



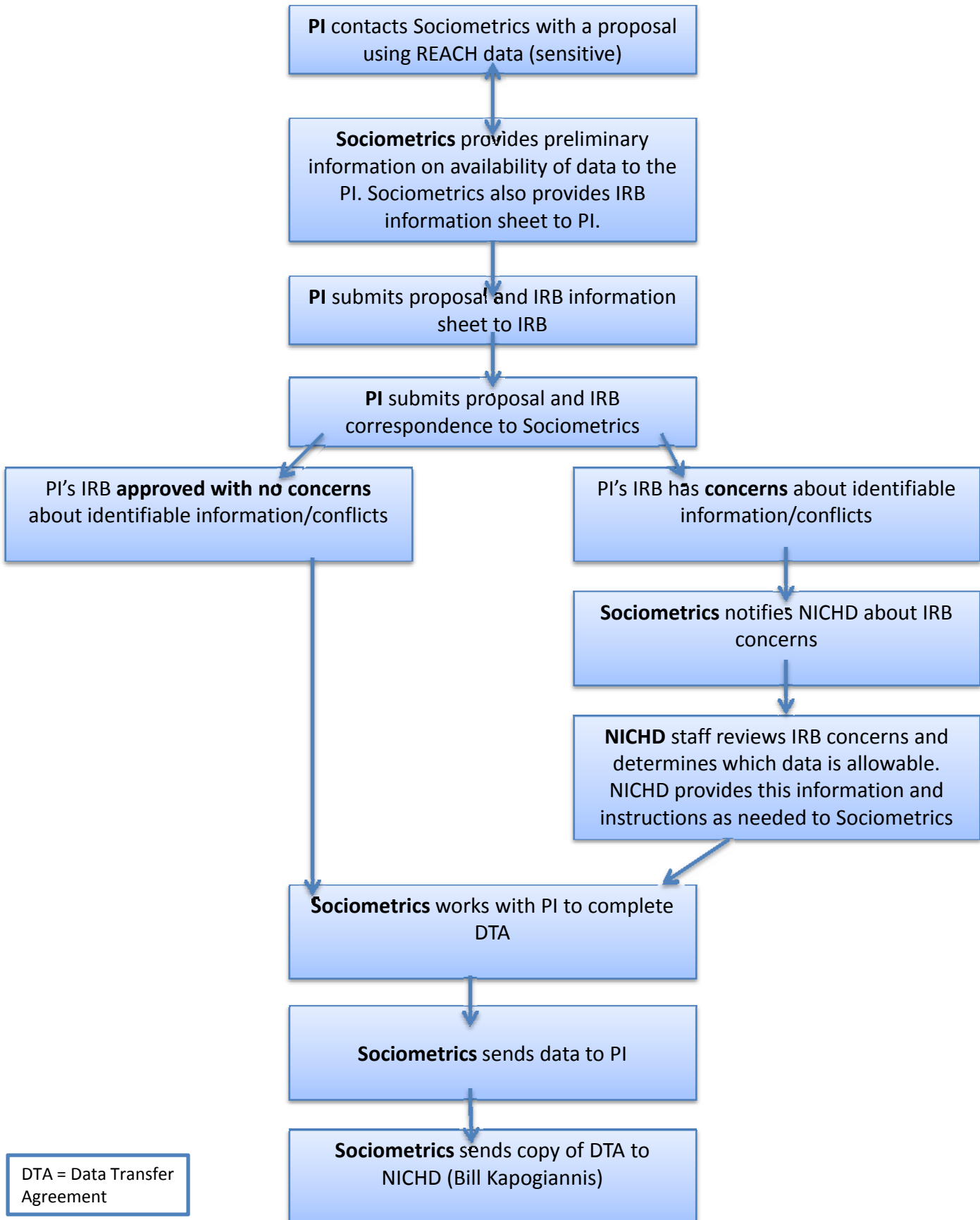
Thank you for your interest in the ***Reaching for Excellence in Adolescent Care and Health*** (REACH) dataset. The documents in this packet are applicable to those wishing to acquire only the **Sensitive** REACH dataset. Note that the Sensitive dataset includes both standard and sensitive data. If you are unsure about which REACH data (standard, sensitive, specimen) would best meet your needs, please review the User's Guide enclosed with this packet, or contact Sociometrics for more information.

