



Thank you for your interest in the ***Reaching for Excellence in Adolescent Care and Health*** (REACH) specimens. The documents in this packet are applicable to those wishing to acquire **Specimens** from the K-12 Biorepository. This packet does not contain the materials to acquire the datasets. 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.

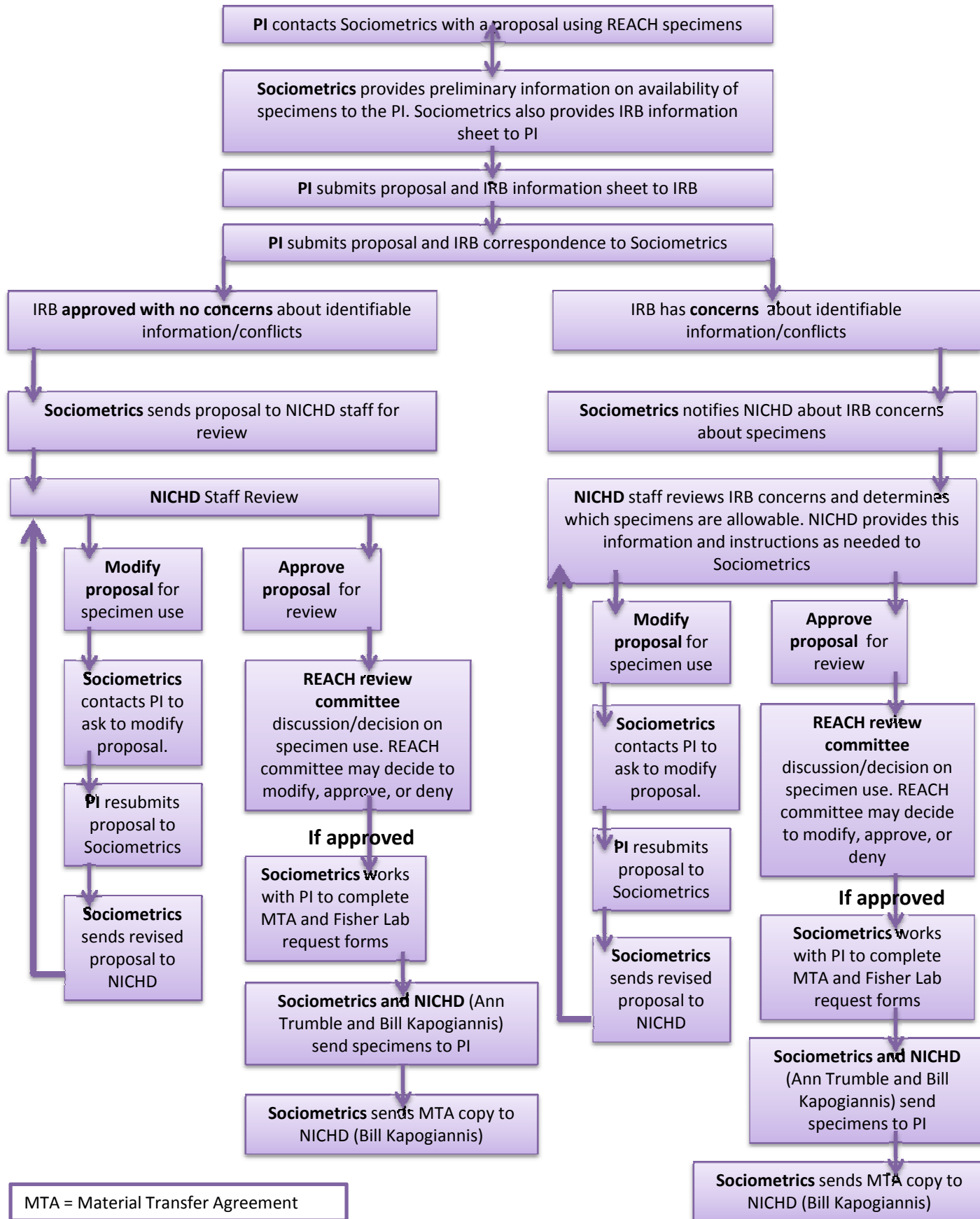
There are several steps that must be completed before you may have specimens shipped to you. You will want to review the materials in this packet paying particular attention to the document titled REACH REQUEST PROCESS. Follow each step of the request process, including, submitting the REACH Research Proposal for Biorepository Specimens, securing IRB approval for your proposed research, completing the material transfer agreement, and mailing, emailing, or faxing the agreement to Sociometrics, and completing and returning the laboratory request form.

