



**OSTEOARTHRITIS INITIATIVE
DATA USE AGREEMENT FOR LIMITED DATA SET(S)**

This Data Use Agreement (“Agreement”) is between the Osteoarthritis Initiative Coordinating Center, University of California, San Francisco and the Data Recipient (noted in Section #7) and is effective as of the “Effective Date” (noted in Section #7).

Both parties are committed to complying with local, state, and federal laws and regulations (including the Privacy Rule under the Health Insurance Portability and Accountability Act [HIPAA] of 1996) relating to privacy, security and confidentiality of the Limited Data Set.

1. Name of Entity Releasing the Limited Data Set:

Osteoarthritis Initiative Coordinating Center
Department of Epidemiology and Biostatistics
University of California, San Francisco
San Francisco, California
United States of America

Principal Investigator: Michael C. Nevitt, PhD

Study Title: Osteoarthritis Initiative (OAI)

Study Sponsor: National Institute of Arthritis and Musculoskeletal &
Skin Diseases / National Institutes of Health
Agency award #: HHSN268201200031C

UCSF IRB Approval #: 10-00532 (Expiration date: 2/23/2018)

2. Preparation of the Limited Data Set. The Limited Data Set provided under this Agreement excludes identifiers as required by the HIPAA Privacy Regulations for the creation of a Limited Data Set, and does not contain any of the following elements:

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| <input type="checkbox"/> Names | <input type="checkbox"/> Vehicle identifiers and serial numbers, including license plate numbers |
| <input type="checkbox"/> Street or postal address, other than town or city, state, or zip code | <input type="checkbox"/> Device identifiers and serial numbers |
| <input type="checkbox"/> Telephone numbers | <input type="checkbox"/> Web Universal Resource Locators (URLs) |
| <input type="checkbox"/> Fax numbers | <input type="checkbox"/> Internet Protocol (IP) address numbers |
| <input type="checkbox"/> Electronic mail addresses | <input type="checkbox"/> Biometric identifiers, including finger and voice prints |
| <input type="checkbox"/> Social Security numbers | <input type="checkbox"/> Full face photographic images and any other comparable images |
| <input type="checkbox"/> Medical record numbers | |
| <input type="checkbox"/> Health plan beneficiary numbers | |
| <input type="checkbox"/> Account numbers | |
| <input type="checkbox"/> Certificate/license numbers | |

3. Purpose of Limited Data Set Disclosure. The Recipient of the Limited Data Set (named in Section #7) and the Agents to whom the Recipient provides the Limited Data Set to, are permitted to use and disclose the Limited Data Set for the following purpose(s):

- Human subjects research
- Educational activities (i.e., teaching activities, development of clinical guidelines)

4. Responsibilities of the Recipient. The Recipient of the Limited Data Set (named in Section #7) and the Agents to whom the Recipient provides the Limited Data Set, agrees to:

- a) Use or disclose the Limited Data Set only as permitted by this Agreement or as Required by Law.
- b) Use appropriate safeguards to prevent the use or disclosure of the Limited Data Set other than as permitted by this Agreement.
- c) All data Recipients must review and sign a Data Use Agreement for Limited Data Set(s). If it is not feasible for all Agents (including subcontractors, students, fellows, analysts, etc.) to review and sign a Data Use Agreement for Limited Data Set(s), the Recipient must ensure that any Agents to whom the Recipient provides the Limited Data Set(s) agrees to the same conditions and restrictions on the use and disclosure of the Limited Data Set(s) that apply to the Recipient through this Agreement. Individuals not working directly with the Recipient should obtain the Limited Data Set(s) directly from the OAI Coordinating Center at the University of California, San Francisco and complete a Data Use Agreement for Limited Data Set(s).
- d) Not attempt to use the information in the Limited Data Set to identify or contact the persons from whom the data originated, their relatives, employers, or household members.
- e) Accept all responsibility for data analysis, results from analyses, and any consequences resulting from breaching study participant privacy in connection with the analysis.
- f) Obtain approval from the Recipient's local IRB, if required, before the initiation of any analyses.
- g) Cite and acknowledge the OAI and its funding sources in all abstracts, presentations and publications, using language detailed in the OAI Publication Guidelines (posted on the OAI Online website), and make a good faith effort to follow the other provisions of these guidelines.
- h) For publications using the OA Biomarkers Consortium FNIH Project data the standard OAI acknowledgements should be included as well as funding acknowledgements specific to this project. See the OAI Publication Guidelines (posted on the OAI Online website) for specific language that should be used.
- i) Report any use or disclosure of the Limited Data Set not permitted by this Agreement in writing to OAIOnlineFeedback (E-mail: OAIOnlineFeedback@psg.ucsf.edu) within five (5) days after the Recipient becomes aware of the unauthorized use or disclosure.

5. Term and Termination

- a) Term. The term of this Agreement shall commence on the Effective Date (noted in Section #7) and shall continue for as long as the Recipient and their Agents retains the Limited Data Set, unless terminated sooner as set forth in this Agreement.
- b) Termination by Recipient. The Recipient may terminate this Agreement at any time by notifying the University of California, San Francisco and returning and/or destroying the Limited Data Set and any copies of the Limited Data Set.
- c) Termination by University of California, San Francisco. The University of California, San Francisco may terminate this Agreement at any time by blocking the Recipient's access to the OAI Online website as well as access to any additional datasets, images and other study materials.
- d) Termination for Cause. Upon the University of California, San Francisco's knowledge of a material breach of this Agreement by the Recipient (and/or the Recipient's Agents), the University of California, San Francisco shall either provide an opportunity for the Recipient to cure the breach or end the violation OR terminate this Agreement if the Recipient does not satisfactorily cure the breach or end the violation within the timeframe set forth and to the satisfaction of the University of California, San Francisco. The University of California, San Francisco may immediately terminate this Agreement if cure is not possible by blocking the Recipient's access to the OAI Online website as well as access to any additional datasets, images and other study materials.

6. Miscellaneous

- a) *Regulatory references*. A reference in this Agreement to a section in the HIPAA Privacy Regulations means the section as in effect or as amended.
- b) *Amendment*. The Parties agree to take action as is necessary to amend this Agreement from time to time as is necessary for the University of California, San Francisco to comply with changes in local, state and federal laws and regulations relating to privacy, security and confidentiality of the Limited Data Set.
- c) *Interpretation*. Any ambiguity in this Agreement shall be resolved to permit the University of California, San Francisco to comply with local, state and federal laws and regulations relating to privacy, security and confidentiality of the Limited Data Set.

7. Agreement Execution. By clicking the “I Agree” button on the website www.oai.ucsf.edu, the Recipient is certifying that he/she as well as any Agents to whom the Recipient provides the Limited Data Set, agrees to use or disclose the information contained in the Limited Data Set only as permitted in Sections #3 and #4 in this Agreement.

Before clicking “I Agree”, please print out a copy of this Data Use Agreement for your records.