MAYO CLINIC

Name and Clinic Number

Approval Date: **April 15, 2026**
Not to be used after: **November 5, 2026**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Senyo Health app - Connecting Primary Care to Substance Use Disorder Treatment Using a Telehealth Collaborative Care Platform

IRB#: 24-007758

Principal Investigator: Tyler Oesterle and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to see if using the Senyo Health app to deliver behavioral change content remotely through a collaborative care management (CCM) model will work within the primary care clinics as an option for substance use disorder treatment. You have been asked to take part in this research because you have been identified to be struggling with substance use.
What's Involved	Study participation involves working with a care manager/licensed alcohol drug counselor/study staff and using the app to receive content to assist with reduction of or stopping substance use.
Key Information	This study is not the only option you have for treatment of substance use disorder. If you decide not to take part in this study, you will still be able to receive medical care. The research team will discuss other treatment options with you.

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Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Tyler Oesterle **Phone:** (507) 284-2088 **Study Team Contact:** Danielle Cox **Phone:** (507) 422-1704 **Study Team Contact:** Kelsey Tuen **Phone:** (507) 422-1542 **Institution Name and Address:** Mayo Clinic 200 First St. SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

A description of this research study will be available on the research study page at mayoclinic.org. This Web site will not include information that can identify you. You can search this Web site at any time.

Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you have concerns about you level of substance use and want to reduce or stop.

The plan is to have about 60 people take part in this study at Mayo Clinic.

Why is this research study being done?

We are doing this research study to see if using the Senyo Health app to deliver behavioral change content remotely through a collaborative care management (CCM) model will work within the primary care clinics as an option for substance use disorder treatment.

Information you should know

Who is Funding the Study?
The Agency for Healthcare Research and Quality (AHRQ) is funding the study. The AHRQ will pay the institution to cover costs related to running the study.

Mayo Clinic funds may also be used to fund portions of the study.

Information Regarding Conflict of Interest:
This research has been reviewed by the Mayo Clinic Conflict of Interest Review Board and is being conducted in compliance with Mayo Clinic Conflict of Interest policies.

Both the Mayo Clinic Conflict of Interest Review Board and the Institutional Review Board have reviewed the financial interest for one or more of the investigators and/or Mayo Clinic related to this research and they have determined that this financial interest poses no additional significant risk to the welfare of participants in this research project or to the integrity of the research.

Additional information is available to any interested study participant regarding the details of this financial interest and how it is being managed by contacting the study coordinator or the Office of Conflict of Interest Review at (507) 284-0075.

One or more of the investigators associated with this project and Mayo Clinic have a financial interest in technology used in the research and that the investigator(s) and Mayo Clinic may stand to gain financially from the successful outcome of the research.

Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

You will be in the study for about 1 year and 3 months.

What will happen to you while you are in this research study?

If you agree to be in the study, you will be asked to participate in the following activities: signing this informed consent, completing an interview to collect medical and psychiatric history or other health problems, , and answering questionnaires about mood and anxiety. Questions specific to suicidal thoughts are required to be answered to participate in the study. This allows us to monitor your safety and determine if clinically your treatment needs to change. You are allowed to refuse to answer questions on other questionnaires.

Baseline Visit involves:

- Signing this consent
- Interview with study staff
    - Evaluate your level of substance use and type of care best suited for you.
    - Timeline Follow Back (TLFB) - gather history of substance use such as how much you used each day.
- Complete questionnaires
    - Brief Substance Craving Scale (BSCS)
    - Patient Health Questionnaire-9 (PHQ-9)
    - Generalized Anxiety Disorder-7 scale (GAD-7)
    - Brief Version of the Pittsburgh Sleep Quality Index (B-PSQI)
    - Drug Abuse Screening Test (DAST)

  - Alcohol Use Disorders Identification Test-Concise (AUDIT-C)
  - Brief Assessment of Recovery Capital (BARC-10)
  - Treatment Attendance Monitoring Questionnaire (TAM)
- In person urine test - we will test your urine for drugs, including alcohol and illegal drugs like cocaine or heroin. The results of the urine drug test will become part of your medical record but not reported to anyone.

Check-in visits will last about 30-45 minutes, depending on your health status updates.

