

## LI Analysis Training Series

### Accessing pooled GAIN and EBTx data

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#### **Purpose:**

This memo describes the process required for evaluators or researchers to obtain permission to receive any Global Appraisal of Individual Needs (GAIN) data from the GAIN Coordinating Center (GCC) and Evidence-Based Treatment (EBTx) data<sup>1</sup> from the EBT Coordinating Center. It also discusses the recommended process for individual sites to share their own local data with another site. All research studies were conducted under the supervision of the institutional review boards for their respective institutions. Both practice and research studies were conducted with general consents under federal guidelines (42 CFR Part 2) that explicitly allow record abstraction for the purpose of program evaluation and development as long as the data is de-identified and kept confidential. Data obtained since the implementation of the Health Insurance Portability and Accountability Act of 1996 ([HIPAA](#)) was covered by formal data sharing agreements between Chestnut Health Systems and each of the participating agencies in accordance with 45 CFR Parts 160 and 164, Subparts A and E. Use of the data for secondary analysis by Chestnut Health Systems staff falls under the supervision of Chestnut's institutional review board.

We absolutely encourage use of local data for evaluation and publication. Evaluators are also encouraged to work directly with other grantees or agencies to use combined local data sets for analysis and publication. Please let the GCC know if you are working independently on a particular topic so that we can add your work to our growing list of analyses and add any publications to our bibliography of GAIN use.

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<sup>1</sup> EBTx data has been collected by treatment sites funded to implement A-CRA and ACC with adolescents presenting for substance use treatment. Clinicians record the open and discharge dates for each treatment episode for each treatment participant, as well as the following data from each treatment session: date, session type (adolescent, caregiver, or both), A-CRA procedures delivered, time spent on each procedure, case management delivered, urine analysis testing results, and perceived session difficulty. A set of summary variables can be generated from EBTx.

The GCC can also provide access to data from other program sites or from up to 20,000 adolescents, young adults, and adults from across many sites. The grant PI has full rights and access to data from their own site and can approve anything an internal evaluator wants to do. Pooled (multisite) and de-identified<sup>2</sup> data may be accessed only with appropriate protections and permission as described below.

**Procedure:**

For one site to share data with another site or for several sites to pool their data, the sites first need to agree to share data. Then each site needs to sign a data sharing agreement (DSA) with the other sites that will share the data. The [DSA options and decision tree](#) available on the GAIN website can be used to select the appropriate agreement. In this situation, each site will have granted permission prior to the transfer of data to create the pooled data set for use by the other sites included in the agreement. Once the appropriate DSAs are in place, sites may work together to determine the details of where and how to pool their data.

To use a data set from the GAIN Coordinating Center or the EBT Coordinating Center, anyone proposing an analysis or evaluation must send an abstract to the Analysis Team to verify the feasibility. The Analysis Team will work with the evaluator or researcher to modify the abstract based on the feasibility review and grant permissions (see “Abstract and Feasibility” below). Be sure to plan ahead, since this process takes at least 2½ weeks and often as long as a month or two. No proposal is necessary to use a data set from a group of sites that have agreed to pool their data and already have appropriate data sharing agreements in place. In addition, the GCC can work with these sites to create and provide their final de-identified data set.

**Data Sharing Agreement**

Before providing any GAIN or EBTx data, Chestnut Health Systems’ GAIN Coordinating Center and the evaluator (user of the data) must have an appropriate data sharing agreement on file at the GCC ([see the DSA options and decision tree](#)). If your work is funded through a grant, your grant PI will have this agreement in place before data are submitted to the GCC. If the grant has ended or if an evaluator’s work is outside of the scope of the grant (i.e., anyone who does not submit data of their own but who wants to use our data for secondary analysis), then the evaluator will need to sign a GCC limited agreement (DSA #3) in order to access the data. If you will be receiving EBTx data or other data directly from another site, you and the other site will need to sign a business associate agreement (DSA #4) before any data files are shared.

