

CHDWB Emory University Data Use Agreement

Please complete the survey below.

Thank you!

Data Use Agreement

Predictive Health Institute

The Center for Health Discovery and Well Being

Introduction

The Predictive Health Institute is committed to rapid and complete data release, and to ensuring that the data remain available to all qualified Emory users at no cost. A fee may be assessed to Emory users with complex requests. Notification of any possible fees will be given before data extracts are performed.

Individuals or organizations without Emory affiliation are eligible to request Predictive Health data. The request will be reviewed on a case-by-case basis with no assurances given in advance that permission will be granted. Fees may be assessed depending on the quantity, complexity and composition of data requested. IRB approval from the appropriate oversight committee is required for non-Emory users.

Request data

Access to the Predictive Health research database and associated biological samples is gained by application to the research access and data subcommittee. Completion of the following test form is required for consideration. Indicate on the form by checking the appropriate boxes which sets of data you are requesting. Submit the completed form accompanied by your research protocol or detailed description of intended use of the data. The request will be reviewed by the Predictive Health data review committee generally within 10 days of submission. If approved, the data extraction will be made available to you approximately three weeks after your submission. Data extractions may be formatted as Excel, SAS, and SPSS files.

Data is meant for research purposes only. It is expected that data will be used in support of funded research activity, either in support of a grant or in generating preliminary data for a grant proposal. Requests that do not, in the judgment of the review committee, adequately support the research purpose will either be returned for revision or rejected. Individuals who have a request rejected are eligible to submit other requests with each again subject to committee review.

Emory University and the Predictive Health Initiative retain ownership rights to all provided data regardless of the purpose or outcome of any subsequent publications or collateral works.

Acknowledgements

Any publication, presentation or any document that includes direct or derived information from the Emory Predictive Health Database must include the following statements:

"This work is based on information from the Emory Predictive Health Institute and Center for Health Discovery and Well Being Database."

"Supported by Emory University and the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number UL1TR000454."

Any publication, presentation or any document that includes direct or derived information from the "laboratory - general" must cite Quest Diagnostics.

Researchers will retain rights to their research product but not the primary data. No restrictions on future, ongoing research work from the data base is implied or possible from this agreement.

The Emory University and Predictive Health Institute data base will be acknowledged in all publications or communications where primary or derived data is used.

The Requestor: _____

The Investigator: _____

The Effective Date: _____

Title of Requestor: _____

Address of Requestor: _____

Phone Number of Requestor: _____

Email Address of Requestor: _____

Entity by which Requestor is employed:

- Emory
- GA Tech
- Other

Entity of employment if other: _____

The undersigned Requestor hereby requests that the Emory Covered Entity provide it with a Data Set described below for the uses and purposes described below. The Requestor agrees and affirms that all information requested to be provided in the Data Set indicated, and all uses and purposes for which the Data Set is requested, are permitted by and are in accordance with the Data Set policy described above.

Type of Data Set Requested: ePHI Limited De-Identified

1. Description of Data Set Requested: _____

2. Does this request include Protective Health Information (PHI)? Yes No

Please provide rationale for requesting PHI: _____

3. The Data Set is being requested for the following purposes: Research Public Health Health care operations Other

State Purpose: _____

Description: _____

Description: _____

Description: _____

4. Please provide the names and titles of all persons who will be permitted to use or receive the data set (e.g., PI and research staff; specific study sponsor, etc.): _____

5. Emory IRB Protocol Information:

eIRB Number: _____

Approval Date: _____

Expiration Date: _____

Please attach a copy of the IRB approval letter.

6. By signing below, the Requestor agrees to, and will ensure that all others working with data received or derived from this Request adhere to the following stipulations:

- a. Will not use or further disclose the information contained in the Data Set other than as permitted in this Data Use Agreement or as required by law. This precludes placement of any primary or derived data in the public domain, including but not limited to open access journal requirements.
- b. Will use appropriate safeguards to prevent the use or disclosure of the information contained in the Data Set other than as permitted in this Data Use Agreement; If the data set contains electronic protected health information (ePHI), the safeguards and technical infrastructure must comply with Emory University's HIPAA security and technical controls, including an annual HIPAA risk assessment.
- c. Will report to data steward and Emory University's Chief Information Security Officer any inappropriate use or disclosure of the Data or any part of it not provided for by this Agreement of which User or any Authorized Party becomes aware.
- d. Will ensure that any of its agents or subcontractors to whom it provides the Data Set agrees in writing to the same restrictions and conditions that apply to the Requestor. The Requestor may do this by providing its agents and subcontractors with a copy of this Data Use Agreement and having them agree in writing that they have received and reviewed the Agreement and agree to abide by its terms.
- e. Will not use the information contained in the Data Set to identify the individuals whose information is contained in the Data Set, nor to contact them under any circumstances unless there is explicit approval by Emory University's IRB.
- f. Understands that it is Emory's current practice that in the event of an inappropriate disclosure, the User's department will be responsible for any costs associated with the investigation and/or remediation directly associated with the inappropriate disclosure.
- g. Promptly following the end of the permitted use (as defined above) or upon termination of this agreement, to return all copies, including backups, of the Data to Source or destroy them and certify to the destruction; or, if User represents and Source agrees that neither return nor destruction is feasible, to continue to extend the protections of this Agreement to the Data.
- h. In any written, audio or video presentations, Requestor will acknowledge support for acquiring and providing these data as described above in "Acknowledgements."
- i. The Requester acknowledges that Emory University and the Predictive Health Initiative retain ownership rights to all provided data regardless of the purpose or outcome of any subsequent publications or collateral works.
- j. Researchers will retain rights to their research product but not the primary data. No restrictions on future, ongoing research work from the data base is implied or possible from this agreement.
- k. Reliance. User acknowledges and agrees that Source has relied upon the promises and covenants made in this Agreement and in disclosing the Data hereunder.
- l. Obligations Following Termination: Upon expiration or termination of this Agreement for any reason, User shall no longer be entitled to receive or use information contained in the Data. All other terms and agreements remain in force after termination or expiration of this agreement.
- m. Termination and Expiration of Agreement. Except as otherwise provided in Section 6.g. above, this Agreement shall expire thirty days following satisfaction of the requirements of Section 6.g. above. Additionally, either Party may terminate this agreement upon 10 days written notice to the other Party.
- n. No Assignment. This Agreement may not be assigned by User without the prior written consent of Source.
- o. Amendments. This Agreement may not be amended except by a written amendment executed by both Parties.

By submitting this form I agree to the terms and conditions of this data use agreement.

Print Name: _____

Signature: _____

Date: _____

For questions, please contact the Program Coordinator at jbclark@emory.edu .

Data request form Please check the box of those data categories or elements you want. Sub-categories indicate information contained within the larger heading and can be de-selected if you do not want a full category.

Questionnaires:

- Personal Information
- Personal and Family Health History (PFH)
- Medication, Supplement and Herb Use (MEDSUP)
- Health Symptoms (SA)
- Perceived Stress Survey (PSS)
- Complementary Medicine Use (COMPALT)
- Occupational History and Exposure (OCCEXP)
- Tobacco and Alcohol Use (TOBALC)
- Absenteeism & Presenteeism Survey
- Oral Health Survey
- Early Trauma Inventory Self Report-Short Form (ETISR-SF)

Personal Information:

- Center ID Number
- Date of Birth
- Gender
- Race Ethnicity
- Education
- Referred by
- Reasons for Participating
- Physician Information
- Referred by

Surveys:

- Food Frequency Survey (BLOCK)
- Physical Activity Survey (CAP)
- Quality of Life Survey (SF36)
- Memory and Cognition Survey (COG)
- Depression Survey (BDI)
- Family Support (FAD)
- Social Support Survey (ESSI)
- General Sleep Survey (EPWORTH)
- Quality of Sleep Survey (PSQI)
- Overall Mental Health Survey (MHCSF)
- Spiritual/Quality of Life Survey (FACT)
- Anxiety Survey (GAD7)
- Reproductive Health Survey (REPR)

Instruments:

- Automatic Blood Pressure Monitor
- Tanita Body Composition Analyzer
- Holtain Skin Fold Thickness Calipers
- Waist to Hip Measurement
- Lunar iDEXA Bone Density
- Lunar iDEXA Body Composition
- GE T2100 Treadmill Modified Balke Protocol
- Vivid 7 Ultrasound Caroid IMT
- SphygmoCor Pulse Wave Velocity
- Itamar Endo-Pat2000
- Flow Mediated Dilation Ultrasound

Laboratory - General

- Lipid panel
- Microalbumin, random urine
- Iron and total iron binding capacity
- Comprehensive metabolic panel
- CBC
- Compounds, Proteins and Hormones
- Vitamin D

Lipid panel field(s)

- Triglycerides
- Total cholesterol
- HDL cholesterol
- LDL cholesterol
- CHOL/HDL ratio

Microalbumin, random urine field(s)

- Random urine creatinine
- Microalbumin
- Microalbumin/creatinine ratio, random urine

Iron and total iron binding capacity field(s)

- Iron, total
- Iron binding capacity
- % saturation

Comprehensive metabolic panel field(s)

- Glucose
- Urea nitrogen (BUN)
- Creatinine
- EGFR, non-African American
- EGFR, African American
- BUN/Creatinine ratio
- Sodium
- Potassium
- Chloride
- Carbon dioxide
- Calcium
- Protein, total
- Albumin
- Globulin
- Albumin/globulin ratio
- Bilirubin, total
- Alkaline phosphatase
- AST
- ALT

CBC field(s)

- WBC
- RBC
- Hemoglobin
- Hematocrit
- MCV
- MCH
- MCHC
- RDW
- Platelet count
- Absolute neutrophils
- Absolute lymphocytes
- Absolute monocytes
- Absolute eosinophils
- Absolute basophils
- Neutrophils
- Lymphocytes
- Monocytes
- Eosinophils
- Basophils

Compounds, Proteins and Hormones field(s)

- C-reactive protein
- Ferritin
- Vitamin B-12
- Insulin
- TSH, 3rd generation
- Estradiol

Vitamin D field(s):

- Vitamin D, 25-OH, total
- Vitamin D, 25-OH, D3
- Vitamin D, 25-OH, D2

Laboratory - Research

- HPLC redox
- MMP-9
- 4-Plex Data
- T-cell Data
- CD34

HPLC redox fields:

- Cyss
- Cys
- CysGSH
- GSH
- GSSG
- Eh (GSH)
- Eh (CyS)
- Total GSH
- Total CyS

MMP-9 field(s)

- MMP-9/NGAL

4-Plex Data field(s)

- IL-6
- IL-8
- TNF-a
- IFN-r

T-cell Data field(s)

- CD3+
- CD3+, CD4+
- CD3+, CD8+

CD34 field(s)

- CD34
- CD45+CD34+CD133
- CD45+CD34+CD133+VEGF2
- CD45+CD34+CD133+VEGF2+CXCR4
- CD45MED Freq of CD34
- CD133+VEGF- on CD45MED
- CD133+VEGF+ on CD45MED
- CD133-VEGF+on CD45MED
- CD133-VEGF-on CD45MED
- CD133+VEGF-on CD34
- CD133+VEGF+on CD34
- CD133-VEGF+on CD34
- CD133-VEGF-on CD34
- CD133+VEGF-on MNCS
- CD133+VEGF+on MNCS
- CD133-VEGF+on MNCS
- CD133-VEGF-on MNCS

Specimens:

- Plasma Citrate (stored in 1mL, ~2 per person per visit)
- Plasma Heparin (stored in 1mL, ~4 per person per visit)
- Plasma EDTA (stored in 1mL, ~6 per person per visit)
- Serum (stored in 1mL, ~6 per person per visit)
- Tempus tube
- Buffy Coat (~2 per person per visit)
- Urine unpreserved (2mL each, ~5 per person per visit)
- Urine-preserved with 0.01%BHT (2mL each, ~5 per person per visit)

Specimen requests should be discussed in advance with the Program Coordinator (jbclark@emory.edu) to ensure specimen availability and to determine costs that may be incurred by the Requestor to receive the requested specimen(s).

Please add no more than one page equivalent of your preliminary project description and specific aims as you now know them.

Project Description: _____

Specific Aims: _____

Upon submitting this data request you are accepting these data and/or specimens under a binding commitment to complete the approved project.