

DHQ3 Researcher Agreement

Electronic Certification (E-Certification) and Agreement for use of the Diet History Questionnaire III
Web-based System ("DHQ3") and Transfer of Data

Epidemiology and Genomics Research Program Division of Cancer Control and Population Sciences
National Cancer Institute

DEFINITIONS:

NCI: Epidemiology and Genomics Research Program, Division of Cancer Control and Population Sciences, National Cancer Institute, National Institutes of Health (NIH), an agency of the United States Public Health Service (PHS) within the Department of Health and Human Services (DHHS)

RESEARCHER: An organization, as represented by its academic, clinical, or private researchers conducting observational studies with human subjects. "RESEARCHER" may also include academic, clinical, or private individuals who conduct observational studies with human subjects under their own legal authority independent of an employer or parent organization for research, treatment or education purposes.

DATA: De-identified human dietary intake data collected by the NCI under auspices of NCI's DHQ3 system and resulting calculations. "DATA" does not mean the DHQ3 system database, associated databases, or software used to create and run the DHQ3 system.

RECITALS:

WHEREAS, the NCI has constructed a research tool in the form of a DHQ3 computerized interview and database, and this database is intended to assist RESEARCHER and human subjects under the RESEARCHER's supervision with management of DATA associated with those human subjects; and

WHEREAS, the RESEARCHER intends to direct human subjects under RESEARCHER's supervision to submit dietary intake data to the DHQ3 database; and,

WHEREAS, the NCI wishes the RESEARCHER to have access to DATA describing the human subjects under RESEARCHER's supervision;

In consideration of the above, the RESEARCHER and NCI agree to the following:

1. The RESEARCHER will be responsible for directing human subjects under its supervision to submit DATA to the NCI. NCI will store the DATA in NCI's DHQ3 database. NCI will maintain the DATA in the absence of identifying information; however, NCI will have the right to assign a unique alphanumeric username tag to records describing individual human subjects. NCI shall ensure that the nature of such tag will prevent NCI from determining human subject identities. The RESEARCHER, but not NCI, will retain the crosswalk for mapping the tag to identify individual human subjects under RESEARCHER's supervision. NCI will not have access to the crosswalk. NCI will not communicate with any human subjects providing DATA.

2. DATA submitted to the NCI is the property of the NCI for distribution purposes and shall be made available as a service to research, academic and clinical communities.

3. The DATA will be used only for research, clinical and academic purposes. THIS DATA WILL NOT BE USED BY NCI TO TREAT OR DIAGNOSE HUMAN SUBJECTS. In the event that:

(a) a party to this agreement is able to deduce the identity of an individual human subject whose information is a component of the DATA;

And,

(b) the human subject is not being supervised by or under care of the party,

then that party agrees it will not attempt to identify or contact such human subject and, furthermore, will notify the other party of its ability to make such identification.

4. Neither NCI nor RESEARCHER will use the DATA unless it has obtained all appropriate clearances to use the DATA, including but not limited to clearance by an Institutional Review Board or equivalent governing body. The use and handling of the DATA by either party will be performed in compliance with all applicable statutes and regulations.

5. The RESEARCHER may redistribute DATA to third parties for research, clinical, and academic purposes under conditions of use no less restrictive than those of this Agreement.

6. The RESEARCHER agrees to acknowledge the source of the DATA in any publications reporting use of it.

7. NCI shall have the right to conduct quality assurance measures of the DATA including, but not limited to, reviews of system logic, evaluation of missing DATA, and summary statistics based on DATA across the entire system. No evaluation of, or publication based on, a single registered study will be performed by NCI. The NCI represents that its role in managing the DATA shall be primarily archival, and that the NCI will not conduct investigative activities with the DATA.

8. Any DATA delivered pursuant to this Agreement is understood to be experimental in nature. THE NCI MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

9. No indemnification for any loss, claim, damage, or liability is intended or provided by any party under this agreement. Each party shall be liable for any loss, claim damage, or liability that said party incurs as a result of said party's activities under this agreement, except that the NCI, as an agency of the United States, assumes liability only to the extent as provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171). If the RESEARCHER is a component of or an agency of a State government then RESEARCHER assumes liability only to the extent authorized under the laws of the State or Commonwealth.

10. RESEARCHER agrees not to claim, infer, or imply endorsement of the RESEARCHER by the NCI and by the Government of the United States of America.

11. Upon request by the NCI, the RESEARCHER will perform any of the following as directed by the NCI: (a) immediately cease use of the DATA; (b) dispose of DATA provided by the NCI that is in the RESEARCHER's possession.

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Agreement are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§ 3801-3812 (civil liability) and 18 U.S.C. § 1001 (criminal liability including fine(s) and/or imprisonment).

By accepting the terms of this agreement, the RESEARCHER certifies that the information submitted by the RESEARCHER is true, complete and accurate to the best of RESEARCHER's knowledge. The person accepting the terms of this agreement for the RESEARCHER has the requisite power and authority to accept the terms of this Agreement.