

GAIN Coordinating Center Data Sharing Agreement Guidelines

Under the terms of the Health Insurance Portability and Accountability Act (HIPAA) and 45 C.F.R. Part 2 (the “privacy rule”), two or more organizations sharing data involving full or limited protected health information (PHI) are required to enter into a data sharing agreement that spells out the terms of their interactions.

The GAIN Coordinating Center (GCC), operated by Chestnut Health Systems, a covered entity under HIPAA, acts as a data clearinghouse, managing data in various stages of de-identification from both covered and noncovered entities. The GCC performs quality assurance on the data, creates summary measures and reports, and creates site-specific and cross-site limited data sets for redistribution to licensees and other analysts designated by each site or each licensee’s sponsors. Unless otherwise spelled out in the agreement, only the licensee receives data from the GCC with PHI; all others receive data that has been de-identified as spelled out in the data sharing agreement. The required agreement depends on whether a licensee sends data to or receives data from the GCC, and separate agreements may be required if a licensee exchanges data with another organization without the GCC’s involvement. In addition, because Chestnut receives audio recordings for training and quality assurance and hosts the server for the GAIN ABS web application, all GAIN ABS licensees must fill out a data sharing agreement regardless of whether they contract with Chestnut for data services.

Attached is a decision tree for determining which agreement is required between the licensee and the GCC or the licensee and other local organizations. Copies of these forms are also available at <http://www.chestnut.org/LI/gain/index.html#Data%20Sharing%20Agreements>.

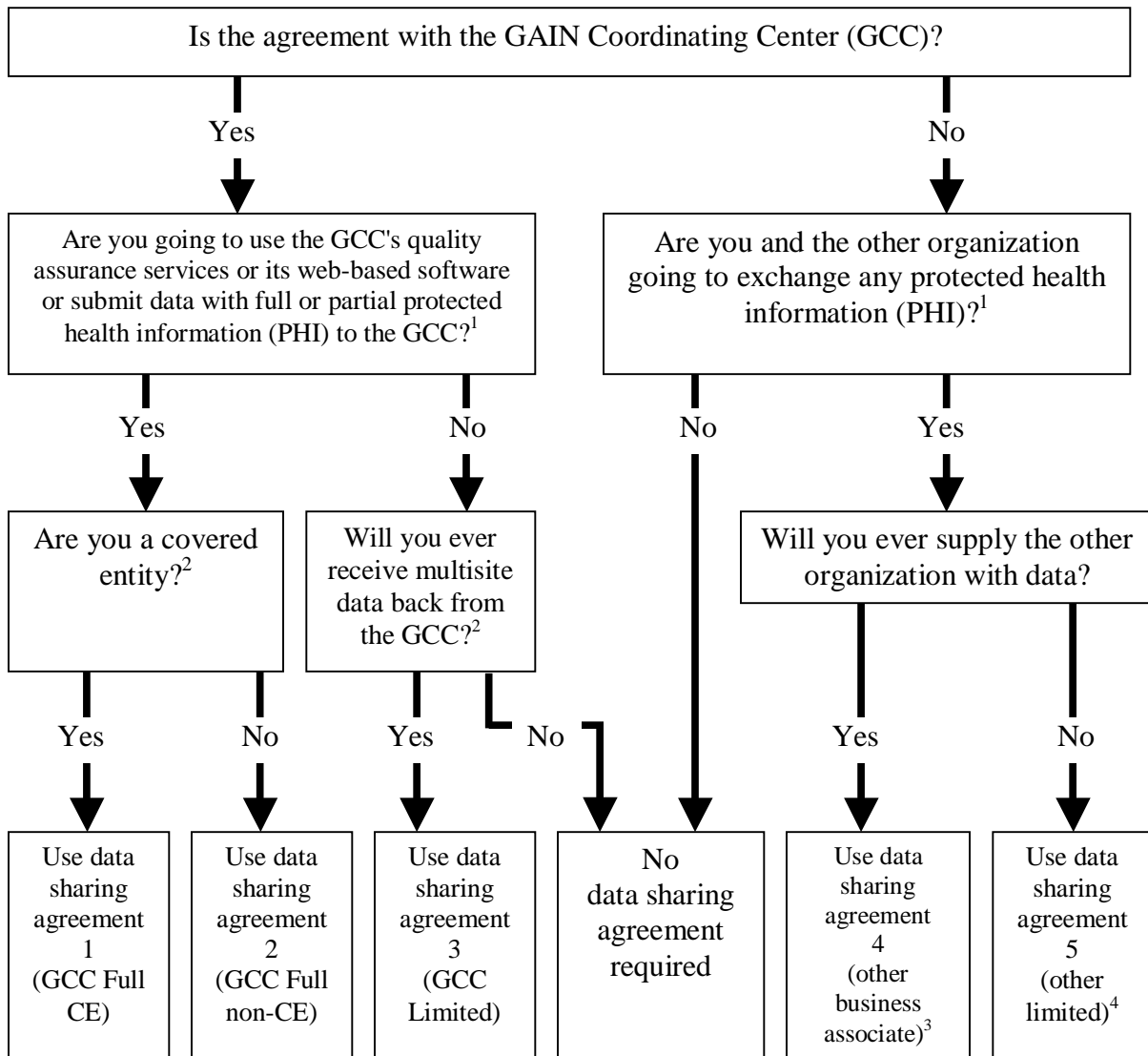
Notes:

- CSAT grantees should fill in the names of the grant program (e.g., ART, SCY, TCE, etc.), grant number, and GAIN license number at the top of the form to help the GCC staff process the data agreement.
- Other licensees need record only their GAIN license number.
- In the “site” field in the first paragraph of data sharing agreements 1 and 2, record the licensee or lead organization that will be sending data to or receiving data from the GCC.
- If applicable, in the “sponsor” field in the second paragraph of data sharing agreements 1 and 2, record the name of the grantor covering the costs of the study (e.g., Center for Substance Abuse Treatment, Robert Woods Johnson Foundation, National Institute on Alcohol Abuse and Alcoholism, National Institute on Drug Abuse, state, etc.).
- Independent licensees should record “self” in the sponsor field if they finance their own GAIN work.
- On the last page of the agreement, record the names of the people responsible for overseeing the agreement for the licensee. A data collection specialist or analyst, a clinical supervisor, or a grant PI usually signs as the technical representative. The second signee has to be authorized to sign for the licensee’s organization and is usually a chief executive officer, chief operating officer, other business officer, director of research, or another person with signing authority in your organization.
- If you have any questions, please contact GAINInfo@chestnut.org.

Please complete, sign, and return data sharing agreements to:

GAIN Info
Chestnut Health Systems
448 Wylie Drive
Normal IL 61761
Phone: (309) 451-7700
Fax: (309) 451-7763
GAINInfo@chestnut.org

HIPAA Data Sharing Agreement Decision Tree (version 11-12-08)



¹ PHI includes names, addresses, phone numbers, and other contact information; medical, state, insurance, license, bank account, and other (nonresearch) identifiers; photographs and biometric identifiers; and all other information defined as PHI by your organization's privacy policy.

² Covered entity within the meaning in the Health Insurance Portability and Accountability Act Privacy Rule and 45 C.F.R. Part 2 (the privacy rule).

³ Or other business associate agreement as determined by local organization and covering the same issues.

⁴ Or other data use agreement as determined by local organization and covering the same issues.