

2023 Mental Illness Calibration Study (MICS)
OMB Addendum

1. Overview

SAMHSA requests a change to the approved data collection - National Survey on Drug Use and Health (NSDUH) (OMB No. 0930-0110, Exp. Date: 10/31/2024). This OMB addendum is to allow the addition of the 2023 Mental Health Calibration Study (MICS) to recalibrate the estimate(s) of serious mental illness using the Diagnostic and Statistical Manual of Mental Disorders (DSM), fifth edition (DSM-5) criteria for the diagnosis of mental disorders. SAMHSA previously conducted the Mental Health Surveillance Study (MHSS) in 2008-2012 that led to the current DSM-IV serious mental illness (SMI) indicator. Similar methods will be followed while leveraging new technology that has developed over the last decade.

The MICS interview will last approximately 60 minutes on average. Like the MHSS, respondents will receive a \$30 pre-incentive at the end of the NSDUH main interview. All clinical interviews will be conducted virtually via Zoom (phone and video). The MICS instrument will largely parallel the instrument that was used in the MHSS. The focus for MICS will be to update the statistical models that are used to compute mental illness estimates. The clinical assessments that are used in the statistical models will be updated under the MICS to use DSM-5 criteria for mental illness rather than DSM-IV criteria, which were used for the prior model.

Clinical interviewers (CIs) will use the NetSCID, a computerized version of the Structured Clinical Interview for DSM-5(SCID) that calculates skip logic in real-time based on responses, leading to faster and more reliable administration than the non-computerized version. The NetSCID is hosted by TeleSage, Health Outcomes Inc. The MICS instrument will include three parts: (1) front-end Blaise, (2) NetSCID, and (3) back-end Blaise. The front- and back-end Blaise portions (Attachment MICS-1) will confirm the respondent's identity, thank them for their time, and allow CIs to independently complete interview debrief questions.

The clinical portion of the instrument (Attachment MICS-2) will consist of the following modules using the electronic version of the SCID-5 (the NetSCID):

- An open-ended **overview module** designed to elicit information about the respondent's diagnostic and treatment history and current status in a way that establishes some level of rapport between the CI and the respondent.
- The **SCID screener instrument** to be administered to all respondents at the end of the overview module. The questions are taken from the body of the SCID and are the initial questions asked for the disorders being assessed. These screening questions may help to reduce the potential effects of a "negative response bias" that may be especially problematic in the later sections of the SCID. Because of the structure of the SCID, there is the potential for the respondent to notice that a "yes" answer to the initial probe question in a section then results in follow-up questions, whereas a "no" answer results in a skip to the next section. Therefore, some subjects might be motivated to provide "no" answers as a way of speeding the interview along. By asking the screening questions up

front and using the answers to these questions to determine whether a section should be skipped, response bias may be minimized.

- Past Year Major Depressive Episode (MDE)
 - Lifetime Manic Episode for respondents who meet criteria for past year major depressive episode
 - This is included to confirm that a past year major depressive episode was not due to bipolar disorder
- Past Year Manic Episode
- Past Year Dysthymic Disorder
- Past Year Psychotic Disorder Screen
- Past Year Post Traumatic Stress Disorder
- Past Year Panic Disorder with and without Agoraphobia
- Past Year Agoraphobia without history of Panic Disorder
- Past Year Social Phobia
- Past Year Specific Phobia
- Past Year Obsessive Compulsive Disorder
- Past Year Generalized Anxiety Disorder
- Past Year Anorexia Nervosa
- Past Year Bulimia Nervosa
- Past Year Intermittent Explosive Disorder
- Past Year Adjustment Disorder

Unlike in the MHSS, lifetime MDE will not be administered to respondents who score positive for past year mania because assessment of lifetime MDE is not needed to rule out bipolar disorder.

Substance Use Disorder (SUD) will not be included because this does not fall under SAMHSA's definition of SMI. Additionally, SUD was not included in the modeling of SMI during the MHSS; thus, there is no compelling reason to justify the addition of this module in the MICS.

