

**Burn Model Systems National Data and Statistical Center
STANDARD OPERATING PROCEDURE 601**

Data Use Agreement

This Data Use Agreement (the “Agreement”) is effective as of [month, day, year] (the “Agreement Effective Date”) until [month, day, year] (the “Agreement Termination Date”) by and between the Burn Model Systems National Data and Statistical Center at **University of Washington** (“Covered Entity”) and **[name of Burn Model System]** (“Data User”).

The Burn Model Systems (BMS) Program is funded by the US Department of Education, National Institute on Disability and Rehabilitation Research (NIDRR). One of the major components of the Burn program is a standardized National Database (NDB) for innovative analyses of burn injury treatment and outcomes. The Burn NDB contains information on cases treated within any BMS center, located around the United States, since the program began. The Burn National Data and Statistical Center (BMS NDSC) located at the University of Washington, in Seattle, WA, is a central resource for researchers and data collectors within the Burn Model Systems (BMS) program. The primary purpose of the BMS NDSC is to advance medical rehabilitation by increasing the rigor and efficiency of scientific efforts to longitudinally assess the experience of burn survivors. The BMS NDSC provides technical assistance, training, and methodological consultation to 4 BMS centers as they collect and analyze longitudinal data from burn survivors in their communities, and as they conduct research toward evidence-based burn rehabilitation interventions. The BMS NDSC (also funded by NIDRR) houses and manages the BMS NDB. This data use agreement is used to allow release of the Burn NDB from the BMS NDSC to any of the BMS centers.

RECITALS

WHEREAS, Covered Entity possesses *Individually Identifiable Health Information* that is protected under HIPAA (as hereinafter defined) and the HIPAA Regulations (as hereinafter defined), and is permitted to use or disclose such information only in accordance with HIPAA and HIPAA Regulations;

WHEREAS, Data User performs certain Activities (as hereinafter defined);

WHEREAS, Covered Entity wishes to disclose a Limited Data Set (as hereinafter defined) to Data User for use by Data User in performance of the Activities (as hereinafter defined);

WHEREAS, Covered Entity wishes to ensure that Data User will appropriately safeguard the Limited Data Set in accordance with HIPAA and the HIPAA Regulations;
and

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WHEREAS, Data User agrees to protect the privacy of the Limited Data Set in accordance with the terms and conditions of this Agreement, HIPAA and the HIPAA Regulations;

NOW THEREFORE, Covered Entity and Data User agree as follows:

1. **Definitions.** The parties agree that the following terms, when used in this Agreement, shall have the following meanings, provided that the terms set forth below shall be deemed to be modified to reflect any changes made to such terms from time to time as defined in HIPAA and the HIPAA Regulations.
 - a. Activities shall mean tasks and actions related to the performance of Burn Model System research projects.
 - b. Covered Entity means a health plan (as defined by HIPAA and the HIPAA Regulations); a health care clearinghouse (as defined by HIPAA and the HIPAA Regulations); or a health care provider (as defined by HIPAA and the HIPAA Regulations) who transmits any health information in electronic form in connection with a transaction covered by the HIPAA Regulations.
 - c. HIPAA means the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.
 - d. HIPAA Regulations means the regulations promulgated under HIPAA by the United States Department of Health and Human Services, including, but not limited to, 45 C. F. R. Part 160 and 45 C. F. R. Part 164.
 - e. Individually Identifiable Health Information means information that is a subset of health information, including demographic information collected from an individual, and;
 - (1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
 - (2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and
 - a) that identifies the individual; or
 - b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

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- f. Limited Data Set shall have the same meaning as the term "limited data set" in 45 CFR 164.514(e) of the Privacy Rule. A limited data set is Protected Health Information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual: names, 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.
- g. Privacy Rule shall mean the Standards for Privacy of Individually Identifiable Information at 45 CFR Part 160 and Part 164, Subparts A and E, as amended from time to time.
- h. Protected Health Information or PHI means Individually Identifiable Health Information, excluding certain education and employment records in accordance with the HIPAA regulations that is transmitted by electronic media; maintained in any medium described in the definition of the term electronic media in the HIPAA Regulations; or transmitted or maintained in any other form or medium.
- i. Required by Law shall have the same meaning as the term "required by law" in 45 CFR Sect. 164.501 of the Privacy Rule.

