STUDY TITLE: Project BETTER: Bringing Education Through Technology, Empathic Listening, and Research – A Feasibility Randomized Controlled Trial

VCU INVESTIGATOR: Caitlin E. Martin, M.D., MPH, Assistant Professor

HM20023314/NCT05214118

Approved date: 12/21/21

HM20023314 - Caitlin Martin
Project BETTER: Bringing Education Through Technology, Empathic listening, and Research - A Feasibility Randomized Controlled Trial

Study Identification

1. * **Select the Principal Investigator:**
   Caitlin Martin

2. * **Study Title:**
   Project BETTER: Bringing Education Through Technology, Empathic listening, and Research - A Feasibility Randomized Controlled Trial

3. * **Is this a student or trainee project in which activities will be carried out by that individual under your supervision (for example, dissertation or degree-required projects):**
   - ○ Yes
   - ● **No**

4. * **Please select the primary department or center that this study is being conducted under:**
   Institute for Drug and Alcohol Studies

5. **Select the VCU IRB numbers assigned to studies that are:**
   1. **Associated with this study**
   2. **Research registries this study will utilize**
   3. **Previously submitted versions of this study (closed, withdrawn, auto-withdrawn studies)**

ID	Title	PI
HM20022131	Project BETTER: Bringing Education Through Technology, Empathic listening, and Research - Pre-Testing Phase	Caitlin Martin

6. **Select all individuals who are permitted to edit the IRB protocol and should be copied on communications (study staff will be entered later). These individuals will be referred to as protocol editors:**

Last Name	First Name	E-Mail	Phone	Mobile
Martin	Caitlin	cemartin@vcu.edu	8046287023	
Parlier	Anna	parlierab@vcu.edu		
Thumma	Lillia	thummadl@vcu.edu	8048281193	

7. * **Select one of the following that applies to the project (selection will branch to new pages):**
   Note: VCU IRB offers guidance for many types of studies, including secondary data analysis studies, internet research, registries, EFIC, HUD, and Emergency Use protocols.
   See *https://research.vcu.edu/human_research/guidance.htm*
   - ● **Research Project or Clinical Investigation [*most exempt, expedited, and full board research studies]**
   - ○ Exception from Informed Consent (EFIC) for Planned Emergency Research
   - ○ Humanitarian Use of Device for Treatment or Diagnosis
   - ○ Humanitarian Use of Device for Clinical Investigation
   - ○ Emergency Use of Investigational Drug, Biologic or Device

- ○ Treatment Use (Expanded Access to Investigational Product for Treatment Use)
- ○ Center or Institute Administrative Grant Review
- ○ Request for Not Human Subject Research Determination (i.e. request a letter confirming that IRB review is not required)

Federal Regulations

1. * **Is this a FDA regulated study?**

   FDA regulated research includes all clinical investigations involving a test article and a human subject(s) that has been submitted for approval to the FDA or may be submitted in the future. Check Yes if
   • the study involves an IND/IDE, abbreviated IDE, IND/IDE exemption, HUD, expanded access, or is otherwise subject to 21 CFR 56,
   • the study involves a test article being administered or dispensed to subjects NOT according to a clinicians' medical judgment but rather, per the study protocol, OR
   • the study does not involve a test article but intends to provide safety or efficacy data to the FDA.

   ○ Yes
   ● **No**

2. * **Is this study supported by the Department of Defense (DoD):**
   ○ Yes
   ● **No**

3. * **Check if any of the following funding sources apply to this research (including Direct and/or Indirect funding):**
   ☐ Department of Education
   ☐ Department of Justice
   ☐ Environmental Protection Agency
   ☑ **None of the above**

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IRB Panel Setup

1. * **To which IRB is this study being submitted for review?**
   - (●) **VCU IRB**
   - ( ) WCG IRB
   - ( ) NCI Central IRB
   - ( ) Advarra IRB
   - ( ) Other IRB

2. * **Is this study transitioning to review by another IRB?**
   - ( ) Yes - transitioning from VCU IRB to an external IRB (WCG, CIRB, Other)
   - ( ) Yes - transitioning from an external IRB (WCG, CIRB, Other) to VCU IRB
   - (●) **No or not applicable**

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Review Setup

1. * **Select which study type best describes the majority of the study. Your response will help determine which IRB panel should review this.**
   - ○ Bio-Medical Research
   - ● **Social/Behavioral/Education (SBE) Research**

2. * **Which option(s) best describe the way(s) this study's procedures will be conducted? (Select all that apply.) This information may be used by the IRB in triaging studies during an emergency.**
   - ☑ **In-person interactions / interventions with participants**
   - ☑ **Remote interactions / interventions with participants**
   - ☐ Secondary data/specimen analyses with or without contact with study participants

3. * **Would it be possible to convert in-person activities in your study to remote if there is an approved contingency protocol?**
   Yes, could convert to remote activities

4. * **Does this study involve greater than minimal risk:**
   ○ Yes ● **No**

5. * **Review type requested: (subject to IRB approval):**
   - ○ Full Board
   - ○ Expedited
   - ● **Exempt**

6. * **Is this study initiated by a VCU investigator or a sponsor:**
   - ● **VCU Investigator initiated**
   - ○ Sponsor or industry initiated

The IRB has determined that the selected types of anticipated individual and social benefit apply to this study

The below information is read-only to investigators, and the categories are set by the IRB during review. All categories will appear blank until the IRB has made a determination. If a category is not checked, it does not apply to this study. This information may be used by the IRB in triaging studies during an emergency situation.
Scientific benefit

The following information applies to studies being reviewed by the VCU IRB.

