July 11, 2016

John K. Hinsdale
38 Quaker Road
Princeton Junction, NJ
USA 08550-1651
Email: hin@alma.com
Day Tel: +1 609-638-1713

By Certified Mail No. 7010-1870-0003-3592-3702

To: Freedom of Information Office, NIH
Building 31, Room 5B35
31 Center Drive, MSC 2107
Bethesda, MD 20892-2107

FREEDOM OF INFORMATION ACT REQUEST

Documents Requested

- For the five calendar years 2012 - 2016 inclusive,
- All **Certificates of Confidentiality (CoCs)** for human subject mental health research:
  - issued by any NIH component to Massachusetts Institute of Technology (MIT), or to University of Michigan (U.Mich.), and
  - where the project name is similar to "Healthy Minds Study" or "Healthy Minds Network"
- All **Certificates of Confidentiality (CoCs)** for human subject mental health research:
  - issued by any NIH component to MIT or to U.Mich. and where
  - the research project is any mental health survey, and
  - the related Principal Investigator or Institutional Official is one of the following individuals:
    - L. Rafael Reif (MIT)
    - Cynthia Barnhart (MIT)
    - Martin A. Schmidt (MIT)
    - Maria T. Zuber (MIT)
    - Jagruti Patel (MIT)
    - Daniel Eisenberg (U. Mich.)
- All **Applications for Certificates of Confidentiality (CoCs)** for the two groups of criteria above, regardless of whether the applications were granted or denied, and to include the signed "assurances" (five paragraphs) and their signatories.

Document Remittance and Billing

Please mail documents to the above street address. I am willing to pay up to $100.00 (One Hundred Dollars) for shipping and processing fees. If the cost will be higher you may phone me or Email at the above address to confirm a larger amount. You may bill me at the above address or charge my Visa card [redacted], Expiration [redacted] for up to the amount authorized.

Documents may be sent electronically if there is *both* advance notice of the transmission *and* confirmation the documents were received. Otherwise U.S. mail is requested.

Sincerely,

John K. Hinsdale

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

Via email to: hin@alma.com

December 6, 2016

John K. Hinsdale
38 Quaker Road
Princeton Junction, NJ 08550

Re: NIH FOI Case No. 45289

Dear Mr. Hinsdale:

This is the final response to your July 11, 2016, Freedom of Information Act (FOIA) request addressed to the Freedom of Information (FOIA) Office, National Institutes of Health (NIH), which was received in our office on July 14, 2016. Department of Health and Human Services (HHS) policy calls for the fullest possible disclosure provided by the FOIA, consistent with the protections contained therein. The implementing HHS FOIA Regulations establish the criteria under which the FOIA is administered. *See* 45 CFR Part 5. Copies of the FOIA and the HHS FOIA Regulations are available on our website at: http://www.nih.gov/icd/od/foia/efoia.htm and http://www.nih.gov/icd/od/foia/cfr45.htm.

You requested records related to Certificates of Confidentiality (COC) for CY 2012 – 2016. Specifically, you requested copies of:

1. All applications for a COC and all COC for human subject mental health research issued to the Massachusetts Institute of Technology (MIT) or the University of Michigan (U. Mich.) where the project name is similar to "Healthy Minds Study" or "Healthy Minds Network;" and

2. All applications for a COC and all COC for human subject mental health research issued to MIT or the University of Michigan where the research project is any mental health survey and the Principal Investigator or the Institutional Official is:
    a. L. Rafael Reif
    b. Cynthia Barnhart
    c. Martin Schmidt
    d. Maria Zuber
    e. Jagruti Patel or
    f. Daniel Eisenberg

We searched the files of the National Institute of Mental Health (NIMH) and the Office of Extramural Research (OER) within the Office of the Director for records responsive to your request. In a partial response dated November 15, 2016, we released 34 pages of responsive records to you with pending support/source of private support redacted. The information

redacted from those records is protected from release pursuant to Exemption 4 of the FOIA, 5 U.S.C. §§552(b)(4) and section 5.65 of the HHS FOIA Regulations, 45 C.F.R. Part 5. Exemption 4 protects from disclosure trade secrets and commercial or financial information that is privileged and confidential.

As noted in our November 15 partial release, our search for responsive records was continuing. That search has now produced the enclosed 14 pages of responsive records.

In a November 21, 2016, letter and a November 22, 2016, email, you asked that we verify that with respect to Item 1, we searched our files for applications submitted by Cynthia "Barnhart," not "Barnhard" as indicated in our interim and partial response letters. In an email from Ms. Lauren Bartok of this office, she explained that our letters contained a typographical error and that we searched our files using the name "Barnhart."

If you are not satisfied with the processing and handling of this request you may contact the NIH FOIA Public Liaison and/or the Office of Government Information Services (OGIS):

NIH FOIA Public Liaison
Marin Allen, Ph.D.
Deputy Associate Director
Office of Communications and
Public Liaison
Building 1, Room 344
1 Center Drive
Bethesda, MD 20892
301-496-4461 (phone)
301-496-0017 (fax)
nihfoia@mail.nih.gov (email)

OGIS
National Archives and Records Admin.
8601 Adelphi Rd - OGIS
College Park, MD 20740-6001
202-741-5770 (phone)
1-877-684-6448 (toll-free)
202-741-5769 (fax)
ogis@nara.gov (email)

You also have the right to appeal the determination to deny you access to information in the Agency's possession. Should you wish to do so, your appeal must be sent within ninety (90) days of the date of this letter, following the procedures outlined in Subpart C of the HHS FOIA Regulations http://www.nih.gov/icd/od/foia/cfr45.htm) to:

Ms. Catherine Teti
Deputy Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201
FOIARequest@hhs.gov
FAX: 202-690-8320

Clearly mark both the envelope and your letter "Freedom of Information Act Appeal."

In certain circumstances, provisions of the FOIA and HHS FOIA Regulations allow us to recover part of the cost of responding to your request. Because no unusual circumstances apply to the processing of your request, there is no charge associated with our response.

Sincerely,

Susan R. Cornell

Susan R. Cornell, J.D.
Freedom of Information Officer, NIH
Building 31, Room 5B35
31 Center Drive, MSC 2107
Bethesda, MD 20892-2107

Enclosure: 14 pages

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institute of Mental Health
6001 Executive Boulevard
Bethesda, MD 20892

10/11/2016

University of Michigan
Dr. Daniel Eisenberg
4080 Fleming Building
Ann Arbor, MI 48109

Dear Dr. Eisenberg,

Enclosed is the Confidentiality Certificate, protecting the identity of research subjects in your multi-site/single-protocol project entitled "Healthy Minds Study: CCMH version also known as: HMS/CCMH."

Please note that the Certificate expires on 12/31/2021.

Please be sure that the consent form given to research participants accurately states the intended uses of personally identifiable information and the confidentiality protections, including the protection provided by the Certificate of Confidentiality with its limits and exceptions.

If you determine that the research project will not be completed by the expiration date, 12/31/2021, you must submit a written request for an extension of the Certificate three (3) months prior to the expiration date. If you make any changes to the protocol for this study, you should contact me regarding modification of this Certificate. Any requests for modifications of this Certificate must include the reason for the request, documentation of the most recent IRB approval, and the expected date for completion of the research project.

Please advise me of any situation in which the certificate is employed to resist disclosure of information in legal proceedings. Should attorneys for the project wish to discuss the use of the certificate, they may contact the Office of the NIH Legal Advisor, National Institutes of Health, at (301) 496-6043.

Correspondence should be sent to:

Eugene Kane III, M.P.H.
National Institute of Mental Health
6001 Executive Boulevard
Suite 6110 MSC 9669
Bethesda, MD 20892

Sincerely,

Approved Date: 10/11/2016

Eugene Kane III, M.P.H.
Certificate of Confidentiality Coordinator
National Institute of Mental Health

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institute of Mental Health
6001 Executive Boulevard
Bethesda, MD 20892

CONFIDENTIALITY CERTIFICATE

CC-MH-16-252

issued to

University of Michigan

conducting research known as

"Healthy Minds Study: CCMH version also known as: HMS/CCMH"

In accordance with the provisions of section 301(d) of the Public Health Service Act 42 U.S.C. 241(d), this Certificate is issued in response to the request of the Principal Investigator, Dr. Daniel Eisenberg, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Daniel Eisenberg is primarily responsible for the conduct of this research.

Under the authority vested in the Secretary of Health and Human Services by section 301(d), all persons who:

1. are enrolled in, employed by, or associated with University of Michigan and its contractors or cooperating agencies, and

2. have in the course of their employment or association access to information that would identify individuals, who are the subjects of the research, pertaining to the project known as "Healthy Minds Study: CCMH version also known as: HMS/CCMH,"

3. are hereby authorized to protect the privacy of the individuals, who are the subjects of that research, by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research.

This research study examines and assesses mental health, health service utilization and determinants therein among college and university student populations through the usage of surveys.

A Certificate of Confidentiality is needed because sensitive information will be collected during the course of the study. The certificate will help researchers avoid involuntary disclosure that could expose subjects or their families to adverse economic, legal, psychological and social consequences.

Identifiable institutional data and survey data will be stored on University of Michigan's Google Drive (M+ Google Drive). Survey responses and identifiable information will be stored in separate files in separate folders. Once data collection has ended, we will destroy the contact information of non-responders but will retain their other information for the purposes of non-response analysis. Files containing student identifiers and the files that contain linking information to the identifiers will be destroyed when no further analysis is required with identifiable information, or after three years, whichever comes first. Data are gathered through Qualtrics, using Transport Layer Security (TLS), encryption (HTTPS), password protection, and HTTP referrer checking.

This research begins on 09/01/2016 and is expected to end on 12/31/2021.

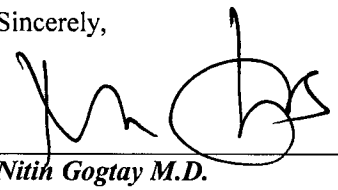
As provided in section 301 (d) of the Public Health Service Act 42 U.S.C. 241(d):

"Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

This Certificate does not protect you from being compelled to make disclosures that: (1) have been consented to in writing by the research subject or the subject's legally authorized representative; (2) are required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or regulations issued under that Act; or (3) have been requested from a research project funded by NIH or DHHS by authorized representatives of those agencies for the purpose of audit or program review.

This Certificate does not represent an endorsement of the research project by the Department of Health and Human Services. This Certificate is now in effect and will expire on 12/31/2021. The protection afforded by this Confidentiality Certificate is permanent with respect to any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during the time the Certificate is in effect.

Sincerely,



Signed Date: 10/11/2016

Nitin Gogtay M.D.
Director of Clinical Research
National Institute of Mental Health

Background: Confidentiality Certificates are issued by NIH Institutes pursuant to Section 301 (d) of the Public Health Service U.S.C. Section 241 (d) to afford special privacy protection to subjects enrolled in biomedical, behavioral, clinical, or other research within NIH mission areas. A Certificate helps the researcher avoid compelled 'involuntary disclosure' (e.g. subpoenas) of identifying information about a research subject.