2. Obligations of Covered Entity.

- a. Limited Data Set. Covered Entity agrees to disclose the following Protected Health Information to Data User: The Burn Model Systems National Database (a "Limited Data Set" as defined herein). Such Limited Data Sets shall not contain any identifiers of the individual who is the subject of the Protected Health Information, or of relatives, employers or household members of the individual as listed above in section 1f.

3. Obligations of Data User.

- a. Performance of Activities. Data User may use and disclose the Limited Data Set received from Covered Entity only in connection with the performance of Burn Model System research activities. Data User shall limit the use or receipt of the Limited Data Set to members of the Burn Model Systems research team at **[name of Burn Model System]** and certain individuals

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within these institutions who are responsible for overseeing research activities.

- b. *Nondisclosure Except As Provided In Agreement.* Data User shall not use or further disclose the Limited Data Set except as permitted or required by this Agreement.
- c. *Use or Disclosure As If Covered Entity.* Data User may not use or disclose the Limited Data Set in any manner that would violate the requirements of HIPAA or the HIPAA Regulations if used or disclosed by Covered Entity.
- d. *Identification of Individual.* Data User may not use the Limited Data Set to identify or contact any individual who is the subject of the PHI from which the Limited Data Set was created.
- e. *Disclosures Required by Law.* Data User may use and disclose the Limited Data Set as required by law. Data User shall advise Covered Entity, in writing, prior to any such disclosure, so that the Covered Entity shall have the opportunity to object or otherwise respond to such disclosure.
- f. *Safeguards.* Data User shall use appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as provided by this Agreement.
- g. *Data User's Agent.* Data User shall not disclose the Limited Data Set to any agent or subcontractor of Data User except with the prior written consent of Covered Entity. Data User shall ensure that any agents, including subcontractors, to whom it provides that Limited Data Set agree in writing to be bound by the same restrictions and conditions that apply to Data User with respect to such Limited Data Set.
- h. *Reporting.* Data User shall report to Covered Entity within 48 hours of Data User becoming aware of any use or disclosure of the Limited Data Set in violation of this Agreement or applicable law.
- i. *Notifications, Presentations and Publications.* Data User shall comply with the following Burn Model Systems Standard Operating Procedures as related to data use: SOP 602 – Internal Use of Burn Model Systems National Database Notification and SOP 603—Request for National Database.

4. Material Breach, Enforcement and Termination.

- a. *Term.* This Agreement shall be effective as of the Agreement Effective Date, and shall continue until the Agreement Termination Date or in accordance with the provisions of Section 4.c.

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- b. *Covered Entity's Rights of Access and Inspection.* From time to time upon reasonable notice, or upon a reasonable determination by Covered Entity that Data User may have breached this Agreement, Data User shall make available for Covered Entity's review and inspection Data User's internal practices, systems, books and records so that Covered Entity may determine Data User's compliance with its obligations under this Agreement. The fact that Covered Entity inspects, or fails to inspect, or has the right to inspect Data User's systems and procedures does not relieve Data User of its responsibility to comply with this Agreement, nor does Covered Entity's (1) failure to detect or (2) detection of, but failure to notify Data User or require Data User's remediation of, any unsatisfactory practices constitute acceptance of such practice or a waiver of Covered Entity's enforcement or termination rights or waiver of Data User's obligations under this Section 4.b. This Section 4.b. shall survive termination of the Agreement.
- c. *Termination.* Covered Entity may terminate this Agreement:
- (1) immediately if Data User is named as a defendant in a criminal proceeding for a violation of HIPAA or the HIPAA Regulations;
 - (2) immediately if a finding or stipulation that the Data User has violated one of the following:
 - i. any standard or requirement of HIPAA or the HIPAA Regulations; or
 - ii. any other security or privacy laws as determined or stipulated in an administrative or civil proceeding in which Data User has been joined; or
 - (3) pursuant to Sections 4.d.(3) or 5.b. of this Agreement.
- d. *Remedies.* If Covered Entity determines that Data User has materially breached or violated a material term of this Agreement, Covered Entity may, at its option, pursue any and all of the following remedies:
- (1) exercise any of its rights of access and inspection under Section 4.b. of this Agreement;
 - (2) take any other reasonable steps that Covered Entity, in its sole discretion, shall deem necessary to cure such breach or end such violation; and/or