Finally, at the end of the back-end Blaise portion of the interview, a section will be included for documenting the CI's impressions of the interview situation, including ratings of the respondent's level of privacy, cooperation, and comprehension, as well as the perceived overall validity of the interview data based on these factors. Any interview deemed by the CI or clinical supervision team to be of questionable validity will be reviewed closely and potentially discarded.

The MICS will incorporate several procedures to ensure that respondents' rights will be protected, including procedures developed for the main NSDUH. The informed consent procedures will be administered at two different parts of the full MICS data collection process, as outlined below:

- During the MICS follow-up clinical interview recruitment screens, the field interviewer (FI) will introduce the follow-up clinical interview and provide general information on why they were selected with recruitment scripts (Attachment MICS-6). These scripts will appear on the computer screen at the end of the initial CAI interview and will be read aloud to each interview respondent selected for the MICS. As part of the process for obtaining informed consent for the follow-up interview, respondents will be given a hard

copy Follow-up Study Description (Attachment MICS-3), which will provide an overview of the study and information on the Confidential Information Protection and Statistical Efficiency Act of 2002 (included as Title V in the E-Government Act of 2002, P.L. 107-347) and the protection that it affords. For web respondents, the recruitment process will be nearly identical. The web-based instrument will display the same recruitment screens the FIs will read to respondents during the in-person interview and the Follow-up Study Description will be displayed on the screen instead of being provided in hard copy by an FI.

- During the MICS clinical interview front-end Blaise, the MICS Informed Consent (Attachment MICS-4) will be administered to respondents prior to starting the clinical portion of the interview.

If a respondent wants more information about the risks and benefits of the MICS, or how their information will be used, an extended version of the MICS informed consent (Attachment MICS-5) will be provided. At the end of the informed consent that's administered in the clinical interview, CIs will offer respondents the chance to ask questions, review the extended version on their own (via the NSDUH public website), or have the CIs read the extended version aloud to them.

2. Background

As mentioned above, the purpose of the MICS is to update NSDUH SMI estimates based on the DSM-5 criteria. The current NSDUH SMI estimates were developed under the MHSS and reflect DSM-IV criteria. In the intervening years, the DSM was updated, and it is important to update the NSDUH mental illness estimates to reflect current criteria. We will use a similar methodological approach as was used for the MHSS, applying similar sampling and weighting algorithms. Using similar sampling, study instrumentation, and statistical modeling procedures between the MHSS and the MICS will minimize the impact of procedural or methodological changes on SMI trends.

3. Respondent Universe and Sampling Methods

The MICS samples will be selected from the 2023–2024 NSDUH samples. Unlike for the Clinical Validation Study (CVS) conducted as part of the 2020 NSDUH, there will be no alteration (i.e., increase) to the NSDUH sample to account for MICS minimal sample requirements. This is because everyone in the sample – those who participate in the MICS and those who do not – will receive the same version of the NSDUH main study survey. The only difference between the MICS and non-MICS groups of respondents is that those who participate in the MICS will receive a follow-up clinical interview after completing the main NSDUH survey.

The 2023 and 2024 MICS samples are designed to yield 2,000 interviews per year. Each year, the probability sample will be distributed across 4 calendar quarters, resulting in approximately 500 MICS follow-up clinical interviews per quarter. Similar to the MHSS, the probability sample will be embedded in the main study sample; therefore, the initial interview for the validation

cases will be included in the target study sample of approximately 50,625 main study adult interviews.

Individuals eligible for the MICS are adults aged 18 or older who answer the NSDUH main study interview questions in English. Persons who complete the main study interview in Spanish will not be eligible for MICS. Based on prior main study NSDUH experience, we expect that approximately 97 percent of the main study respondents aged 18 or older will be eligible for MICS. Similar to the MHSS, a subsample of NSDUH respondents will be selected with probabilities determined by their K6 nonspecific distress scale (Kessler et al., 2003), WHODAS score, and age group. A probability sampling algorithm will be programmed in the main study interview instrument so that selected respondents are recruited for the follow-up clinical interview at the end of the main study interview.