1 Institution Information

This is the institution with which the applicant (principal investigator) is affiliated and the recipient of funding for the research, if there is any. The principal investigator must be a faculty member of this institution. Individuals who are in a temporary status such as graduate students or post-doctoral fellows may only be listed as co-investigators in this application.

Institution Name: University of Michigan
Institutional Official: James A. Ashton-Miller
Organizational Title: Associate Vice President - Research Policy and Compliance
Address 1: 4080 Fleming Building
Address 2:
Address 3:
Address 4:
Address 5:
Country: United States
City: Ann Arbor
State: MICHIGAN
Postal Code: 48109

2 Research Sites

List the primary site where the research will be conducted and a brief description of the facilities available for the conduct of the research. The lead site of a multi-site project should apply for a single Certificate to protect participants enrolled at all sites and should maintain a current listing of other sites.

Primary Site University of Michigan
Brief Description of Facilities The research will be conducted at the University of Michigan in both the Institute for Social Research and the School of Public Health. The principal investigator has offices in each of the aforementioned facilities, and the study coordinator has a cubicle in the Institute for Social Research.

3 Research Project Title

Please enter the title of the research project in the box below. If the project title on the IRB form (see item 5 below) is different from title given here, the applicant must document that the IRB approval pertains to this project.

Include all alternate titles in addition to the IRB approved title. Alternate titles may be listed on the consent form, award letters, collaborative agreements, clinical trials registry listing, etc. When entering the titles below, put "also known as" between them.

Title(s): Healthy Minds Study: CCMH version also known as: HMS/CCMH

4 Source of Project Funding Support

Is the research funded by NIH

○ YES
◉ NO

☐ Internal Institutional funding

☐ Other DHHS agency

☐ Other Federal agency

☐ State or local government funding

☐ Foundation or non-profit organization

☒ Other Source Performance sites

☐ None

5.a Human Subjects Protection Requirements

A Certificate of Confidentiality will not be issued to an applicant unless the project has IRB approval. The approving IRB must be in compliance with applicable Federal requirements. If the applicant institution is receiving DHHS funding for research involving human subjects, an OHRP-approved IRB for that institution must approve the project for which a Certificate of Confidentiality is sought. For additional information on OHRP and IRB assurances, see http://www.hhs.gov/ohrp/assurances/

If the applicant institution has not received DHHS funding for this research but has an IRB that complies with the requirements for IRBs imposed by another Federal agency, that IRB must approve the research. If the applicant institution does not have an IRB, the project should be reviewed by an IRB in accordance with 45 CFR Part 46.

5.b IRB Approval

Attach letter or form signed by an authorized IRB representative. Approval must be current and unconditional, or conditioned only upon the issuance of a Certificate of Confidentiality. If this is a multi-site project, only the lead site IRB approval needs to be submitted, but the lead site must maintain copies of the IRB approval from each site, to be made available to the NIH upon request.

Name Of IRB: University of Michigan Institutional Review Board
Letter Of Approval: Eisenberg HMS-CCMH CoC Sept 2016.pdf

5.c FederalWide Assurance (FWA) Number/Statement of Qualifications

Submit for the IRB that reviewed the project, the federalwide assurance (FWA) number assigned by OHRP or a statement of qualifications that the IRB complies with the applicable Federal regulations governing research involving human subjects. If this is a multi-site project, only the FWA from the lead site IRB is required.

FWA Number: 00004969

6 Applicant/Principal Investigator Information

Please provide the work information for the applicant/principal investigator (PI) as well as name and title of other key personnel . Also include a brief summary of the scientific training of the PI and key personnel. If this is a multi-site project, only information for PI of the lead site should be submitted to the NIH. However, the lead site must collect and maintain this information from each site. Also, you may add an email address for an alternate contact person for this application (such as the PI's administrative assistant or research coordinator).

If there are multiple co-investigators, they can be added using the "Enter More Key Personnel" button. If any of these additional investigators are co-principal investigators, this should be noted in the summary of scientific training box. Alternatively, a listing of key personnel can be uploaded and the additional co-principal investigators can be noted in that document.

Briefly, in no more than 2 or 3 sentences, state the qualifications of the Principal Investigator and note the PI's faculty affiliation with the submitting institution.

Example of Summary of Scientific Training
- PhD received from Green University in Clinical Psychology in 1978
- Academic Faculty full time at Orange University from 1981 until present

Applicant Title: Dr.
First Name: Daniel
Last Name: Eisenberg
Organizational Title: Associate Professor of Health Management and Policy
Address 1: 1415 Washington Heights, SPH II
Address 2:
Address 3:
Address 4:
Address 5:
City: Ann Arbor
State: MICHIGAN
Postal Code: 48109
Country: United States
Telephone: (734) 615-7764
Fax:
Email: daneis@umich.edu
Alternate Email: adamkern@umich.edu
Summary Of Scientific Training: -PhD received from Stanford University in Economics in 2002 -NIMH postdoctoral trainee at UC Berkeley from 2002-2004

Key Personnel

If you have more than one key person to add, either add them individually by selecting the Enter More Key Personnel button or by uploading a document containing a list of the key personnel by selecting the Browse button. If you intend to add more than 20 key personnel, you must upload a document.

7 Project Date Range

Please enter the date the project began or will begin and the date the project is expected to end; these will be used to set the start and expiration dates on your Certificate. If the research will not be completed by the expected end date, the Applicant must contact the NIH Certificate Coordinator about extending the protection; this should be done three months prior to the end date.

Beginning Date

09/01/2016

End Date
12/31/2021

8 Description of Study Project Aims and Research Methods

This section should include a description of the project as well as a 2 or 3 sentence brief summary of the project which will be included in the Certificate. If significant changes are made to the project aims or methods after a Certificate has been issued the Applicant should contact the NIH Certificate Coordinator to determine if the Certificate can be modified or if the Applicant will need to submit an amendment application.

Example of Description of Study:
The proposed study will investigate the occurrence of maternal depression, parenting attitudes and social support, and the effects of these on infant developmental risk in a group of rural, Native American mothers. The study also examines the detrimental effects of poverty and environmental deprivation on children as mediated through mothers' psychological and social well-being and parenting behavior in the early years. In addition, the proposed study would determine prevalence rates of infant cognitive and developmental delay at one year as a developmental outcome measure. Finally the study will look at social support as a powerful moderator of maternal psychological functioning, and a buffer to risk for children.

The study has four main objectives

1. To determine the relatedness of maternal depressive symptoms to maternal prenatal risk behaviors, ie., smoking, alcohol and drug abuse during pregnancy.
2. To determine the occurrence and relatedness of maternal depressive symptoms and poor parenting attitudes at infant age 2 days, 2 months, and at 1 year in this population.
3. To discover maternal perceptions of social support (extended family and partner),and test the hypothesis that social support alleviates maternal depressive symptoms and poor parenting attitudes.
4. To test the hypothesis that infant developmental delay at 1 year is related to maternal depressive symptoms and attitudes, moderated by social support.

Example of Brief Summary:
This behavioral research study examines the relationship between maternal depressive symptoms, pre-natal risk behavior, perceived social support, and infant outcomes. Approximately 200 Native American mother-infant pairs will be recruited as subjects and evaluated at baseline and scheduled intervals for one year.

Description Of Study
This is a survey-based study assessing mental health, health service utilization and determinants therein among college and university student populations. The survey gathers data on a variety of domains connected to mental health: mental health status, access and barriers to services, utilization of services, social environment, academic environment, academic performance, and health behaviors (e.g. sleep and substance use). The study has an emphasis on understanding service utilization and help-seeking behavior, including factors such as stigma, knowledge, and the role of peers and other potential gatekeepers. Our primary aims are as follows: 1. To understand the mental health needs and relevant health behaviors of college and university students. 2. To understand the extent to which college and university students are receiving needed services. 3. To understand key determinants of whether students receive needed services. 4. To provide relevant resources to college and university students. 5. To inform mental health practice and policy on college and university campuses.

Brief Summary
This research study examines and assesses mental health, health service utilization and determinants therein among college and university student populations through the usage of surveys.

9 Means Used to Protect Subjects' Identities

Describe the procedures used for collection and storage of personally identifiable information.

For Example: *Subjects are coded by numbers not names, linking information is kept in locked files, identifiers will be destroyed when the study is completed, etc.*

Means Used
Identifiable institutional data and survey data will be stored on University of Michigan's Google Drive (M+ Google Drive). Survey responses and identifiable information will be stored in separate files in separate folders. Once data collection has ended, we will destroy the contact information of non-responders but will retain their other information for the purposes of non-response analysis. Files containing student identifiers and the files that contain linking information to the identifiers will be destroyed when no further analysis is required with identifiable information, or after three years, whichever comes first. Data are gathered through Qualtrics, using Transport Layer Security

(TLS), encryption (HTTPS), password protection, and HTTP referrer checking. Qualtrics has SAS 70 Certification and meets the rigorous privacy standards imposed on health care records by the Health Insurance Portability and Accountability Act (HIPAA).

10 Reasons for Requesting a Certificate of Confidentiality

Include a brief description of sensitive and identifying information to be collected.

Examples for Reason for Requesting Certificate of Confidentiality:

- *Sensitive information regarding drug and alcohol use, physical habits and dream content are being collected.*
- *Genetic material is being collected in patients and their families who may be at risk of developing specified diseases.*
- *Genome analysis will be performed to search for familial, disease-influencing genes and their alleles.*

This information, if disclosed, could expose subjects or their families to adverse economic, legal, psychological or social consequences

Reason for Request
Sensitive information regarding substance use, alcohol use, and mental health are being collected. This information, if disclosed, could expose subjects or their families to adverse economic, legal, psychological or social consequences. Note: not a single question on the survey will have forced response (with the exception of the consent page).

11 Informed Consent Form(s) for Human Subjects, as it Will Read if the Certificate of Confidentiality is Issued (Attach Copy)

The informed consent form must include an accurate description of the protections and limitations of the Certificate of Confidentiality, including the circumstances in which the investigators plan to voluntarily disclose identifying information about research participants (e.g., child abuse, harm to self or others, etc.).

Researchers may adapt the sample language below to the needs of their research participants and the subject matter of their study. However, the consent must cover the basic points about Certificates of Confidentiality (CoC) noted below. Researchers should also review any institutional "boilerplate" language about confidentiality and data security often included in consent forms to be certain that it is consistent with the protections of the CoC. Please contact the NIH IC CoC Coordinator if you have any questions about your consent language.

The researchers must also include language regarding circumstances that could lead to voluntary disclosure to authorities and appropriate professionals, without consent of the participant, such as information about child abuse, intent to hurt self or others, or other disclosures (including a description of the circumstances under which disclosures would be made).

If this is a multi-site project, only submit the consent form used by the lead site. The lead site must maintain copies of the IRB-approved consent form(s) from each participating site and must ensure that informed consent form for each site contains appropriate language about the protections and limitations (voluntary disclosures) of the Certificate of Confidentiality.

If a study uses several consent forms (e.g. a consent form and an assent form), please merge them into a single document prior to uploading.

If significant changes are made to the informed consent form after the Certificate has been issued, the Applicant should contact the Certificate Coordinator to determine if a revised consent form should be submitted to NIH.

Information for research projects with children: A Certificate of Confidentiality cannot be used to refuse to disclose identifiable research information about a minor if a parent or legal guardian requests it. The researchers may use other basis for a refusal to disclose information - after checking with their IRB about waivers of parental permission and other issues. In any case, researchers should discuss this possibility with their institution's officials.

Researchers may contact the Certificate Coordinator at the NIH IC for which they are applying with questions or additional recommendations and suggestions on language to be included in consent and assent forms regarding the Certificate of Confidentiality. (IC Contacts)

Informed Consent Form(s): HMS_CCMH_Consent Form_clean_8.1.2016.docx

12 Administration of Drugs in Research Not Funded by NIH

Research not funded by NIH in which drugs will be administered to human subjects must provide the following additional information:

- Identification of drugs to be administered; e.g. Phenobarbital
- Description of methods for administration of these drugs, including a statement of dosages; e.g. 50 to 100 mg 2 to 3 times daily.
- Evidence that individuals who will receive the drugs are authorized to do so under applicable Federal and State law. e.g. Patients with Alzheimer's are allowed to use anti-epileptic medications in the State of Rhode Island.

This section is not applicable (n/a) to your application

13 All Research in which a Controlled Drug or Drugs will be Administered (Attach Copy)

All research in which a controlled drug or drugs will be administered must upload a copy of the Drug Enforcement Administration Certificate of Registration (DEA Form 223) under which the research project will be conducted.

This section is not applicable (n/a) to your application

14 Research Project Plans for Reporting Communicable Diseases

If the research project is testing for reportable communicable diseases, the applicant must submit information relating to its plans for working with State and local authorities as specified in the August 9, 1991 memorandum from the Assistant Secretary for Health (http://grants.nih.gov/grants/policy/coc/cd_policy.htm).

This section is not applicable (n/a) to your application

15 Assurances

Please provide a scanned copy, on institutional letterhead, of the assurances referencing this application with signatures, identification of the signatories, and the date of the signing. Both the PI and the Institutional Official named in this application must sign this letter. If you are a lead site applying for a Certificate for a multi-site project, please upload the assurance from your institution. The lead site is also responsible for obtaining similar signed assurances from all of the participating institutions and should develop appropriate agreements with these institutions to implement the assurances. **Sample language can be viewed here**

The following assurances are required and should be inserted verbatim into the assurance letter to be signed and uploaded into this application:

This institution agrees to use the Certificate of Confidentiality to protect against the compelled disclosure of personally identifiable information and to support and defend the authority of the Certificate against legal challenges.

The institution and personnel involved in the conduct of the research will comply with the applicable Federal regulation for the protection of human subjects or, if no such Federal regulation is otherwise applicable, they will comply with 45 CFR Part 46.

This Certificate of Confidentiality will not be represented as an endorsement of the project by the DHHS or NIH or used to coerce individuals to participate in the research project.

All subjects will be informed that a Certificate has been issued, and they will be given a description of the protection provided by the Certificate.

Any research participant entering the project after expiration or termination of the Certificate will be informed that the protection afforded by the Certificate does not apply to them.

Scanned signed assurance form: Eisenberg.HUM113817.Signed LOA.9.15.2016.pdf

Daniel Eisenberg, PhD
Associate Professor
Department of Health Management & Policy
School of Public Health, University of Michigan
1415 Washington Heights
Ann Arbor, Michigan 48109-2029

September 14th, 2016
RE: Certificate of Confidentiality
Research Title: Healthy Minds Study: CCMH version
Application: HUM00113817
FWA: 00004969

Assurances

This institution agrees to use the Certificate of Confidentiality to protect against the compelled disclosure of personally identifiable information and to support and defend the authority of the Certificate against legal challenges.

The institution and personnel involved in the conduct of the research will comply with the applicable Federal regulation for the protection of human subjects or, if no such Federal regulation is otherwise applicable, they will comply with 45 CFR Part 46.

This Certificate of Confidentiality will not be represented as an endorsement of the project by the DHHS or NIH or used to coerce individuals to participate in the research project.

All subjects will be informed that a Certificate has been issued, and they will be given a description of the protection provided by the Certificate.

Any research participant entering the project after expiration or termination of the Certificate will be informed that the protection afforded by the Certificate does not apply to them.

Daniel Eisenberg

Signature of Principal Investigator

9/14/2016
Date

Daniel Eisenberg, PhD
Department of Health Management and Policy
School of Public Health, University of Michigan
1415 Washington Heights, SPH II
Ann Arbor, MI 48109-2029

James Ashton-Miller

Signature of Institutional Official

9/15-2016
Date

James A. Ashton-Miller, Ph.D.
Associate Vice President -
Research Policy and Compliance
University of Michigan
4080 Fleming Building
503 Thompson Street
Ann Arbor, MI 48109-1340

HEALTH SCIENCES &
BEHAVIORAL SCIENCES IRB
UNIVERSITY OF MICHIGAN

September 13, 2016

Daniel Eisenberg, Ph.D.
School of Public Health
Health Management & Policy
University of Michigan
Ann Arbor, MI 48109-2029

Dear Dr. Eisenberg:

The study, *Healthy Minds Study: CCMH Version* (HUM00113817), was reviewed at a convened meeting of the Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS) at the University of Michigan on July 21, 2016. The IRB-HSBS determined to approve the study with contingencies. The following recruitment, consent, and survey documents were considered as part of the review:

Recruitment Document(s)
Recruitment and Reminder Email Templates v.01

Informed Consent Document(s)
Consent Form with Conditional Sections (Sweepstakes) v.05

Survey Instrument(s)
HMS/CCMH Questionnaire v.04

As of September 13, 2016, all contingencies were met except to obtain a Certificate of Confidentiality (CoC) for the study. When the CoC is obtained for the research, the study will comply with regulations for human subjects protections in 45 CFR 46.111.

Upon receipt of the CoC, you must upload the documentation to the study application. Once the application is approved, the consent and recruitment documents will be stamped with the approval date.

Please note: Research activities with subjects may not begin until the CoC has been obtained and added to the application.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Mary Donnelly

Mary E. Donnelly, CIP
Full Board Administrator / Senior Research Compliance Specialist
Health Sciences and Behavioral Sciences Institutional Review Board
University of Michigan

Building 520, Suite 1169
2800 Plymouth Road
Ann Arbor, MI 48189-2800

Phone: 734-936-0933
Fax: 734-936-1852
Email: irbhsbs@umich.edu

CONSENT FORM (with conditional sections)

You have been randomly selected to participate in this online survey from a list of all current students at [name of school]. *Participation is completely voluntary and responses are strictly confidential.*

Why is this study important?

The purpose of this study is to better understand issues related to students' well-being, sources of support, use of alcohol and other drugs, and mental and emotional health. This study is important to furthering knowledge about how students are handling the stresses of university life and how well their mental and emotional health needs are being met. Your participation in this confidential survey will provide valuable information that will inform programs and resources on campus.

The Healthy Minds Study is a campus-wide study about student health and well-being. The study has been designed specifically for students, and its success depends on gathering diverse perspectives across campus – therefore your participation, though voluntary, is vital. This data collection is for University of Michigan's research, your school's use, and a data repository maintained by the Center for Collegiate Mental Health (CCMH). Your school's use of the data is intended to evaluate and inform programs and services that are provided to students.

What will taking this survey be like?

We estimate it will take you about 20 minutes to complete the survey. You will be asked questions about your mood and emotions, mental health and emotional issues you may have experienced, use of alcohol and other drugs, support you may or may not have received, and your academic life.

Conditional section
Additionally, you will be entered into a sweepstakes for one of ten $100 prizes and one of two $500 prizes. All randomly selected students at all participating institutions for this study and a similar study will be eligible to win the prizes, regardless of participation. The sweepstakes will be conducted in June 2017 by researchers at the University of Michigan School of Public Health in Ann Arbor, MI. The chances of winning a prize are approximately 3 in 200,000. Winners will be notified by email and provided with information about how to collect the prize.

Following statement will always be included in Consent Form
Your own institution may provide their own incentive as outlined in your recruitment material.

What if I don't have time to take the whole survey?

If you aren't able to take the whole survey at one time, that's no problem. You may return to this website to continue where you left off.

What are the benefits of participation?

By participating in this survey, you may learn important information about available mental health services. It is anticipated that some students may seek needed services as a result of study participation. This research will be used to gain an understanding of how to best provide such services.

What are the risks of participation?

Some of the questions will ask you about sensitive or personal information such as your emotional health substance use, and sexual assault. You can skip any questions you do not wish to answer. Even if you decide to participate now, you may change your mind and stop at any time. Upon completion of the survey, you will receive feedback about the way you responded to validated screening tools embedded in our survey. Depending on how you respond to the survey, your scores may indicate areas of your mental health you may not have thought about before. At the end of the survey, you will be able to choose whether you want to view and print off these scores. As with all screening instruments, the results (phrases and numbers) correspond simply to your pattern of responding and are compared to other people who have taken the instrument. This

screening is not a substitute for a clinical evaluation and is not an actual diagnosis, and only suggests that compared to other people you MAY have the presence of mental health symptoms. You should contact a health professional for more information and a complete evaluation, if you are interested, by consulting the resources noted for your campus. The feedback consists of Depression, Generalized Anxiety, Social Anxiety, Academic Distress, Eating Concerns, Hostility, and Alcohol Use scores, which could trigger feelings of discomfort. If responding to any questions makes you feel worried or unhappy, we urge you to contact the resource mentioned at the top of each page of the survey, or the resources provided at the very end of the survey.

Is this survey confidential?

This survey was designed to protect your privacy and confidentiality. For all randomly selected students at your institution, the [name of school] Registrar's Office provided basic information necessary to administer the study (name, email address) and to conduct non-response analyses (date of birth, gender, race/ethnicity, citizenship, degree program, year in program, academic major, and grade point average). Even if you do not participate, these data will be stored and used for non-response analyses. Your name and personal information will not be attached to any survey data. Any information that you provide in the survey will be stored in a file that is separate from your name, email address, or any other identifiable information. The data from this study, without any identifiable information, will be retained in a secure repository by the research team for future research purposes. Any reports or articles written about this survey will describe the data in the aggregate (as a whole) and will contain no information that could allow someone to identify you. Participating institutions will receive a de-identified data set and will not be given access to individually identifiable survey data.

In addition, our partners at the CCMH , an international Practice-Research-Network that brings together clinical work, research, and technology, will receive the aggregated de-identified data, which will include the names of schools, but not individual identifiers, linked institutional data, nor individual student data While CCMH has no role in the research being conducted, this survey contains measures owned by CCMH and the data collected is useful for their records, which is why they are receiving a copy of the aggregated de-identified data of this study. If you do not want your de-identified data to be shared with CCMH, you should not participate in this study.

The Institutional Review Board or university officials responsible for monitoring this study may inspect these records. If you participate in the study, we will retain your identifiers for up to three years. We may contact you for one or more follow-up surveys on similar topics. Participating in the current survey does not obligate you in any way to participate in the future. CCMH will receive de-identified data from any subsequent HMS surveys conducted in the three years following this survey administration. After three years, all identifiable information will be destroyed.

Some schools may request additional analysis on how measures from the survey correlate with academic outcomes. In this case, we will link your survey data to your academic records (cumulative and semester GPA, enrollment status, and degrees obtained), and analyze the merged data set without any identifying information, solely for the purpose of this research analysis. We would obtain these academic records by providing your institution with a list of students who participated in the survey, along with a non-identifying study ID for each student in the list. We would ask your institution to return to us a database with the academic information for each student, along with the non-identifying study ID and without any identifiers (name or email). We would then use the non-identifying study ID to link the academic records to the deidentified survey data. Thus, your survey data will never be directly attached to your name or other identifying information. Note, however, that the office providing academic information would, by necessity, know which students participated in the survey (but not what the students answered to any of the questions. The aim of this analysis would be to gain knowledge about how to promote successful academic outcomes. We will protect the confidentiality of these records using the measures described throughout this consent form. CCMH will receive de-identified data from additional analyses requested by the schools.

To provide additional protections to your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained here. If you indicate you may harm yourself or someone else, we may report this to the authorities. Also, as noted earlier in this document, if your institution requests an analysis of academic outcomes, your identity as a participant in this study will be shared in the process of obtaining that data, but again, your survey responses will not be shared. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Who's doing this study?

This study is being conducted by the Healthy Minds Study research team at University of Michigan's School of Public Health and [local school contact name] at [name of school].

What if I have questions about the survey?

If you would like to learn more about the Healthy Minds Study, you can visit http://healthymindsnetwork.org/hms.

If you have any questions, comments or concerns, you can contact the researchers at healthyminds@umich.edu. You may also contact the principal investigator of this study, Daniel Eisenberg at daneis@umich.edu, or [local contact name, email address, phone]. You can also the CCMH researchers at bdl10@psu.edu if you have any questions about the de-identified data they will be receiving. If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researchers, please contact the University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board, 2800 Plymouth Rd. Building 520, Room 1169, Ann Arbor, MI 48109-2800, (734) 936-0933, irbhsbs@umich.edu, or toll free (866) 936-0933.

Please click HERE if you wish to print a copy of this consent form.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Freedom of Information Office
Building 31, Room 5B-35
31 Center Drive, MSC 2107
Bethesda, Maryland 20892-2107
phone: (301) 496-5633
fax: (301) 402-4541

Via email to: hin@alma.com

November 15, 2016

John K. Hinsdale
38 Quaker Road
Princeton Junction, NJ 08550

Re: NIH FOI Case No. 45289

Dear Mr. Hinsdale:

This is a partial response to your July 11, 2016, Freedom of Information Act (FOIA) request addressed to the Freedom of Information (FOIA) Office, National Institutes of Health (NIH), which was received in our office on July 14, 2016. You requested records related to Certificates Confidentiality for CY 2012 – 2016. Specifically, you requested copies of:

1. All applications for a COC and all COC for human subject mental health research issued to the Massachusetts Institute of Technology (MIT) or the University of Michigan (U. Mich) where the project name is similar to "Healthy Minds Study" or "Healthy Minds Network;" and
2. All applications for a COC from and all COC for human subject mental health research issued to MIT or the University of Michigan where the research project is any mental health survey and the Principal Investigator or the Institutional Official is:
    a. L. Rafael Reif
    b. Cynthia Barnhard
    c. Martin Schmidt
    d. Maria Zuber
    e. Jagruti Patel or
    f. Daniel Eisenberg

Upon receipt of your request we searched the files of the National Institute of Mental Health (NIMH) and the Office of Extramural Research (OER) for records responsive to your request. Thus far, our search has produced the enclosed 34 pages of responsive records from which pending support/source of private support has been redacted. The information redacted from the enclosed records is protected from release pursuant to Exemption 4 of the FOIA, 5 U.S.C. §§552(b)(4) and section 5.65 of the HHS FOIA Regulations, 45 C.F.R. Part 5. Exemption 4 protects from disclosure trade secrets and commercial or financial information that is privileged and confidential.

Please be advised that the enclosed records pertain to all of the criteria listed in your request, however, pages 29-34 are the only records that actually occurred during the specified time period of 2012-2016. Pages 1-28 document the original application and earlier extensions.
Please note that this partial response does not constitute a final agency action on your request. Therefore, the right to appeal this disclosure decision will be extended concurrent with our final response.

We are continuing to process your request and will make additional releases as the documents become available. We will do everything possible to complete your request in a timely manner. Please feel free to contact me at nihfoia@mail.nih.gov or on (301) 496-5633 for additional information or to inquire about the status of your request.
If you are not satisfied with the processing and handling of this request you may contact the NIH FOIA Public Liaison:

NIH FOIA Public Liaison
Marin Allen, Ph.D.
Deputy Associate Director
Office of Communications and
Public Liaison
Building 1, Room 344
1 Center Drive
Bethesda, MD 20892
301-496-4461 (phone)
301-496-0017 (fax)
nihfoia@mail.nih.gov (email)

Provisions of the FOIA allow us to recover part of the cost of complying with your request. We shall charge you for records in accordance with the Department of Health and Human Services (HHS) FOIA Regulations as they apply to commercial-use requesters; you will be charged for duplication at 10-cents per page; and for search and review time at the hourly rate ($23.00, $46.00 and $83.00) of the searcher and reviewer. Please be advised that the HHS FOIA Regulations allow us to charge for search time even if we do not locate any responsive records or if we determine that some or all of the responsive records are exempt under one of the FOIA's nine exemptions. We have noted your $100.00 fee limit and will contact you if anticipated fees will exceed that amount. However, at this time, we do not anticipate that there will be any applicable fees.

Sincerely,

Lauren Bartok
Government Information Specialist, NIH

Enclosure: 34 pages

THE UNIVERSITY OF MICHIGAN
DEPARTMENT OF HEALTH MANAGEMENT AND POLICY
SCHOOL OF PUBLIC HEALTH
109 OBSERVATORY
ANN ARBOR, MICHIGAN 48109-2029
FAX 734 764-4338

September 30, 2005

Olga Boikess
National Institute of Mental Health
6001 Executive Boulevard, Room 8102
MSC 9653
Bethesda, Maryland 20892-9653

Dear Dr. Boikess:

The following is our application for an NIMH Certificate of Confidentiality for our research project, "The Michigan Healthy Minds Study." Please contact me at (734) 615-7764, or at daneis@umich.edu if you have any questions or concerns.

Thank you kindly,

Daniel Eisenberg, Ph.D.
Assistant Professor

Enclosures

1. Name and address of the applicant research institution

Department of Health Management and Policy, School of Public Health, University of Michigan. 109 S. Observatory, SPH II. Ann Arbor, MI 48109-2029.

2. Sites where the research will be conducted and a brief description of the facilities available for the conduct of the research. Please indicate if this is a multi-site project.

This is a single-site project. The data will be collected from students at the University of Michigan, Ann Arbor via web survey. The data will be collected by the Survey Sciences Group, LLC (SSG). SSG maintains a secure data environment by using dedicated, password-protected servers. SSG also maintains a company policy that includes respondent confidentiality. Violation of respondent confidentiality may result in termination under the policy. At the conclusion of data collection, SSG will deliver a de-identified dataset to the PI.

3. Title of the research project.

The Michigan Healthy Minds Study: Needs for, Barriers to, and Utilization of Mental Health Services by UM Students.

4. Source and number of the supporting grant, if applicable.

(b) (4)

(b) (4)

Decision pending.

5. IRB Approval.

Documentation of approval from the University of Michigan IRB-Health, is included in the text of the email. The University of Michigan Federalwide Assurance number is: FWA00004969, Expiration 6/12/06.

6. Name, title, mailing, and email address of the applicant and key personnel.

Daniel Eisenberg, PhD is the **Principal Investigator** for this project.

Daniel Eisenberg, PhD
Department of Health Management and Policy
School of Public Health, University of Michigan.
109 S. Observatory, SPH II.
Ann Arbor, MI 48109-2029.
daneis@umich.edu
Phone: 734.615.7764
Fax: 734.764.4338

Dr. Eisenberg is an Assistant Professor in the Department of Health Management and Policy in the School of Public Health. He received his PhD in Economics from Stanford University in 2002. Since arriving at Michigan in 2004, he has participated in and developed a number of research projects related to mental health. For example, he recently submitted for publication two manuscripts regarding Attention Deficit Hyperactivity Disorder in American elementary schools. He is also a co-investigator on a research team based out of the Ann Arbor Veterans Administration which is studying relationships between depression treatments and suicide risks (PI: Marcia Valenstein, MD).

Our team includes two **Senior Consultants**. **Harold Neighbors, PhD** is a Professor in the School of Public Health and the Director of the Center for Research on Ethnicity, Culture and Health (CRECH) and the Program for Research on Black Americans (PRBA) in the Institute for Social Research. **Jamie Abelson**, MSW is a clinical social worker and Senior Research Associate at the Institute for Social Research. Both Senior Consultants have many years of experience conducting surveys for mental health research. Their role is to provide guidance on the most important issues at each step of the project. For example, they helped choose the instruments to assess depression and anxiety symptoms in the survey.

Finally, our research team includes three doctoral students in the Department of Health Management and Policy as **Co-Investigators**. All three students are pursuing the sociology cognate within the Health Services, Organization, & Policy program. **Ezra Golberstein** is a third year doctoral student who gained two years experience in mental health services and policy research, including survey projects, working for Human Services Research Institute in Cambridge, MA before coming to UM. **Sarah Gollust**, also a third year student, analyzed survey data on the quality of life of people with disabilities while completing a two-year fellowship in clinical research ethics at the NIH before coming to UM. **Jennifer Hefner,** MPH is a first year doctoral student who recently graduated from the department's master's program and has experience in survey research at the Ann Arbor VA's Health Services Research Department.

7. Beginning and end date of the project.

10/1/05 – 10/1/08

8. Project aims and research methods.

Mental health needs have increased steadily in recent years at UM and at college campuses nationwide. Our aims are to understand the extent to which university students with mental health problems are receiving needed services and to understand key determinants of whether students receive needed services. In order to accomplish these aims, we will conduct a web-based survey sent to 6,000 UM students in late October and early November 2005. We expect about 3,800 respondents. In early December 2005 we will then conduct a follow-up of a randomly selected group of non-respondents. The follow-up will consist of a much shorter phone interview (15 questions) and will allow us to determine whether our initial sample was representative of the full student population. We expect about 200 respondents (out of an initial random sample of 400) from this non-respondent follow-up, for a total of about 4,000 subjects in the study.

