

MEMORANDUM

TO Board of Global Tracheostomy Collaborative

FROM Amy Leopard

DATE March 17, 2014

SUBJECT Global Tracheostomy Collaborative Registry and Data Use Agreement

Per the request of the Global Tracheostomy Collaborative (“GTC”), we prepared the attached Registry and Data Use Agreement (the “Registry Agreement”) between GTC and its participating hospital centers who are covered entities under the HIPAA and HITECH regulations (“Centers”). Our assumptions and comments on the Registry Agreement and protected health information (“PHI”) maintained in the GTC registry are as follows:

1. We understand that the PHI collected in and reported from the registry will be limited to a Limited Data Set (“LDS”)¹ used primarily for the Centers’ health care operations (i.e., quality improvement activities) and potentially for future research studies (i.e., retrospective studies approved under a GTC protocol). Quality improvement activities will include aggregating and reporting data from the Centers for outcomes metrics and benchmarking. A GTC oversight committee composed of representatives from Centers will advise on data integrity, technical operations, and publication and research activities.
 - a. Under HIPAA, a Business Associate Agreement (BAA) with the Centers is not required, but the compilation and reporting of LDS data for these purposes is subject to a data use agreement. See www.hhs.gov/ocr/privacy/hipaa/faq/business_associates/251.html and the GTC data use restrictions in Section 3.4.
 - b. Although the parties intend for only a LDS to be used, to the extent a Center did submit any direct identifiers to the registry, a BAA would be required and has been provided pursuant to Section 4.2 and Exhibit C.
2. Vanderbilt University Medical Center (“VUMC”) will host the web application for managing the registry using its Research Electronic Data Capture (“REDCap”) software. VUMC will establish unique user accounts, passwords and authentication for individuals authorized by GTC to submit data using REDCap. (See www.project-redcap.org and attached REDCap security background).
3. The GTC oversight committee protocol allows Centers to review their own data at liberty, but requires aggregate data to be reported through GTC with restrictions on identifying any Centers. Section 8 of the Registry Agreement contains this general limitation on using data that identifies

¹ A Limited Data Set is PHI excluding the following direct identifiers of individuals, their family and household members or employers: Name; postal address (other than town, city, state and zip); phone and fax number; email address; SSN; medical record number; health plan number; account number; certificate/license number; vehicle ID and serial number, including license plate; device ID and serial number; URL and IP address; biometric identifiers, including finger and voice prints; full face photos and comparable images.

another Center without that Center's consent and the consent of GTC as well as restrictions requiring GTC approval for publications and disseminated materials.

4. Other general comments on the Registry Agreement are as follows:

- a. *Term and Fees.* The Registry Agreement is for three-year term, but would automatically renew unless terminated pursuant to Section 7. The initial fee of \$3,500 is intended to be a participation fee, adjusted annually by the GTC Board on notice to the Centers.
- b. *LDS Use Agreement between GTC and third parties.* The Registry Agreement permits GTC to plan for situations where it may in the future permit registry data to be shared with third parties under an approved protocol for research, public health or health care operations purposes consistent with HIPAA. However, the LDS recipient would be required to enter a data use agreement with GTC, provision for which has been made in Section 3.4 and the LDS Use Agreement form in Exhibit B. GTC and its oversight committee may want to establish additional restrictions beyond those set forth here for the types of protocols it may approve, but at a minimum, Exhibit B includes the same restrictions on publication and dissemination as those in the Registry Agreement.
- c. *Data Rights.* Please note that under Section 6, ownership of source data and local data submitted by Centers remain with the Centers, with rights granted to GTC. De-identified data and aggregated data compiled in the Registry is intended to vest with GTC, with license rights granted to Centers for noncommercial uses of research, education and the provision of health care services. GTC and Centers agree to standard confidentiality provisions in Section 6.5.
- d. *Disclaimer of Warranties and Limitations of Liability.* Given the GTC membership model, the compilation of data created in the course of care from many Centers, the nominal participant expense, and the use of the RedCap platform, the registry data is provided "As Is" and "As Available", with a disclaimer of warranties in Section 9 and a limitation of liability in Section 10.
- e. *Indemnification.* Section 10 provides that each party is responsible for their own acts and omissions, subject to force majeure events and the limitation of liability. GTC would provide a limited indemnification for GTC intellectual property infringement claims from third parties, and Centers would provide a limited indemnification of third party claims based on data errors from the Centers, medical treatment rendered by the Centers, and any peer review actions based on registry data.
- f. *Miscellaneous Provisions.* The Registry Agreement provides for binding arbitration under American Health Lawyers Association rules as the mechanism for alternative dispute resolution and consistent with the standard REDCap agreement, adopts Tennessee law as the governing law.

Please do not hesitate to contact me at (615) 252-2309 or aleopard@babbc.com with any questions or concerns.