GHUCCTS Research Participant Advocate Program

Research Participant Advocate Program (RPA)

The major responsibility of the RPA is to help ensure the rights, safety, and well-being of current and potential participants in *GHUCCTS*-supported research studies. Whereas many federal, state and institutional regulations and policies are in place to protect participants in clinical research, RPAs enhance these protections through advocacy for study participants, as a resource for investigators, and through independent oversight.

ADVOCACY FOR STUDY PARTICIPANTS

- Provide information about research in general.
- Facilitate communication between participant and all members of the research team.
- Discuss questions or concerns at any time about participation in research.

RESOURCE FOR INVESTIGATORS

Assist investigators to understand and comply with the ethical guidelines and regulatory requirements for research. Areas of assistance may include:

- Inclusion of Vulnerable Populations in your research
- Informed Consent development
- Data and safety monitoring
- Informed consent process and documentation
- Clarification of ethical and regulatory role and obligations
- Reporting procedures

INDEPENDENT OVERSIGHT

RPA activities which provide additional oversight include:

- Review protocols to ensure an ethical design and with adequate participant safety and protection though the Data and Safety Monitoring Plans (DSMPs).
- Serve as unbiased observer and counsel to study participants and research teams on informed consent.
- Monitor research activities to ensure compliance with the most recent IRB and SEPCOM-approved protocols.
- Track and monitor selected protocols via QA processes.
- Serve as a resource for study participants, investigators, nurses and other key personnel
- Have a voice in policy on research ethics, participants' rights and research safety, and a role in the protection of human subjects and responsible conduct of research educational programs.

GHUCCTS Regulatory and Ethics Knowledge and Support (REKS)
Research Participant Advocates (RPA)

Jane Otado, PhD
Howard University
Research Participant Advocate
j_otado@howard.edu

Sarah Vittone, RN, MSN, MA
Georgetown University
Research Participant Advocate
sarah.vittone@georgetown.edu

Claudia Gunawan, MS
Washington DC Veterans Administration Medical Center
claudia.gunawan@va.gov