



Research Design

1a.) Objective

The Healthy Minds Study (HMS) is a survey-based study assessing mental health, health service utilization, and related factors among college and university student populations. HMS is one of the only annual surveys of college/university populations that focuses exclusively on mental health and related factors, allowing for substantial detail in this area. The survey gathers data on a variety of domains connected to mental health, including: 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 a special emphasis on understanding service utilization and help-seeking behavior, including factors such as stigma, knowledge, and the role of peers and other potential gatekeepers.

The survey has several variants, all with the same basic design and scope, that are used for different cohorts of colleges/universities to investigate questions specific to their student population. Towards the end of this Research Design Document (see Section 4c), any differences from the standard design are highlighted and explained.

The research design for HMS has remained consistent over the years, and the design described in this application is nearly identical to the design used in academic year 2018-2019.

1b.) Acronym Key

To help with ease of reading this document, we have provided a key of common acronyms used throughout the protocol:

- HMN = Healthy Minds Network
- HMS = Healthy Minds Study
- SC = Study Coordinator
- PI = Principal Investigator
- RA = Research Assistant
- PC = Primary Contact (at participating institution - not an HMS Study Team member)
- UM = University of Michigan
- ORSP = Office of Research Sponsored Projects
- ITS = Information and Technological Services
- HMNs = Healthy Minds Network Terminal Server
- JED = Jed Foundation or JED Campus Program
- CCMH = Center for Collegiate Mental Health

2.) Specific Aims

Mental health needs have increased steadily in recent years at campuses nationwide.¹⁻⁵ Our primary aims are as follows:

- Understand the mental health needs and relevant health behaviors of college and university students.
- Understand the extent to which college and university students are receiving needed services.
- Understand key determinants of whether students receive needed services.
- Provide information about relevant resources to college and university students upon completing the survey.
- Provide data to colleges and universities to inform their mental health practices and policies.
- Explore a variety of topics related to student mental health via use of our elective module topics (see Section 4a.i of this document, and the Questionnaires uploaded to Section 3, "Other Protocol Materials" of the CIRBI Document Upload Page).

HMS has been successfully conducted with over 200 college and university campuses since 2005. Each year a different set of campuses participates in the study, although many campuses have participated multiple times over the years.

3.) Background and Significance

Mental illnesses have been referred to as the "chronic diseases of the young".⁶ Unlike with most physical health conditions, the disabling consequences of mental illness begin early in life. Roughly half of all lifetime mental disorders have first onset by mid-adolescence and nearly three quarters by the mid-twenties.⁷ Among adolescents and young adults in the U.S., mental illness accounts for a larger burden of disease than any other

class of health conditions.⁸ Though mental health treatment is increasingly effective and accessible,⁹ utilization rates remain low: less than 50% of adolescents and young adults with a serious mental illness receive any form of treatment.¹⁰ Left untreated, symptoms often become more frequent, severe, and treatment-resistant.¹¹ The Institute of Medicine (2009)¹² estimates the annual financial toll of mental health problems among young people to be roughly \$250 billion (not including lost productivity) with only \$45 billion directed to mental health treatment. With so few individuals seeking treatment, the vast majority of this financial burden is borne by the education, welfare, and justice systems. For these reasons and more, improving adolescent and young adult mental health is of key public health importance.

College and university campuses provide an ideal setting to identify, prevent, and treat mental illness during an epidemiologically vulnerable and psychosocially significant life period. For most of the 21 million students enrolled in U.S. postsecondary education (roughly half of all young adults nationwide),¹³ their college years will be the only time when a single setting encompasses the main aspects of their daily existence—academic, residential, social, and health. Four-year colleges and universities are typically integrated communities with substantial human and organizational resources that can be leveraged to enact change for entire student populations. There is a pressing need for change given that mental health problems are highly prevalent,¹⁴ appear to be increasing,¹⁵⁻¹⁶ and are typically untreated in college student populations.¹⁷ Estimates from nationally representative samples reveal that roughly one in three undergraduates meets diagnostic criteria for a mental illness.¹⁸ Student mental health is a significant predictor of many important functional outcomes, including social connectedness,¹⁹⁻²⁰ academic performance and retention,²¹⁻²² and future employment/workplace productivity.²³ Thus, improving student mental health would have not only a direct impact on individual wellbeing but also positive returns to colleges, universities, and society at large.

The HMS team brings a diverse collection of expertise to address these issues, from economics, education, health education, counseling, statistics, and more, and has been successfully conducting the survey study since 2005. Profiles on the HMS team are listed under the CIRBI Investigator and Administrative Personnel section. For the purposes of this document, “HMS team” refers to the Principal Investigator and co-Principal Investigator (PIs), the Study Coordinators (SCs), and Research Assistants (RAs), unless noted otherwise.

4a.) Methodology—Survey Design, School Recruitment, Participant Recruitment, Sharing Survey Results

Each wave of our project will proceed in four steps: (1) survey design; (2) school recruitment; (3) participant recruitment; and (4) sharing survey results.

(i.) Survey Design. The survey has remained largely consistent over the years, with minor changes each year to explore new topics or refine the measurement of existing topics. In the original survey design in 2005, we consulted with several other experts in the student mental health and substance abuse fields at UM and elsewhere and we reviewed the existing literature on student mental health. In developing our survey, we used previously validated and widely used instruments wherever possible. For example, we included depression and anxiety scales from the well-known Patient Health Questionnaire (PHQ) and Generalized Anxiety Disorder 7-item (GAD-7) scale (with exception of two variants of HMS—see Section 4c). In other parts of the survey we modified previously used questions to the campus setting. We also created new questions in order to address issues that have not been addressed in this type of survey. The survey has taken 20-25 minutes on average for respondents to complete in the most recent study years, and in compiling the current survey, we have maintained a similar length.

