

## DATA USE AGREEMENT

**THIS AGREEMENT** is entered into between the MEDICAL COLLEGE OF OHIO AT TOLEDO, a state medical college established pursuant to *Ohio Revised Code* Section 3350.01, *et seq.* (“COVERED ENTITY”) and \_\_\_\_\_ (“DATA RECIPIENT”).

### WITNESSETH:

**WHEREAS**, COVERED ENTITY permits DATA RECIPIENT to have access to and/or receive from COVERED ENTITY certain information, in conjunction with research being done by DATA RECIPIENT, that is confidential and must be afforded special treatment and protection; and

**WHEREAS**, DATA RECIPIENT can use or disclose such information only in accordance with this Agreement and the HHS Privacy Regulations of the Health Insurance Portability and Accountability Act of 1996.

**WHEREAS**, the purpose of this Agreement is to satisfy the obligations of COVERED ENTITY under the HHS Privacy Regulations and to ensure the integrity and confidentiality of certain information disclosed or made available to DATA RECIPIENT.

**NOW, THEREFORE**, COVERED ENTITY and DATA RECIPIENT agree as follows:

- 1. Definitions.** The following terms shall have the meaning ascribed to them in this Section. Other capitalized terms shall have the meaning ascribed to them in the context in which they first appear.
  - A.** “Agreement” refers to this document.
  - B.** “DATA RECIPIENT” means the party so identified in the first paragraph above.
  - C.** “COVERED ENTITY” means the Medical College of Ohio at Toledo.
  - D.** “Electronic media” means the mode of electronic transmission. It includes, but not limited to, the Internet (wide-open), Extranet (using Internet technology to link a business with information only accessible to collaborating parties), leased lines, dial-up lines, private networks, and those transmissions that are physically moved from one location to another using magnetic tape, disk, compact disk or optical media.
  - E.** “Limited Data Set” means Protected Health Information that excludes the following direct identifiers of the Individual or of relatives, employers or household members of the individual (*Ref 164.514(e)(2)*):
    - (i) Names;
    - (ii) Postal address information, other than town or city, state and zip code;
    - (iii) Telephone numbers;
    - (iv) Fax numbers;
    - (v) Electronic mail addresses;
    - (vi) Social security numbers;
    - (vii) Medical record numbers;
    - (viii) Health plan beneficiary numbers;
    - (ix) Account numbers;
    - (x) Certificate/license numbers
    - (xi) Vehicle identifiers and serial numbers, including license plate numbers;
    - (xii) Device identifiers and serial numbers;
    - (xiii) Web Universal Resource Locators (URLs);

- (xiv) Internet Protocol (IP) address numbers;
- (xv) Biometric identifiers, including finger and voice prints; and
- (xvi) Full face photographic images and any comparable images.

F. “HHS Privacy Regulations” means the Code of Federal Regulations (“CFR”) at Title 45, Sections 160 and 164, Subparts A and E.

G. “Individual” means the person who is the subject of the Protected Health Information. *(Ref 164.501)*

H. “Protected Health Information” means any individually identifiable health information that is transmitted by electronic media, maintained in any medium described as electronic media, or transmitted or maintained in any other form or medium. *(Ref 164.501)* It includes:

- (i) Names;
- (ii) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
  - (a) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
  - (b) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
- (iii) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
- (iv) Telephone numbers;
- (v) Fax numbers;
- (vi) Electronic mail addresses
- (vii) Social Security Numbers;
- (viii) Medical record number;
- (ix) Health plan beneficiary numbers;
- (x) Account numbers;
- (xi) Certificate/license numbers;
- (xii) Vehicle identifiers and serial numbers, including license plate numbers;
- (xiii) Device identifiers and serial numbers;
- (xiv) Web Universal Resource Locators (URLs);
- (xv) Internet Protocol (IP) address numbers;
- (xvi) Biometric identifiers, including finger and voice prints;
- (xvii) Full face photographic images and any comparable images.

I. “Parties” means DATA RECIPIENT and COVERED ENTITY.

J. “Secretary” means the Secretary of the Department of Health and Human Services (“HHS”) and any other officer or employee of HHS to whom the authority involved has been delegated.

**2. Limits on Use and Disclosure Established by Terms of Agreement.** DATA RECIPIENT hereby agrees that it shall be prohibited from using or disclosing the Limited Data Set provided or made available by COVERED ENTITY for any purpose other than as expressly permitted or required by this Agreement or by law. *(Ref 164.514(e)(4)(ii)(C)(1))*

**3. Stated Purposes for Which DATA RECIPIENT May Use or Disclose Limited Data Set.** Except as

otherwise specified herein, Data Recipient may make all Uses and Disclosures of the Limited Data Set necessary to conduct the research described herein: \_\_\_\_\_ (include a brief description of the research and/or protocol number) \_\_\_\_\_ (“Research Project”). (Ref 164.514(e)(4)(ii)(A))

4. **Other Permitted Recipients of the Limited Data Set.** In addition to the Data Recipient, the individuals, or classes of individuals, who are permitted to Use or receive the Limited Data Set for purposes of the Research Project, include \_\_\_\_\_ (Ref 164.514(e)(4)(ii)(B))

5. **DATA RECIPIENT Obligations.**

A. **Appropriate Safeguards.** DATA RECIPIENT shall establish and maintain appropriate procedural, physical and electronic safeguards to prevent any use or disclosure of the Limited Data Set, other than as provided for by this Agreement. (Ref 164.514(e)(4)(ii)(C)(2))

B. **Reports of Improper Use or Disclosure.** DATA RECIPIENT hereby agrees that it shall report to COVERED ENTITY within five (5) days of discovery any use or disclosure of the Limited Data Set not provided for or allowed by this Agreement. (Ref 164.514(e)(4)(ii)(C)(3))

