Subject: Procedure for the Use of an Ombudsman and/or Participant Advocate

Procedure:
This procedure outlines the process for the use of an ombudsman and/or a participant advocate in assisting the Human Research Protections Program (HRPP) in the protection of human research participants.

I. Investigator's Responsibilities.
   A. It is the responsibility of the Investigator to assign or appoint an ombudsman or a participant advocate, at the discretion of the Investigator or the IRB, to assist and/or oversee the research process in studies that involve a vulnerable population or in studies in which the participant may become vulnerable throughout the course of the study.
   B. The Investigator will assure the advocate, advocate group, or the ombudsman does not have a conflict of interest, is impartial to the research being conducted, and able to remain unbiased throughout.

II. IRB Committee Responsibilities.
   A. It is the responsibility of the IRB Committees to require, at their discretion, an ombudsman, participant advocate or advocacy group in research involving a vulnerable population or where the research is such that the participant may become incapacitated and therefore, vulnerable during participation.
   B. The IRB Committee may request the ombudsman/participant advocate be involved in specific activities associated with the research, e.g. observation of the informed consent process.

III. Regulatory Compliance Analyst (RCA) Responsibilities.
   A. The RCA will conduct a pre-review of the study application and informed consent documents submitted with a new study application to determine the vulnerability of the research participants or the potential for vulnerability of the targeted population. If more information is needed regarding additional protections for inclusion of a vulnerable population, the informed consent process or documentation, the RCA will contact the Investigator and request the additional information.
   B. The RCA will assure the informed consent document contains the proper language for the use of an ombudsman or participant advocate, if applicable.
   C. The RCA will assist the Investigator in the appointment of an advocate, an advocacy group or an ombudsman, if deemed appropriate by the IRB Committee or by the Investigator.