Like the MHSS, the MICS will be a stratified sample selected from the NSDUH respondents based on strata defined by their K6 and WHODAS scores. Neyman optimal allocation (Lohr, 1999) will be applied to the strata (i.e., stratum selection probabilities are proportional to the standard deviation of the measure in question). Neyman allocation results in increased precision of key outcome variables (e.g., SMI) compared with other allocations, assuming a fixed sample size and equal costs across strata. Also, in the event that sample sizes fall short in some strata, Neyman allocation produces robust estimates of stratum sample sizes (i.e., meaning that moderate deviations will result in only a small loss of precision). This design minimizes the sample size required for the MICS in two ways: (1) by increasing the yield of SMI cases within the MICS sample (i.e., the closer the yield is to 50 percent, the smaller the required sample size will be for analysis, given all else is equal), and (2) by reducing the design effect within the MICS sample due to the Neyman allocation.

4. Information Collection Procedures

NSDUH Main Study

Both main study interview respondents selected for the MICS and those not selected for the MICS will complete the NSDUH main study interview. The NSDUH instrument does not differ based on whether the respondent is selected for MICS, as the selection process occurs after the main study interview is complete. All respondents who agree to participate in the follow-up clinical interview will receive \$30 (see *Section 6* for more details on the incentive process).

MICS Recruitment

Respondents aged 18 years and older who complete the main study interview, either web-based or in-person, and are selected for the MICS interview, will be recruited to participate. FIs and respondents will be blind to the respondent selection criteria for the MICS and will not know a respondent has been selected for the MICS until the follow-up clinical interview recruitment scripts (Attachment MICS-6) appear at the end of the main study interview.

Web-based Recruitment

The follow-up clinical interview recruitment scripts that appear at the end of the web-based main study interview are self-administered. The respondent will be led through screens that let them

know they have been selected for the follow-up clinical interview, provided a web version of the Study Description (Attachment MICS-3), and, if the respondent agrees, asked to provide their first name, phone number, and email address so they can be contacted. Although the respondent's first name, phone number, and email address will be collected within the main study interview, it will be used only for re-contact purposes. Respondents will also be asked whether or not they are willing to receive text messages as part of their re-contacts.

If a respondent agrees to complete a follow-up interview, verbiage in the web-based main study interview encourages them to schedule their follow-up interview appointment as close as possible to the current date and then automatically launches the project's online scheduling system in a new internet browser. This allows the respondent to select a follow-up clinical interview date and time on the spot. After these recruitment screens are completed, all future contact will come from CIs or MICS systems.

In-person Recruitment

NSDUH FIs will be trained on the in-person MICS recruitment process as part of veteran and new-to-project FI trainings. The follow-up clinical interview recruitment scripts that appear at the end of the in-person main study interview are FI-administered. The FI will read the scripts from the laptop verbatim to the selected respondent and provide them with a hard copy of the Follow-up Study Description (Attachment MICS-3). The Follow-up Study Description will include important details about the follow-up clinical interview, a clear description of the follow-up clinical interview procedures, and information about confidentiality protections identical to the information provided for the main study.

If the respondent agrees, the FI will ask for the respondent's first name, phone number, and email address so the respondent can be contacted later to schedule the follow-up interview. Respondents will also be asked whether or not they are willing to receive text messages as part of their re-contacts. The FI will then hand the respondent a scheduler card (Attachment MICS-7) that will allow them to access the project's online scheduling system, via URL or QR code, to select an interview date and time. At the end of the recruitment process, the FI will also encourage the respondent to schedule their follow-up interview appointment as close as possible to the current date. After these recruitment screens are completed, the FI will no longer have contact with the respondent, and all future contact will come from CIs or MICS systems.