C. **Subcontractors and Agents.** DATA RECIPIENT hereby agrees to ensure that any agent, including a subcontractor, to whom it provides the Limited Data Set received from COVERED ENTITY, agrees to the same terms, conditions and restrictions on the use and disclosure of the Limited Data Set as contained in this Agreement. (Ref 164.514(e)(4)(ii)(C)(4))

D. **Identification or Contact with the Individual.** DATA RECIPIENT hereby agrees not to identify the information contained in the Limited Data Set or contact the Individual. (Ref 164.514(e)(4)(ii)(C)(5))

E. **Return or Destruction of Protected Health Information.** At termination of this Agreement, DATA RECIPIENT hereby agrees to return or destroy, at its expense, all Protected Health Information contained in the Limited Data Set received from the COVERED ENTITY. DATA RECIPIENT agrees not to retain any copies of the Limited Data Set after termination of this Agreement. If return or destruction of the Limited Data Set is not feasible, DATA RECIPIENT agrees to extend the protections of this Agreement for as long as necessary to protect the Limited Data Set and to limit any further use or disclosure. If DATA RECIPIENT elects to destroy the Limited Data Set, it shall certify to COVERED ENTITY that the Limited Data Set has been destroyed.

6. **Term and Termination.**

A. **Term.** The term of this Agreement shall commence as of the date last written herein, and shall expire when the Limited Data Set received from the COVERED ENTITY is destroyed or returned to COVERED ENTITY pursuant to Paragraph 5.E above.

B. **Termination for Cause.** DATA RECIPIENT agrees that COVERED ENTITY has the right to immediately terminate this Agreement, and discontinue disclosure of further Protected Health Information to the DATA RECIPIENT, if COVERED ENTITY determines that DATA RECIPIENT has violated a material term of this Agreement or failed to comply with the HHS Privacy Regulations. (Ref 164.514(e)(4)(iii)(A))

**C. Cure of Breach.** The COVERED ENTITY may, but is not obligated, provide an opportunity for DATA RECIPIENT to cure a breach.

**D. Reporting to Secretary.** If neither termination nor cure is unsuccessful, the COVERED ENTITY will be required to report the violation to the Secretary. . (Ref 164.514(e)(4)(iii)(A))

7. **Notices.** Whenever under this Agreement one Party is required to give notice to the other, such notice shall be deemed given if mailed by First Class United States mail, postage prepaid, and addressed as follows:

COVERED ENTITY: Associate Vice President for Research  
Medical College of Ohio at Toledo  
3035 Arlington Avenue  
Toledo, OH 43614

DATA RECIPIENT: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Either Party may at any time change its address for notification purposes by mailing a notice stating the change and setting forth the new address.

8. **Miscellaneous.**

**A. Property Rights.** The Limited Data Set shall be and remain the property of COVERED ENTITY. DATA RECIPIENT agrees that it acquires no title or rights to the Limited Data Set, including any de-identified Protected Health Information, as a result of this Agreement.

**B. Choice of Law.** This Agreement shall be governed by the laws of the State of Ohio and, with respect for purposes of privacy rights, the HHS Privacy Regulations.

**C. Regulatory References.** A reference in this Agreement to a section of the HHS Privacy Regulations means the section as in effect or as amended.

**D. Binding Nature and Assignment.** This Agreement shall be binding on the Parties hereto and their successors and assigns, but neither Party may assign this Agreement without the prior written consent of the other which consent shall not be unreasonably withheld.

**E. Amendment.** The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for COVERED ENTITY to comply with the requirements of the Health Insurance Portability and Accountability Act of 1996 and the rules and regulations promulgated thereunder.

**F. Article Headings.** The article headings used are for reference and convenience only, and shall not enter into the interpretation of this Agreement.

**G. Non-Waiver.** Failure by any Party to insist upon strict compliance with any term or provision of this Agreement, to exercise any option, to enforce any right, or to seek any remedy upon any default of the other Party shall not affect nor constitute a waiver of, any Party's right to insist upon such compliance, exercise that right, or seek that remedy with respect to that default or an prior,

contemporaneous, or subsequent default.

**H. Counterparts.** This Agreement may be executed simultaneously in one or more counterparts, each of which shall be deemed an original, but all of which shall constitute one instrument

**I. Severability.** With respect to any provision of this Agreement finally determined by a court of competent jurisdiction to be unenforceable, such court shall have the jurisdiction to reform such provision so that it is enforceable to the maximum extent permitted by applicable law. If any provision of this Agreement shall be deemed unenforceable, such provision shall not effect the enforceability of the other provisions of this Agreement, which can be given effect without the unenforceable provision.

**J. Survival.** All representations, covenants and agreements in or under this Agreement or any other documents executed in connection with the transactions contemplated by this Agreement, shall survive the termination of this Agreement and such other documents.

**9. Entire Agreement.** This Agreement constitutes the entire agreement between the Parties concerning the subject matter herein. There are no understandings or agreements relating to this Agreement which are not fully expressed in this Agreement and no change, waiver or discharge of obligations arising under this Agreement shall be valid unless in writing and executed by the Party against whom such change, waiver or discharge is sought to be enforced.

**IN WITNESS WHEREOF,** DATA RECIPIENT and COVERED ENTITY have caused this Agreement to be signed and delivered by their duly authorized representatives.

**DATA RECIPIENT:**

**MEDICAL COLLEGE OF OHIO  
AT TOLEDO:**

By: \_\_\_\_\_

By: \_\_\_\_\_

Print Name: \_\_\_\_\_

Print Name: \_\_\_\_\_

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

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

Date: \_\_\_\_\_

Date: \_\_\_\_\_

v. 1/31/03