Once we have secured approval from NICHD to make the specimens available to you, we will let you know how to proceed and will work with you and NICHD on delivery of the specimens.

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: Specimens



MTA = Material Transfer Agreement

REACH REQUEST PROCESS: SPECIMENS

PI contacts Sociometrics with a proposal using REACH specimens

When a PI decides to use REACH specimen in a research proposal, they will download the REACH Research Proposal for Biorepository Specimens Template from the Sociometrics website (also contained in this packet), complete the proposal, and send it to Sociometrics.

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

Sociometrics will query the specimen database and provide a report of the available specimens to the PI. This person 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 and specimens.

PI submits proposal and IRB information sheet to IRB

The PI must submit both the research proposal and IRB information sheet to an IRB. All proposals must be submitted to an 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 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 specimens

Sociometrics sends proposal to NICHD staff for review

Sociometrics will send the proposal to Dr. Kapogiannis at NICHD so that he and other designated NICHD staff can review the proposal for specimen use.

NICHD staff review

Dr. Kapogiannis and other designated NICHD staff will review the research proposal and the IRB communications and will either ask the PI to modify the proposal, approve the proposal for review of scientific merit by the REACH Review Committee, or deny the proposal.

1) Modify the proposal for specimen use

Dr. Kapogiannis will tell Sociometrics that NICHD would like the PI to modify the proposal and will provide information on why the proposal was not accepted in its current form and suggestions for modifications.

Sociometrics contacts PI to ask to modify the proposal

Sociometrics will contact the PI to ask them to modify the proposal and will forward the information and suggested changes from NICHD.

PI re-submits proposal to Sociometrics

The PI revises the research proposal based on the suggestions from NICHD review and resubmits the proposal to Sociometrics.

Sociometrics sends the revised proposal to NICHD

Sociometrics sends the revised proposal to Dr. Kapogiannis at NICHD. Dr. Kapogiannis and other designated NICHD staff review the proposal and either ask the PI to modify the proposal, approve the proposal for review of scientific merit by the REACH Review Committee, or deny the proposal.

2) *Approve the proposal for specimen use*

Dr. Kapogiannis and other designated NICHD staff approve the proposal to be reviewed for scientific merit by the REACH Review Committee and forward the proposal to this committee.

REACH Review committee review discussion/decision on specimen use

The REACH review committee will discuss the proposal and vote on a final decision on approval for specimen use, request to modify for re-review or denial of the request.

After approval, Sociometrics works with PI to complete Material Transfer Agreement (MTA) and Fisher Laboratory request forms

Sociometrics will work with the PI to complete the Material Transfer Agreement (MTA) and the Fisher Laboratory request forms, both of which are required to use REACH specimens. Both forms will be available on the Sociometrics website (also contained in this packet). Any costs associated with acquiring the specimens will be the responsibility of the PI requesting the data.

Sociometrics and NICHD (Ann Trumble, trumblea@mail.nih.gov) send specimens to PI

Sociometrics coordinates with Ann Trumble to send specimens from Fisher Laboratory to the PI. Dr. Kapogiannis should be copied on all correspondence.

Sociometrics sends MTA copy to NICHD

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

B) PI's IRB has concerns about identifiable information/conflicts

After reviewing the research proposal and the IRB information sheet, the IRB has concerns about identifiable information or conflicts with the specimens

Sociometrics notifies NICHD about IRB concerns about specimens

Sociometrics will send the IRB concerns, along with the proposal to Dr. Kapogiannis at NICHD so that he and other designated NICHD staff can review the concerns and the proposal for specimen use.

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

Dr. Kapogiannis and other designated NICHD staff will review the research proposal and the IRB communications and will determine which, if any, specimens are allowable. NICHD staff will provide this information and instructions to Sociometrics. NICHD staff will either ask the PI to modify the proposal, approve the proposal for review of scientific merit by the REACH Review Committee, or deny the proposal.

1) Modify the proposal for specimen use

Dr. Kapogiannis will tell Sociometrics that NICHD would like the PI to modify the proposal and will provide information on why the proposal was not accepted in its current form and suggestions for modifications.

Sociometrics contacts PI to ask to modify the proposal

Sociometrics will contact the PI to ask them to modify the proposal and will forward the information from NICHD

PI re-submits proposal to Sociometrics

The PI revises the research proposal based on the suggestions from NICHD review and resubmits the proposal to Sociometrics.

Sociometrics sends the revised proposal to NICHD

Sociometrics sends the revised proposal to Dr. Kapogiannis at NICHD. Dr. Kapogiannis and other designated NICHD staff review the proposal and either ask the PI to modify the proposal, approve the proposal for review of scientific merit by the REACH Review Committee, or deny the proposal.

