The National Addiction & HIV Data Archive Program (NAHDAP) is funded by the National Institute on Drug Abuse (NIDA) to acquire, preserve and disseminate data relevant to drug addiction and HIV research. Both organizations recognize that these types of research data are often from complex studies about sensitive topics from vulnerable populations. As a result, Institutional Review Boards (IRBs) want to know why researchers should share data with NAHDAP and how NAHDAP safeguards the confidentiality of human subjects in shared research datasets.

ICPSR’s Confidentiality Policies

NAHDAP is part of the Inter-university Consortium for Political and Social Research (ICPSR) at the University of Michigan. ICPSR’s confidentiality policies are often of interest to IRBs that make policies regarding data sharing and analysis. The most relevant statements are ICPSR’s Confidentiality Policy Statement, the Agreement about Confidentiality from the ICPSR By-laws, and the Responsible Use Statement that data users agree to before downloading data. These policies are available from the ICPSR Web site.

Informed Consent Language

Protection of the confidentiality of respondents is a core tenet of responsible research practice that begins with obtaining each subject’s informed consent. Informed consent must include a statement describing how the confidentiality of subject records will be maintained. However, it is also important that informed consent is written in a way that does not unduly limit an investigator’s ability to share data with the research community.

Researchers going into the field are encouraged to review the model language provided in the informed consent section of the ICPSR Web site.

Informed Consent Services

Contact NAHDAP staff if you are interested in our informed consent services:

- Review of and feedback on informed consent forms relative to data sharing.
- Assistance for researchers in sharing data from older studies that used informed consent language written before data sharing plans were made.

Data Release Options

NAHDAP selects data release methods that protect human subjects while maximizing the data’s analytic utility, including the list to the right.

A full public release is only warranted when risk of re-identification is minimal or the data are sufficiently transformed to substantially reduce that risk.

Contact NAHDAP staff for more information on any of these data release options.

- Public-use and public-use online analysis
- Restricted-use with an approved data use agreement
- Enclave-only access with an approved data use agreement
- Online access after disclosure protections are applied (may require a data use agreement)
- Delayed dissemination
Sharing Public-Use Datasets

Sharing public-use data typically involves less interaction with IRBs. Data providers still should confirm with their IRB if they need to take any additional steps. This is less likely if the data management plan and/or informed consent anticipated sharing the data as a public-use file. If not, data providers may need to file a modification to the original IRB submission. NAHDAP also recommends that data providers reassign ID values to break the link to any copies of the data stored at their institution before depositing the data with NAHDAP.

Sharing Restricted-Use Datasets

NAHDAP has an optional Restricted-Use Data Deposit and Dissemination Agreement (RUDDDA) available to cover the transfer, processing, and dissemination of restricted-use data with NAHDAP. NAHDAP does not require the RUDDDA. It is available upon request from NAHDAP staff. If required by the data provider’s institution, the RUDDDA is customized for each restricted-use dataset and is signed by a legal representative of that institution and the University of Michigan (the host institution of ICPSR and NAHDAP).

Information needed to customize the RUDDDA is:

- Data provider’s institution’s legal name and address
- Official name AND familiar reference of the project or dataset,
- Contact name of the legal representative at the provider’s institution, and
- If the institution prefers executing the RUDDDA as electronic or hard copy and the number of copies needed.

NAHDAP’s Restricted-Use Data Deposit and Dissemination Procedures are available from the NAHDAP Web site under the Deposit Data tab.

It explains procedures to execute the above RUDDDA and includes sections about addressing direct and indirect identifiers, elements that must be removed to create a de-identified dataset using the safe harbor method, elements that can be retained in a restricted-use dataset, and the Restricted Data Use Agreement (see box above) required for users to access the restricted-use dataset.

Data Preparation and Deposit

NAHDAP has tips for Preparing Data for Deposit with NAHDAP available as one of the Quick Links for Data Producers on the NAHDAP Web site. ICPSR’s Guide to Social Science Data Preparation and Archiving contains information on disclosure review and best practices in data preparation and is available on the ICPSR Web site under Deposit Data.

After data preparation is complete, securely upload the files and sign the deposit electronically using the ICPSR online deposit form. Requests for a restricted-use dissemination option can be made using the comment box on the first page of the deposit form. A fully executed RUDDDA supersedes the standard online deposit agreement, as it covers the standard terms and also addresses the restricted-use nature of the data being deposited.

Data preparation for release at NAHDAP always includes a confidentiality review on the deposited data to look for disclosure risks, even if the data are deposited as a public-use file. NAHDAP staff may adjust the data prior to release. Since staff cannot be certain the data are appropriately de-identified until after the review, all processing tasks are conducted in ICPSR’s Secure Data Environment. All NAHDAP staff sign a confidentiality pledge as a condition of employment, receive disclosure risk review training, and are certified after passing the required test.