Active intervention phase lasts 12 weeks and involves:

- You will receive an invitation email to download the Senyo Health app on your personnel device.
- Daily quotes and questions will be sent to you via the Senyo app in the chat feature to encourage engagement, provide motivation, and things for you to think about.
- Weekly check-in visits by phone or virtual zoom call with care coordinator/Licensed Alcohol and Drug Counselor (LADC) to provide health and substance use updates, be provided with encouragement and motivational care management, and receive any counseling to assist with reduction of use or to quit completely.
- Timeline Follow Back (TLFB) - gather history of substance use such as how much you used each day.
- Monthly in person urine test to check for certain drugs, including alcohol and illegal drugs like cocaine or heroin. The results of the urine drug test will become part of your medical record but not reported to anyone.
- Use the Senyo app to view educational content that can help you with things such as managing thoughts, identifying feelings and emotions, self-esteem and self-talk, and addictive thinking. Completing goals, questionnaires, meetings with your care coordinator/LADC, and other activities will allow you to earn points which can be exchanged for money.
- Complete questionnaires
  - Brief Substance Craving Scale (BSCS) – weekly
  - Generalized Anxiety Disorder-7 (GAD-7) - weekly
  - Patient Health Questionnaire-9 (PHQ-9) - weekly
  - Brief Version of the Pittsburgh Sleep Quality Index (B-PSQI) - monthly
  - Brief Assessment of Recovery Capital (BARC-10) – monthly
  - Treatment Attendance Monitoring Questionnaire (TAM) - monthly
- At the final weekly visit, you will be asked to complete questionnaires about how you liked using the app. This will help us make future improvements to fit patient needs.
  - System Usability Scale (SUS)
  - Acceptability of Intervention Measure (AIM)

- Intervention Appropriateness Measure (IAM)
- Feasibility of Intervention Measure (FIM)

Check-in visits will last about 30-45 minutes, depending on your health status updates. Each questionnaire should take no more than about 5-10 minutes to complete each one (about 25-50 minutes total).

You will be asked about completing a semi-structured interview at the end of the active phase in the study. The interview is voluntary and will be recorded with your oral permission to participate. The goal of the interview is to collect feedback on the app and LADC process.

NOTE: If a wearable device is detected the sensor will track activity, heart rate, and oxygen saturation. We may use this to create goals. The study will not provide a wearable device. This data will only be collected from those who already have and wear a personal device.

Follow-up Phase lasts 12 weeks and involves

- Monthly check-in phone or virtual zoom calls to provide health and substance use updates
- Timeline Follow Back (TLFB) - gather history of substance use
- Monthly in person urine test to check for certain drugs including alcohol and illegal drugs like cocaine or heroin. The results of the urine drug test will become part of your medical record but not reported to anyone.
- Use the Senyo app to view educational content that can help you with things such as managing thoughts, identifying feelings and emotions, self-esteem and self-talk, and addictive thinking.
- Complete questionnaires
  - Brief Substance Craving Scale (BSCS)
  - Generalized Anxiety Disorder-7 (GAD-7)
  - Patient Health Questionnaire-9 (PHQ-9)
  - Brief Version of the Pittsburgh Sleep Quality Index (B-PSQI)
  - Brief Assessment of Recovery Capital (BARC-10)
  - Treatment Attendance Monitoring Questionnaire (TAM)

Check-in visits will last about 30-45 minutes, depending on your health status updates.

NOTE: If a wearable device is detected the sensor will track activity, heart rate, and oxygen saturation. We may use this to create goals. The study will not provide a wearable device. This data will only be collected from those who already have and wear a personal device.

1 year follow-up involves (One year from week 12 intervention.)

- Check-in by phone or virtual Zoom calls to get health and substance use updates
- Timeline Follow Back (TLFB) – gather history of substance use
- In person urine test - check for certain drugs, including alcohol or illegal drugs such as cocaine. The results of the urine drug test will become part of your medical record but not reported to anyone.
- Complete questionnaires
    - Brief Substance Craving Scale (BSCS)
    - Generalized Anxiety Disorder-7 (GAD-7)
    - Patient Health Questionnaire-9 (PHQ-9)
    - Brief Version of the Pittsburgh Sleep Quality Index (B-PSQI)
    - Brief Assessment of Recovery Capital (BARC-10)
    - Treatment Attendance Monitoring Questionnaire (TAM)

For monitoring and safety purposes, the care coordinator/LADC/study staff and the principal investigator will review the information you provided during your check-in visits to evaluate your appropriateness for the current level of care. You must remain eligible for outpatient substance use disorder (SUD) care to stay in the study. If you enter into a residential treatment program, you will automatically be moved to the follow-up phase of the study.

If there is concern during your weekly visit about your addiction care and mental health that information will be shared with your primary care provider. The psychiatrist will make recommendations for care, but the primary care provider may want a clinical evaluation to be completed to determine the best treatment based on your individual needs. Appropriateness of continued participation will be determined based on the outcome of that evaluation. Clinical care visits and medications to assist with improved clinical care will be the responsibility of the patient or insurance to pay for.

In addition, any injuries or illnesses should be reported to study staff. Details may be needed to evaluate and determine what action (if any) needs to be taken.

What are your responsibilities?
If you take part in this research, you will be expected to:

- Come to study visits and follow the instructions you are given by the study doctor or other study staff.
- Immediately report to the study doctor or other study staff any changes in your health or regular medications.
- Tell your study doctor or study staff if you think you are experiencing a harmful effect from the study participation.
- Do not participate in other research studies while participating in this study before discussing with your study doctor or study staff.