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<sup>2</sup> An SPSS multisite data set with the following adjustments: a) all site IDs (XSITE2) are recorded as the numeric portion of the grant ID; b) the client ID (XPID2) is a combination of XSITE2 and a random ID number that both uniquely identifies the client within any data set where this ID exists and is not traceable to data that could be used to identify the client; c) the GAIN-I observation date has been shortened to only a year; d) all other client date fields have been converted to the number of days since the GAIN-I was administered (dates before the GAIN-I will be negative values, e.g., the client’s date of birth); and e) names, Social Security numbers, health insurance identifiers, certificate or license numbers, and items marked as confidential in GAIN ABS are always excluded from any data export and are not included in any files outside of GAIN ABS.

## **Abstract and Feasibility**

For evaluators or researchers to obtain access to other sites' GAIN or EBTx data that has been submitted to the GCC or EBT CC, the evaluator must send an abstract proposing the specific analysis to be conducted and the data being requested to the GCC ([GAINEval@chestnut.org](mailto:GAINEval@chestnut.org)) for feasibility review and recommendations for any changes. This abstract needs to identify the sample to be used (inclusion-exclusion criteria and samples), the questions to be asked or hypotheses (with as explicit link to variables as possible), the time periods (intake only, or which specific follow-ups may also be needed), the type of analyses planned, and the target audience. To assist in abstract creation, evaluators can download the [GAIN-I Administration Manual](#) (Dennis, White, Titus, & Unsicker, 2008) and the [GAIN-I Scales and Variables file](#), an electronic encyclopedia of more than 2,000 pages that provides information about the GAIN items and calculated scales, indices, and calculated variables and helps evaluators determine which variables to use. For grantee sites, the [Adolescent Program Support Site](#) and the [GAIN Program Support Site](#) are specific to individual grant programs and include reports and summaries for each program. To access these websites, you will need to get the logon and password from your grant's PI. Examples of data request abstracts and a summary of previous data request topics can be found on the FTP Common site.<sup>3</sup> The list of EBTx summary variables is also available upon request.

The GAIN Analysis Team and, if applicable, the EBT analysis staff will do a preliminary review of the abstract to make sure that the proposed analyses are feasible in terms of available data, sample size, and variables, and the staff will also comment on any potential methodological problems. Some key issues that can come up in this process include the absence of the requested variable (or any similar item that could be used instead), a variable that is optional and collected only in a subset of sites, the availability of follow-up data, or limited sample size in a subgroup or over time. To start this process or request feedback on the feasibility of an abstract, submit it to [GAINEval@chestnut.org](mailto:GAINEval@chestnut.org).

## **Approval**

Depending on what data will be used and the analysis being proposed, approval of the final abstract is needed from one or more of the following sources:

- **Principal investigator (PI) approval:** Any PI or group of PIs can authorize the use of data they collectively have rights to. With their approval GCC staff will create a file containing their combined data.
- **Funder/GCC/EBT CC approval:** For analyses on general topics (e.g., withdrawal, comorbidity) that do not use data from current programs or that do not identify sites or clients, approval can be requested from the project funder (e.g., the CSAT project officer) or director of the GCC or EBT CC.
- **Funder/GCC approval/EBT CC approval plus PI approval:** For analyses that will identify specific sites or studies, the GCC will also notify the involved sites' PIs and give them the opportunity to decline use of their data. Active sites are given 2 weeks to review the abstract and decline use of their data if they so desire. Note that some

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<sup>3</sup> The FTP Common site is located at <ftp://data.chestnut.org>; username = Common, password = public (both case-sensitive).

- **Current Grant Program Approval:** Abstracts proposing preliminary analyses of data from a cohort currently in the field are a special case. These abstracts will be submitted to the PIs of the cohort via e-mail. Active sites are given 2 weeks to review the abstract and decline use of their data if they so desire.