The IRB has determined that the selected Exempt and/or Expedited categories apply to this study.

The below information is read-only to investigators, and the categories are set by the IRB during review. All categories will appear blank until the IRB has made a determination. If a category is not checked, it does not apply to this study or the study is being reviewed by an external IRB.

7. **For Exempt Studies under the Pre-2018 Common Rule:**

There are no items to display

8. **For Exempt Studies under the 2018 Common Rule:**

Category 2(iii)	Research that only includes interactions involving educational tests, survey or interview procedures, or observation of public behavior when Identifiable information is recorded by the investigator, and the IRB conducted a limited IRB review
Category 3(i)(C)	Research involving benign behavioral interventions when the information obtained is recorded by the investigator in an identifiable manner, and the IRB conducted a limited IRB review
Category 4(iii)	Secondary research for which consent is not required when the research involves only collection and analysis of identifiable health information when the research use is regulated by HIPAA

Initial Setup Complete

Protocol Progress:
● **INITIAL SETUP**
② BACKGROUND, RATIONALE & GOALS
③ RESEARCH PLAN
④ CONSENT PLAN
⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

HM20023314 - Caitlin Martin

Project BETTER: Bringing Education Through Technology, Empathic listening, and Research - A Feasibility Randomized Controlled Trial

Background, Rationale and Goals

1. * **Describe the study's background and what is currently known from the scientific literature, including citations, or upload a citation list in document upload. Use lay language whenever possible.**

   Overdose has become a leading cause of pregnancy-associated deaths, with most occurring during the postpartum period [1]. Providers and health systems across the country, including VCU, are responding to this crisis by integrating women's health and addiction medicine practices for opioid use disorder (OUD) treatment [2]. Evidence-based OUD treatment includes medication for OUD (MOUD). A known effect of prenatal MOUD use is neonatal opioid withdrawal syndrome (NOWS). Medically, we have witnessed advancements in NOWS and OUD treatments that lead to better outcomes for women and their families [2]. However, we continue to see rising opioid related deaths and rapid decreases in OUD treatment continuation rates as women progress farther from delivery [3]. This disconnect between science and reality highlights the urgent need for improvements in the quality and effectiveness of the care this high-risk population receives during pregnancy and postpartum.

   During the transition from pregnancy to postpartum, women with OUD and in treatment for OUD face a host of stressors including those common to the 'Fourth Trimester' (period after delivery) [4] and often a child welfare (ChildProtective Services) in addition to caring for a NOWS infant [5]. Despite provider counseling and traditional prenatal preparation for families affected by OUD, women after delivery commonly report feeling overwhelmed and frustrated by NOWS management, child welfare interactions, and the postpartum transition [3,5]. This interplay between stressors may be driving the high vulnerability women with OUD face after delivery manifesting in opioid overdose, now rated a leading cause of death through 12 months postpartum [1].

   Current standard prenatal educational approaches for families in OUD treatment are insufficient, likely due to a lack of tools tailored to patient needs that are also easy to use in clinical settings. Providing better prenatal education and support for this vulnerable population is a high priority. Use of technology can supplement standard care and extend the reach of prenatal educational interventions. It is important that any patient educational intervention for this unique population be both feasible to implement in a clinical setting and acceptable to pregnant people in treatment for OUD. Our research team designed a technology-based intervention using a process of iterative modification grounded in formative data. First, interviews assessing patient (n=12) and provider (n=9) preferences identified three topic areas: 1) recovery-oriented strategies for the postpartum transition, 2) guidance around caring for an infant with withdrawal symptoms, and 3) preparation for child welfare interactions. Then novel modules matching these areas were drafted and reviewed in successive rounds by an expert panel of patients, multidisciplinary providers, and technology-based intervention researchers. After iterative revisions, modules were programmed into the web-based, easily accessible platform (CIAS 3.0). Additionally, our team used a similar process to develop a brochure covering the same topics as the technology-based intervention. Preliminary evaluation data indicate the intervention is highly acceptable to patients and feasible to complete in a clinical setting and remotely. Therefore, the next phase is to scale up to an RCT to assess the acceptability and feasibility of the novel technology-based intervention compared to the brochure.

   References.
   1. Smid, M.C., et al., Pregnancy-Associated Death in Utah: Contribution of Drug-Induced Deaths. Obstet Gynecol,2019. 133(6): p. 1131-1140.
   2. Wakeman, S.E. and M.L. Barnett, Primary Care and the Opioid-Overdose Crisis - Buprenorphine Myths andRealities. N Engl J Med, 2018. 379(1): p. 1-4.
   3. Wilder, C., D. Lewis, and T. Winhusen, Medication assisted treatment discontinuation in pregnant and postpartumwomen with opioid use disorder. Drug Alcohol Depend, 2015. 149: p. 225-31.
   4. Tully, K.P., A.M. Stuebe, and S.B. Verbiest, The fourth trimester: a critical transition period with unmet maternalhealth needs. Am J Obstet Gynecol, 2017. 217(1): p. 37-41.
   5. Nielsen, T., et al., Maternal and infant characteristics associated with maternal opioid overdose in the year followingdelivery. Addiction, 2019.

2. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
   1. How feasible and acceptable is the technology-based intervention with content on NOWS, child welfare interactions, and the postpartum transition compared to a brochure for pregnant patients receiving MOUD?

   We hypothesize that integration of the technology based intervention into a busy prenatal clinic will be as feasible as the brochure and more acceptable to patients.

   2. How effective is the intervention for improving exploratory outcomes (i.e., mental health, recovery, functioning, and quality of life)?

3. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
   The primary objectives of this RCT are to assess the feasibility and acceptability of the technology-based educational intervention with content on NOWS, child welfare interactions, and the postpartum transition compared to a brochure for pregnant patients receiving MOUD.

Additional exploratory objectives are to evaluate intervention effectiveness on improving outcomes (i.e., mental health, recovery, functioning, and quality of life).

4. * **Describe the scientific benefit or importance of the knowledge to be gained:**

   Integrated treatment programs for pregnant and parenting women with OUD, like ours at VCU, need better educational tools specific to the postpartum transition. The proposed study will provide critical feasibility and acceptability data to improve the novel patient education materials and inform future studies evaluating clinically applicable patient centered interventions focused on the mother-infant dyad affected by OUD. Ultimately, implementation of clinically applicable patient-centered interventions focused on the mother-infant dyad could have broad positive impacts on the long-term health of families in the opioid crisis.

5. * **Describe any potential for direct benefits to participants in this study:**
   Participants may gain additional knowledge to help them prepare for the pregnancy to postpartum transition and take care of their recovery.

6. * **Describe any potential for direct social impact in this study . For example, any engagement with specific communities to respond to community-identified needs, or ways the study will strengthen the well-being of the specific communities if applicable:**
   At the conclusion of this study, we will make this program free and available to patients and providers.

7. **Upload a supporting citation list if applicable:**

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Project BETTER Consent Form Community-based recruitment	Community-based recruitment Project BETTER Consent Form_clean IRB 10.25.pdf	0.05	11/7/2022 10:47 AM	Anna Parlier	Consent/Assent/Information Sheet	Yes
View	Community-based Study Interest Form	StudyInterest_ProjectBETTERCom.pdf	0.01	10/31/2022 4:01 PM	Anna Parlier	Recruitment/Advertising	Yes
View	SOP	HM20023314 Project BETTER RCT SOP 10.31.22.docx	0.05	10/31/2022 3:59 PM	Anna Parlier	Research Protocol	Yes
View	Project BETTER Community-based recruitment email template	Project BETTER Community Recruitment Study Notification Email Template.docx	0.01	10/31/2022 3:58 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Project BETTER Community-based recruitment script	Project BETTER Community Remote Recruitment Scripts.docx	0.01	10/31/2022 3:58 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Project BETTER Community-based recruitment flyer	Project BETTER Community-based Flyer.docx	0.01	10/12/2022 5:00 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Project BETTER RA Forms 3 Delivery Questions	Project BETTER Study Visit 3 Delivery Questions.docx	0.01	10/5/2022 2:33 PM	Anna Parlier	Research Measure	Yes
View	Eligibility Form	Revised 7.18.22 Project BETTER Eligibility Form.docx	0.02	7/18/2022 5:45 PM	Anna Parlier	Research Measure	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	In-person Recruitment Script	Revised 7.18.22 Project BETTER In Person Recruitment Scripts.docx	0.04	7/18/2022 5:44 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Remote Recruitment Script	Revised 7.18.22 Project BETTER Remote Recruitment Scripts.docx	0.02	7/18/2022 5:43 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Recruitment Flyer	Revised Project BETTER Flyer 7.18.22.docx	0.02	7/18/2022 5:41 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Consent form	Project BETTER Consent Form_revised 12.15.21.pdf	0.07	12/21/2021 10:35 AM	Anna Parlier	Consent/Assent/Information Sheet	Yes
View	Informatics consult	BETTER_Informatics_Email.pdf	0.01	12/3/2021 9:57 AM	Jessica Lantz	Other	Not Applicable
View	PROC APPROVAL	BETTER_PROC_Approval.pdf	0.01	11/17/2021 1:27 PM	Caitlin Martin	Ancillary Committee Approval	Not Applicable
View	Study Notification Email Template	Project BETTER Study Notification Email Template.docx	0.01	11/17/2021 9:27 AM	Anna Parlier	Recruitment/Advertising	Yes
View	Project Better Module Transcript	Project BETTER Peedy Transcript.docx	0.01	11/17/2021 9:24 AM	Anna Parlier	Research Measure	Yes
View	Project BETTER Module Video Links	Project BETTER Video Links.docx	0.01	11/15/2021 12:02 PM	Anna Parlier	Other	Yes
View	Project BETTER Brochure Webpage	Project BETTER Webpage.pdf	0.01	11/15/2021 12:01 PM	Anna Parlier	Other	Yes
View	Project BETTER Overview	Project BETTER Technology-based Program Overview.pdf	0.01	11/15/2021 12:01 PM	Anna Parlier	Other	Yes
View	Technology-based modules	Project BETTER Technology-based module links.docx	0.01	10/11/2021 7:42 PM	Anna Parlier	Other	Yes
View	Brochure	Project BETTER Brochure.pdf	0.01	10/11/2021 7:41 PM	Anna Parlier	Research Measure	Yes
View	Demographic questions	Project BETTER Demographic Questions .docx	0.01	10/11/2021 7:41 PM	Anna Parlier	Recruitment/Advertising	Yes
View	RA forms 3	Project BETTER Study Visit 3 RA Form.docx	0.01	10/11/2021 7:40 PM	Anna Parlier	Research Measure	Yes
View	RA forms 2	Project BETTER Study Visit 2 RA Form.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes
View	RA forms 1	Project BETTER Study Visit 1 RA Form.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes
View	Follow up survey 2	Project BETTER Follow-up Survey 2.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes
View	Follow up survey 1	Project BETTER Follow-up Survey 1.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes
View	Pre-survey	Project BETTER Pre-Survey.docx	0.01	10/11/2021 7:38 PM	Anna Parlier	Research Measure	Yes
View	Chart abstraction	Project BETTER Study Visit 3 Chart Abstraction Form.docx	0.01	10/11/2021 7:38 PM	Anna Parlier	Research Measure	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	form 3						
View	Chart abstraction form 2	Project BETTER Study Visit 2 Chart Abstraction Form.docx	0.01	10/11/2021 7:37 PM	Anna Parlier	Research Measure	Yes
View	Chart abstraction form 1	Project BETTER Study Visit 1 Chart Abstraction Form.docx	0.01	10/11/2021 7:37 PM	Anna Parlier	Research Measure	Yes
View	Scheduling and Reminder Scripts	Project BETTER Follow Up Scheduling and Reminders Scripts.docx	0.01	10/11/2021 7:36 PM	Anna Parlier	Study reminders/communications	Yes
View	Follow up visit scripts	Project BETTER Follow-up Visits Script.docx	0.01	10/11/2021 7:36 PM	Anna Parlier	Study reminders/communications	Yes
View	Martin CV	CEM_CV_08.15.21_BT.pdf	0.01	10/10/2021 9:23 PM	Caitlin Martin	CV/Biosketch	Yes
View	Parlier CV	Parlier CV .pdf	0.01	10/10/2021 5:44 PM	Anna Parlier	CV/Biosketch	Not Applicable

