



CONFIDENTIALITY CERTIFICATE

Issued to

Employees of

RTI International
and Other Participants

conducting research known as

MEDICATION-ASSISTED TREATMENT (MAT) FOR OPIOID USE DISORDER
(MAT STUDY)

The overarching objective of this study is to assess the type of MAT (methadone, buprenorphine, naltrexone, or no-MAT), and the contextual, provider, and individual factors that influence implementation and improved patient well-being over a 2 year follow up period.

In accordance with the provisions of Section 301(d) of the Public Health Service Act (42 U.S.C. § 241(d)), as amended, this certificate is issued to protect the privacy of research subjects by withholding their identities and other covered information from all persons not connected with the research.

Under authority vested in the Secretary of Health and Human Services (HHS) under that section, all persons who:

- (1) are employed by the RTI International and their contractors and cooperating agencies; and
- (2) have, in the course of that employment, access to identifiable, sensitive information which would identify individuals who are the subjects of a research project entitled "Medication-Assisted Treatment (MAT) for Opioid Use Disorder (MAT Study)," a project funded in whole or in part by HHS, are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research, with the exceptions and limitations set forth below.

As provided in Section 301(d) of the Public Health Service Act (42 U.S.C. § 241(d)), as amended, persons to whom a certificate is issued to protect the privacy of individuals about whom identifiable, sensitive information is collected as part of biomedical,

behavioral, clinical, or other research, “shall not disclose or provide to any other person not connected with the research the name of such an individual 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.”

The following conditions apply to the protection provided under this certificate:

- (1) “Identifiable, sensitive information” means information that is about an individual and that is gathered or used during the course of research covered by Section 301(d) and through which an individual is identified or 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 an individual.
- (2) The disclosure prohibition described above shall not apply to disclosure or use that is:
 - (a) Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and is made with the consent of such individual.
 - (b) Made with the consent of the individual to whom the information, document, or biospecimen pertains. Authorized personnel of the United States Department of Health and Human Services request such information for audit or program evaluation of the research project, or for investigation of the RTI International or their contractors or cooperating agencies in carrying out the research project.
 - (c) Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.
 - (d) Required by Federal, State, or local law (e.g., state mandatory reporting laws). However, this provision does not permit the RTI International in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, to disclose or provide the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research except with the consent of such individual.
- (3) Identifiable, sensitive information protected by Section 301(d) and this certificate, and all copies thereof, shall be immune from the legal process, and shall not, without the consent of the individual to whom the information pertains, be

admissible as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding.

- (4) This confidentiality certificate does not limit the access of an individual who is a subject of research to information about himself or herself collected during such individual's participation in the research.
- (5) This confidentiality certificate does not represent an endorsement of the research project by the Department of Health and Human Services.
- (6) All research subjects in the project will be given a fair, clear explanation of the protection this certificate affords, and of the limitations and exceptions to the protection.
- (7) This certificate is effective upon issuance. Identifiable, sensitive information collected as part of this project, and all copies thereof, shall be subject to the protections afforded by Section 301(d) for perpetuity.

Date:

11/2/2017



Ron A. Otten, PhD

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