Once the abstract and sharing of data have been approved, the GCC and EBT Analysis Team will prepare the necessary de-identified data set for use by the evaluator. On occasion, the Analysis Team will be asked to conduct the approved data analyses and provide specific output and tables to the evaluator. This work has to be approved by the GCC or EBT CC director and, where applicable, the person who will be covering the cost of the work (e.g., CSAT Technical Assistance (TA) contract, project officer, PI).

### **Describing the Pooled Data in Reports and Articles:**

Below is an example adapted from Chan, Dennis, & Funk (2008, p. 17) showing how this kind of pooled data can be described:

*The pooled data come from studies funded by the Center for Substance Abuse Treatment, National Institute on Alcohol Abuse and Alcoholism, National Institute on Drug Abuse, Robert Wood Johnson Foundation and Interventions Foundation. The studies were conducted in a variety of institutional settings, including across adolescent and adult levels of care, student assistance programs, criminal and juvenile justice agencies, mental health agencies, and child protective service and family service agencies. All data were collected as part of general clinical practice or specific research studies under their respective voluntary consent procedures with identifiers subsequently encrypted for research analysis. All research studies were conducted under the supervision of the Institutional Review Boards for their respective institutions. Both practice and research studies were conducted with general consents under federal guidelines (42 CFR Part 2) that explicitly allow record abstraction for the purpose of program evaluation and development as long as the data is de-identified and kept confidential. Data obtained since the implementation of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) was covered by formal Data Sharing Agreements between Chestnut Health Systems and each of the participating agencies per 45 CFR Parts 160 and 164, Subparts A and E. Use of the data for secondary analysis by Chestnut Health Systems Staff is under the supervision of Chestnut's Institutional Review Board. In order to continue complying with 42 CFT Part 2, HIPAA, Chestnut and other IRBs, it is necessary for anyone accessing the pooled de-identified data to enter into a data sharing agreement in which they agree to respect the privacy and confidentiality of the participants and not to attempt to re-identify individuals. (See <http://www.chestnut.org/LI/gain/index.html#Data Sharing Agreements> for different types of data sharing agreement, which vary by context.)*

### **Bibliography of URLs Mentioned Above**

Adolescent Program Support Site accessed 11/24/10 (username and password required)  
<http://www.chestnut.org/li/apss/>

Data Sharing Agreement website accessed 11/24/10  
<http://www.chestnut.org/LI/gain/index.html#Data Sharing Agreements>

FTP Common site (username and password required)  
<ftp://data.chestnut.org>

GAIN Administration Manual accessed 11/24/10  
<http://www.chestnut.org/LI/gain/index.html#Data Sharing Agreements>

GAIN Program Support Site accessed 11/24/10 (username and password required)  
<http://www.chestnut.org/LI/GPSS/main.asp>

GAIN-I Scales and Variables accessed 11/24/10  
[http://www.chestnut.org/LI/gain/Scales\\_Crosswalks/GI\\_Scales\\_and\\_Variables.xls](http://www.chestnut.org/LI/gain/Scales_Crosswalks/GI_Scales_and_Variables.xls)

Office for Civil Rights - HIPAA: Medical Privacy - National Standards to Protect the Privacy of Personal Health Information accessed 11/24/10.  
<http://www.hhs.gov/ocr/hipaa/>

### **Bibliography**

Chan, Y.-F., Dennis, M. L., & Funk, R. R. (2008). Prevalence and comorbidity of major internalizing and externalizing problems among adolescents and adults presenting to substance abuse treatment. *Journal of Substance Abuse Treatment, 34*(1), 14–24.

Dennis, M. L., White, M., Titus, J. C., & Unsicker, J. (2008). *Global Appraisal of Individual Needs (GAIN): Administration guide for the GAIN and related measures (version 5)*. Bloomington, IL: Chestnut Health Systems. Retrieved from <http://www.chestnut.org/LI/gain/index.html#Administration Manual>