The HMS survey is comprised of a series of sections, or “modules”. There are three standard modules (Demographics, Mental Health Status, and Mental Health Service Utilization/Help-Seeking) that form the core of the survey and are always present. In addition to these three standard modules, schools elect to administer two or three elective modules from a menu of options (Knowledge and Attitudes about Mental Health and Mental Health Services, Upstander/Bystander Behaviors (half module), Campus Culture and Climate, Resilience and Coping, Sleep (half module), Substance Use, Eating and Body Image, Sexual Assault, Overall Health, Academic Competition, Academic Persistence and Retention, Financial Stress, Diversity, Equity, and Inclusion, and Attitudes About Mobile Resources) (see Questionnaires uploaded to section 3, “Other Protocol Materials,” of the CIRBI Document Upload Page), if their variant allows for the choice (see Section 4c of this document). Participating colleges and universities also have the option to add up to 10 custom questions to the survey (which the research team may use for research purposes). These questions are chosen by the participating campuses, and our study team does not impose any restrictions except that we look at the questions to confirm that they are not introducing any new risks to the participants (e.g., questions that are substantially more sensitive or might cause substantially more discomfort than the existing questions). Among schools that have included these extra questions, they have typically chosen questions that are very similar to the general topics in the core questionnaire—a mix of non-sensitive (e.g., asking about perceptions of campus climate) and sensitive questions (e.g., asking about drinking behavior and mental health). When a college or university elects to add custom questions, our study team will thoroughly review and vet them, using our expertise in the field, and will reserve the right to exclude any of the custom questions if they do not (1) maintain minimal risk and discomfort to student respondents, and (2) if they do not hold up to our standards of collecting reliable data of integrity.

(ii.) School Recruitment. Though HMS is now quite well known throughout the campus mental health networks, our research team will continue to actively recruit colleges and universities to participate in the

study. To find schools to recruit, the team advertises HMS through several channels including but not limited to listservs, the Healthy Minds Network (healthymindsnetwork.org), and research briefs. If a school is interested in enrolling, they will contact the study team (primary email contact: healthyminds@umich.edu). Otherwise, schools will be recruited through partner organizations (see Section 4c).

Enrolling school in study. Schools that elect to participate will first provide SCs with the name and contact information of someone who the school has designated their Primary Contact (PC). The PC is responsible for coordinating all communication between the participating school and the HMS team (usually through the SCs). The PC will then work with their school's administration to have the appropriate official sign a participation contract (Research Agreement) with UM [drafted and overseen by the UM Office of Research Sponsored Projects (ORSP) and Contracts Office]. These two steps must be completed before any data collection may occur. The schools will also submit payment to the study team (collected through the UM School of Public Health, Department of Health Management and Policy), although this does not necessarily have to occur prior to data collection. Unless part of an organization or cohort which predetermines the schools' elective module choices (see Section 4c), participating colleges and universities will also select which modules to administer on their campus. All schools (regardless of variant) will participate in the three standard modules. Schools not part of a cohort with pre-determined modules will select approximately two additional modules from a list of elective modules.

Participating schools will also provide customization specifications for local resources to include in the survey endings and recruitment documents, as well as customized questions or additional module selections, if desired.

Obtaining recruitment data. To finish the enrollment process, schools will provide our team with a sample file of students from their Registrar's Office by submitting their sample file in the Qualtrics enrollment form (see Section 4a.ii-3). We will need to collect the following student-level variables from each school's Registrar's office for recruitment, sampling, assessment of nonresponse bias, and analysis (described below): first name, email address, sex, race/ethnicity, degree level (undergraduate/graduate), year in program, and cumulative GPA.

Aside from name and email, the other variables are optional for institutions to provide; these variables are not required to administer the survey, but contribute to data quality by allowing us to construct survey sample weights, adjusting for potential differences between survey responders and non-responders. Rigorous adjustment for survey non-response is essential, because overall response rates in HMS have been in the range of 20-25% most years, which is typical for online surveys.

This information will be obtained before the recruitment of individual students. The institution may be permitted to share the administrative data listed above for all students recruited for the study consistent with the guidelines of the Family Educational Rights and Privacy Act (FERPA). These guidelines allow schools to disclose those records, without consent, to the following parties or under conditions (34 CFR 99.31(a)(6)) including organizations conducting certain studies for or on behalf of the school. In particular, an academic institution could determine that these studies help develop, administer, or validate predictive tests, administer student aid programs, or improve instruction. Our study is consistent with these specifications in multiple ways. For example, our study is administering and validating mental health screening tests to see how well they predict academic outcomes. More generally, our study aims to understand more about how the learning environment (i.e., instruction) can be improved through addressing mental health.

A school may, if they so choose, omit any of the variables above from their sample file, with the exception of (1) student first names and (2) email addresses. Student's first name is necessary for customizing the email templates using Qualtrics' piped-text feature. The email addresses are necessary for dissemination of the recruitment/reminder emails to recruited students.

The optional variables, when provided, will be part of the sample file uploaded to Qualtrics, and will thus be embedded to students' survey data. Due to Qualtrics' anonymizing function, no contact information will be embedded or directly linked to any survey data (see Section 4a.iii-2).

The HMS team will receive the data file of students at each participating college or university in Excel format. The school's local IRB or Registrar's Office randomly pre-selects the HMS recruitment sample (this is our preferred method because campuses usually administer many surveys and thus have a system for creating random samples, and ensuring that surveys are equally distributed across the student body). Furthermore, we seek to avoid receiving any information about students who will not participate in our study. Otherwise, if the school cannot create a random sample with which to provide us, the school may provide the HMS team with a data file that will contain all possible students that are eligible to participate. If the HMS team conducts the random sampling to create the recruitment sample, the remaining data on students that were not selected will be destroyed.

Upon receiving the sample file from the institution, the HMS team will assign a unique numeric identifier to each participant. This number corresponds to when the participant was recruited to our study during the given academic year (e.g., 1 = first student listed in the first school sample recruited to HMS that year,

10189 = the 10,189th student recruited to HMS that year). The unique, numeric identifier is used to link students' de-identified survey data to their contact information provided in the original sample file, for the purposes of conducting the sweepstakes drawing and any additional incentive drawings (see Section 4a.iii-5 of this document), or for potential follow-up (longitudinal) analyses (see Section 4b), should a school request such analyses. This is a necessary precaution, enabling us to keep students survey data strictly confidential—only the HMS team (PIs and SCs) will ever have access to the key to link identifying sample data to survey data.

