

If Applicable, please complete:

Grant Program: _____

Grant No.: _____

GAIN License Number: _____

**GAIN Coordination Center Data Agreement
For Non-Covered Entities
(2. GCC Full Non-CE, version 6-23-03)**

This Data Agreement (the “Agreement”) is entered into as of _____, 200_, (the “Effective Date”) by and between _____, (the “SITE”) and Chestnut Health Systems, Inc.’s GAIN Coordination Center (“GCC”).

WHEREAS, SITE has received funding from _____ (the “SPONSOR”) for purposes of participating in the following research project:
_____(the “PROJECT”);

WHEREAS, Chestnut Health Systems is, but SITE is NOT, a Covered Entity within the meaning in the Health Insurance Portability and Accountability Act Privacy Rule, 45 C.F.R. Parts 160-164 (the “Privacy Rule”);

WHEREAS, SITE (and/or its affiliates) operates a drug and alcohol treatment program and information obtained in the program is governed by the Federal Confidentiality of Alcohol and Drug Abuse Patient Records law and regulations (42 C.F.R. Part 2);

WHEREAS, SITE has collected data as part of the PROJECT;

WHEREAS, SITE wishes to have access to GCC’s data collection expertise, including training, instruments, manuals, computer applications and technical assistance;

WHEREAS, because of its data collection expertise, GCC has been selected by SPONSOR to serve as a data-coordinating center;

WHEREAS, as the data-coordinating center, GCC receives data from several sites, including SITE, in order to aggregate, clean and de-identify data for cross-site analysis; and

WHEREAS, as the data coordinating center, GCC also discloses data back to the sites, including SITE, for their internal purposes and also to the SPONSOR as necessary to comply with the terms of the funding contracts; and

WHEREAS, the parties wish to enter into an agreement that will permit the sharing of data between them as necessary to fulfill the purposes of the PROJECT and their reporting requirements to SPONSOR.

NOW, THEREFORE, SITE and GCC agree as follows:

SECTION 1. DEFINITIONS

1.1 De-identified Information does not identify an individual, and cannot be used to identify an individual. Health information is de-identified if all the following items of information are removed for the individual patient, and his/her relatives, employers and household members:

- Names
- All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census: 1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and 2) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, and date of death
- All ages over 89 and all elements of dates (including year) indicative of such age, except a single category may be used for age 90 or older
- Telephone and fax numbers
- Electronic mail addresses
- Social Security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic, or code, except permitted re-identifiers
- Any other information the staff member actually knows could be used alone or in combination with other information to identify an individual

If all the information listed above is not removed, health information can also be considered de-identified if an expert in generally accepted statistical and scientific principles relating to rendering information not individually identifiable determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, to identify an individual. The methods and results of the expert's analysis must be documented.

1.2 A Limited Data Set means a data set that has had the following Protected Health Information for the individual, his/her relatives, employers or household members removed:

- Names;
- Street or Postal address information (other than town or city, state, and zip code)
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social Security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers

- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images.

The Limited Data Set may include the following identifying information:

- The town or city, state and zip code of the individual, his/her relatives, employers or household members
- Dates, including dates of behaviors or services converted to days before or after intake and the federal fiscal year of intake
- Age (in years) at intake
- A unique research identifying number, characteristic or code

The Limited Data Set may also include non-identifying information, including the type of treatment or service received or randomly assigned and the amount of services received as well as the facility location. The Limited Data Set will require two linkage files (one at the SITE and one at GCC) to connect it back to PHI.

1.3 Research is the systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

1.4 All other capitalized terms not defined herein shall have the same meaning as in the Privacy Rule.

SECTION 2. SERVICES TO BE PROVIDED

2.1 The parties mutually agree that the following named individual(s) will oversee the receipt and disclosure of data under this Agreement on behalf of

GCC: _____ (*insert name and contact info*)

2.2 The parties mutually agree that the following named individual(s) will be designated as point-of-contact on behalf of SITE: _____ (*insert name and contact info*).

2.3 GCC will provide the following services to SITE, as requested by SITE (the “Services”):

- Training of SITE’s staff on data collection techniques
- Software to initially de-identify the data prior to transmittal
- Further de-identification of data
- Creation of a Limited Data Set
- Technical assistance on systems
- Data aggregation services
- Analytic and publication assistance

SECTION 3: GCC’S RECEIPT OF SUBSTANCE ABUSE TREATMENT RECORDS (Qualified Service Organization Provisions)

3.1 To the extent that GCC has access to substance abuse treatment information in the course of providing Services or technical assistance to SITE, then GCC shall be operating as a qualified service

organization of SITE (as that term is defined by 42 C.F.R. §2.11) and this section of the Agreement shall apply.

3.2 In receiving, storing, processing or otherwise dealing with any protected substance abuse information from SITE, GCC is fully bound by the provisions of the federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2.

3.3 If necessary, GCC will resist in judicial proceedings any efforts to obtain access to patient records except as expressly permitted under 42 C.F.R. Part 2.