2) Approve the proposal for specimen use

Dr. Kapogiannis and other designated NICHD staff approve the proposal to be reviewed for scientific merit by the REACH review committee and forward the proposal to this committee.

REACH Review committee review

The REACH review committee will discuss the proposal and vote on a final decision on approval for specimen use, request to modify for re-review or denial of the request.

After approval, Sociometrics works with PI to complete MTA and Fisher Laboratory request forms

Sociometrics will work with the PI to complete the MTA and the Fisher Laboratory request forms, both of which are required to use REACH specimens. Both forms will be available on the Sociometrics website (also contained in this packet). Any costs associated with acquiring the specimens will be the responsibility of the PI requesting the data.

Sociometrics and NICHD (Ann Trumble, trumblea@mail.nih.gov) send specimens to PI

Sociometrics coordinates with Ann Trumble to send specimens from Fisher Laboratory to the PI. Dr. Kapogiannis should be copied on all correspondence.

Sociometrics sends MTA copy to NICHD

A designated contact from Sociometrics emails a copy of the signed MTA to Dr. Kapogiannis at NICHD.

STUDY CONCEPT PROPOSAL FOR USE OF REACH BIOREPOSITORY SPECIMENS

Study Title

Lead Investigator and co-investigators

Study Objectives and Aims

Study Design

Specimens

Which specimens (PBMC, plasma, urine, etc)

Which visits (cross-sectional, longitudinal)

What population (HIV+, HIV-)

How much volume is needed for completion of planned analyses

NOTE: The suggested length for this format is no more than 4 single-spaced pages excluding references

**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



SPECIMEN SHIPPING REQUEST FORM FOR NICHD REPOSITORY

DATE:
INVESTIGATOR:
REQUESTOR:
EMAIL ADDRESS:
PHONE:

NAME OF STUDY COLLECTION:
NUMBER OF SAMPLES:

SHIP TO ATTENTION OF:
CONTACT PERSON'S PHONE #
EMAIL:
ALTERNATE POINT OF CONTACT:
ALTERNATE'S PHONE #
EMAIL:

Should both persons be contacted?
SHIPPING ADDRESS:

SPECIAL INSTRUCTIONS:
Minimum volume needed:
Are previously thawed samples acceptable?
Temperature of shipped samples:
Preferred Carrier (if not FedEx):
Preferred day of the week for arrival:
Electronic file needed in addition to packing list?
Preferred due date if exception from regular queue (please explain):
Other:

ALIQUOTS (if applicable):
Number per sample:
Volume per aliquot:
Minimum volume acceptable:
Label contents:
Other instructions:

APPROVALS for SHIPMENT (name and date approval given):
1.
2.

Please attach spreadsheet file of the requested samples in either Excel.xls, database.dbf, or text.txt format.



Date received by BioServices
Projected date for shipment
Additional comments:



MATERIAL TRANSFER AGREEMENT
for Reaching for Excellence in Adolescent Care and Health (REACH) Biorepository Specimens
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). Specimens from the study are available to investigators. In order to gain access to specimens from the REACH Biospecimen Repository, the investigator requesting the specimen (the requestor) must submit a completed material 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. Specimen Use.

- (a) Specimen is to be used solely for teaching, scientific research, and academic research purposes.
- (b) Specimen will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects.
- (c) Specimen is to be used only at the requestor's organization and only in the requesting scientist's laboratory under the direction of the requesting scientist or others working under his/her direct supervision.
- (d) Specimen will not be transferred to anyone else or any other organization. The requestor agrees to refer to Sociometrics any request for the material from anyone other than those persons working under the requestor's direct supervision.
- (e). The requestor agrees to use the specimen in compliance with all applicable statutes and regulations, including Public Health Service and National Institutes of Health regulations and guidelines such as, for example, those relating to research involving the use of animals or recombinant DNA.

2. Warranty. Sociometrics makes no representations and extends no warranties of any kind, either expressed or implied for the fitness of use of the specimens for a particular purpose.

3. Liability. To the extent prohibited by law, the requestor assumes all liability for damages which may arise from its use, storage or disposal of the specimen. Sociometrics or NICHD will not be liable to the requestor for any loss, claim or demand made by the requestor, or made against the requestor by any other party, due to or arising from the use of the specimen.

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

5. Acknowledgment of Specimens. You will acknowledge the source in all reports based on the material. Suggested acknowledgment:

The specimens/data 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 specimen to the requestor will be the responsibility of the requestor. The requestor should request a cost quote from Sociometrics prior to submitting a final request.

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 Working with Specimens:

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.