Enrollment methods and security. All files, information, and additional customization resources from schools will be sent to our study team via a Qualtrics “school enrollment” form. The primary contact at each school will be given an individualized link to the enrollment form, creating a form unique to their school, accessible only to those with whom they share their form link. No one else other than the HMS SCs and PIs will have access to a school’s form. This Qualtrics form will serve as a step-by-step guide to the above steps necessary for enrolling and on-boarding a school in HMS for the given academic year. There will be one task per page, and at the end of each page, PCs will be able to enter the necessary information, or upload the necessary files, to complete that task. PCs will be given the ability to skip through the form and complete what they can, when they are able—they will not be required to complete one page before advancing to the next. All data entered in and uploaded to a school’s form will be downloaded by one of the HMS SCs, who will download all school-related information and files directly to the Study Team’s O:Drive (refer to Section 4b of this document). School information is organized by (1) academic year, (2) HMS-version, and (3) school, to avoid misplacement or mislabeling of information. Only the HMS team will have access to these school folders on the Drive. Finally, these folders will be kept completely separate from the folders which will contain participating schools’ de-identified survey data (which will also be accessible only to the HMS team). The process of having the SCs download the data directly to the Drive, and avoiding sharing Drive folders with PCs, is used to (1) increase data security by limiting access to any folders on our Drive to only people on the HMS team, and avoid sharing of school and student information over email, which is non-secure due to risk of hacking, breach, and data loss. Furthermore, Qualtrics has been deemed by the UM Information and Technological Services (ITS) as a “Safe Computing” resource for all of our purposes outlined above (<https://www.safecomputing.umich.edu/dataguide/?q=node/211>).

Each student in a given school sample will be assigned a unique survey link, generated by Qualtrics’ email distribution function. In other words, if there are 4,000 students in a random sample from a participating institution, Qualtrics will automatically generate 4,000 unique survey links, once we upload the sample file to Qualtrics. This unique link will be piped into the student emails. The unique survey link has no significance outside of the study.

(iii.) Participant Recruitment and Communication: On campuses with $\geq 4,000$ students, the HMS team will invite 4,000 students per school to complete the survey (or all students at schools with $< 4,000$ students). All invited participants will be currently enrolled students who are at least 18 years old. The HMS team does not wish to exclude 18 year olds in states where the age of majority is greater than 18 as the study does not pose more than minimal risk to participants. We believe that including these 18 year olds in this study will enhance the value of the research to society and the relevance of findings for these institutions. If we are to produce results representative of the first year population, we will need to include 18 year olds in these states. The risks for 18 year olds residing in these select states should not be different than for other 18 year olds. They are at the same stage of education and undergoing the same developmental transitions.

Email logistics. Dissemination of the online survey to students will be conducted by email. To send out emails to students on each of the participating campuses, the HMS team is working with Qualtrics, a web-based survey and communications company.

After enrolling in the study, the HMS team will create an email address for HMS at that school, through Qualtrics. The study team will request that the email address be `healthyminds_[schoolname]@umich.edu`, but some schools may prefer to use a different address. The name of the email address will in no way impact the protection of human subjects. The email address must use the `@umich.edu` domain in order to be compatible with Qualtrics’ emailing distribution function. We work with the school to create this address because this partnership enhances the legitimacy of the study for students (because emails come from an account with the school’s name or abbreviation referenced—e.g., `healthyminds_[schoolname]@umich.edu`, as described below), is a sustainable approach to recruitment/communication as the study expands to more sites (asking each participating institutions’ ITS department to send out the emails is an unrealistic approach for a national study of this nature), and upholds the privacy and confidentiality for human subjects. In creating this email account, the HMS Team will set the forwarding address to `tohms-coordination@umich.edu` (the coordination account for HMS). The HMS team has access to this email account, and is thus able to respond to any questions or concerns students may have regarding the study. All communication from students will be delivered to `hms-coordination@umich.edu`, including any bounced-back emails or out of office replies.

Security. There are several other reasons that justify our decision to work with Qualtrics and our confidence in the proposed system. HMS is a large-scale study. If we recruit 4,000 from a given school, that will mean sending out 4,000 emails in a single day. The UM Gmail system will not allow for more than 2,000 emails to be sent, making it impossible for us to disseminate our survey to students using the UM email system.

To ensure confidentiality of survey responses, while still using Qualtrics for emailing students, we utilize Qualtrics' option to anonymize responses, thus preventing contact info from ever being directly linked to individuals' survey data, as well as preventing contact data from ever being downloaded with survey data. More information about Qualtrics anonymizing function can be read, here:

<https://www.qualtrics.com/support/survey-platform/survey-module/survey-options/survey-termination/#AnonymizingResponses>. This is why we will create the unique numeric identifiers to be assigned to each student in an institutions' sample file. This unique number will be entered in as an embedded data element to the Qualtrics survey software, and will be included in the survey data download. This way, when needed for incentivization, and if needed for non-response or longitudinal follow-up analyses, students' institutional data can be indirectly linked to their survey data, only by the HMS team.

To further ensure data security for both surveying and emailing, Qualtrics accounts are hidden behind passwords and all data is protected with real-time data replication. Only the HMS research team has access to the data through Qualtrics, protected by their individual passwords. Qualtrics' security is further detailed below (see Section 4.b). To learn more about how Qualtrics can be used to send emails and host the survey, while still keeping participants' identities confidential, Qualtrics Support has provided our team with the following videos on "anonymizing" surveys and using embedded data for indirect identifying: <https://www.screencast.com/t/1y3TwMYX> and <https://www.screencast.com/t/G21u47qE1DY>.