- Tell the study doctor or study staff if you want to stop being in this research study.

We ask that you provide contact information for a person close to you who we can reach out to in case of emergency or inability to reach you.

Tests done only for research purposes are not meant to provide clinical information or care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you, except for the results of your urine drug testing which will be put into your medical record. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

What are the possible risks or discomforts from being in this research study?

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk. All data collected in the Senyo Health app will be kept protected within Mayo Clinic firewall. Also, there will be no data shared with other people that are not involved with the study.

Some questions that you are asked during an interview or in a questionnaire may make you uncomfortable. If so, you may choose not to answer any of those particular questions. However, certain questions provide information for your eligibility and safety. If you choose not to answer these questions, you may not be able to participate in the study. If at any time during the study the study team feels you are endorsing suicidality or depression, you will be assessed for safety and if needed a referral to the emergency room or another treatment option will be made.

Participation involves using a phone and pregnant woman can participate with no additional risk to the fetus.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- If it is in your best interest (i.e. safety and health concerns),
- If you don't follow the study procedures,
- If the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

What are the possible benefits from being in this research study?

This study may not make your health better. However, it may help you reduce the frequency of your use of substances or help you completely stop using substances.

Others with substance use disorder may benefit in the future from what we learn in this research study.

What alternative do you have if you choose not to participate in this research study?

You don't have to be in this study to receive treatment for your condition. Your other choices may include any outpatient or inpatient treatment options outside of this research.
Talk to the Principal Investigator or your doctor if you have any questions about any of these treatments or procedures or the benefits and risks of these alternatives.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study.

These tests and procedures are:

- *Urine tests*
- *Care Coordinator/Licensed Alcohol Drug Counselor/Study staff check-in visits*
- *Senyo Health app*
- *Questionnaires*
- *Interviews*

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles. For example, if provided medication (i.e. suboxone, acamprosate, etc.) to assist with treatment is part of clinical care and would be billed to you and/or your insurance.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

The active intervention phase of this project uses the contingency management method. You will earn points for completing tasks within the Senyo Health app. Those points can be exchanged for a specified dollar amount. The number of points you can earn is about 1500 (converts to

about $399) but this will vary depending on your involvement, activities completed, and points received. The money will be given on a reloadable cash card (PEX Card) and each time you turn in your points for a cash reward that amount will be loaded on the card for you to use. Follow up phase will be paid $25 for each visit. Total remuneration should not exceed $599 per patient. In order to provide this compensation, the study team may need your Social Security number.

You will be paid using the PEX Card, debit card that your funds are loaded onto and can be used at your discretion. Your card will be activated once registered to you, and mailed to you (can take 10-15 days). When a visit is completed, the study team will load your study payments onto your card. The funds will be available within 1 business day. For Mayo Clinic employees, research payments are included in your paycheck.

To get paid with the PEX Card, additional informational may be needed such as; home address, email address, and date of birth. This information will be collected from you by the study staff and entered into the PEX Card dashboard for the study. If you choose to not provide the required information, the study team will have a check issued to you through the mail.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). You will be required to provide your Social Security number to receive any individual research payment of $1,500 or more, or if you receive research payments totaling $2,000 or more in a calendar year. Accounts Payable at Mayo Clinic will be given your name, address, date of birth and Social Security number in order to issue a check for your study participation. If you receive research payments totaling $2,000 or more in a calendar year, a tax Form 1099 will be sent to you. For Mayo Clinic employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W 2 after calendar year-end.

Will your information or samples be used for future research?

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information collected in this study, allowing the information to be used for future research or shared with other researchers at institutions and companies without your additional informed consent.

The urine collected will be tested and discarded.

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How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

We will need limited personal information, such as mayo clinic number, date of birth, name, address, phone and email, to set up your account in the Senyo Health application platform. The data collected through the platform is saved within the Mayo Clinic firewall on password-protected computer servers. Collected data will be de-identified and coded with a study ID. Database access will be limited to necessary study staff.

The Agency for Healthcare Research and Quality (AHRQ) is funding the study. Because of this, any information that we collect about you and that identifies you can only be used for the reason that it was collected and with your permission. There are civil monetary penalties for violation of this confidentiality requirement. Information can be found in the AHRQ statute, 42 USC 299c-3.

If the results of the research are made public, information that identifies you will not be used.

Representatives from the Mayo Clinic Institutional Review Board (the committee that reviews, approves, and monitors research on human subjects) may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.

- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Mayo Clinic staff involved in your clinical care.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- Federal Data Repositories

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you.

However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private, and it may no longer be protected by the Privacy Rule.

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Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
Plummer Building, PL 3-02
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts forever, unless you cancel it.

There is no expiration or end date related to the Sponsor's use of your health information received from Mayo Clinic as part of this study.

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Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature