than excluding them; or

◇ Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not but the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or

◇ Study deigns aimed at colleting additional data on pre-enrolled adult study participants, (e.g., longitudinal follow-up studies that did not includes data on children); or

◇ Other special cases justified by the investigator and found acceptable to the IRB.