Acquiring the Sensitive dataset is fairly straight forward, however several steps must be completed before you may access the data. To acquire the data, simply review the materials in this packet paying particular attention to the document titled REACH REQUEST PROCESS, secure IRB approval for your proposed research, complete the data transfer agreement, and mail, email, or fax the agreement to Sociometrics. Sociometrics will notify you when the data are available for download. Sociometrics will make the data available in a password secured location for a period of 3 business days. Please download the data during that time.

If you have any questions or need assistance, please contact Sociometrics.

Sociometrics Corporation
170 State St, Suite 160
Los Altos, CA 94022
650-949-3282 or 800-846-3475
socio@socio.com

REACH Request Process: Sensitive Data



DTA = Data Transfer Agreement

REACH REQUEST PROCESS: SENSITIVE DATA

PI contacts Sociometrics with a proposal using REACH sensitive data

When a PI decides to use REACH sensitive data in a research proposal, they will send a request to Sociometrics.

Sociometrics provides preliminary information on availability of data to the PI. Sociometrics also provides IRB information sheet to PI

Once the request has been received at Sociometrics, Sociometrics will query the database and provide a report of the available data to the PI. Sociometrics will also provide the IRB information sheet to the PI (also contained in this packet). This IRB information sheet includes information on the REACH data, including information on potential identifiable data. This document should be available for download on the Sociometrics website (contained in this packet).

PI submits REACH research proposal and IRB information sheet to IRB

The PI must submit both the research proposal and IRB information sheet to their IRB. All proposals must be submitted to the IRB with the corresponding IRB information sheet.

PI submits proposal and IRB correspondence to Sociometrics

Once the IRB responds to the research proposal and IRB information sheet, the PI will submit the IRB response to Sociometrics.

A) IRB approved with no concerns about identifiable information/conflicts

After reviewing the research proposal and the IRB information sheet, the IRB approves the proposal with no concerns about identifiable information or conflicts with the data.

Sociometrics works with PI to complete Data Transfer Agreement (DTA)

Sociometrics will work with the PI to complete the DTA and answer any questions the PI might have about the DTA. The DTA will be available for download on Sociometrics website (also contained in this packet).

Sociometrics provides secure links to data to PI

Sociometrics sends requested data to PI in the appropriate form.

Sociometrics sends copy of DTA to NICHD

Sociometrics emails a copy of the signed DTA to Dr. Bill Kapogiannis at NICHD

B) IRB has concerns about identifiable information/conflicts

After reviewing the research proposal and IRB information sheet, the PI's IRB has concerns about data being potentially identifiable, or about the PI having a conflict with the REACH data.

Sociometrics notifies NICHD about IRB concerns

Sociometrics notifies Dr. Kapogiannis at NICHD about the IRB concerns. The correspondence from the IRB, as well as the proposal, should be forwarded in this notification.

NICHD staff reviews IRB concerns and determines which data is allowable. NICHD provides this information and instructions as needed to Sociometrics

Dr. Kapogiannis and other designated NICHD staff will review the IRB concerns and determine which, if any, data are allowable. The REACH database includes a linker file while allows data to be further de-identified. The extent to which this file will be provided to PIs, if at all, will be determined by NICHD staff based on IRB concerns. Dr. Kapogiannis will provide this information and instructions to Sociometrics.

Sociometrics works with PI to complete Data Transfer Agreement (DTA)

Sociometrics will work with the PI to complete the DTA and answer any questions the PI might have about the DTA. The DTA will be available for download on Sociometrics website (also contained in this packet).

Sociometrics provides secure links to data to PI

Sociometrics sends approved data to PI in the appropriate form. Note that any costs associated with making the data available (i.e. specially created dataset files to comply with IRB requirements) will be the responsibility the PI acquiring the dataset.