Survey dissemination. As mentioned, the HMS team will recruit students to complete the survey via email. The HMS team will begin recruitment with a brief "pre-notification" email. Survey methodologists have concluded that this initial notification can boost participation rates. Two to three days later, the team will schedule a recruitment email with a link to the online survey (i.e., data collection will begin with the recruitment email), and the team will follow-up with reminder emails to non-responders (up to three reminder emails in total, separated by approximately 5-7 days each), all via Qualtrics. In total, students may receive up to 5 emails about participating in HMS over the roughly 3 week data collection period (see Table 1). Students who complete the survey, or indicate they do not wish to participate (by emailing the research team to indicate this, clicking a Qualtrics-automated "opt-out" link at the bottom of any of their HMS-related emails, or not consenting on the consent page of the online survey), will not receive any further invitations. Based on our experience in recent years, we anticipate a total survey response rate of approximately 20 - 25%, with substantial variation across different types of institutions (e.g., residential v. commuter schools, 4-year v. 2-year institutions, small v. large schools, etc.).

Table 1. Communication with students randomly selected to participate in HMS

Email	Recipients	Timeframe
Pre-notification	All randomly selected students	2-3 days before data collection begins
Recruitment	All randomly selected students	First day of data collection
Reminder #1	Students who have not responded and have not indicated that they do not want to participate (by emailing the research team or by not consenting on the online consent form)	5-7 days after the recruitment email
Reminder #2	Students who have not responded and have not indicated that they do not want to participate (by emailing the research team or by not consenting on the online consent form)	10-14 days after the recruitment email
Reminder #3	Students who have not responded and have not indicated that they do not want to participate (by emailing the research team or by not consenting on the online consent form)	15-19 days after the recruitment email

Students will voluntarily access the HMS survey via the unique survey link listed in the recruitment and reminder emails. The link will take students to the online survey, where they will be presented with the HMS consent form. Students must give their consent in order to progress and confirm that they are at least 18 years old. If students consent to the survey, before they land on the first question, they will be shown a page that briefly re-iterates the component of minimal risk from the consent form. Specifically, students will be reminded that some of them may find the topics of our questions sensitive in nature, and thus they may be uncomfortable responding. We remind them of our research purposes for asking these questions, and thank them for their participation. The student will then click the “next button,” and be taken to the first question of the online survey (“What is your age in years?”). After the initial page (the consent form), the rest of the online survey will be the same for these students as for all other participants. If students are unable to take the whole survey at one time, they may return to their unique survey link at any point during the data collection period to continue where they left off. The final reminder email indicates the exact date of data collection completion.

Post-survey. Upon completion of the survey, participants will receive a list of helpful resources that are programmed into the last page of the survey. For students who do not consent, the survey ending will provide them with the contact information for their local counseling services. Students who do not complete the survey (i.e., begin but do not complete) see the main resources at the top of each page but because there is no survey ending (because they have not completed the survey), there is no other way to provide them with additional resources above and beyond the resources listed on every page. The list includes custom local resources that school contacts have provided for their students.

Survey endings are displayed within Qualtrics and are not sent via email (i.e., sensitive identifiable information is not being transmitted via email). There will be two types of survey endings: (1) for students who do not consent, and (2) for students who complete the survey (see document titled “HMS_Survey Endings” uploaded to Section 2, Recruitment Materials, of CIRBI Document Upload Page).

Note that the survey endings reflect a recent enhancement to HMS, relative to study years before 2015. There is a growing trend in online health screens/interventions whereby respondents receive immediate feedback (this is increasingly the expectation). In response to this, the HMS survey endings (for respondents only) now provide some basic information with results from the validated mental health screens. Our hope is that this feedback will increase the relevance of listed mental health resources and thus increase the likelihood of help-seeking for students in need. Another important enhancement that is operationalized in the survey endings is that we are taking a more proactive approach to connect students with relevant resources based on their survey results. Over the years we have developed many partnerships with interventionists (e.g., the Healthy Body Image Program at Stanford, through which we ran a pilot program linking from one of our previous surveys). Our hope is that we will be able to connect students in need with available online resources following completion of HMS.

All of the emailing templates, survey templates, and current survey-ending templates are stored in a Qualtrics HMS group library, which each HMS team member has monitored access to via their UM Uniqname institutional Qualtrics account. A Qualtrics group library is a shared library between certain accounts that enables users to store surveys, graphics, messages, and other file types within their Qualtrics libraries. A Qualtrics group library is used to facilitate secure content sharing. Group members will see an associated library where they can access content shared by all group members. The HMS group library is maintained by the UM ITS Qualtrics team, and permission to access the group library must be approved by the study PIs, and ultimately granted by the UM ITS Qualtrics team.

Incentives. Incentives have been shown to improve response rates significantly in survey studies of college students. All students recruited to HMS will be entered into a drawing with all other participants at all participating institutions for one of ten \$100 prizes and one of two \$500 prizes. Prizes will be in the form of Amazon.com gift cards.

In addition to the standard incentives, some schools wish to offer their own student samples an additional, school-specific incentive. In every case, this has been additional prizes as part of the sweepstakes. To ensure that this type of school-specific customization is properly documented and reviewed, the HMS team only considers allowing school-specific incentives that are requested by schools several weeks in advance of the planned data collection.

After data collection has concluded at a given school, the HMS team will provide the PC with the randomly selected student(s)' first name(s) and email(s) of the winner(s) of the school-specific incentive(s) for him/her to contact them with instructions on how to obtain their prize. As an example, if a school offers three Amazon gift cards as additional incentives, our team will provide the primary contact of that school with the first names and emails of three randomly selected students for him/her to contact those students with instructions on how to obtain their prize. Our study team provides the primary contacts at each school the names and emails of winners because our study team doesn't have the specific information/instructions on how students should obtain their prize.

