



MASSACHUSETTS
GENERAL HOSPITAL



HARVARD
MEDICAL SCHOOL

*Massachusetts General Hospital
Tobacco Research and Treatment Center
50 Staniford Street, 9th Floor
Boston, MA 02114*

Susan Regan, Ph.D.
*Instructor
Department of Medicine
Harvard Medical School*

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Surviving Sepsis Campaign of the Society of Critical Care Medicine
International Sepsis Forum
European Society of Intensive Care Medicine
C/o Society of Critical Care Medicine
701 Lee Street, Suite 200
Des Plaines, IL 60016

Dear Sir or Madam:

I have been asked to comment on the nature of the data transmitted to the Society of Critical Care Medicine (SCCM) server by users of the Surviving Sepsis database. Specifically, I have been asked to address whether the data transmitted constitute de-identified data as defined in Section 164.514(a) of the HIPPA regulations. This letter is intended to satisfy the requirements of Section 164.514(b)(1) of those regulations.

I believe I possess the appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable. I hold a Ph.D. in experimental psychology and have over 20 years of experience analyzing scientific data. I have been the primary statistician on more than fifty scientific publications. I have served as data manager on many clinical research projects with primary responsibility for maintaining patient confidentiality.

As the developer of the Surviving Sepsis database application, I am completely familiar with its functioning. The database is designed to be used by remote sites, hospitals where patients with severe sepsis are treated. Participating sites install the database on a local computer or server of their choosing. They enter data about these patients into the database, including some information that render the patients identifiable to the site, specifically including several dates (e.g. admission, diagnosis, and discharge) and a patient identifier of their choosing that is meaningful to them and potentially renders the patients identifiable. There is also a free text field that in which the user can record any pertinent notes about the patient. The application assigns an anonymous id to each case, and creates

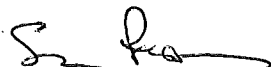
additional data elements storing all dates as elapsed time from the date of diagnosis. As discussed below, much of this data is not transmitted to SCCM. The hospital site uses these data internally to perform activities that constitute “health care operations” under HIPAA.

Transmission of select parts of the data to the SCCM server for use in research and benchmarking activities occurs at the discretion of the local user. The database application includes a utility that creates a partial data set from the contents of the database and sends it via FTP to the SCCM server. The data elements that are transmitted were selected to help assure that the data is not patient identifiable. In addition to clinical data that is devoid of any patient-identifiable elements, the partial data set includes the name and location of the site, the database-assigned anonymous id number, the calculated elapsed time data elements and the month and year of diagnosis. SCCM has no information that would permit it to decode the anonymous id number. For data quality monitoring purposes, the transmission includes the date and time the data were first entered into the database and the date they were last updated. It does not include the site-assigned patient identifier, any other dates, or the free text field. The month of diagnosis is the only data element included in the transmission that would need to be removed in order for the data transferred to fit within the de-identification “safe harbor” under Section 164.510(b)(2) of the HIPAA regulations. I have verified this by examining data files that have been transmitted from the database application to the SCCM server.

Under Section 164.514(a) of the HIPAA regulations, a facility directory can disclose to the public the names of patients, their location in the facility their general condition and religious affiliation, unless a patient objects to the disclosure of that information. However, such information can only be released to members of the clergy or persons who identify the patient by name. Therefore, SCCM will not have access to a list of patients in any of the transmitting sites.

The data transmitted to the SCCM server, the anticipated recipient, do not identify an individual and there is no reasonable basis to believe that the information can be used, alone or in combination with other available information, to identify any individual. Therefore, in my opinion, they meet the requirements for de-identified data set out in Section 164.514(b)(1) and are not individually identifiable health information. The month of diagnosis is not sufficient, even in combination with the year and elapsed time information, to establish any date. There is no information in the transmission that would allow anyone at SCCM to determine who the patient was.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Regan".

Susan Regan, Ph.D.