Online Scheduling System & Public and Private Sites

After an in-person or web respondent agrees to participate in the follow-up interview and provides a valid email address, the respondent will receive via email information for accessing the project's online scheduling system. This will contain a respondent-specific URL. In-person respondents will receive the same information on the card handed to the respondent by the FI. Access is provided through logging into a specific page on the NSDUH website, either manually when the passcode is provided by the FI or automatically from the URL included in the email, which embeds the respondent-specific password.

CIs will have access to the project's private website, which includes a calendar system that works in real-time alongside the project's online scheduling system to offer interview

appointment options for each respondent. Once a respondent selects an interview appointment time, that timeslot is no longer offered to other respondents, and the case is assigned to the CI.

MICS Interview Contacting Procedures

Post-selection contacting will occur on MICS using two distinct, yet connected, processes – automated contacting and CI contacting – that differ based on case status.

Automated contacting methods include email and text messaging (Note: during MICS recruitment, respondents are asked whether they consent to receiving text messages) that are generated by various project systems based on current case status.

- Automated emails – Multiple systems work together to enable this process, which is used to automatically send emails to respondents and CIs at different stages of the data collection process based on current status or recent event. For example, when an interview is scheduled, rescheduled, or canceled using the project’s online scheduling system, a missed appointment or refusal code is entered, a case is unassigned or does not have a scheduled interview code (this process will run twice per week), or when an appointment is upcoming (Attachment MICS-8), an event-specific email is automatically sent after the codes are processed by the system. If respondents do not provide a valid email address, these messages are not delivered.
- Automated text messaging – This method will be used to send respondents messages when an appointment is scheduled or missed (Attachment MICS-9). CIs will request text messages be sent to respondents through the Case Management System. If respondents do not provide a valid phone number and/or do not consent to text messaging during recruitment, this will not occur. Respondents who receive the automated text messages and later decide they no longer wish to receive them, can unsubscribe by replying “STOP” to any of the automated text messages they receive. After replying “STOP”, the respondent will immediately receive a final automated text message confirming that they have been successfully unsubscribed.

CI contacting methods will include phone calls and emails from the CI assigned the case. CIs will be provided with talking points (Attachment MICS-10) to use when contacting respondents. All CIs will be required to call or email respondents both on the day they send the interview’s Zoom meeting invitation (Attachment MICS-11) and the day before the scheduled interview.

All contacts between CIs and respondents will be documented within the project’s Case Management System on the day the contact occurs. This will ensure automated systems work hand-in-hand with CI contacting procedures.

Additionally, letters will be sent to respondents who have refused to participate (Attachment MICS-12), are unable to contact via phone or email (Attachment MICS-13) or have not scheduled an interview and previous contacting attempts have been unsuccessful to date (Attachment MICS-14). These letters are requested ad-hoc by project Data Collection Managers.

Missed appointments will be handled in several ways:

- No show protocol – CIs will follow this procedure when a respondent is late or does not show up during their scheduled interview time:

- If a respondent has not joined Zoom within the first 5 minutes, the CI will call (if a valid phone number was provided) the respondent to ensure they are not having technical difficulties. If the respondent doesn't answer, the CI will leave a message. The CI will then send a follow-up email (if a valid email address was provided), reminding the respondent of their appointment, and asking if the respondent needs to reschedule. This process will take about 5 minutes. If the respondent does not show up within 15 minutes of the scheduled start time, the CI will document this as a missed appointment.
- First and second missed appointments – CIs will enter an event code based on how many times a respondent misses an appointment. After the first two times, if a respondent provides a valid email address, missed appointment emails will be automatically sent to the respondent asking them to reschedule.
 - Contact with respondents will be different based on whether and how the interview appointment was rescheduled. If the interview was not rescheduled, the respondent will receive instructions on how to reschedule via email (see MICS Contacting Procedures for more detail). If the interview was rescheduled with a CI, the CI will send a new Zoom meeting invitation via email. If the interview was rescheduled via the online scheduling system, the MICS systems will send the respondent an email with updated interview appointment details.
 - Respondents who do not complete the follow-up interview during their scheduled time and subsequently reschedule directly with a CI, will not receive any automated emails.
 - Respondents who do not complete the follow-up interview during their scheduled time and subsequently reschedule using the project's online scheduling system, will receive automated emails. In this scenario, if the interview is assigned to a new CI, project systems will automatically manage the case transfer and notification processes.
- Third missed appointment – Respondents will no longer be contacted unless the respondent uses the online scheduling system or contacts the project on their own.

