18-33-CDER
CERTIFICATE OF CONFIDENTIALITY
issued to
Research Triangle Institute (RTI) International
and other persons engaged in research funded under FDA Contract #HHSF223201510002B. The purpose of this research is to assess comprehension of the Drug Facts Label in adult prescription-opioid and heroin users by conducting in-person survey interviews for over-the-counter naloxone use in emergency response.

Under the authority vested in the Secretary of Health and Human Services by section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)) and delegated to the Commissioner of Food and Drugs, this Certificate is issued to require **Research Triangle Institute (RTI) International** and other persons engaged in the research to protect the privacy of research subjects by withholding, from all persons not connected with the research, the subjects' names or any information, document, or biospecimen that contains identifiable, sensitive information about such individuals and that was created or compiled for the purpose of the research.

Identifiable, sensitive information means information that is about an individual and that is gathered or used during the course of the research, and:

(1) through which an individual is identified; or

(2) for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of the an individual.

All persons who:

(1) are employed by or affiliated with **Research Triangle Institute (RTI) International** and, if applicable, its contractors, subgrantees, and cooperating agencies; and

(2) have access to information, documents, or biospecimens that contain identifiable, sensitive information created or compiled for the purposes of the research

shall not,

(1) disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, the names of the research subjects or any information, document or biospecimen that contains identifiable, sensitive information about those

individuals and that was created or complied for purposes of the research, except in circumstances described below; or

(2) disclose or provide to any other person not connected with the research the name of a research subject or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Disclosure is permitted only when:

(1) required by Federal, State, or local laws (e.g. state mandatory reporting laws; as required by the Federal Food, Drug and Cosmetic Act, or regulations promulgated thereunder; or in connection with an HHS audit or program evaluation of the research project), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;

(2) necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

(3) made with the consent of the individual to whom the information, document, or biospecimen pertains; or

(4) made for the purpose of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

This Certificate does not represent an endorsement of the research project by the Department of Health and Human Services or by the Food and Drug Administration.

For studies in which informed consent is sought, all research subjects will be informed that a Certificate has been issued, and they will be given a clear explanation of the protection that this Certificate affords, and of the limitations and exceptions to the protection.

This Certificate is effective upon issuance. The privacy protection afforded to the individual subjects by this Certificate of Confidentiality is permanent (including after the death of a subject) and is not subject to termination.

David C. Burrow, PharmD, JD
Acting Director
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration