



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.

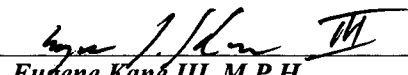
Please advise me of any situation in which the certificate is employed to resist disclosure of information in legal proceedings. Should attorneys for the project wish to discuss the use of the certificate, they may contact the Office of the NIH Legal Advisor, National Institutes of Health, at (301) 496-6043.

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



**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.

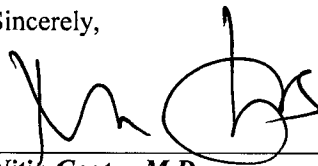
As provided in section 301 (d) of the Public Health Service Act 42 U.S.C. 241(d):

"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

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***Nitih 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
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## 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
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## 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](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 14<sup>th</sup>, 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.

\_\_\_\_\_  
 Signature of Principal Investigator

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

\_\_\_\_\_  
 9/14/2016  
 Date

\_\_\_\_\_  
 Signature of Institutional Official

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

\_\_\_\_\_  
 9/15-2016  
 Date



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

### **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](mailto:healthyminds@umich.edu). You may also contact the principal investigator of this study, Daniel Eisenberg at [daneis@umich.edu](mailto:daneis@umich.edu), or [local contact name, email address, phone]. You can also the CCMH researchers at [bdl10@psu.edu](mailto: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](mailto:irbhsbs@umich.edu), or toll free (866) 936-0933.

Please click [HERE](#) if you wish to print a copy of this consent form.