Study Population

1. * **Provide the maximum number of individuals that**

   1. May participate in any study interaction or intervention (Including screening, consenting, and study activities)
   AND/OR
   2. You obtain any data/specimens about (regardless of identifiability)

   at VCU and at other sites under the VCU IRB's oversight. See the help text for additional guidance.
   70

2. **If this is a multi-Center Project, what is the maximum anticipated number of subjects across all sites?**
   N/A

3. * **Provide justification for the sample size by explaining how you arrived at the expected number of participants and why this number is adequate for answering the research questions:**
   Target sample size: N=30 (15 per study condition)

   As this is a pilot feasibility trial, 30 study participants is the recommended sample size (Browne, 1995).

   Browne R.H. (1995) On the use of a pilot sample for sample size determination. Statistics in Medicine 14, 1933–1940.

   Based on our prior experience, we anticipate about 20% of eligible participants we approach will not be interested in the study, which will be about 10.

   Additionally, we will abstract information from the medical record on the birth hospitalization for participants' infants, which includes an additional 30.

   This makes a total of 70 as above.

4. * **List the study inclusion criteria:**
   1) Female
   2) ≥18 years of age
   3) Meet criteria for Opioid Use Disorder
   4) Currently receiving MOUD pharmacotherapy (including buprenorphine, buprenorphine/naloxone, or methadone)
   5) Pregnant (<34 weeks EGA)
   6) Engaged in treatment at OB MOTIVATE for ≤10 weeks during the current pregnancy OR engaged in community-based OUD treatment for ≤10 weeks during the current pregnancy

5. * **List the study exclusion criteria:**
   1) Considering/planning adoption
   2) Present with a serious cognitive/psychiatric impairment
   3) Existing language barriers making true informed consent impossible

6. **Justify the inclusion and exclusion criteria if you are either targeting, or excluding, a particular segment of the population / community. Provide a description of the group/organization/community and provide a rationale.**
   Pregnant people in treatment for OUD will be selected because the patient education intervention targets this specific population. We want to make sure the program is feasible and acceptable to this unique population.

Background, Rationale & Goals Section Complete

Protocol Progress:

● **INITIAL SETUP**

● **BACKGROUND, RATIONALE & GOALS**

③ RESEARCH PLAN

④ CONSENT PLAN

⑤ RISKS, PRIVACY & CONFIDENTIALITY

⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS

⑦ INSTITUTIONAL REQUIREMENTS

⑧ DOCUMENTS

Click Continue below to go to the next section

Study Procedures

1. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
   1. How feasible and acceptable is the technology-based intervention with content on NOWS, child welfare interactions, and the postpartum transition compared to a brochure for pregnant patients receiving MOUD?

   We hypothesize that integration of the technology based intervention into a busy prenatal clinic will be as feasible as the brochure and more acceptable to patients.

   2. How effective is the intervention for improving exploratory outcomes (i.e., mental health, recovery, functioning, and quality of life)?

2. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
   The primary objectives of this RCT are to assess the feasibility and acceptability of the technology-based educational intervention with content on NOWS, child welfare interactions, and the postpartum transition compared to a brochure for pregnant patients receiving MOUD.

   Additional exploratory objectives are to evaluate intervention effectiveness on improving outcomes (i.e., mental health, recovery, functioning, and quality of life).

3. * **Choose all types of recruitment materials that may be used <u>and upload them below</u>:**
   - [x] **E-mail invitations**
   - [x] **Phone Solicitation scripts (i.e. cold calls or random-digit-dialing)**
   - [x] **Flyers, Mailed Letters or Newspaper/TV/Radio Ads**
   - [ ] TelegRAM announcements
   - [ ] Website text
   - [ ] Study-specific web sites (provide the design and text)
   - [ ] Social Media
   - [ ] EPIC MyChart Patient Portal research study descriptions
   - [ ] Psychology Research Participant Pool (SONA) study descriptions
   - [ ] Scripts for announcements made to groups
   - [x] **Other recruitment document**
   - [ ] No recruitment materials

4. * **If Other was selected above, describe the recruitment document that will be used:**
   In person recruitment script

5. * **Describe the study procedures/methods for identifying and recruiting participants. Address all of the following three aspects of recruitment in your response.**

   ***1.** Identification of potentially eligible participants or secondary data/specimens of interest.*
   - **What database(s) will be queried to identify secondary data/specimens**
   - **How VCU Informatics or VCU IRDS will be used for cohort identification (when applicable, see help text)**
   - **How potential participants' contact information will be obtained**

   ***2.** Recruitment procedures to invite participation in the study (when applicable):*
   - **How each of the written or verbal recruitment materials and reminders (selected above) will be used**
   - **Who will contact, approach, or respond to potential participants**
   - **Locations where recruitment procedures will take place**
   - **The timing and frequency of recruitment attempts**

   3. Eligibility screening prior to consent and how those activities will be carried out (when applicable)

See the help text for additional guidance.