Lastly, CIs will have the option to send a missed appointment text to respondents who consent to texting and provide a valid phone number. If an email address is provided, automated emails will also be utilized. Respondents who schedule interviews themselves using the online scheduling system and complete the interview at the initial scheduled time will have been contacted three times – an automated email confirming the appointment has been scheduled (Attachment MICS-8), Zoom meeting details and scheduling confirmation from their CI (Attachments MICS-8, MICS-11), and a reminder the day before the interview (automated email, phone call, or text) (Attachments MICS-8, MICS-9, MICS-11).

Additional MICS Procedures

The total average interview time for MICS respondents is expected to be about 120 minutes. This includes approximately 60 minutes for the main study interview and approximately 60 minutes for the follow-up clinical interview. The estimated time to complete the follow-up interview is based primarily on timing observed during the Mental Disorder Prevalence Study (MDPS) sponsored by SAMHSA. The SCID-5 used for MDPS, which included the overview and 9 full diagnostic modules including schizophrenia and substance use disorders, averaged about 83

minutes, and this included about 20 minutes of back-end Blaise material that was part of MDPS but will not be part of MICS. The abbreviated SCID-5 being used for MICS does not include the schizophrenia or substance use disorder modules, each of which take 10-20 minutes, on average, to complete. Although MICS includes more disorders, many are rare disorders and/or have much shorter administration times (fewer questions) than the modules shared with MDPS. In addition, the use of the SCID screener items will allow respondents to skip out of modules entirely if they do not endorse specific gate items. We believe these factors, combined with the use of the NetSCID and seasoned CIs who have gained efficiency working on MDPS, will keep the MICS instrument close to a 60-minute administration time. The RTI team will perform testing of the instrument prior to data collection to ensure timing estimates are accurate.

Follow-up clinical interviews must be completed within four weeks following the completion of the NSDUH main study interview. Except for Quarter 4 data collection, MICS interviews generated during the last month of the quarter will be completed up to four weeks into the next data collection quarter. For Quarter 4, the final date to complete a MICS interview will be December 31st. These data collection procedures mirror those used on prior NSDUH follow-up studies.

The follow-up interview will be conducted in English only. The interview will include four sections: front-end Blaise, SCID overview, pertinent SCID screener modules, and back-end Blaise. The total number of questions asked of each respondent will depend on their answers to each SCID screener module. At the end of the follow-up interview, after the respondent leaves the Zoom meeting room, CIs will answer debriefing questions about the interview quality and confidentiality on their own.

CIs will record respondents' answers directly into the Blaise and NetSCID instruments. At the beginning of the interview, after the informed consent process, CIs will ask respondents if they consent to the interview being recorded. During this process, CIs will also inform respondents that their recording and interview responses may be de-identified and used for quality or training purposes for the MICS but will not be used for other research studies in the future. If the respondent does not consent to the recording, the interview will not be recorded. If the respondent does consent to the recording, the interview will be recorded, and the CI will upload the Zoom recording URL and passcode to the project's secure private site, from which the interview can be reviewed for quality purposes. Recordings will automatically delete from Zoom after 35 days.

5. Information Technology Use

The selection of NSDUH main study interview respondents for the MICS follow-up clinical interview will be calculated at the end of NSDUH main study questionnaire. Individuals eligible for the MICS will be those aged 18 and older who chose to answer the NSDUH main study interview questions in English. Eligible respondents will be selected for the MICS based on their K6 and WHODAS scores and their age group. Two hundred twenty-five strata will be constructed from combinations of 25 possible WHODAS and 9 possible K6 scores.

