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;

<sup>\*</sup> 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

<sup>\*\*</sup>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	loh Title			

DATA	COLL	ECTION	AGREEN	<b>IFNT</b>

Project Name: National Survey on Drug
Use and Health
Project No.: XXXXXXX

f, collection ser	rvices for the ben	nefit of RTI in			nal, agree to pro	
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- am aware that the research being conducted by RTI is being performed under contractual arrangement with the **Substance Abuse and Mental Health Services Administration** (SAMHSA);
- 2) hereby accept all duties and responsibilities of performing specified data collection tasks and will do so **personally,** in accordance with the training and guidelines provided to me. At no time will I engage the services of another person to perform any data collection tasks for me without the prior written approval of my employer (RTI);
- 3) agree to treat as **confidential** all information secured during interviews or obtained in any Project-related way during the period I am working on the Project, as required by the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA), and understand, under Section 513 of this Act, I am subject to criminal felony penalties of imprisonment for not more than five years, or fines of not more than \$250,000, or both, for voluntary disclosure of confidential information. Any breach of confidentiality must be reported immediately to the National Field Director. This information will be shared with the SAMHSA Project Officer and RTI. I have also completed and fully understand the CIPSEA training provided to me;
- 4) agree to treat as **confidential and proprietary** to RTI/SAMHSA any and all information provided by the public, whether collected or accessed in electronic or printed form during the course of my service on this Project, including but not limited to all data collection computer software and respondent data, and will protect such items from unauthorized use or disclosure;
- 5) am aware that the survey instruments completed form the basis from which all analyses will be drawn, and therefore, agree that all work for which I submit invoices will be legitimate, of high quality and performed in compliance with all Project specifications to ensure the scientific integrity of the data;
- 6) understand that I am fully and legally responsible for taking all reasonable and appropriate steps to ensure that any computer equipment issued to me for use on this Project is safeguarded against damage, loss, or theft. I also understand that I have a legal obligation to immediately return all equipment at the conclusion of my assignment or at the request of my supervisor;
- fully agree to conduct myself at all times in a manner that will obtain the respect and confidence of all individuals that I encounter as a representative of the Project and I will not betray this confidence by divulging information obtained to anyone other than authorized Project representatives of RTI;
- 8) understand that evidence of **falsification, fabrication or distortion of any data** collected for this Project will be reported to RTI's Scientific Integrity Committee, and such acts are grounds for immediately removing me from the Project and can result in my suspension from any government-funded research. Also, if falsification of data is substantiated, I understand a **formal fraud complaint** will be submitted to the U.S. Department of Health and Human Services' **Office of Inspector General** (OIG) and I could be subject to **criminal and/or civil prosecution** and thereby face imprisonment, financial penalties or both;