1. We will recruit pregnant women in treatment with the VCU OB MOTIVATE program. The OB MOTIVATE program sees pregnant, postpartum, and parenting women for substance use disorder treatment no matter if they plan to or delivered at VCU with no time limitation for treatment continuation, making our program a growing referral provider for surrounding OBGYN and behavioral health practices. OB MOTIVATE currently sees approximately 70 pregnant and postpartum/parenting women for at least one outpatient encounter each month between our two VCU locations (Nelson/AOP Women's Health and MOTIVATE Addiction Medicine clinics). The OB MOTIVATE at Nelson/AOP clinic schedule and the medical record will be accessed by the research assistant to assess potential eligibility (18 or older, pregnant, <34 weeks gestation, receiving MOUD, engaged in treatment at OB MOTIVATE for ≤10 weeks during the current pregnancy) in order to identify which potential participants to approach about the study.

**We will also passively recruit participants from community-based sites including local addiction treatment centers and OB/GYN clinics. Recruitment flyers will be posted at sites with a QR code. Individuals who are interested in participant can use the QR code to provide contact information. The RA will contact potential participants to assess study eligibility (18 or older, pregnant, <34 weeks gestation, receiving MOUD, engaged in OUD treatment for ≤10 weeks during the current pregnancy).

2. Recruitment and enrollment will occur by phone or in-person during OB MOTIVATE clinics, located at Nelson/AOP clinic (Thursday/Fridays) or MOTIVATE (Tuesday & Wednesday afternoons) based on potential COVID restrictions and participant preference using the appropriate IRB-approved scripts. The IRB-approved study flyer will be provided to potential participants during clinic visits. The IRB-approved recruitment scripts will be used by the research assistant to assess potential participant interest in study participation and confirm eligibility. Additionally, the IRB-approved study flyer will be used as a visual aid during the in-person recruitment conversation. In-person and phone recruitment will be conducted by a research assistant (not a healthcare provider) who is a member of the research team. The research assistant is embedded in the clinic and has access to patients during clinic hours; the RA will approach eligible participants in private exam rooms while they are waiting to see their provider or by phone before/after a virtual appointment with their provider. If the research staff is unable to get in touch with the potential participant with communication linked to an in-person or virtual visit, then eligible participants will be sent a study notification email that includes information about the study with a note that the research staff will follow-up with a phone call within one week to assess their interest in participating. This email will also provide an option to opt-out of further contact. Eligible and interested subjects will undergo the informed consent process and complete the baseline assessment (Study visit 1). Subjects who are eligible and decline participation will be asked to answer 5 demographic questions by self-administration of the 5 questions.

If participants are unable to complete the any part of the study in person at the clinic OR they prefer to complete the study visits remotely, they will have the option to complete study visits by a confidential link to a unique redcap survey that will be emailed or texted to them at their preferred email or phone number (which will be confirmed with them before emailing the link) from the research assistant who will also call the patient over the phone for some questions.

No recruitment or consent procedures will be done by the PI who is clinical director of the OB MOTIVATE program.

**The IRB-approved study flyer will be posted in community-based addiction treatment and OB/GYN clinics. The study research assistant will contact potential participants who provide contact information within one week of providing information. The IRB-approved remote recruitment scripts will be used by the research assistant to assess potential participant interest in study participation and confirm eligibility. Phone recruitment will be conducted by a research assistant who is a member of the research team. If the research staff is unable to get in touch with the potential participant by phone, then eligible potential participants will be sent a study notification email that includes information about the study with a note that the research staff will follow-up with a phone call within one week to assess their interest in participating. This email will also provide an option to opt-out of further contact. Eligible and interested subjects will undergo the informed consent process and complete the baseline assessment (Study visit 1). Subjects who are eligible and decline participation will be asked to answer 5 demographic questions by self-administration of the 5 questions.

3. Potential participants will be called and/or emailed by the research assistant (up to 4 times over 10 weeks) or approached in the clinic when they arrive for a scheduled clinic appointments while waiting to see their provider in the private exam rooms. If the potential participant does not answer the phone, the research assistant will leave a generic voicemail without any identifying information (i.e., "This is (RA name) calling from VCU health about potential participation in a research study. If you are interested in learning more, please return the call to XXX-XXX-XXXX"). When the RA talks to the potential participants, they will confirm their eligibility for the study verbally using the eligibility form (see uploaded recruitment scripts).

**Potential participants who use the recruitment flyer QR code to provide contact information will be called and/or emailed by the research assistant (up to 4 times over 10 weeks). If the potential participant does not answer the phone, the research assistant will leave a generic voicemail without any identifying information (i.e., "This is (RA name) calling from VCU health about potential participation in a research study. If you are interested in learning more, please return the call to XXX-XXX-XXXX"). When the RA talks to the potential participants, they will confirm their eligibility for the study verbally using the eligibility form (see uploaded recruitment scripts).