In the survey we will gather data on a variety of domains important to mental health:

mental health status, access and barriers to services, utilization of services, social context, academic environment, academic performance, and healthiness of lifestyles (e.g. substance use and gambling). This set of domains represents key factors affecting students' mental health.

9. Protection of subjects' identities.

Identifying information will be linked to the study records by unique identifiers, but stored separately. Respondent confidentiality will be protected through the data management and security procedures including keeping the linking file in a locked office, limiting access to this file to the PI, protecting electronic files with encryption and password protection, limiting who has access to the network where the file will be kept, and use of a dedicated server during the data collection efforts. Additionally, the survey firm will restrict access to survey respondents to only those whose job requires the knowledge. SSG also maintains a company policy that includes respondent confidentiality. Violation of respondent confidentiality may result in termination under the policy. Use of study generated IDs in all respondent communications that have no significance outside of this study will also protect respondent confidentiality. And ultimately, in the final analytic data file, no identifiable information will be included. When responses are reported, they will be so in aggregate and will not uniquely identify a respondent.

10. Reason for requesting a Certificate of Confidentiality.

We will be collecting sensitive information related to mental health status, mental health services use, and substance use. We will also have identifying information for our entire sample, although this information will be kept in a separate file that is matched by unique identifiers. We are requesting a certificate of confidentiality so that we may give our subjects every possible assurance that their survey data will not be able to be identified.

11. Informed consent.

The informed consent form is attached.

12. Drugs to be administered in extramural research.

No drugs of any kind will be delivered in this research.

13. This research does not involve the administration of any types of drugs.

14. This research project is not testing for reportable communicable diseases.

Assurances

The following assurances are required and the following information should be inserted verbatim into the Certificate application letter. Both the PI and the Institutional Official must sign this letter:

This institution agrees to use the Certificate of Confidentiality to protect against the compelled disclosure of personally identifiable information and to support and defend the authority of the Certificate against legal challenges.

The institution and personnel involved in the conduct of the research will comply with the applicable Federal regulation for the protection of human subjects or, if no such Federal regulation is otherwise applicable, they will comply with 45 CFR Part 46.

This Certificate of Confidentiality will not be represented as an endorsement of the project by the DHHS or NIH or used to coerce individuals to participate in the research project.

All subjects will be informed that a Certificate has been issued, and they will be given a description of the protection provided by the Certificate.

Any research participant entering the project after expiration or termination of the Certificate will be informed that the protection afforded by the Certificate does not apply to them.

Signature of Principal Investigator

Signature of Institutional Official
Assoc VP Research
Univ of Michigan

To: <daneis@umich.edu>
Subject: IRB approval has been granted for one of your new applications

Health Sciences Institutional Review Board (IRB) • 540 East Liberty Street, Suite 202, Ann Arbor, MI 48104-2210 • phone (734) 936-0933 • fax (734) 998-9171 • irbhsbs@umich.edu

Date: 9/30/2005

To: Dr. Daniel Eisenberg

Cc: DRDA, IRB Health Sciences

Subject: Initial Study Approval

The Health Sciences Institutional Review Board (IRB) has reviewed and approved the research proposal referenced below. The IRB determined that the research is compliant with applicable guidelines, state and federal regulations, and the University of Michigan's Federalwide Assurance with the Department of Health and Human Services (HHS).

Any proposed changes/amendments in the research (e.g., personnel, procedures, or documents), no matter how minor, must be approved in advance by the IRB unless necessary to eliminate apparent immediate hazards to research subjects.

The approval period for this project is listed below. *Please note your expiration date.* If the project is scheduled to continue beyond this date, submit a Scheduled Continuing Review application **at least two months prior** to the expiration date to allow the IRB sufficient time to review and approve the project. **If the approval lapses, no work may be conducted on this project until appropriate approval has been obtained, except as necessary to eliminate apparent immediate hazards to research subjects.**

The IRB must be informed of all unanticipated or adverse events (i.e., physical, social, or emotional) or any new information that may affect the risk/benefit assessment of this research.

The online forms for amendments, adverse event reporting, and scheduled continuing review can be obtained by accessing the eResearch workspace for this approved study at https://eresearch.umich.edu.

It is expected that only the current IRB-approved version of the informed consent document(s) will be used in conjunction with this research. To obtain and download a copy of the current IRB-approved informed consent document(s), PIs and Study Staff should access the eResearch workspace for this approved study and view the "Documents" tab.

Submission Information:
Title: UM Healthy Minds Study: Needs for, Barriers to, and Utilization of Mental Health Services by UM Students
Study eResearch ID: HUM00000297
Initial IRB Approval Date: **9/30/2005**
Current IRB Approval Period: **9/30/2005 - 9/29/2006**
Expiration Date: **9/29/2006**
eResearch workspace: UM Healthy Minds Study: Needs for, Barriers to, and Utilization of Mental Health Services by UM Students
UM Federalwide Assurance: FWA00004969 Expiration 6/12/06

Sincerely,

Charles Kowalski
Co-chair, IRB Health Sciences

Alfred Franzblau
Co-chair, IRB Health Sciences

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Mental Health
6001 Executive Boulevard
Bethesda, Maryland 20892

January 8, 2006

Daniel Eisenberg, Ph. D.
University of Michigan
School of Public Health
109 S. Observatory, SPH II
Ann Arbor, MI 48109-2029

Dear Dr. Eisenberg:

Enclosed is the Confidentiality Certificate protecting the identity of research subjects in your project entitled, "The Michigan Healthy Minds Study: Needs for, Barriers to, and Utilization of Mental Health Services by UM Students." Please note that the Certificate expires on December 31, 2007.

Please be sure that the consent form given to research participants accurately states the intended uses of personally identifiable information and the confidentiality protections, including the protection provided by the Certificate of Confidentiality with its limits and exceptions.

If you determine that the research project will not be completed by the expiration date, December 31, 2007, you must submit a written request for an extension of the Certificate three (3) months prior to the expiration date. If you make any changes to the protocol for this study, you should contact me regarding modification of this Certificate. Any requests for modifications of this Certificate must include the reason for the request, documentation of the most recent IRB approval, and the expected date for completion of the research project.

Please advise me of any situation in which the certificate is employed to resist disclosure of information in legal proceedings. Should attorneys for the project wish to discuss the use of the certificate, they may contact the Office of the NIH Legal Advisor, National Institutes of Health, at (301) 496-6043.

Correspondence should be sent to:

Ms. Olga Boikess
Office of Resource Management
National Institute of Mental Health
6001 Executive Boulevard, Room 8102 (MSC 9653)
Bethesda, Maryland 20892-9653
Telephone: (301) 443-3877
Fax: (301) 443-2578

Sincerely,

Olga Boikess

Enclosure

CONFIDENTIALITY CERTIFICATE

MH-06-003

issued to

University of Michigan

conducting research known as

"The Michigan Healthy Minds Study: Needs for, Barriers to,

and Utilization of Mental Health Services by UM Students"

In accordance with the provisions of section 301(d) of the Public Health Service Act 42 U.S.C. 241(d), this Certificate is issued in response to the request of the Principal Investigator, Daniel Eisenberg, Ph. D. to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Eisenberg is primarily responsible for the conduct of this research.

Under the authority vested in the Secretary of Health and Human Services by section 301(d), all persons who:

1. are enrolled in, employed by, or associated with the University of Michigan and its contractors or cooperating agencies, and

2. have in the course of their employment or association access to information that would identify individuals who are the subjects of the research pertaining to the project known as "The Michigan Healthy Minds Study: Needs for, Barriers to, and Utilization of Mental Health Services by UM Students"

are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research

This purpose of this study is to understand the extent to which university students with mental health problems are receiving needed services and to understand key determinants of whether students receive needed services.

A Certificate of Confidentiality is needed because sensitive genetic information and sensitive information about mental health, substance use, illegal activity and psychological well being will be collected during the course of the study. The certificate will help researchers avoid involuntary disclosure that could expose subjects or their families to adverse economic, legal, psychological and social consequences.

All subjects will be assigned a coded number and identifying information and records will be kept in locked files.

This research is underway, and is now expected to end on December 31, 2007.

As provided in section 301 (d) of the Public Health Service Act 42 U.S.C. 241(d):

> "Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

This Certificate does not protect you from being compelled to make disclosures that: (1) have been consented to in writing by the research subject or the subject's legally authorized representative; (2) are required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or regulations issued under that Act; or (3) have been requested from a research project funded by NIH or DHHS by authorized representatives of those agencies for the purpose of audit or program review

This Certificate does not represent an endorsement of the research project by the Department of Health and Human Services. This Certificate is now in effect and will expire on December 31, 2007. The protection afforded by this Confidentiality Certificate is permanent with respect to any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during any time the Certificate is in effect.

Date: January 8, 2006

William T. Fitzsimmons
Executive Officer

THE UNIVERSITY OF MICHIGAN
DEPARTMENT OF HEALTH MANAGEMENT AND POLICY
SCHOOL OF PUBLIC HEALTH

109 OBSERVATORY
ANN ARBOR, MICHIGAN 48109-2029
FAX 734 764-4338

AUG 30 2007

8/29/07

Dear Dr. Boikess,

The following is our application for an amendment to our NIH Certificate of Confidentiality for our research project, "The Healthy Minds Study." Please note that this study is a simply an extension to multiple sites of "The Michigan Healthy Minds Study," for which we received a Certificate of Confidentiality dated January 8th, 2006. That is, the present study is a multi-site (12 sites) version of the previous study. All sites are universities, and are listed in this application.

If there is any way we could receive this amended Certificate by September 15, 2007, we would be very grateful, as our study is scheduled to launch September 20, 2007.

Please contact me at 734.615.7764 or at daneis@umich.edu if you have any questions or concerns.

Thank you kindly,

Daniel Eisenberg

Daniel Eisenberg, PhD
Assistant Professor of Health Management and Policy
School of Public Health, University of Michigan
daneis@umich.edu, 734-615-7764
www-personal.umich.edu/~daneis
PI, www.healthymindsstudy.net

1. Name and address of the applicant research institution

Department of Health Management and Policy, School of Public Health, University of Michigan. 109 S. Observatory, SPH II. Ann Arbor, MI 48109-2029.

2. Sites where the research will be conducted and a brief description of the facilities available for the conduct of the research. Please indicate if this is a multi-site project.

This is a multi-site project. The data will be collected from students at 12 universities via web survey. The data will be collected by the Survey Sciences Group, LLC (SSG). SSG maintains a secure data environment by using dedicated, password-protected servers. SSG also maintains a company policy that includes respondent confidentiality. Violation of respondent confidentiality may result in termination under the policy. At the conclusion of data collection, SSG will deliver a de-identified dataset to the PI. The 12 sites are: University of Michigan, California State-Chico, Emory University, Illinois-Chicago, Illinois-Springfield, Illinois-Champaign Urbana, New Mexico State, North Carolina-Chapel Hill, North Carolina-Greensboro, Penn State, Tufts and Yeshiva.