Sociometrics sends copy of DTA to NICHD

Sociometrics emails a copy of the signed DTA to Dr. Kapogiannis at NICHD

**Information Sheet for Investigators
Proposing to Conduct Research with the Anonymized Reaching for Excellence in
Adolescent Care and Health (REACH) Database
(January 20, 2012)**

All investigators conducting research using the anonymized REACH Database should submit this information along with their protocol to their IRB.

Background:

It has always been the intention of NICHD to make the REACH Database a public use data set after the study was completed and primary analyses were finished.

- Enrollment in REACH ceased in November 30, 1999.
- Effective August 1, 2003, all sites participating in REACH had completed destruction of their Subject Identification Lists which linked subject names to assigned code numbers rendering the REACH Database anonymized.

Since REACH participants were promised that their answers to sensitive questionnaires would not be shared with anyone at their site, a special plan was implemented to separate the anonymized coded database with sensitive information from that containing the basic sociodemographic data.

- Both databases reside at Sociometrics, the company also in possession of a special coded linking variable file to be used for analysis between the two anonymized databases.
- This file has previously been shared only in a very limited capacity (viz. primarily investigators with no affiliation with institutions participating in REACH).

Consistent with NICHD intent to make this dataset publically available, an investigator can submit a proposal reviewed by their IRB directly to Sociometrics to obtain the databases along with the linking variable file to conduct analysis at their own expense.

Research performed on anonymized, existing databases should be exempt from IRB review [CFR 46.101 (b)(4)]. However, it is the IRB that makes that determination and in the case where the proposing investigator has ever been directly involved in the delivery of care for REACH subjects or the conduct of REACH study visits at any institution, the IRB may determine this research not to be exempt from review.

Considerations:

The reason for the above measures is that some REACH sites enrolled limited numbers of subjects with particular sociodemographic characteristics.

- Therefore, there is a very small possibility that a REACH site investigator directly involved with the care of the subjects and/or the conduct of REACH at their site who receives the linking variable file may be able to identify youth from their site who provided sensitive information.

REACH closed 12 years ago, with the youngest participant now being at least 25 years old; thus subjects and their medical records will most likely have moved on to adult care clinics at other locations not easily accessible to REACH investigators, though some records may remain archived at these sites.

**Information Sheet for Investigators
Proposing to Conduct Research with the Anonymized Reaching for Excellence in
Adolescent Care and Health (REACH) Database
(January 20, 2012)**

Implications:

- Care should be taken by the proposing investigator to not share the linking variable file with anyone except members of their study team
 - **If the linking variable file is shared with anyone who has ever been directly involved in the delivery of care for REACH subjects or the conduct of REACH study visits at this or any other institution, extra caution should be exercised not to compromise subject confidentiality (e.g. access to old medical records, etc). The IRB at such institutions may determine that research involving this anonymized database is not exempt from review.**
- The proposing investigator(s) must hold the information about all study volunteers in total confidence.
- The proposing investigator(s) will always honor the privacy of study volunteers and respect the fact that information disclosed within the context of this research study cannot be available to those who render or have rendered clinical care.
- The proposing investigator(s) will disclose no identifying information about study volunteers to anyone except other research team members and then only on a “need-to-know” basis.
- Public dissemination of any data received with unique REACH site identifiers will be limited to that of aggregate information.
- The proposing investigator(s) will adhere to the HHS Policy for Protection of Human Research Subjects as stated in the Code of Federal Regulations 45 Part 46.

This informational document must be submitted along with the proposal to the investigator’s IRB. All IRB correspondence along with the proposal should be submitted to Sociometrics in order to execute any requests for the REACH Database and the linking variable file.

Any further questions or concerns should be forwarded to the NICHD program official, Dr. Bill Kapogiannis.