6. * **Does this study have a separate protocol document (i.e. a multisite or sponsor's protocol) that contains a detailed description of the study's methodology?**

- (●) **Yes**
- ( ) No

7. * **Upload the separate protocol document, and in the response below, provide all of the following information:**

1. Identify which specific sections of the protocol describe the study design and procedures.
2. A statement explaining the study design
3. A lay language overview of all research activities/procedures
4. For multisite studies, a description of whether there are any local changes to the protocol's procedures, and if so, what those changes are (i.e. different, omitted, or additional procedures)
5. Any necessary clarifications of the protocol's content (i.e. what local standard of care or routine practice is)
1. Entire Standard Operating Procedures (SOP) document
2. Pilot feasibility randomized controlled trial comparing technology-based modules (intervention) to a brochure (control)
3. Following consent, participants will complete the first study visit, a baseline assessment (electronic survey & brief RA questions). Then participants will be randomized (1:1) to either the technology-based modules (intervention) group or the brochure (control) group. Randomization and intervention introduction can be completed at the same time of the other first study visit procedures (ie, pre-survey) or as a supplemental unpaid visit based on participant preference (ie, if the participant wants to complete the pre-survey remotely and the intervention introduction in person). Participants will be provided access via email/text to the modules or the electronic brochure (based on randomization) for three weeks. Following the 3-week study intervention period, participants will complete two follow-up study visits (electronic survey & brief RA questions): 1) during pregnancy within two weeks of intervention timeframe (Study visit 2) and 2) within 4-8 weeks postpartum (Study visit 3). Enrolled, randomized participants not completing Study visit 2 within 5 weeks of study condition introduction, but wishing to do so, will be reviewed by the PI on a case-by-case basis for the opportunity of continued study participation. Specifically, if the participant is no longer pregnant, study continuation will not be allowed; if still pregnant, the PI will consider the option of study continuation (e.g., completion of follow-up visit 1) for the participant. For each study visit, we will also obtain health information (as per secondary data page and uploaded document) via the health record after participants have agreed to the HIPAA authorization in the consent form. Participants will be compensated $20 per study visit (up to $60 total).

Module condition: Participants in the module condition will have access to the 3 modules in the technology-based intervention covering content on the pregnancy to postpartum transition, NOWS, and child welfare interactions (approximately 25-minutes each). Modules can be reviewed in the OB MOTIVATE clinic using research tablets or they can be reviewed remotely on a personal device in any order the participant chooses. Modules deliver information via the Computerized Intervention Authoring System, Version 3 (CIAS 3.0) using professionally produced videos and an interactive avatar using behavioral techniques, such as psychoeducation and aspects of motivational interviewing. Participants in the technology-based modules intervention condition will access the modules through a link emailed/texted to them by the study RA. They will enter their Study ID into the modules. No personal identifying information will be collected or stored in CIAS 3.0 modules. All participants in this condition will be oriented to the intervention with the RA via the program introduction (5 minutes).

CIAS 3.0 is an authoring tool that allows creation or editing of electronic screening and intervention packages without the need of a programmer. Interventions built using CIAS feature a synthetic text to speech engine that reads all questions and speaks aloud to the participant (usually via headphones); synchronous interactivity, natural language reflections, branching logic, a clean user interface, and the ability to easily incorporate specific images, graphs, figures, text, or videos. CIAS applications are HIPAA compliant with encryption of all data in transit and at rest, and are hosted on a HIPAA-compliant cloud server. CIAS 3.0 is cross-platform compatible, meaning that it deploys readily on any device including those running the Android or Apple mobile operating systems. CIAS 3.0 was developed by researchers at Michigan State University under an award from NIH (1U24EB028990). Therefore, the Michigan State University logo appears as part of the CIAS program. However, no information from our modules are shared with Michigan State; they are solely providing the online platform for our intervention. The VCU logo will appear on the final version of the technology based modules for the current study. Module links are provided for the current study (see attachment).

Brochure condition: Provision of written materials to patients is often a component of standard care. Therefore, participants in the brochure condition will be provided a paper copy and/or provided an electronic pdf of the study brochure via email/text (in order to facilitate ease of participation for those who prefer remote study completion) covering content on the pregnancy to postpartum transition, NOWS, and child welfare interactions. There is a QR code within the brochure that leads to a website with additional information on the three educational topic areas. The brochure is uploaded in the documents.

4. N/A

5. N/A

8. * **The IRB only reviews research activities, so indicate for each of the study activities described in the question above or in the protocol which activities are:**

- Being performed exclusively for research purposes (i.e. they would not otherwise be done apart from this study) VERSUS.
- Alterations of routine activities/procedures (e.g. the study is altering the timing, frequency, method, location, amount, etc.) VERSUS.
- Being done for other purposes and whose data/results will be used secondarily in the study (e.g. standard medical or psychological tests, routine education practices, quality improvement initiatives, etc.).
See the help text for additional guidance

Participants will complete the three study visits and review the modules or brochure entirely for research purposes. Their medical care will proceed in same manner regardless study participation and study group condition.