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- (3) terminate this Agreement immediately.
- e. *Knowledge of Non-Compliance.* Any non-compliance by Data User with this Agreement or with HIPAA or the HIPAA Regulations automatically will be considered a material breach or violation of a material term of this Agreement if Data User knew or reasonably should have known of such non-compliance and failed to take reasonable steps immediately to cure the non-compliance.
- f. *Reporting to United States Department of Health and Human Services.* If Covered Entity's efforts to cure any material breach or end any material violation are unsuccessful as determined in the sole discretion of Covered Entity, and if termination of this Agreement is not feasible, Covered Entity shall report Data User's material breach or material violation to the Secretary of the United States Department of Health and Human Services. Covered Entity shall advise Data User that Covered Entity has made such a report to the United States Department of Health and Human Services and Data User agrees that it shall not have or make any claim(s) whether at law, in equity, or under this Agreement, against Covered Entity with respect to such reports(s).
- g. *Disposition of Records.* Upon termination of this Agreement, Data User may retain the Limited Data Set but may only use and disclose the Limited Data Set for the purposes specified in this Agreement and only in accordance with the terms of this Agreement (unless said termination is due to a HIPAA violation, in which case the Limited Data Set must be returned to Covered Entity or destroyed in accordance with HIPAA regulations). This section shall survive termination of this Agreement.
- h. *Injunctions.* Covered Entity and Data User agree that material violations of the provisions of this Agreement may cause irreparable harm to Covered Entity. Accordingly, in addition to any other remedies available to Covered Entity at law, in equity, or under this Agreement, in the event of any material breach or violation of any of the provisions of this Agreement by Data User, or any explicit threat thereof, Covered Entity shall be entitled to an injunction or other decree of specific performance with respect to such violation or explicit threat thereof without the necessity of demonstrating actual damages. The parties' respective rights and obligations under this Section 4.h. shall survive termination of the Agreement.

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- i. *Indemnification.* Data User shall indemnify, hold harmless and defend Covered Entity from and against any and all claims, losses, liabilities, costs and other expenses to the extent resulting from the negligence, recklessness, or intentional misconduct of Data User, including without limitation, the negligent, reckless or intentional acts or omissions of Data User in connection with the representations, duties and obligations of Data User under this Agreement. Covered Entity shall indemnify, hold harmless and defend Data User from and against any and all claims, losses, liabilities, costs and other expenses to the extent resulting from the negligence, recklessness, or intentional misconduct of Covered Entity, including without limitation, the negligent, reckless or intentional acts or omissions of Covered Entity in connection with the representations, duties and obligations of Covered Entity under this Agreement. The parties' respective rights and obligations under this Section 4.i. shall survive termination of the Agreement.

5. Miscellaneous Terms.

- a. *State Law.* Nothing in this Agreement shall be construed to require Data User to use or disclose the Limited Data Set without a written authorization from the individual who is the subject of the PHI from which the Limited Data Set was created; or written authorization from any other person, where such authorization is required under state law for such use or disclosure.
- b. *Amendment.* Covered Entity and Data User agree that amendment of this Agreement may be required to ensure that Covered Entity and Data User comply with changes in state and federal laws and regulations relating to the privacy, security, and confidentiality of PHI or the Limited Data Set. Covered Entity may terminate this Agreement upon 30 days written notice in the event that the Covered Entity and Data User cannot agree upon such an amendment that ensures that Covered Entity and Data User will be in compliance with such laws and regulations within that timeframe. Whether Covered Entity or Data User agrees upon such an amendment is within the sole discretion of each party hereto.
- c. *No Third Party Beneficiaries.* Nothing express or implied in this Agreement is intended or shall be deemed to confer upon any person other than Covered Entity and Data User, and their respective successors and assigns, any rights, obligations, remedies or liabilities.

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Any notices, demands, and other communications delivered personally shall be deemed to have been received by addressee at the time and date of its delivery. Any notices, demands, and other communications so mailed shall be deemed to have been received by the addressee seven (7) days after the time and date of its being mailed.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the Agreement Effective Date.

Burn Model Systems
National Data and Statistical Center

[name of Burn Model System]

Dagmar Amtmann
Principal Investigator
Burn Model Systems
National Data and Statistical Center
University of Washington

[Name of Authorized Representative]
[Title of Authorized Representative]