Bill G. Kapogiannis, M.D.
Medical Officer, PAMAB, NICHD
REACH Program Officer
6100 Executive Blvd., Rm 4B11J
Bethesda, MD 20892-7510
Email: kapogiannisb@mail.nih.gov
Phone: 301-402-0698



DATA TRANSFER AGREEMENT
for Reaching for Excellence in Adolescent Care and Health (REACH) Data
Between Sociometrics Corporation and

Reaching for Excellence in Adolescent Care and Health (REACH) has been deposited with Sociometrics Corporation, for public distribution, by the Basic Science and Clinical Science Groups, Adolescent Medicine HIV/AIDS Research Network and the National Institute of Child Health and Human Development (NICHD). In order to access the data, the investigator requesting the data (the requestor) must submit a completed data transfer agreement. Signing and submitting this agreement indicates your agreement to all terms and conditions of the agreement. This signed agreement will be retained by Sociometrics Corporation and a copy shared with the National Institute of Child Health and Human Development.

The undersigned is agreeing to these requirements:

1. Data Use.

- a. Use the REACH data for statistical reporting, analysis, and teaching only.
- b. Make no use of the identity of any person or establishment discovered inadvertently and notify Sociometrics if the identity of any study subject/volunteer has been discovered.
- c. Not link REACH data with individually identifiable data from other datasets.
- d. Exercise extra caution to not compromise subject confidentiality if sensitive data or the linking file is shared with anyone who has ever been directly involved in the delivery of care for REACH subjects or the conduct of REACH study visits at this or any other institution.
- e. Hold the information about all study volunteers in total confidence.
- f. Always honor the privacy of study volunteers and respect the fact that information disclosed within the context of this research study cannot be available to those who render or have rendered clinical care to the study volunteers.
- g. Disclose no identifying information about study volunteers to anyone except other research team members and then only on a “need-to-know” basis.

h. Ensure that public dissemination of any data received with unique REACH site identifiers will be limited to that of aggregate information.

i. Adhere to the HHS Policy for Protection of Human Research Subjects as stated in the Code of Federal Regulations 45 Part 46.

2. Data Users and Transfer. The data is only to be used by the research team, at the requestors organization under the direction of the requestor or others working under his/her direct supervision. Data will not be transferred to anyone else within the requestor organization without the prior written consent of Sociometrics. Others requesting to use the data will be directed to acquire the data from Sociometrics.

3. Download Access. Access to download the data, including a login and password, will be provided to you for three business days. You agree to download the data during that time, and not share download access, including login information to others.

4. Protection of Data. The requestor will provide appropriate administrative, technical, and physical safeguards to ensure confidentiality and security of the data and prevent unauthorized use.

5. Acknowledgment of Data. You will acknowledge the data source in all reports based on these data. Suggested acknowledgment:

The data used in this publication were made available by the REACH Archive, Sociometrics Corporation, 170 State Street, Suite 260, Los Altos, CA 94022-2812. The study entitled Reaching for Excellence in Adolescent Care and Health was conducted by the Adolescent Medicine HIV/AIDS Research Network. Funding for the data collection was provided by the following agencies: the National Institute of Child Health and Human Development, the National Institute of Allergy and Infectious Diseases, the National Institute of Drug Abuse, the National Institute of Mental Health, and the Health Resources and Services Administration. Funding for the work done by the REACH Archive to prepare the data for public use was provided by the National Institute of Child Health and Human Development under Contract No. HHSN275201000008C to Sociometrics Corporation. The original investigators, funding agency, and the REACH Archive are not responsible for the analyses or interpretations presented here.

6. Costs. Any costs associated the preparation and distribution of the data to the requestor will be the responsibility of the requestor. The requestor should request a cost quote from Sociometrics prior to downloading the data.

Your signature indicates your agreement to comply with the above-stated requirements with the knowledge that deliberately making a false statement in any matter may be punishable under the law.

Name of person entering agreement: _____

Title: _____

Organization: _____

Address: _____

Email address: _____

Signature: _____

Date: _____

Research Staff:

Name

Email Address

Date

Please fax or email this completed agreement to Sociometrics Corporation at 650-949-3299 or socio@socio.com. Contact Sociometrics at 650-383-6253 or socio@socio.com if you have any questions.