9. **If applicable, describe alternatives (research or non-research) that are available to potential participants if they choose not to participate in this study:**
N/A

10. **Upload any supporting tables or documents (e.g. protocol documents, figures/tables, data collection forms, study communications/reminders):**

Upload ALL instruments/guides that will be used or that participants will experience (i.e. see, hear, complete), including measures, scripts/questions to guide interviews, surveys, questionnaires, observational guides, etc,:

Upload ALL recruitment and screening materials, including such as ads, flyers, telephone or in-person scripts, letters, email invitations, TelegRAM announcements, and postcard reminders, screening scripts, screening forms, and screening measures:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Project BETTER Consent Form Community-based recruitment	Community-based recruitment Project BETTER Consent Form_clean IRB 10.25.pdf	0.05	11/7/2022 10:47 AM	Anna Parlier	Consent/Assent/Information Sheet	Yes
View	Community-based Study Interest Form	StudyInterest_ProjectBETTERCom.pdf	0.01	10/31/2022 4:01 PM	Anna Parlier	Recruitment/Advertising	Yes
View	SOP	HM20023314 Project BETTER RCT SOP 10.31.22.docx	0.05	10/31/2022 3:59 PM	Anna Parlier	Research Protocol	Yes
View	Project BETTER Community-based recruitment email template	Project BETTER Community Recruitment Study Notification Email Template.docx	0.01	10/31/2022 3:58 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Project BETTER Community-based recruitment script	Project BETTER Community Remote Recruitment Scripts.docx	0.01	10/31/2022 3:58 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Project BETTER Community-based recruitment flyer	Project BETTER Community-based Flyer.docx	0.01	10/12/2022 5:00 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Project BETTER RA Forms 3 Delivery Questions	Project BETTER Study Visit 3 Delivery Questions.docx	0.01	10/5/2022 2:33 PM	Anna Parlier	Research Measure	Yes
View	Eligibility Form	Revised 7.18.22 Project BETTER Eligibility Form.docx	0.02	7/18/2022 5:45 PM	Anna Parlier	Research Measure	Yes
View	In-person Recruitment Script	Revised 7.18.22 Project BETTER In Person Recruitment Scripts.docx	0.04	7/18/2022 5:44 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Remote Recruitment Script	Revised 7.18.22 Project BETTER Remote Recruitment Scripts.docx	0.02	7/18/2022 5:43 PM	Anna Parlier	Recruitment/Advertising	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Recruitment Flyer	Revised Project BETTER Flyer 7.18.22.docx	0.02	7/18/2022 5:41 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Consent form	Project BETTER Consent Form_revised 12.15.21.pdf	0.07	12/21/2021 10:35 AM	Anna Parlier	Consent/Assent/Information Sheet	Yes
View	Informatics consult	BETTER_Informatics_Email.pdf	0.01	12/3/2021 9:57 AM	Jessica Lantz	Other	Not Applicable
View	PROC APPROVAL	BETTER_PROC_Approval.pdf	0.01	11/17/2021 1:27 PM	Caitlin Martin	Ancillary Committee Approval	Not Applicable
View	Study Notification Email Template	Project BETTER Study Notification Email Template.docx	0.01	11/17/2021 9:27 AM	Anna Parlier	Recruitment/Advertising	Yes
View	Project Better Module Transcript	Project BETTER Peedy Transcript.docx	0.01	11/17/2021 9:24 AM	Anna Parlier	Research Measure	Yes
View	Project BETTER Module Video Links	Project BETTER Video Links.docx	0.01	11/15/2021 12:02 PM	Anna Parlier	Other	Yes
View	Project BETTER Brochure Webpage	Project BETTER Webpage.pdf	0.01	11/15/2021 12:01 PM	Anna Parlier	Other	Yes
View	Project BETTER Overview	Project BETTER Technology-based Program Overview.pdf	0.01	11/15/2021 12:01 PM	Anna Parlier	Other	Yes
View	Technology-based modules	Project BETTER Technology-based module links.docx	0.01	10/11/2021 7:42 PM	Anna Parlier	Other	Yes
View	Brochure	Project BETTER Brochure.pdf	0.01	10/11/2021 7:41 PM	Anna Parlier	Research Measure	Yes
View	Demographic questions	Project BETTER Demographic Questions .docx	0.01	10/11/2021 7:41 PM	Anna Parlier	Recruitment/Advertising	Yes
View	RA forms 3	Project BETTER Study Visit 3 RA Form.docx	0.01	10/11/2021 7:40 PM	Anna Parlier	Research Measure	Yes
View	RA forms 2	Project BETTER Study Visit 2 RA Form.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes
View	RA forms 1	Project BETTER Study Visit 1 RA Form.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes
View	Follow up survey 2	Project BETTER Follow-up Survey 2.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes
View	Follow up survey 1	Project BETTER Follow-up Survey 1.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes
View	Pre-survey	Project BETTER Pre-Survey.docx	0.01	10/11/2021 7:38 PM	Anna Parlier	Research Measure	Yes
View	Chart abstraction form 3	Project BETTER Study Visit 3 Chart Abstraction Form.docx	0.01	10/11/2021 7:38 PM	Anna Parlier	Research Measure	Yes
View	Chart abstraction form 2	Project BETTER Study Visit 2 Chart Abstraction Form.docx	0.01	10/11/2021 7:37 PM	Anna Parlier	Research Measure	Yes
View	Chart abstraction	Project BETTER Study Visit 1 Chart Abstraction Form.docx	0.01	10/11/2021 7:37 PM	Anna Parlier	Research Measure	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	form 1						
View	Scheduling and Reminder Scripts	Project BETTER Follow Up Scheduling and Reminders Scripts.docx	0.01	10/11/2021 7:36 PM	Anna Parlier	Study reminders/communications	Yes
View	Follow up visit scripts	Project BETTER Follow-up Visits Script.docx	0.01	10/11/2021 7:36 PM	Anna Parlier	Study reminders/communications	Yes
View	Martin CV	CEM_CV_08.15.21_BT.pdf	0.01	10/10/2021 9:23 PM	Caitlin Martin	CV/Biosketch	Yes
View	Parlier CV	Parlier CV .pdf	0.01	10/10/2021 5:44 PM	Anna Parlier	CV/Biosketch	Not Applicable

Project Details

An intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

An interaction includes communication or interpersonal contact between investigator and subject. It may include in-person, online, written, or verbal communications.