(iv.) Sharing Survey Results. Following data analysis, we will prepare academic articles for publication. We will also prepare a summary report for each participating institution. This report will not contain any identifiable information (i.e., name, email address, numeric identifier, other Registrar-obtained data, or a student's sports team affiliation or country of origin) or provide detail that would allow an institution to come close to identifying a participant. The report will be univariate, a simple descriptive statistic (percentage or mean) of the overall sample for each survey item, with an indication of how this institution compares to other HMS participating institutions during that academic year (e.g., significantly higher or lower than the other institutions). An example of this report is available here (note that this is the 2016-17 national HMS report and is not school-specific):

http://healthymindsnetwork.org/system/resources/W1siZiIsIjIwMTcvMDkvMTIvMTNfMjZfMDRfMTgzXohNU19uYXRpb25hbC5wZGYiXVo/HMS_national.pdf. We will provide this report to the participating school contact. It is expected that the school contact will share the report with school administrators as well as communicate the findings to the student community. The school contact will also receive an economic case memo report, which includes only aggregate data, and translates some of the survey findings into an economic case for supporting student mental health services and programs. School contacts will be given access to a data interface tool (<http://data.healthymindsnetwork.org/>), which may be used to visualize graphical representations of their aggregate results, and compare it to the national sample and similar (but de-identified) institutions. These graphs are created from mean scores or counts and percentages for given items, and can be stratified by certain demographics. Finally, school contacts will be given a de-identified data set of their survey data (i.e., name, email address, and other Registrar-obtained data will never be included in data regardless; numeric identifier, students' sports team affiliations and countries of origin will all be removed to prevent direct and deductive-identification), including calculated scores for mental health scales (depression, anxiety, eating disorders), and clarifying labels/names ascribed to each column in the data set. The data shared with the school contact or other researchers will always be de-identified. Additionally, in order to reduce the risk of re-identification, the study team looks for and eliminates select demographic variables for unique cases that may be easy to identify (e.g., eliminating the race item response for the only African American female in a university's pharmacy program) within a dataset prior to providing the dataset to the participating school. Furthermore, these individuals will never have access to any other identifiable data. Identifiable data will never be shared with the school contact or other institutions.

All de-identified data and related data reports shared with schools will be shared with them using the UM+Box file sharing platform (refer to Section 4b of this document).

Data sharing: cohort administrators (see Section 4c). For JED Campus Program (JED) or Center for Collegiate Mental Health (CCMH) member schools, school-identified (not individual-identified) data will be shared with researchers at CCMH and JED. The data shared with CCMH and JED will contain aggregated de-identified data from all of the survey measures. CCMH and JED will also receive de-identified data sets for any follow-up surveys or additional analyses conducted for this study. This will be stated in the consent form. As mentioned in Section 4c of this document, each school participating in the HMS-CCMH+JED survey will have two iterations of the study, separated by 3-4 years. These iterations will each be cross-sectional by design, employing a random sampling technique. We will not implement any longitudinal surveying techniques, even among students who may be randomly sampled during both iterations (i.e., there will be no individual-level pre/post analyses or follow-up). JED's main interest in looking at this survey data is evaluating the potential relations between administrative data, policy change and student level data. CCMH's main interest is looking at this survey data as a point of comparison to the data they routinely collect on their end from counseling center clients. They want to know how counseling center clients compare to general student populations.

As mentioned earlier in this document, for other cohorts that are coordinated by a third-party

organization, collaborative group, or government agency, we may share school-identified data sets and reports with the overseeing organization, if they so request, in the exact same manner that we do with CCMH and JED for their member schools. Member schools of any special cohort will be made clear of the terms of data sharing in the terms of agreement in their Research Agreement contract, and students will be made clear of how their data is shared in their consent forms. As with JED and CCMH, and the schools themselves, no one outside of the HMS team will ever be shared survey data that has any sort of direct identifiers of individual students. Furthermore, all data will be removed of variables that may lead to deductive identification of individual students.

Data sharing: outside researchers. Finally, upon request, researchers who propose a legitimate use of our study data to advance their own research on mental health may be given access to our national, de-identified data set, for any of our completed study years. This data set will not have any individual direct or indirect (deductive) identifiers (as described in Section 4a), and will also be de-identified with regards to participating institutions (i.e., the names of respondents' affiliated schools will not be included in the data set).

In specific cases, some researchers wish to conduct regional analyses of student mental health. In these cases, we have created data sets that break up the schools into one of ten regional variables (Northeast Region-New England, Northeast Region-Middle Atlantic, Midwest Region East North, Midwest Region West North, South Region South Atlantic, South Region East South Central, South Region West South Central, West Region Mountain, West Region Pacific, International). This data set is still completely de-identified on the individual respondent level, and is still de-identified on the institutional level. Our study team has made sure that there is no risk of deductive identification of schools or individuals in the regional data sets that we share with outside researchers.

In even rarer cases, in which a researcher proposes a legitimate need for school names to be included in the data set (e.g., comparisons between specific institutions, analysis of data in context of programs or campaigns in which specific schools are participating, etc.), researchers will be granted access to school-identified data sets. These data sets will still be completely de-identified, with regard to individual respondents. The only difference is that these data sets include a variable that has the name of the school with which the respondent is affiliated. Researchers using a school-identified data set will be required to agree to never publish, present, or otherwise publicize any participating institution's name, or allow for the possibility of deductive-identification of participating institutions and their school-specific results. If researchers outside of the HMS team request this school-identified data set, rather than the standard de-identified and school-de-identified data sets (described in the beginning of Section 4a.iv-2 of this document), the external researcher will be expected to sign and abide by the Data Use Agreement associated with our HMS data repository application (regulated by UM-IRB, application number: REPO0000042), and oversight by the UM ORSP.

4b.) Methodology—Data Storage, Transfer, and Security

The identifiable institutional data and the survey data will both be stored in separate file-paths on the O:Drive. The O:Drive is an external file server, accessible only to the HMS team, and managed by the UM Institute for Social Research (ISR) ITS. This file server is password-protected via individual Study Team member's institutional login-information, and is regularly backed-up on-site. Any sensitive data will be stored on this file server. Access to the file server is highly restricted. Designated project members will be granted access to the file server. Access is controlled by Active Directory users and groups (O:Drive security specifications are further detailed, below).

For added security, the HMS team, along with UM ITS (both general and ISR-specific), have put two other safeguards in place.

The first added security measure is the use of a terminal server. All data uploading (i.e., uploading student info into Qualtrics survey distribution panel, and uploading analyzed data into UM+Box), downloading (i.e., downloading student contact and Registrar demographic data from Qualtrics Enrollment Form, and downloading survey data from Qualtrics HMS surveys), cleaning, and analysis (both non-response analyses and all other analyses), that may involve any "sensitive" data (i.e., identifiable data, Registrar data, or survey responses in which a respondent may be identified via deductive identification) will be performed on a dedicated terminal server, titled the "Healthy Minds Network Terminal Server" (HMNTs). Access to this server is restricted to the HMS team and UM ISR ITS computing administrators. Access is controlled by UM ISR ITS Active Directory users and groups. Non-sensitive and aggregate data may be stored on the HMNTs (rather than or in addition to the O:Drive) for fast processing and access.