3.4 GCC acknowledges that any unauthorized disclosure of information under this part is a federal criminal offense.

SECTION 4: SITE'S USE OR DISCLOSURE OF A CROSS-SITE LIMITED DATA SET

4.1 This section shall serve as the Data Use Agreement between SITE and GCC and shall govern SITE's use or disclosure of any cross-site Limited Data Set received from GCC.

4.2 SITE may use or disclose the Limited Data Set to GCC or SPONSOR only for the purposes of research, public health or health care operations.

4.3 SITE may not use or disclose the Limited Data Set if such use or disclosure would be a violation of the Privacy Rule if done by GCC.

4.4 SITE agrees it will not use or further disclose the Limited Data Set other than as permitted or required by this Agreement or as required by law.

4.5 SITE agrees to use appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as provided for by this Agreement.

4.6 SITE agrees to report to GCC, in writing, any use or disclosure of the Limited Data Set not provided for by this Agreement of which it becomes aware.

4.7 In the event that SITE is permitted by law to provide the Limited Data Set to a third party, SITE agrees to have the third party execute a Data Use Agreement in the form attached to this Agreement.

4.8 SITE will not (re)identify the information or contact the individuals who are the subjects of the information.

SECTION 5: DE-IDENTIFIED INFORMATION

5.1 De-identified information may be disclosed or used in accordance with §164.514 (a) and (b) of the Privacy Rule. De-identified Information is not addressed in 42 C.F.R. Part 2. GCC shall be permitted to use or disclose de-identified information without restriction.

5.2 GCC's de-identified data set shall contain a randomly assigned research identification number, which will be linked only to the research identification number assigned by the SITE. SITE will not have access to this link. Similarly, GCC will not have access to the link between the SITE's research identification number and personal identifiers.

SECTION 6: TERM AND TERMINATION

6.1 Term. This Agreement shall become effective on the Effective Date and shall terminate when data is no longer being provided to GCC by SITE or to SITE by GCC. GCC agrees that all identifying information will be destroyed within five (5) years of the PROJECT's termination, unless continuation funding and/or an updated consent are obtained or as otherwise required by law.

6.2 Termination. Either party shall be permitted to terminate this Agreement immediately, and any other agreement between the parties, in the event that the other party has materially breached this Agreement. If termination is not feasible, the non-terminating party, if a Covered Entity, shall have the responsibility to report any problems to the Secretary.

SECTION 7. MISCELLANEOUS

7.1 Compliance with Law. The parties shall each be solely responsible for their own compliance with all applicable law, including the following:

- The terms of its funding relationship with the SPONSOR
- Statutes and regulations governing human subject research and any requirements imposed by an Institutional Review Board
- Statutes and regulations governing data safety and monitoring plans, monitors or boards
- The Federal Drug and Alcohol Confidentiality Law (42 C.F.R. Part 2)
- The Health Insurance Portability and Accountability Act.

Nothing in this agreement shall be construed as altering in any way any requirements imposed upon SITE under the terms of its funding agreement with the SPONSOR. In addition, this Agreement shall not replace any existing steering committees, executive committees or other approval mechanisms for cross-site sharing of data.

7.2 Indemnification. Each party shall indemnify and hold the other harmless from and against all claims, liabilities, judgments, fines, assessments, penalties, awards or other expenses, of any kind or nature whatsoever, including, without limitation, attorney's fees, expert witness fees, and costs of investigation, litigation or dispute resolution, relating to or arising out of any breach of this Agreement by the indemnifying party as determined by a court of competent jurisdiction.

7.3 Regulatory Reference. A reference in this Agreement to a section in the Privacy Standards or 42 C.F.R. Part 2 means the section as in effect or as amended.

7.4 Preemption. In the event of an inconsistency between the provisions of this Agreement and mandatory provisions of the Privacy Rule or 42 C.F.R. Part 2, as amended, the Privacy Rule or 42 C.F.R. Part 2 shall control.

7.5 Independent Entities. None of the provisions of this Agreement is intended to create, nor shall any be construed to create, any relationship between the parties other than that of independent entities contracting with each other solely to effectuate the provisions of the Agreement.

7.6 Severability. The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision.

7.7 Amendments. The parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for either party to comply with the requirements of the Privacy Rule, the

Security Rule or 42 C.F.R. Part 2. This agreement shall not be amended without the mutual written consent of the parties.

7.8 No Third-Party Beneficiaries. This Agreement shall not in any manner whatsoever confer any rights upon or increase the rights of any third-party.

7.9 Entire Agreement. The parties acknowledge that this Agreement represents the entire understanding between the parties with respect to the subject matter hereof and that there are no other agreements, either oral or written, between them.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the day and year written below.

SITE: _____
INC.

GCC: CHESTNUT HEALTH SYSTEMS,

Corporate Representative:

Corporate Representative:

By: _____

By: _____

Mark D. Godley, Ph.D.

Title: _____

Title: Director of Research and Development

Date: _____

Date: _____

Technical Representative:

Technical Representative:

By: _____

By: _____

Michael Dennis, Ph.D.

Title: _____

Title: Senior Research Psychologist

Date: _____

Date: _____