For those selected for the follow-up interview, recruitment scripts (Attachment MICS-6) programmed within the NSDUH main study questionnaire will be administered at the end of the main study interview.

- Web-based – The respondent will not know if they are selected for the follow-up clinical interview until the recruitment scripts appear on the screen. Respondents will enter contact information if they agree to participate. This information will only be available on secure project systems for access by the CI assigned to contact the respondent for the follow-up interview. If a respondent agrees to participate, the project’s online scheduling system will be launched so the respondent can immediately schedule their follow-up interview.
- In-person – The FI and respondent will not know if the respondent is selected for the follow-up clinical interview until the recruitment scripts appear on the laptop screen. Contact information for those who agree to participate in the follow-up clinical interview will be entered into the laptop by the FI. This information will only be available on secure project systems for access by the CI assigned to contact the respondent for the follow-up interview. The FI will also provide in-person respondents a scheduler card (Attachment MICS-7) that will provide instructions for accessing the project’s online scheduling system.

CIs will use the Zoom platform for interviews. Respondents will join the meeting room to participate in a video call. For phone interviews, respondents will either call into the Zoom meeting or the CI will call the respondent directly from the Zoom meeting room. If the CI or respondent experiences technical difficulties with the Zoom platform that cannot be solved through troubleshooting, CIs will use the I3 system to call respondents directly from their personal phones without providing respondents with their phone number(s).

6. Payment to Respondents

The MICS follow-up clinical interview will constitute an additional burden on respondents and may make it more difficult to obtain respondent participation. To maintain adequate response rates, SAMHSA believes it is necessary to offer MICS respondents an additional \$30 incentive for completing the follow-up clinical interview, which will take about the same amount of time as the initial interview, so an equitable incentive is prudent. Evidence indicates that prepaid incentives, like the MICS incentive, are usually more effective than promised (or conditional) incentives (Gelman, Stevens, & Chan, 2002; Singer, 2002; Singer & Ye, 2013).

Respondents who agree to complete the follow-up interview will receive a total of \$60 at the end of the main study interview – consistent with incentive amounts provided to respondents as part of the 2008-2012 NSDUH MHSS. The additional incentive for the follow-up clinical interview is mentioned in the following respondent materials: Follow-up Clinical Interview Recruitment Scripts (Attachment MICS-6), Follow-up Study Description (Attachment MICS-3), and the Follow-up Interview Incentive Receipt (Attachment MICS-15).

Web respondents who agree to complete the follow-up interview at the end of the main study interview will be asked to select a preferred method for receiving the \$60 – either an electronic Visa or MasterCard gift code sent to an email address provided or a physical Visa or MasterCard

gift card delivered to their address and directed to the respondent (based on age and gender only) along with a thank you hard copy letter or email. Information collected for the delivery of the incentive will be kept separate from interview responses.

In-person respondents who agree to participate in the follow-up interview will receive \$30 cash from the FI. FIs will provide respondents who agree to participate with a Follow-up Interview Incentive Receipt (Attachment MICS-15).

7. Assurance of Confidentiality

The MICS will incorporate several procedures to ensure respondents' rights will be protected, including procedures developed for the NSDUH main study. The FI will introduce the follow-up clinical interview and provide general information on why they were selected with recruitment scripts (Attachment MICS-6). These scripts will appear on the computer screen at the end of the main study interview and will be read aloud by the FI to each interview respondent selected for the MICS. As part of the process for obtaining informed consent for the follow-up clinical interview, respondents will be given a Follow-up Study Description (Attachment MICS-3) by the FI, which includes information on CIPSEA and the protection it affords. Specifically, the Follow-up Study Description states that respondents' answers will only be used by authorized personnel for statistical purposes and cannot be used for any other purpose. The dwelling unit address information, which is maintained in a separate file for Contractor use in sampling, fielding, and weighting cases, as well as the respondent's first name, phone number, and email address, will be destroyed when all final data files are delivered to SAMHSA.