Both the file server (O:Drive) and terminal server (HMNTs) are physically located within a secure ISR server room. Room access is controlled by swipe and pin access. Access list is tightly controlled and swipe records regularly reviewed. Server rooms are equipped with 24/7 video surveillance. Sensors are in place to detect movement, sound, moisture, and temperature changes. Alerts are delivered to on call staff via multiple methods. Servers are equipped with full disk encryption. All remote connections are fully encrypted.

Servers are connected to the ISR restricted access network. This network is behind a dedicated firewall managed by the ISR Data Security team. The network is also actively monitored for potential attackers or intruders. The ISR restricted access network connects to the internet via the UM networks. UM runs its own firewall, as well as an Intrusion Detection System (IDS) and an Intrusion Protection System (IPS).

The second additional security measure is the use of a two-factor digital authentication process. All HMS team members granted permission to any HMS-related materials found on either the O:Drive, the HMNTs, or the UM+Box, will be required to use UM's Duo Two-factor authentication process in order to access any of these folders (including those containing survey data, or identifying data). Duo Security's privacy statement can be read here: <https://duo.com/legal/privacy>.

For questions regarding further specifics of data security specifications and logistics, please contact Matthew Toaz (mtoaz@umich.edu), Data Security Analyst Senior for UM ISR ITS, or the UM ITS Service Center (4help@umich.edu).

As mentioned in Section 4a.iv. "Sharing Survey Results" of this document, all de-identified data and related data reports created to be shared with participating institutions will be stored and shared via an entirely different platform, the UM+Box file sharing service. UM+Box is a cloud-based storage solution that allows you to share files with people inside and outside of the university. UM+Box is the UM ITS and UM ISR ITS preferred method of de-identified data sharing with people who are not affiliated with UM. UM+Box folders are encrypted, password- and UM ITS firewall-protected, similarly to the protections in place for the O:Drive and HMNTs. In order for a school to access their data on UM+Box, an HMS team member must create a folder for the school in UM+Box, upload all of that school's de-identified data and related data reports to the folder, and then grant specific individuals at the participating school access to the folder via their email. Participating school individuals who are granted access to the folder must create a password-protected account in order to access the contents of the folder. Once the individual has set up their account, they may access the folder and download the data or reports to their preferred device. Only HMS team members have the ability to grant access to an UM+Box folder. For more information on UM+Box, please review UM ITS Permitted Data and Service Description of UM+Box (<https://www.safecomputing.umich.edu/dataguide/?q=node/197>), and UM ITS Secure Use of UM+Box (<https://www.safecomputing.umich.edu/protect-the-u/safely-use-sensitive-data/box-with-sensitive-data>) webpages.

As explained in other sections of this application, survey responses and respondents' identifiable information (name, email address, numeric identifier) will be stored in separate files in separate folders. Non-identifying registrar data (sex, race/ethnicity, degree level (undergraduate/graduate), year in program, and cumulative GPA) are linked with the survey data using the student's unique numeric identifier. However, identifying registrar contact data (name and email address) are never linked with the survey data. The two files (identifiable data and survey data) will be linkable by the student's unique numeric identifier (added by the HMS team or school contact as a column in the spreadsheet of identifiable data before recruitment and contained as an embedded-data column in the survey data file downloaded from Qualtrics). Identifiable data will never be merged with survey responses (i.e., this information will always be stored in two separate files, the only linking piece of data being the numeric identifier). While the study is in the field, it is necessary to retain all identifying information originally provided by the institution in order for Qualtrics to be able to send any remaining email reminders to students who have yet to respond to the survey invitations. Once data collection has ended, we will destroy the contact information of non-responders (name, email address) but we will retain their other information for the purposes of non-response analysis (sex, race/ethnicity, degree level (undergraduate/graduate), year in program, and cumulative GPA.). We will destroy identifiable information of non-responders when processing schools' data at the conclusion of data collection for the academic year. We will retain the full information provided for responders, again with the identifiable data and survey data in separate files in separate folders linkable only by their unique numeric identifiers.

Student identifiable data will never be shared with other researchers or institutions. The data which can be shared with researchers will always be completely de-identified.

We will encrypt all survey data given its sensitive nature.

Each participating school will have two designated folders on the O:Drive: one for school information and institutional student data containing individual identifiers (see Section 4a.ii-2-3) and another for de-identified survey data (e.g., (1) University X identifiable institutional data; (2) University X survey data). An institutional contact (commonly someone from the institution's Registrar's Office) will upload the student data file with identifiable information to the school's Qualtrics Enrollment form (see Section 4a.ii-2). Ability to do this will be restricted, with this individual's ability to edit or re-download the file removed immediately after the file is successfully uploaded. After successfully uploading this file, only the HMS team will have access to this file. The HMS team will download this file directly to the aforementioned identifiable data folder on our O:Drive, so the file does not sit on any individual study team member's hard drive. The study team will then add a column to this file for the unique numeric identifiers. That file will then be used in

Qualtrics to generate individual emails for each randomly sampled student at each participating institution for the initial recruitment. These emails will be from templates saved to Qualtrics, with customized information pertaining to the particular school and the particular recruited student piped in using Qualtrics' ability to pipe in "embedded data" from an uploaded sample file into mailing distributions. Qualtrics Emailing function will be able to automatically discern who has responded v. who has not, and send our reminder emails (see Section 4a.iii-3) to only those who have not completed the survey or opted-out of emailing, automatically. The school's other folder (the survey data with no identifiable information) will contain no files until the data collection period has begun.

The folder where de-identified survey data will be stored will be accessible to the HMS team.

Maintaining respondent identifiers (i.e., identifiable information for those who completed the survey) after the original round of data collection will be necessary for any schools that would like to conduct follow-up analysis (see the Consent Form uploaded to Section 4, "Informed Consent Form(s)" of the CIRBI Document Upload Page). If a school does not indicate interest in a future follow-up (i.e., longitudinal) analysis, we will destroy all respondent identifiers for that school during the summer following the survey data collection. For schools that are interested, the HMS team may follow-up with a subset of respondents within three years of original data collection in order to understand the changing needs of college and university students related to the survey topics. We can only study these issues satisfactorily through individual-level longitudinal analysis. Individual-level longitudinal analysis will allow us to analyze how changes over time relate to specific individual characteristics at baseline as well as changes in individual characteristics from baseline to follow-up. The HMS team may also collect additional academic records such as retention and GPA, which would be linked to the institutional data by identifiable information and then the unique numeric identifier contained in the identifiable institutional data file would be used to link the academic records data to the survey data without any identifiable information making its way into the file/folder of survey data. The following language is included in the consent form in order to inform participants of this possibility:

Are my survey results linked to my grades?

In almost all cases, no. The final data sets used by any researchers do not have any official GPA information linked to the survey responses.

However, a small amount of schools want to analyze how mental health correlates with academic outcomes. In this case, we will create a data set that includes the following academic data:

*cumulative GPA
semester GPA
enrollment status
degrees obtained*

Still, your survey data will never be directly attached to your name or other identifying information. While the office providing academic information would know who participates in the survey, they wouldn't know how the students answered to any of the questions.

If follow-up of additional academic and school records is requested from a participating institution, the HMS team will use the following protocol:

- I. The HMS team will provide to the school's registrar (or academic information office) the list of student identifiers (university emails) for the students who participated in the survey. We will do this through sharing a UM+Box folder (with only that school's list of students).
- II. The registrar then returns to us the academic records (GPA, credits, degrees conferred, enrollment status) for those students with the identifiers still attached. Again, this transfer will be through Qualtrics.
- III. The HMS team will use the linking file (with mapping between identifiers and non-identifying study IDs) to link the academic records to the study IDs, and remove the identifiers, leaving a file with just the academic records and study IDs.
- IV. The HMS team will then link the academic records to the survey data using the study IDs.

The additional academic records and follow-up analysis described in this paragraph will only be collected and conducted at institutions that request this additional research. With this protocol, as with previous years of the study, we will not request amendments for each follow-up using academic records. Note: CCMH and JED will each receive de-identified data sets for any follow-up surveys or additional analyses conducted for this study.

Data will be 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). All Qualtrics accounts are hidden behind passwords and all data is protected with real-time data replication. Only the HMS team will have access to the data through Qualtrics, protected by a password. Qualtrics servers are protected by high-end firewall systems, and scans are performed regularly to ensure that

any vulnerabilities are quickly found and patched. Complete penetration tests are performed yearly. All services have quick failover points and redundant hardware, with complete backups performed nightly. Qualtrics also has a confidential system component design, which uses multiple checks to certify that packets from one subsystem can only be received by a designated subsystem. Access to systems is severely restricted to specific individuals, whose access is monitored and audited for compliance. Customer data are stored in a specific location; it does not float around in the “cloud.” In addition, all data are processed in that location, and are not moved to another jurisdictional area. In other words, if data are collected in the U.S., all data are processed in the U.S. Qualtrics uses TLS encryption (also known as HTTPS) for all transmitted data. Qualtrics can also protect surveys with passwords and HTTP referrer checking. Qualtrics services are hosted by data centers that are independently audited using the industry standard SSAE-16 method. Qualtrics deploys the general requirements set forth by many Federal Acts, including the FISMA Act of 2002. Qualtrics meets or exceeds the minimum requirements as outlined in FIPS Publication 200. More information can be found reading Qualtrics’ Security Statement (<https://www.qualtrics.com/security-statement/>), Privacy Statement (<https://www.qualtrics.com/privacy-statement/>), and Email Distributions Guide (<https://www.qualtrics.com/support/survey-platform/distributions-module/email-distribution/emails/emails-overview/>). To learn more about how Qualtrics can be used to send emails and host the survey, while still keeping participants’ identities confidential, Qualtrics Support has provided our team with the following videos on “anonymizing” surveys and using embedded data for indirect identifying: <https://www.screencast.com/t/1y3TwMYX> <https://www.screencast.com/t/G21u47qE1DY>

The 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. The de-identified results will be stored indefinitely on the PIs’ O:Drive for future aggregate analyses.

4c.) Methodology—HMS variants

As mentioned earlier in the beginning of this document (see Section 1) HMS has several variants, all with the same basic design and scope, that are used for different cohorts of colleges/universities to investigate questions specific to their student population. These different variants include: HMS-CCMH, HMS-JED, HMS CCMH+JED combo, HMS-MCubed, HMS-Sage, and other less substantial variants that are all covered under the same NIH Certificate of Confidentiality, and minimally differ from the study protocol covered in Sections 2 - 4b of this application, if they differ at all.

As a short overview of the objectives of the variants mentioned above, the CCMH, JED, and CCMH+JED version of HMS, specifically, will be administered among schools who are members of either CCMH, JED, or both. [CCMH](http://ccmh.psu.edu/) is a multidisciplinary, member-driven, Practice-Research-Network focused on providing accurate and up-to-date information on the mental health of today’s college students (see <http://ccmh.psu.edu/>).²⁴ CCMH maintains a national, clinical database of mental health service utilization on hundreds of campuses across the U.S. While CCMH has no role in the research being conducted, we are partnering with them and including some of their survey measures into our HMS questionnaire, which increases their repository of data for those measures. This is why we will be providing CCMH with an aggregated version of individually de-identified (but school-identified) data of all of the survey measures (see Section 4a-iv). [JED](https://www.jedcampus.org/about/) is a program offered by the Jed Foundation to help schools develop a campus-wide strategic plan for mental health promotion and suicide prevention (see <https://www.jedcampus.org/about/>).²⁵ Specifically, this is an intensive four-year collaboration between JED and key stakeholders from across a campus community to assess and strengthen mental health, substance abuse, and suicide prevention systems on campus. HMS data collected at HMS-JED schools will be shared with the JED Campus Program team, enabling them to strengthen their examination of and collaboration with the campus.

The MCubed variant of the study differs minimally from the standard study design, and has no special requirements for data sharing. The MCubed study is a UM internally funded project which investigates the mental health of marginalized students at diverse institutions. Although most schools participating in this variant follow the exact same cross-sectional protocol as the majority of our participating institutions, some MCubed campuses are part of a cohort of schools where a longitudinal design will be administered, asking the same students to take the survey twice within 4 years. Students who participate in the follow-up survey will be awarded a \$10 Amazon.com gift card for their participation. Other than the targeted focus on marginalized students and the follow-up incentive, this design does not actually differ from our longitudinal study design option which is open to any school that wishes to participate (described in Section 4b).

The HMS-Sage variant of the study is a pilot that is intended to be given to a small sub-group of HMS performance sites. The variant does not alter the research study, itself, but rather pilots a different mode of showing participants their mental health screen feedback and associated resources at the end of the study. Specifically, we have built a website, titled *Sage*, that, with student explicit permission at the end of the survey, will take their screen results from the HMS survey and display them in a user-friendly, graphic format. Once shown their screen feedback, participants will be taken to a resource page, containing a much more extensive list of local and national mental health resources than otherwise shown at the end of our

survey. Furthermore, the display of resources is tailored to the user, with resources that are most relevant to them based on their screen results and demographics shown at the top of the resource page. Ultimately, all participants can view all of the resources, however--only the displayed prioritization of these resources is tailored. No personally identifiable information is transferred from the HMS survey to *Sage*--only their mental health screens and demographic response items. Furthermore, we are not using any data collected in *Sage* (e.g., page views, resource views, click-data, etc.) for any research purposes--only for evaluation of the program as a mode of feedback and education.

Below is a summary of the differences between variants of the study from what is otherwise described in this protocol:

- All schools that participate in the HMS-JED or HMS-CCMH+JED versions are schools that are members of the JED Campus Program. JED's work focuses on institutional assessment and change at the system level. Therefore, we seek to supplement their work with student data collected via HMS.
- Whereas schools participating in the standard HMS may choose their elective modules, the listed variants have the following restrictions on elective module choice:
 - Schools participating in the HMS-CCMH+JED version must include our Knowledge and Attitudes about Mental Health and Mental Health Services, Upstander/Bystander, Campus Culture and Climate, Resilience and Coping, and Sleep elective modules. Participating schools may elect to sample more students in order to field additional elective modules, if they choose.
 - Schools participating in the HMS-JED version must include our Knowledge and Attitudes about Mental Health and Mental Health Services, Upstander/Bystander, Resilience and Coping, and Campus Culture and Climate elective modules. Participating schools may elect to sample more students in order to field additional elective modules, if they choose.
 - Schools participating in the HMS-CCMH version must include the Sleep half-module and their choice of either: (1) one additional elective module, or (2) the Upstander/Bystander half-module, plus up to 10 custom questions. We limit schools to choose between these two options to ensure the survey stays at a reasonable length (between 20-25 minutes). Participating schools may elect to sample more students in order to field additional elective modules, if they choose.
 - Schools participating in the MCubed variant must utilize the Diversity, Equity, and Inclusion elective double-module. Participating schools may elect to sample more students in order to field additional elective modules, if they choose.
 - Similarly, we may choose to enact elective-module requirements for other cohorts of schools that are members of an overarching organization, collaborative partnership, or government agency, dependent upon that organization's priorities.
- All schools that participate in the HMS-CCMH or HMS-CCMH+JED version are schools that are members of the CCMH network. Their version of the survey includes CCMH's CCAPS-34 questionnaire. As a result of using the CCAPS-34 in HMS, CCMH counseling centers that gather this data locally will be able to directly compare a general student population (HMS data) to a counseling center population (CCMH client service utilization data). This type of comparison can be particularly helpful when advocating for additional services.
- For schools that are a member of JED, CCMH, or both, their respective organization(s) will receive a copy of each participating school's de-identified student survey data upon completion of the school's survey. Consenting to this data sharing with JED and/or CCMH is a prerequisite of participation in the HMS-JED, HMS-CCMH, and HMS-CCMH+JED study for schools. Student participants are notified of this data sharing in the consent form.
 - Similarly, we may choose to follow this data-sharing protocol for other cohorts of schools that are members of an overarching organization, collaborative partnership, or government agency. In these cases, we will follow the exact same protocol as we do with JED and CCMH, and make sure that both institutions and individual students are made aware of these de-identified data sharing practices via their terms of agreement and consent forms, respectively.
- Each school participating in the HMS-JED or HMS-CCMH+JED study will have two iterations of the study, separated by 3 years. These iterations will each be cross-sectional by design, each employing a random sampling technique. For these schools, we will not implement any longitudinal surveying techniques, even among students who may be randomly sampled during both iterations (i.e., there will be no individual-level pre/post analyses or follow-up).
- Although utilizing a longitudinal design is a study option for all HMS schools, for a select group of MCubed schools, the longitudinal design described in this Research Design document will be mandatory for participation. Otherwise, the MCubed protocol does not differ from our standard study design.
- All schools except JED schools will be asked if they would like to participate in a student-athlete sub-study. This sub-study is the addition of questions asked solely to those who indicate that they are a varsity student athlete. These questions will be shown in lieu of any custom questions a school might have, only for student-athletes. Self-reported student-athlete status and responses will be used to collect valuable data about athlete mental health and service utilization.

5.) Statistical Design

The survey will be run through Qualtrics, and will be entirely online. Our data analysis will consist of both univariate and multivariate analyses. Our univariate analyses will include describing the data and identifying correlations. We will employ more sophisticated methods such as regression to publish findings from in peer-

reviewed journals. Multivariate analyses will include linear and nonlinear (e.g. logistic) regressions. For both univariate and multivariate analyses we will examine differences across sub-groups, such as graduates versus undergraduates and racial/ethnic groups. We will compare characteristics of non-respondents to those of respondents and assign statistical weights to respondents accordingly. All analyses will be performed using Stata 14-SE, and any analyses involving identifiable or sensitive data will be conducted using Stata 14-SE on the HMNTs.

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