

This agreement is intended for review and signature by employees of RTI International and all its subcontractors who have access to information designated as confidential on a research study sponsored by SAMHSA/CBHSQ covered under CIPSEA. This agreement must be renewed each year as part of mandated CIPSEA training to maintain access to confidential project information.

Assurances of Confidentiality under CIPSEA

For any research study sponsored by the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Behavioral Health Statistics and Quality (CBHSQ) that is covered under the **Confidential Information Protection and Statistical Efficiency Act (CIPSEA) of 2002*** and Section 501(n) of the Public Health Service Act, all data and associated materials collected and/or utilized on that study are subject to protection by CIPSEA. CIPSEA ensures the confidentiality of all information provided is protected by Federal Law and stipulates that all information collected shall be used exclusively for statistical purposes. All research subjects contacted on SAMHSA/CBHSQ's behalf by RTI International are notified of these protections prior to study participation.

You have been identified as a person who has access to confidential information on a SAMHSA/CBHSQ-sponsored study covered under CIPSEA (NSDUH, etc.***) and therefore have been designated as an **Agent under CIPSEA**. This confidential information includes (but is not limited to) all electronic and hard copy documents containing respondent information and data, as well as non-data related records containing information that could identify a location or respondent associated with a particular study.

Protection Agreement under CIPSEA

Per CIPSEA regulations, you agree that any materials that would permit the identification of research subjects are to be treated as confidential, and that you will never share or use that confidential information with anyone else or in a manner other than those authorized by CBHSQ. This includes never disclosing confidential information with law enforcement officials, officers of the court or your supervisor (if not also authorized as an Agent).

To ensure the protection of all confidential information in both physical and electronic form, as an Agent, you also agree to:

- 1) keep all confidential information in a space where access is limited only to authorized personnel, whether on a computer or in hard copy form;
- 2) keep all confidential information within computer memory controlled by password protection;
- 3) maintain a secure location (such as file cabinet or locked drawer) for printed materials, diskettes, and data on hard disks of personal computers when not in use;
- 4) never remove confidential information from your approved worksite without prior approval from CBHSQ and/or RTI International;
- 5) never permit any unauthorized removal of any confidential project information from the limited access space protected under the provisions of this agreement without first notifying and obtaining written approval from RTI;
- 6) notify RTI when you no longer have access to electronic or hard copy files or printed materials containing confidential project information;

* Public Law 107-347, Title V; for more info:

https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/federal_register/FR2007/061507_cipsea_guidance.pdf

***National Survey on Drug Use and Health (NSDUH)

- 7) when appropriate, return all confidential project information to RTI;
- 8) complete annual training on restrictions associated with the use of confidential information;
- 9) agree that representatives of CBHSQ have the right to make unannounced and unscheduled inspections of the facilities where you work to evaluate compliance with this agreement;

10) notify RTI International immediately upon receipt of any legal, investigatory, or other demand for disclosure of confidential project information;

11) notify RTI International immediately upon discovering any breach or suspected breach of security or any disclosure of confidential project information to unauthorized parties or agencies.

12) and agree that obligations under this agreement will survive the termination of any assignment with SAMHSA/CBHSQ and/or RTI International.

Penalties under CIPSEA

Any violation of the terms and conditions of this agreement may subject you, the Agent, to immediate termination of access to confidential information by RTI International or CBHSQ, and will require the immediate return of all electronic and hard copy files and materials in your possession.

Any violation of this agreement may also be a violation of Federal criminal law under Title V, subtitle A of the E-Government Act of 2002 (P.L. 107-347); and/or Section 501(n) of the Public Health Services Act. Alleged violations under the Title V, subtitle A of the E-Government Act of 2002 are subject to prosecution by the United States Attorney. The penalty for violation of subtitle A of the E-Government Act of 2002 is a **fine of not more than \$250,000 and imprisonment for a period of not more than 5 years**. In addition to the above, all relevant statutory and regulatory penalties apply.

Your signature (whether in electronic or written form) below affirms your understanding and acknowledgement of all the regulations, requirements and penalties associated with CIPSEA as part of your work on this SAMHSA/CBHSQ project for RTI International.

Name

ID Number (if applicable, RTI employees only)

Signature

Company Name

Date

Job Title