The respondent's first name, phone number, and email address will be collected within the main study interview and will be used only for recontact purposes. Contact information for respondents will be stored in a dedicated secure database in the FIPS-Moderate network zone, and not recombined with interview responses or clinical interview result data. Upon completion of data collection for a quarter, the collected data will be converted into a SAS data file format. Identifiers used for recontacting respondents will be stripped and dropped from the SAS data files and merged onto the master data file. All personally identifiable information (PII) will be removed from the data files prior to removal from the FIPS-Moderate environment, and prior to delivery to SAMHSA.

CIs will be assigned cases automatically based on the availability they entered into the calendar system on the project's private site, which will reside within the FIPS-Moderate network zone where access requires two-factor authentication. Cases will be accessed by CIs via the project's private site on a project-issued laptop computer. CIs will be required to confirm that project-issued computers will not contain any electronic notes from interviews and will not have other programs or websites running in the background while they are accessing the site.

The follow-up clinical interview will be conducted via Zoom or by telephone by clinicians trained in the administration of the NetSCID. Each clinical interview case will be identified by a case-specific ID code unique to that case that identifies the main study interview from which the follow-up clinical interview was generated. No PII including respondent name, telephone number, email address, or other contact information will be recorded in the MICS instrument.

To initiate interviews, CIs will open the interview-specific Zoom meeting then either: (1) wait for the respondent to join the call (video or phone) or (2) directly call the respondent. The Zoom system will also be utilized for all interview recordings, upon respondent permission. All recordings will be saved on a secure private project website in the FIPS-Moderate network zone.

Access permissions to files and data sets on the network are carefully controlled using a combination of domain usernames/passwords and other forms of authentication, such as SQL Server logins. Usernames and passwords on the networks are subject to enforced security checks, password length requirements, and corporate policies requiring adherence to security procedures. As a project operating policy, all sensitive and PII data are stored only on file servers running and implementing full Microsoft or UNIX security, within the Contractor's FIPS-Moderate network zone.

Following the conclusion of the MICS data collection, analyses of data will be conducted. The Restricted Use Data File (RUF) will be stored securely on file storage appliances within the FIPS-Moderate network zone and can be accessed by only a small group of authorized project staff. Any use of RUF files is contained entirely within the FIPS-Moderate network zone.

The permanent sampling records will contain no record of which addresses were selected for the MICS.

8. Questions of a Sensitive Nature

Some of the sensitive questions contained in the MICS follow-up clinical interview may cause some respondents to feel emotional distress. All CIs will be trained mental health professionals who can recognize signs of cognitive impairment or significant distress in respondents. A Distressed Respondent Protocol (Attachment MICS-16) will be used to guide CIs on helping respondents who disclose intent to harm themselves or others. CIs will remain alert for signs of distress and utilize their professional mental health training to identify when a respondent exhibits active suicidal or homicidal symptoms or seems upset during a follow-up clinical interview. In these circumstances, the CI will stop the interview and follow the appropriate guidelines outlined in the Distressed Respondent Protocol. The protocol will also include provisions for respondents who may not be in imminent danger of harm, but who become distressed or agitated during the follow-up clinical interview. CIs will not report any information about the respondent to anyone except in accordance with this protocol. The Distressed Respondent Protocol also includes procedures to be followed if a respondent reveals information that leads the CI to believe that someone is being abused or neglected. The Distressed Respondent Protocol for the MICS was developed based on similar versions used on MDPS from 2020–2022.

The MICS interview procedures are designed to reduce and mitigate the risk associated with revealing potentially sensitive information. First, CIs will administer the follow-up clinical interview over Zoom, either video or phone, from a private location in their home or office. During the informed consent process, CIs will ensure the respondent is in a private location. Secondly, like main study FIs, all MICS CIs will complete SAMHSA- and RTI-required

trainings on confidentiality and privacy, which state they agree to treat as confidential all information secured during interviews or obtained in any project-related way.

