Subject: The Role of an Ombudsman and/or Participant Advocate

Definitions:
1. Ombudsman: A neutral third party that advocates for the participant or their family or legally authorized representative.
2. Participant Advocate or Advocacy Group: An individual or group of individuals that seek to safeguard the rights and welfare of research participants.

Policy:
It is the policy of the Human Research Protections Program (HRPP) to enlist the use of an ombudsman or participant advocate as a liaison between an Investigator and a research participant, participant’s family, or a participant’s legally authorized representative in situations where the IRB has determined additional protections are necessary in a vulnerable population.

I. Ombudsman Role.
   A. The role of an ombudsman is to oversee the research process in situations where the participant may be exceptionally vulnerable or may have the capacity to become vulnerable during the course of the research. The appointed ombudsman typically is a scientist or individual with expertise in the area of the research. However, they must be unbiased regarding the research and the participants they serve.
   B. The role of the ombudsman may be served by a member of the Clinical Research and Ethics Department or may be an impartial third party who serves as an advocate for the proposed population or the participant.
   C. The IRB Committee may require the Investigator obtain or appoint an ombudsman if the study involves a vulnerable population or a population that has the potential to become incapacitated and therefore, vulnerable.

II. Participant Advocate Role.
   A. The role of a participant advocate is to assure that the participant receives equitable and ethical recruitment measures and treatment throughout the course of the research study. The advocate could be a single person with an interest in the population studied or a group of people interested in the safety of human research participants, usually within a certain population (e.g., breast cancer patients, patients with schizophrenia, etc.).
   B. The IRB Committee may require at their discretion; the Investigator use a participant advocate or provide an advocacy group as a contact to the participants.