The project directors at each site are listed below.

Chico State
Mimi Bommersbach
Licensed Psychologist, Interim Director
MLIB 141
CNTS - Psychological Counseling and Wellness Center
Chico. CA 95929
530-898-6345
mbommersbach@csuchico.edu

Emory
Mark McLeod
Director, Counseling Center; Adjunct Psychology Professor
Drawer TT
Atlanta, GA 30322
404-727-7450
rmcleod@emory.edu

University of Illinois. Springfield
Judy Shipp
Director. Counseling Center and Student Support Services
One University Plaza, HRB 64
University of Illinois at Springfield
Springfield, IL 62703-5407
217-206-7122
jship1@uis.edu

University of Illinois, Chicago
Patricia Inman
Assistant to the Vice Chancellor
Office of the Vice Chancellor for Student Affairs (MC 600)
Suite 3010 Student Services Building
Chicago, IL 60607-7165
312-996-7744
pinman@uic.edu

University of Illinois, Urbana
Renee Romano
Vice Chancellor for Student Affairs
120 Swanlund
601 E. John Street
Champaign, LI 61820
217-333-1300
romano@sab.uiuc.edu

New Mexico State
John Irvine
Director, Counseling
NSC 3575
Las Cruces, NM 88015
505-646-2731
jirvine@nmsu.edu

University of North Carolina, Greensboror
Jeanne Irwin-Olsen
UNCG Student Health Services
007 Grove Building-107 Gray Drive
Greensboro, NC
336-334-3079
jrirwino@uncg.edu

University of North Carolina, Chapel Hill
Dan Darnell
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Counseling and Wellness Services (CWS) CB# 7470 Campus Health Services Bldg.
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(919) 966-3658
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Penn State
Ben Locke
Assistant Director, Research and Technology
0221 Ritenour Building

University Park, PA 16802
814-863-0395
BDL10@sa.psu.edu

Tufts
Marilyn Downs
Supervising Clinician/Prevention Director Counseling and Mental Health Service
120 Curtis Street
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617/627-3360
Marilyn.Downs@tufts.edu

Yeshiva
Chaim Nissel
Director, Counseling Center
500 West 185 Street
New York, NY 10033
646-685-0115
drnissel@yu.edu

3. Title of the research project.

The Healthy Minds Study: Needs for, Barriers to, and Utilization of Mental Health Services by University Students.

4. Source and number of the supporting grant, if applicable.

(b) (4)

5. IRB Approval.

Documentation of approval from the University of Michigan IRB-Health Sciences is appended to this application. The University of Michigan Federalwide Assurance number is: FWA00004969, Expiration 5/10/09.

We also have IRB approvals from the following sites on file and are prepared to show them to NIH upon request:

Illinois-Chicago
Illinois-Springfield
Yeshiva

We expect to obtain IRB approvals from the other sites very soon, and will notify NIH as we receive them.

6. Name, title, mailing, and email address of the applicant and key personnel.

Daniel Eisenberg, PhD is the Principal Investigator for this project.

Daniel Eisenberg, PhD
Department of Health Management and Policy
School of Public Health, University of Michigan.
109 S. Observatory, SPH II.
Ann Arbor, MI 48109-2029.
daneis@umich.edu
Phone: 734.615.7764
Fax: 734.764.4338

Dr. Eisenberg is an Assistant Professor in the Department of Health Management and Policy in the School of Public Health. He received his PhD in Economics from Stanford University in 2002, and completed a NIMH-funded postdoc at UC-Berkeley from 2002 to 2004. Since arriving at Michigan in 2004, he has participated in and developed a number of research projects related to mental health. He is Principal Investigator of the Healthy Minds Study and has published several papers from this study.

Other key personnel at the lead site (University of Michigan) include Kamilah Neighbors, MHSA, and Emily Nicklett, MSW. Both are doctoral students at the University of Michigan School of Public Health, in the Health Services, Organization, and Policy program.

7. Beginning and end date of the project.

10/1/07 – 10/1/09

8. Project aims and research methods.

Mental health needs have increased steadily in recent years at college campuses nationwide. Our aims are to understand the extent to which university students with mental health problems are receiving needed services and to understand key determinants of whether students receive needed services. In order to accomplish these aims, we will conduct a web-based survey sent to 1,000 students at each of 13 universities in October 2007. We expect about 6,500 respondents, assuming a 50% response rate. In early November 2007 we will then conduct a follow-up of a randomly selected group of 500 non-respondents (from the full national sample of non-respondents). The follow-up will consist of a much shorter phone interview (15 questions) and will allow us to determine whether our initial sample was representative of the full student populations. We expect about 250 respondents (out of an initial random sample of 500) from this non-respondent follow-up, for a total of about 6,750 subjects in the study.

In the survey we will gather data on a variety of domains important to mental health: mental health status, access and barriers to services, utilization of services, social context,

academic environment, academic performance, and healthiness of lifestyles (e.g. substance use and gambling). This set of domains represents key factors affecting students' mental health.

9. Protection of subjects' identities.

Identifying information (email addresses) will used to recruit subjects but will be stored separately from survey response data. Respondent confidentiality will be protected through the data management and security procedures including keeping the linking file in a locked office, limiting access to this file to the PI, protecting electronic files with encryption and password protection, limiting who has access to the network where the file will be kept, and use of a dedicated server during the data collection efforts. Additionally, the survey firm will restrict access to survey respondents to only those whose job requires the knowledge. SSG also maintains a company policy that includes respondent confidentiality. Violation of respondent confidentiality may result in termination under the policy. Use of study generated IDs in all respondent communications that have no significance outside of this study will also protect respondent confidentiality. And ultimately, in the final analytic data file, no identifiable information will be included. When responses are reported, they will be so in aggregate and will not uniquely identify a respondent.

10. Reason for requesting a Certificate of Confidentiality.

We will be collecting sensitive information related to mental health status, mental health services use, and substance use. We will also have identifying information for our entire sample, although this information will be kept in a separate file that is matched by unique identifiers. We are requesting a certificate of confidentiality so that we may give our subjects every possible assurance that their survey data will not be able to be identified.

11. Informed consent.

The informed consent form is attached.

12. Drugs to be administered in extramural research.

No drugs of any kind will be delivered in this research.

13. This research does not involve the administration of any types of drugs.

14. This research project is not testing for reportable communicable diseases.

Assurances

The following assurances are required and the following information should be inserted verbatim into the Certificate application letter. Both the PI and the Institutional Official must sign this letter:

> This institution agrees to use the Certificate of Confidentiality to protect against the compelled disclosure of personally identifiable information and to support and defend the authority of the Certificate against legal challenges.
>
> The institution and personnel involved in the conduct of the research will comply with the applicable Federal regulation for the protection of human subjects or, if no such Federal regulation is otherwise applicable, they will comply with 45 CFR Part 46.
>
> This Certificate of Confidentiality will not be represented as an endorsement of the project by the DHHS or NIH or used to coerce individuals to participate in the research project.
>
> All subjects will be informed that a Certificate has been issued, and they will be given a description of the protection provided by the Certificate.
>
> Any research participant entering the project after expiration or termination of the Certificate will be informed that the protection afforded by the Certificate does not apply to them.

Signature of Principal Investigator

Signature of Institutional Official

Judith A. Nowack
Associate Vice President for Research

Name and Title of Institutional Official

Healthy Minds Study Consent Form

- Who is doing this study?

This study is a partnership between Daniel Eisenberg, PhD, Assistant Professor at the University of Michigan School of Public Health and [insert local contact].

- Why are you doing this research?

We are trying to better understand issues related to undergraduate and graduate students' well-being, sources of support, and mental and emotional health. This study is important to furthering knowledge about how students are handling the stresses of university life and how well their mental and emotional health needs are being met. We will provide the results (without any individually identifiable information) to school administrators and other community members to help them think about how to improve student life.

- What will taking this survey be like?

The survey takes 10-20 minutes for most students to complete, though it may take less or more time for some students. You must be 18 or older to take this survey. You will be asked questions about your moods and emotions, mental health and emotional issues you have experienced, support you may or may not have received, and your academic life. While in the survey, you will be able to stop at any time by closing your browser. You may then return to the questionnaire later. All responses you had entered and submitted will be saved. We ask that you complete the survey within 14 days.

- What are the risks associated with my participation?

Some of the questions will ask you about sensitive or personal information such as your emotional health. These questions might make you feel uncomfortable or anxious. You can skip any questions you do not want to answer. At the conclusion of the survey you will receive a list of resources on campus that can provide you with help and support. If responding to any questions makes you feel worried or unhappy, we urge you to call any of the resources listed. Your participation is voluntary -- your refusal to participate will involve no penalty of any sort. You may discontinue participation at any time.

- Who will benefit from my participation in this research?

We expect this research to be used to improve student life, so students at your school and nationwide may ultimately benefit from the knowledge obtained in this study.

Additionally, you will be entered into a sweepstakes to be conducted on December 15, 2007 for cash prizes totaling $4,000 (ten $250 prizes and three $500 prizes) regardless of whether you complete the survey. The drawing will be conducted by the Survey Sciences Group, LLC on 220 E. Huron St. in Ann Arbor, MI. The chance of winning a

prize is approximately 1 in 300. Winners will be notified immediately by email, and prizes will be mailed as checks.

- How will my privacy and confidentiality be protected?

Your confidentiality will be maintained to the degree permitted by the technology used. Specifically, no guarantees can be made regarding the interception nof data sent via the Internet by any third parties. The survey was designed to protect your privacy and confidentiality. The Survey Sciences Group, LLC (SSG), has been hired to help ensure your confidentiality by maintaining all study records. They will use Secure Sockets Layer (SSL) encryption technology to ensure that your responses are not intercepted in transmission, and will provide physical and logical restrictions to protect your data once it has been collected. The researchers will never know your name, email address, or any other identifiable information. Any reports or articles that we write will describe the data in the aggregate and will contain no information that could allow somebody to identify you. Survey Sciences Group, LLC has conducted several studies of sensitive issues among college student populations, and they use the most sophisticated technology available to assure security and confidentiality. The security and confidentiality maintained by the Survey Sciences Group has never been breached.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project if you indicate that you are at imminent and serious risk to harm yourself or others.

The data from this study, without any identifiable information, will be retained in a secure repository for future research purposes. Records will be kept confidential to the extent provided by federal, state, and local law. However, the Institutional Review Board, the sponsor of the study, or university and government officials responsible for monitoring this study may inspect these records. Also, please be aware that even though researchers will not know your name, the data collection firm will have your name in order to send you follow up emails if necessary. If you participate in the present study, you may be contacted in future years for a follow-up study.

- What if I have questions about the survey?

If you have questions about this research, the survey questions, or this consent process, you can contact the researchers at info@healthymindsstudy.net or (734) 213-4600, ext 470. You may also contact the PI of this study, Dr. Daniel Eisenberg at (daneis@umich.edu) or 734-615-7764, or the local PI, [insert local contact info].

Should you have questions regarding your rights as a research participant or feel that you have been harmed by this research, please contact the Institutional Review Board at the University of Michigan, 540 E. Liberty Street, Suite 202, Ann Arbor, MI 48104-2210, (734) 936-0933, email: irbhsbs@umich.edu.

Please click the link at the bottom of the screen if you wish to print a copy of this consent form.

- I have read the information given above, I am at least 18 years old, and I CONSENT to participate in this study.
- I do not wish to participate in this study and understand that there is no penalty for not participating.

THE UNIVERSITY OF MICHIGAN

BEHAVIORAL SCIENCES INSTITUTIONAL REVIEW BOARD
HEALTH SCIENCES INSTITUTIONAL REVIEW BOARD
540 EAST LIBERTY STREET, SUITE 202
ANN ARBOR, MICHIGAN 48104-2210
PHONE 734 936-0933 FAX: 734 998-9171
E-MAIL: irbhsbs@umich.edu WEBSITE: www.irb.research.umich.edu

November 27, 2006

Dr. Daniel Eisenberg
Department of Health Management and Policy
School of Public Health
University of Michigan
M3517 SPH II
Ann Arbor, MI 48109-2029

Dear Dr. Eisenberg,

This letter is to confirm that the Health Sciences Institutional Review Board (IRB) has reviewed and approved the amendment to your research proposal, UM Healthy Minds Study (HUM00000297/Ame00001869), pending resolution of the issue described below. Because this is a multi-site study, the UM IRB grants approval to conduct research at each participating institution when local IRB approval has been granted. The IRB determined that the research is compliant with applicable guidelines, state and federal regulations, and the University of Michigan's Federalwide Assurance with the Department of Health and Human Services (HHS).

- Submit documentation of the extension of the protections of the current study's Certificate of Confidentiality to each performance site.

Any proposed changes/amendments in the research (e.g., personnel, procedures, or documents), no matter how minor, must be approved in advance by the University of Michigan IRB unless necessary to eliminate apparent immediate hazards to research subjects.

The approval period for this project is 11/27/06-11/26/07. *Please note your expiration date.* If the project is scheduled to continue beyond this date, submit a Scheduled Continuing Review application at least two months prior to the expiration date to allow the University of Michigan IRB sufficient time to review and approve the project. If the approval lapses, no work may be conducted on this project until appropriate approval has been obtained, except as necessary to eliminate apparent immediate hazards to research subjects.

The University of Michigan IRB must be informed of all unanticipated or adverse events (i.e., physical, social, or emotional) or any new information that may affect the risk/benefit assessment of this research.

Sincerely,

Charles J. Kowalski

Charles J. Kowalski
Health Sciences IRB Co-Chair

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Mental Health
6001 Executive Boulevard
Bethesda, Maryland 20892

September 25, 2007

Daniel Eisenberg, Ph. D.
University of Michigan
School of Public Health
109 S. Observatory, SPH II
Ann Arbor, MI 48109-2029

Dear Dr. Eisenberg:

Enclosed is the amended Confidentiality Certificate protecting the identity of research subjects in your project entitled, "The Michigan Healthy Minds Study: Needs for, Barriers to, and Utilization of Mental Health Services by UM Students" also known as, "The Health Mind Study". Please note that the Certificate expires on March 31, 2010.

Please be sure that the consent form given to research participants accurately states the intended uses of personally identifiable information and the confidentiality protections, including the protection provided by the Certificate of Confidentiality with its limits and exceptions.

If you determine that the research project will not be completed by the expiration date, March 31, 2010, you must submit a written request for an extension of the Certificate three (3) months prior to the expiration date. If you make any changes to the protocol for this study, you should contact me regarding modification of this Certificate. Any requests for modifications of this Certificate must include the reason for the request, documentation of the most recent IRB approval, and the expected date for completion of the research project.

Please advise me of any situation in which the certificate is employed to resist disclosure of information in legal proceedings. Should attorneys for the project wish to discuss the use of the certificate, they may contact the Office of the NIH Legal Advisor, National Institutes of Health, at (301) 496-6043.

Correspondence should be sent to:

Ms. Olga Boikess
Office of Resource Management
National Institute of Mental Health
6001 Executive Boulevard, Room 8102 (MSC 9653)
Bethesda, Maryland 20892-9653
Telephone: (301) 443-3877
Fax: (301) 443-2578

Sincerely,

Olga Boikess

Enclosure

CONFIDENTIALITY CERTIFICATE

MH-06-003A

issued to

University of Michigan

conducting research known as

"The Michigan Healthy Minds Study: Needs for, Barriers to,

and Utilization of Mental Health Services by UM Students"

also known as

"The Healthy Minds Study"

In accordance with the provisions of section 301(d) of the Public Health Service Act 42 U.S.C. 241(d), this amended Certificate is issued in response to the request of the Principal Investigator, Daniel Eisenberg, Ph. D. to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Eisenberg is primarily responsible for the conduct of this research.

Under the authority vested in the Secretary of Health and Human Services by section 301(d), all persons who:

1. are enrolled in, employed by, or associated with the University of Michigan and its contractors or cooperating agencies, and

2. have in the course of their employment or association access to information that would identify individuals who are the subjects of the research pertaining to the project known as "The Michigan Healthy Minds Study: Needs for, Barriers to, and Utilization of Mental Health Services by UM Students" also known as "The Healthy Minds Study",

are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research

This certificate amends and extends the protections of Certificate of Confidentiality MH-06-003, "The Michigan Healthy Minds Study: Needs for, Barriers to, and Utilization of Mental Health Services by UM Students". The study is now being conducted at multiple sites.

This multi-site research study investigates mental health status, access and barriers to services, utilization of services, social context, academic environment, academic performance, and healthiness of lifestyles in a sample of university students.

A Certificate of Confidentiality is needed because sensitive information about mental health, substance use, illegal activity and psychological well being will be collected during the course of the study. The certificate will help researchers avoid involuntary disclosure that could expose subjects or their families to adverse economic, legal, psychological and social consequences.

All subjects will be assigned a coded number and identifying information and records will be kept in locked files.

This research is underway, and is now expected to end on March 31, 2010.

As provided in section 301 (d) of the Public Health Service Act 42 U.S.C. 241(d):

> "Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

This Certificate does not protect you from being compelled to make disclosures that: (1) have been consented to in writing by the research subject or the subject's legally authorized representative; (2) are required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or regulations issued under that Act; or (3) have been requested from a research project funded by NIH or DHHS by authorized representatives of those agencies for the purpose of audit or program review

This Certificate does not represent an endorsement of the research project by the Department of Health and Human Services. This Certificate is now in effect and will expire on March 31, 2010. The protection afforded by this Confidentiality Certificate is permanent with respect to any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during any time the Certificate is in effect.

Date: September 25, 2007

Patrick Shirdon
Acting Executive Officer

Olga Boikess
National Institute of Mental Health
6001 Executive Boulevard, Room 8222, MSC 9653
Bethesda, MD 20892-9653

Brent Loomis, Office of Resource Management
National Institute of Mental Health
6001 Executive Boulevard, Room 8222, MSC 9653
Bethesda, MD 20892-9653

February 12, 2010

Dear Ms. Boikess and Mr. Loomis:

I am writing to request an extension of the Certificate of Confidentiality that you granted on September 25, 2007 to our study, "The Healthy Minds Study." That certificate has an expiration date of March 31, 2010—I apologize for not sending this request at least three months prior to the expiration.

The reason for this request is that we are continuing our study as an annual data collection (using a very similar survey each year). We expect to continue this study for several years, and do not have a predetermined completion date. If you require a completion date for the purpose of the renewed certificate, then for now we could say July 1, 2012.

With this request we are enclosing our most IRB approval for the project, as well as the consent form (which remains nearly identical to the version in our application in 2007).

Please let us know if you need any other information.

Thank you for your help.

Best,

Daniel Eisenberg

Daniel Eisenberg, PhD
Assistant Professor of Health Management and Policy
School of Public Health, University of Michigan
daneis@umich.edu, 734-615-7764

Subject: eResearch Notification: Amendment Approved
From: <eresearch@umich.edu>
Date: Wed, 2 Dec 2009 11:12:29 -0500
To: <daneis@umich.edu>

Health Sciences and Behavioral Sciences Institutional Review Board • 540 East Liberty Street, Suite 202, Ann Arbor, MI 48104-2210 • phone (734) 936-0933 • fax (734) 998-9171 • irbhsbs@umich.edu

To: Daniel Eisenberg

From:
Richard Redman

Cc:
Jennifer Hefner
Justin Hunt
Marianne Hillemeier
Ezra Golberstein
Alisha Serras
Daniel Eisenberg
Emily Nicklett
Sarah Gollust
Kamilah Neighbors
Steven Brunwasser
Kara Zivin
Leslie Wimsatt
Daphne C Watkins
Corey Keyes
Scott Crawford
James Cranford
Kerri Wakefield

Subject: Amendment [Ame00015429] Approved for [HUM00000297]

SUBMISSION INFORMATION:
Study Title: Healthy Minds Study: Needs for, Barriers to, and Utilization of Mental Health Services among Undergraduate and Graduate Students
Full Study Title (if applicable):
Study eResearch ID: HUM00000297
Amendment eResearch ID: Ame00015429
Amendment Title: HUM00000297_Amendment - Wed Nov 25 13:25:01 EST 2009
Date of this Notification from IRB: 12/2/2009
Date of Approval for this Amendment: 12/2/2009
Current IRB Approval Period: 11/19/2009 - 11/18/2010
Expiration Date: Approval for this expires at **11:59 p.m. on 11/18/2010**
UM Federalwide Assurance (FWA): FWA00004969 expiring on 11/17/2011
OHRP IRB Registration Number(s): IRB00000245

Approved Risk Level(s) as of this Amendment:

Name	Risk Level
HUM00000297	No more than minimal risk

NOTICE OF IRB APPROVAL AND CONDITIONS:
The IRB HSBS
has reviewed and approved the amendment to the study referenced above. The IRB determined that the proposed research continues to conform with applicable guidelines, State and federal regulations, and the University of Michigan's Federalwide Assurance (FWA) with the Department of Health and Human Services (HHS). You must conduct this study in accordance with the description and information provided in the approved application and associated documents, as amended.

APPROVAL PERIOD AND EXPIRATION:
The approval period for this study is listed above. Please note the expiration date is not changed by the approval of this amendment. If the approval lapses, you may not conduct work on this study until appropriate approval has been re-established, except as necessary to eliminate

apparent immediate hazards to research subjects. Should the latter occur, you must notify the IRB Office as soon as possible.

IMPORTANT REMINDERS AND ADDITIONAL INFORMATION FOR INVESTIGATORS

APPROVED STUDY DOCUMENTS:
You must use any date-stamped versions of recruitment materials and informed consent documents available in the eResearch workspace (referenced above). Date-stamped materials are available in the "Currently Approved Documents" section on the "Documents" tab.

RENEWAL/TERMINATION:
At least two months prior to the expiration date, you should submit a continuing review application either to renew or terminate the study. Failure to allow sufficient time for IRB review may result in a lapse of approval that may also affect any funding associated with the study.

FUTURE AMENDMENTS:
All proposed changes to the study (e.g., personnel, procedures, or documents), must be approved in advance by the IRB through the amendment process, except as necessary to eliminate apparent immediate hazards to research subjects. Should the latter occur, you must notify the IRB Office as soon as possible.

AEs/ORIOs:
You must inform the IRB of all unanticipated events, adverse events (AEs), and other reportable information and occurrences (ORIOs). These include but are not limited to events and/or information that may have physical, psychological, social, legal, or economic impact on the research subjects or others.

Investigators and research staff are responsible for reporting information concerning the approved research to the IRB in a timely fashion, understanding and adhering to the reporting guidance (http://www.med.umich.edu/irbmed/ae_orio/index.htm), and not implementing any changes to the research without IRB approval of the change via an amendment submission. When changes are necessary to eliminate apparent immediate hazards to the subject, implement the change and report via an ORIO and/or amendment submission within 7 days after the action is taken. This includes all information with the potential to impact the risk or benefit assessments of the research.

SUBMITTING VIA eRESEARCH:
You can access the online forms for continuing review, amendments, and AEs/ORIOs in the eResearch workspace for this approved study, referenced above.

MORE INFORMATION:
You can find additional information about UM's Human Research Protection Program (HRPP) in the Operations Manual and other documents available at: www.research.umich.edu/hrpp.

Richard Redman
Chair, IRB HSBS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Mental Health
6001 Executive Boulevard
Bethesda, Maryland 20892

February 24, 2010

Daniel Eisenberg, Ph.D.
Assistant Professor
1415 Washington Heights
M3517 SPH II
Ann Arbor, Michigan 48109-2029

Dear Dr. Eisenberg:

RE: Confidentiality Certificate MH-06-003A, "The Michigan Healthy Minds Study: Needs for, Barriers to, and Utilization of Mental Health Services by UM Students" also known as, "The Health Mind Study".

This letter amends the Confidentiality Certificate protecting the identity of research subjects in your project entitled "The Michigan Healthy Minds Study: Needs for, Barriers to, and Utilization of Mental Health Services by UM Students" also known as, "The Health Mind Study", to extend the expiration date until June 30, 2013. This will enable the investigators to complete the research.

Be sure to attach this amendment to your copy of the original certificate.

If you determine that the research project will not be completed by the new expiration date June 30, 2013, you must submit a written request for an extension of the Certificate 3 months prior to the expiration date. Any such request must include the justification for the extension, documentation of the most recent IRB approval, and the expected date for completion of the research project.

Correspondence should be sent to:

Ms. Olga Boikess
Office of Resource Management
National Institute of Mental Health
6001 Executive Boulevard, Room 8102 (MSC 9653)
Bethesda, MD 20892-9653
Telephone: 301-443-3877

Sincerely,

Patrick Shirdon
Associate Director for Management, NIMH

Date: February 24, 2010

Green, Yolanda (NIH/NIMH) [E]

From: Boikess, Olga (NIH/NIMH) [E]
Sent: Monday, March 04, 2013 8:14 AM
To: Green, Yolanda (NIH/NIMH) [E]
Subject: FW: Renewing Healthy Minds Study CoC
Attachments: Extension of CoC (2010).pdf; Certificate of Confidentiality (2006).pdf; FINAL.IRB.APPROVAL2013.pdf; main survey consent -- AME33302 OCTOBER 2012 for 2013 STUDY.CLEAN.doc

Follow Up Flag: Follow up
Flag Status: Flagged

Please enter on the log, print out copies and make a file for this. You can also prepare a renewal letter.

Please visit me this AM to go over a few of the COC documents you worked on last week. Or let me know a good time and I will visit you. thanks Olga

From: Sarah Ketchen Lipson [mailto:sklipson@umich.edu]
Sent: Sunday, March 03, 2013 8:56 AM
To: Boikess, Olga (NIH/NIMH) [E]
Cc: Daniel Eisenberg
Subject: Renewing Healthy Minds Study CoC

Good morning, Olga,

I am writing to request an extension of the Certificate of Confidentiality, issued to the Healthy Minds Study by NIMH. I have attached the original approval letter and the extension issued on February 24, 2010. Our current CoC expires on June 30, 2013.

We are continuing to conduct the study on college campuses and would like to extend our coverage for another 3 years. Per the instructions online, I have also attached documentation of the University of Michigan Institutional Review Board's most recent approval for the Healthy Minds Study and a copy of the study's current consent form.

The address for correspondance is:
Daniel Eisenberg
M3517, SPH II
Department of Health Management & Policy
School of Public Health, University of Michigan
1415 Washington Heights
Ann Arbor, MI 48109-2029

Please let me know if you require any additional information. Thank you in advance for your help.

My best,
Sarah

--
Sarah Ketchen Lipson

University of Michigan, PhD student

School of Public Health, *Department of Health Management & Policy*
School of Education, *Center for the Study of Higher & Postsecondary Education*

Principal Investigator, U-SHAPE
University Study of Habits, Attitudes, and Perceptions around Eating
www.umich.edu/~ushape

www-personal.umich.edu/~sklipson
sklipson@umich.edu

UNIVERSITY OF MICHIGAN
eResearch.umich.edu

Health Sciences and Behavioral Sciences Institutional Review Board • 540 East Liberty Street, Suite 202, Ann Arbor, MI 48104-2210 • phone (734) 936-0933 • fax (734) 998-9171 • irbhsbs@umich.edu

To: Daniel Eisenberg

From:

Richard Redman

Cc:

Toben Nelson
Daniel Eisenberg
Joseph Himle
Sarah Lipson
Jamie Pease
Justin Hunt
Scott Crawford
Nikhil Dhawan
Todd Favorite

Subject: Amendment [Ame00033302] Approved for [HUM00000297]

SUBMISSION INFORMATION:
Study Title: Healthy Minds Study: Needs for, Barriers to, and Utilization of Mental Health Services among Undergraduate and Graduate Students
Full Study Title (if applicable):
Study eResearch ID: HUM00000297
Amendment eResearch ID: Ame00033302
Amendment Title: HUM00000297_Amendment - Wed Sep 26 13:37:03 EDT 2012
Date of this Notification from IRB: 1/24/2013
Date of Approval for this Amendment: 11/15/2012
Review: Full Committee
Current IRB Approval Period: 11/7/2012 - 11/6/2013
Expiration Date: Approval for this expires at **11:59 p.m. on 11/6/2013**
UM Federalwide Assurance (FWA): FWA00004969 expiring on 6/13/2014
OHRP IRB Registration Number(s): IRB00000245

Approved Risk Level(s) as of this Amendment:

Name	Risk Level
HUM00000297	No more than minimal risk

NOTICE OF IRB APPROVAL AND CONDITIONS:
The IRB HSBS has reviewed and approved the amendment to the study referenced above. The IRB determined that the proposed research continues to conform with applicable guidelines, State and federal regulations, and the University of Michigan's Federalwide Assurance (FWA) with the Department of Health and Human Services (HHS). You must conduct this study in accordance with the description and information provided in the approved application and associated documents, as amended.

APPROVAL PERIOD AND EXPIRATION: The approval period for this study is listed above. Please note the expiration date is not changed by the approval of this amendment. If the approval lapses, you may not conduct work on this study until appropriate approval has been re-established, except as necessary to eliminate apparent immediate hazards to research subjects. Should the latter occur, you must notify the IRB Office as soon as possible.

IMPORTANT REMINDERS AND ADDITIONAL INFORMATION FOR INVESTIGATORS

APPROVED STUDY DOCUMENTS:
You must use any date-stamped versions of recruitment materials and informed consent documents available in the eResearch workspace (referenced above). Date-stamped materials are available in the "Currently Approved Documents" section on the "Documents" tab.

RENEWAL/TERMINATION:
At least two months prior to the expiration date, you should submit a continuing review application either to renew or terminate the study. Failure to allow sufficient time for IRB review may result in a lapse of approval that may also affect any funding associated with the study.

FUTURE AMENDMENTS:
All proposed changes to the study (e.g., personnel, procedures, or documents), must be approved in advance by the IRB through the amendment process, except as necessary to eliminate apparent immediate hazards to research subjects. Should the latter occur, you must notify the IRB Office as soon as possible.

AEs/ORIOs:
You must inform the IRB of all unanticipated events, adverse events (AEs), and other reportable information and occurrences (ORIOs). These include but are not limited to events and/or information that may have physical, psychological, social, legal, or economic impact on the research subjects or others.

Investigators and research staff are responsible for reporting information concerning the approved research to the IRB in a timely fashion, understanding and adhering to the reporting guidance (http://www.med.umich.edu/irbmed/ae_orio/index.htm), and not implementing any changes to the research without IRB approval of the change via an amendment submission. When changes are necessary to eliminate apparent immediate hazards to the subject, implement the change and report via an ORIO and/or amendment submission within 7 days after the action is taken. This includes all information with the potential to impact the risk or benefit assessments of the research.

SUBMITTING VIA eRESEARCH:
You can access the online forms for continuing review, amendments, and AEs/ORIOs in the

eResearch workspace for this approved study, referenced above.

MORE INFORMATION:
You can find additional information about UM's Human Research Protection Program (HRPP) in the Operations Manual and other documents available at: www.research.umich.edu/hrpp.

Richard W Redman

Richard Redman
Chair, IRB HSBS

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Institute of Mental Health
6001 Executive Boulevard
Bethesda, Maryland 20892

March 5, 2013

Daniel Eisenberg, Ph.D.
M3517, SPH II
Department of Health Management & Policy
School of Public Health, University of Michigan
1415 Washington Heights
Ann Arbor, MI 48109-2029

Dear Dr. Eisenberg:

RE: Confidentiality Certificate MH-06-003, "Healthy Mind Study: Needs for, Barriers to, and Utilization of Mental Health Services among Undergraduate and Graduate Students".

This letter amends the Confidentiality Certificate protecting the identity of research subjects in your project entitled "Healthy Mind Study: Needs for, Barriers to, and Utilization of Mental Health Services among Undergraduate and Graduate Students", to extend the expiration date until December 31, 2017. This will enable the investigators to complete the research.

Be sure to attach this amendment to your copy of the original certificate.

If you determine that the research project will not be completed by the new expiration date December 31, 2017, you must submit a written request for an extension of the Certificate three months prior to the expiration date. Any such request must include the justification for the extension, documentation of the most recent IRB approval, and the expected date for completion of the research project.

Correspondence should be sent to:

Ms. Olga Boikess
Office of Resource Management
National Institute of Mental Health
6001 Executive Boulevard, Room 7101 (MSC 9653)
Bethesda, MD 20892-9653

Sincerely,

Philip Sung-En Wang, M.D., Dr.P.H.
Deputy Director
National Institute of Mental Health