

# MUSC DATA USE AGREEMENT AND APPROVAL

HR#: \_\_\_\_\_ PI Name: \_\_\_\_\_ Department: \_\_\_\_\_

Study Title: \_\_\_\_\_

Study Sponsor: \_\_\_\_\_

A Data Use Agreement is an assurance between a covered entity and a researcher using a Limited Data Set that the data will only be used for specific uses and disclosures.

This Data Use Agreement (the "Agreement") is by and between The Medical University of South Carolina, an agency of the State of South Carolina, (hereinafter "MUSC"), with its principal place of business in Charleston, South Carolina, and \_\_\_\_\_, (hereinafter "\_\_\_\_\_") and its effective date as of \_\_\_\_\_ (the "Effective Date").

A Limited Data Set is Protected Health Information\* that has all direct identifiers removed. However, the minimum necessary\* standard applies. A Limited Data Set **EXCLUDES** the following direct identifiers of the individual or of relatives, employers or household members of the individual:

- Names
- Postal Address (other than town or city, State and zip code)
- Telephone Numbers/Fax Numbers
- E-mail Addresses/Web Universal Resource Locators (URLs)/Internet Protocol (IP) Address Numbers
- Social Security Numbers, Medical Record Numbers, Health Plan Beneficiary Numbers, Account Numbers, Certificate/License Numbers, Vehicle Identifiers/Serial Numbers including license plate numbers
- Device Identifiers and Serial Numbers
- Biometric Identifiers (e.g. finger or voice prints)
- Full face photographic images and any comparable images

The following identifiers can be **INCLUDED** in the LDS. Check below all that apply:

\_\_\_\_\_ Dates (of treatment, birth dates)

\_\_\_\_\_ Geographic information (not street address)

\_\_\_\_\_ Other unique identifying numbers, characteristics or codes that are not expressly excluded (list below):

\_\_\_\_\_

\_\_\_\_\_

*\*Protected Health Information is defined as individually identifiable health information transmitted or maintained in any form (electronic means, paper, or oral communication) that relates to the past, present, or future health or conditions of an individual.*

*\*Minimum Necessary is defined as only the minimum information needed for the immediate use of disclosure should be made available by the health care provider or other covered entity.*

WHEREAS, both MUSC and \_\_\_\_\_ maintains certain information that each wishes to use and /or disclose for research, public health, or health care operations such as quality assurance or benchmarking purposes permitted under 42 C.F.R. 164.514(e):

NOW, THEREFORE, the parties, in consideration of the mutual promises and obligations set forth herein, the sufficiency of which is hereby acknowledged, and intending to be legally bound, agree as follows:

1. MUSC shall provide \_\_\_\_\_ with access to certain data (the “Limited Data Set”) in accordance with the terms and conditions of this Agreement. Under no circumstances shall MUSC or \_\_\_\_\_ be required under this Agreement to provide the other party with any information that does not qualify as part of a “Limited Data Set” under 42 C.F.R. 164.514(e).
2. The following individuals (the “Authorized Parties”) are authorized to use the Limited Data Set or any part of it on behalf of MUSC or \_\_\_\_\_ and agree to abide by the terms of this Agreement:

Name: \_\_\_\_\_ Signature: \_\_\_\_\_ MUSC

Name: \_\_\_\_\_ Signature: \_\_\_\_\_

Name: \_\_\_\_\_ Signature: \_\_\_\_\_

*Use an attachment to list any additional individuals. The attachment must be signed by authorized representatives of MUSC and \_\_\_\_\_.*

3. The parties, and any Authorized Party on the parties behalf, may use the Limited Data Set only for the following purposes:

\_\_\_\_\_ may use the data to create a registry to be used for quality assurance, bench marking and research with appropriate permission and in accordance with the requirements of the “Common Rule” 45 CFR 46 and the Privacy regulations 45 CFR 160 and 164.

*Use an attachment to list any additional permitted uses. The attachment must be signed by authorized representatives of MUSC and \_\_\_\_\_.*

4. The Parties agree as follows:

- ✓ Not to use or further disclose the Limited Data Set or any information contained therein other than as permitted by this Agreement or required by applicable law.
- ✓ To use appropriate safeguards to prevent use or disclosure of the information other than as provided for by this Agreement.
- ✓ To report to the other party any use or disclosure of the Limited Data Set or any part of it not provided for by this Agreement of which MUSC or \_\_\_\_\_ or any Authorized Party becomes aware.

- ✓ To ensure any agents, including subcontractors, to whom a Party provides the Limited Data Set or any part of it to agree to the same restrictions and conditions that apply to the Parties under this Agreement.
- ✓ Not to use the information contained in the Limited Data Set to identify the individuals whose information is contained in the Limited Data Set, nor to contact them under any circumstances.

5. In the event MUSC or \_\_\_\_\_ becomes aware of any use of the Limited Data Set or any part of it that is not authorized under this Agreement or required by applicable law, they may (i) terminate this Agreement upon notice; (ii) disqualify (in whole or in part) the Party at fault and/or any Authorized Parties from receiving protected health information in the future; and/ or (iii) report the inappropriate use or disclosure to the Secretary of the Department of Health and Human Affairs. Further sanctions may apply under 42 C.F.R. parts 160 and 164.

WHEREFORE, the parties, through their authorized representatives, hereby accept and agree to the terms and conditions of this Agreement.

_____ By: _____  Name (Printed): _____  Title: _____  Date: _____	<u>The Medical University of South Carolina</u> By: _____  Name (Printed): _____  Office of Research Title: <u>and Sponsored Programs</u>  Date: _____
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