9. Estimates of Annualized Hour Burden

For the MICS, the sample has been designed to yield approximately 2,000 completed clinical interviews in 2023. Based on previous experience with MDPS and MHSS, administration of the follow-up clinical interview questions is expected to take an average of 60 minutes per respondent.

The data collection field period for the 2023 MICS is 12 months, spanning the period from January 2023 through December 2023. The annualized estimated respondent burden for the MICS is shown in Table 3. The hourly wage of \$19.53 was calculated based on weighted data from 2021 NSDUH respondents' personal annual income reports.

For the MICS, approximately 33 CIs will be hired to conduct the follow-up clinical interviews. Minimum CI credentials are a master's degree in Clinical Psychology, or a related field, 1-2 years of relevant working experience, ability to work 6-10 productive hours per week, and the flexibility to attend a live, virtual training session in early November 2022. A 3-day CI training session will be held virtually via Zoom prior to data collection. In addition, a replenishment training session will take place mid-data collection if needed.

In addition to attending a training session prior to MICS data collection, all CIs will be required to complete and pass a certification process before being cleared to collect data. Phase 1 of the certification process will be passing of a CI training-specific, 50-question online exam. The exam will test CIs on their knowledge of the NetSCID, instrument administration skills, diagnostic efficiency, and additional project-specific requirements. After passing the final training exam and immediately following training, Phase 2 of the certification process will begin. This will involve each CI completing a roleplay interview with their supervisor playing the role of respondent, using a script provided by the contractor's trainers. The CI must receive a passing score on the roleplay to move on to the final phase of certification. CIs who move to Phase 3 of certification will be assigned a MICS respondent to interview and record. Supervisors will review this interview and score the CI on a rigorous evaluation form (Attachment MICS-17) developed by SCID authors and the contractor's clinical team leaders. CIs will have up to three chances to receive a passing score and pass certification. Those who do not pass after the first or second attempts will receive feedback from their supervisor to improve their performance for their subsequent attempt. If a CI fails three certification interviews, they will be released from the project.

Certification interviews will be conducted using actual respondents. These data will be used only for training and quality purposes. Based on experience on the MHSS and MDPS, the project expects most CIs to pass certification after one interview.

Table 9.1 Annualized Estimated Respondent Burden for 2023 MICS

Instrument	No. of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours	Hourly wage rate	Total hour cost (excludes incentives)
2023 MICS	2,000	1	2,000	1	2,000	\$19.53	\$39,060

10. Estimates of Annualized Cost to the Government

Total contract costs associated with the 2023 MICS are \$2,128,811.

11. Changes in Burden

SAMHSA is requesting 2,000 total burden hours for the 2023 MICS (of the 85,225 hours total for 2023).

12. List of Attachments

Attachment Label	Attachment Name
Attachment MICS-1	Blaise Instrument Specs
Attachment MICS-2	NetSCID Instrument Specs
Attachment MICS-3	Study Description
Attachment MICS-4	MICS Informed Consent
Attachment MICS-5	Extended MICS Informed Consent
Attachment MICS-6	NSDUH CAI MICS Recruitment Scripts
Attachment MICS-7	Field Scheduler Card
Attachment MICS-8	Scheduler Automated Emails
Attachment MICS-9	Text System Messages
Attachment MICS-10	Email, Voicemail Contacting Scripts
Attachment MICS-11	Interview Confirmation Scripts
Attachment MICS-12	Refusal Letter Template
Attachment MICS-13	Unable to Contact Letter Template
Attachment MICS-14	Scheduling Letter Template
Attachment MICS-15	Follow-up Interview Incentive Receipt
Attachment MICS-16	Distressed Respondent Protocol
Attachment MICS-17	Phase 2 and 3 SCID Review Form

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