Vanessa Boudewyns, PhD.
RTI International
2987 Clairmont Road, Suite 400
Atlanta, GA 30345
Re: FDA award HHSF223201810113C; *A Formative Research Study to Understand the Impact of Generic Drug-Device Substitutes for Various Patient and Caregiver Populations.*

Dear Awardee:

The purpose of this letter is to inform you of requirements that may be applicable to your research. Section 2012 of the 21st Century Cures Act, enacted December 13, 2016, includes amended provisions to enhance privacy protections for individuals who are the subjects of research, including significant amendments to the previous statutory authority for such protections, under subsection 301(d) of the Public Health Service Act (PHS Act) (42 U.S.C. 241) (See attached).

Specifically, the amended authority requires the Secretary of the Department of Health and Human Services to issue to investigators or institutions engaged in biomedical, behavioral, clinical, or other research in which identifiable, sensitive information is collected ("Covered Information"), a Certificate to protect the privacy of individuals who are subjects of such research, if the research is funded wholly or in part by the Federal Government. This is known as a Certificate of Confidentiality. The authority also specifies the prohibitions on disclosure of the names of research participants or any information, documents, or biospecimens that contain identifiable, sensitive information collected or used in research by an investigator or institution with a Certificate. Exceptions to the general prohibition on disclosure are also described in the attached statutory language. This letter informing you of these requirements is deemed to be your "Certificate of Confidentiality". You are responsible for determining whether your FDA-funded research is covered by these requirements.

Awardees are expected to ensure that any investigator or institution not funded by FDA who receives a copy of identifiable, sensitive information protected by these requirements, understand they are also subject to the requirements of subsection 301(d) of the PHS Act. Awardees are also responsible for ensuring that any subrecipient that receives funds to carry out part of the FDA award involving a copy of identifiable, sensitive information protected by these requirements understand they are also subject to subsection 301(d) of the Public Health Service Act.

If you have any additional questions, please contact Mitchell.Frost@fda.hhs.gov or Minori.Kinjo@fda.hhs.gov.

David Burrow -S

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David Burrow, PharmD, JD
Director, Office of Scientific Investigations,
Office of Compliance, Center for Drug Evaluation and Research, FDA

Encls.