Secondary information/biospecimens are information or biospecimens that have been or will be collected for some other "primary" or "initial" activity and that will be used secondarily in the research study.

1. * **Select all of the following types of interventions that apply to this study (selections will branch):**
   - [x] **Social/Behavioral interventions or experimentation / Tasks / Environmental manipulations**
   - [ ] Deception (misleading participants through false or incomplete information)
   - [ ] Drug(s) / Biologics / Supplement(s) / Other Compounds (investigational products or products whose administration is dictated by the study protocol and not per the physician's clinical judgment)
   - [ ] IV contrast administration for research-related imaging (will branch to the Drugs page)
   - [ ] Placebos
   - [ ] Safety and/or effectiveness evaluation of Bio-Medical Device(s), including in-vitro diagnostic devices/assays, mobile medical apps, software functions, and HUDs used in clinical investigations
   - [ ] Washout Periods
   - [ ] Expanded Access – Treatment Use of an Investigational Product
   - [ ] Medical or Surgical Procedures (eg: physical exam, clinical procedures, scans, etc)
   - [ ] Specimen/biological sample collection
   - [ ] None of the Above

2. * **Select all of the following types of interactions and methods of data collection that apply to this study (selections will branch):**
   - [x] **Surveys / Questionnaires /Written responses to questions (including data entry)**
   - [x] **Active Internet data collection (i.e. using the internet to collect data, including online surveys, data collection via Zoom, apps, etc.)**
   - [ ] Passive Internet data collection (i.e. passively observing online behavior, bots)
   - [x] **Interviews / Focus Groups / Verbal responses to questions**
   - [ ] Audio / Video recording or photographing participants
   - [ ] Observations
   - [ ] Educational Settings/Assessments/Procedures
   - [ ] None of the Above

3. * **Select all types of secondary information and/or specimens that apply to this study (selections will branch):**
   See the help text for definitions.
   - [x] **Individually Identifiable Health Information (PHI)**
   - [x] **Secondary data/specimens NOT from a research registry or repository**
   - [ ] Information/specimens from a research registry or repository (Usage Protocol)
   - [ ] Information/specimens originally collected for a previous research study
   - [ ] Publicly available information/specimens

- [ ] Government-generated or collected information that was or will be obtained for nonresearch activities [only applicable to research conducted by or on behalf of a Federal department or agency]
- [ ] No secondary data/specimens will be used

Behavioral Intervention/Task Details

This page asks for details about the social/behavioral intervention, task, or environmental manipulation in the research.

Interventions include both physical procedures by which information is gathered and manipulations of the subject or the subject's environment that are performed for research purposes. This might include activities such as playing computer games, performing a task, thought/cognition activities, environmental manipulations, and educational activities.

If the study only involves surveys, interviews, or secondary data collection, go back to the Project Details page and uncheck "Social/Behavioral interventions or experimentation / Tasks / Environmental manipulations" in Question 1.

1. * **Describe the duration of the social/behavioral intervention, task, or environmental manipulation:**
   Module condition: Participants in the module condition will have access to the 3 modules in the technology-based intervention covering content on the pregnancy to postpartum transition, NOWS, and child welfare interactions (approximately 25-minutes each). Modules can be reviewed in the OB MOTIVATE clinic using research tablets or they can be reviewed remotely on a personal device in any order the participant chooses. Modules deliver information via the Computerized Intervention Authoring System, Version 3 (CIAS 3.0) using professionally produced videos and an interactive avatar using behavioral techniques, such as psychoeducation and aspects of motivational interviewing. Participants in the technology-based modules intervention condition will access the modules for 3 weeks through a link via email/text. Participants will enter their Study ID into the modules. No personal identifying information will be collected or housed in CIAS 3.0 modules. All participants in this condition will be oriented to the intervention with the RA via the program introduction (5 minutes).

   Brochure condition: Provision of written materials to patients is often a component of standard care. Therefore, participants in the brochure condition will be provided a paper copy and/or provided an electronic pdf of the study brochure via email/text (in order to facilitate ease of participation for those who prefer remote study completion) covering content on the pregnancy to postpartum transition, NOWS, and child welfare interactions. There is a QR code within the brochure that leads to a website with additional information on the three educational topic areas. The participants will have 3 weeks to review the brochure content (including the additional educational content through the QR code). Review of all brochure information will take approximately 25-45 minutes.

2. * **Describe any potential harms or discomforts that participants could experience during the intervention activity:**
   Few risks are expected by taking part in this study. There is the possibility that participants may experience some fatigue and/or discomfort when reviewing the content in the brochure or modules. The content in the brochure and modules is a review of information covered in standard medical treatment for this population. Participants will be informed of their right to refuse or stop study participation at any time, and their right to refuse to answer any questions that make them uncomfortable. The following message will also be provided in each of the modules and on the brochure, "If you have concerns or are experiencing a negative reaction to any of the content, please contact the research assistant at 804-229-1261."

   Participants may be disappointed if they are not assigned to their preferred group or are not able to access the technology-based modules throughout the study. Following the conclusion of the study, research team plans to make the technology-based modules accessible to clinicians and patients.

3. * **Will the intervention activity be physically invasive or painful?**
   - ○ Yes
   - ● **No**

4. * **Describe the impact the intervention activity will have on participants, including the nature and duration of any impact(s):**
   The brochure content will take approximately 25-45 minutes to review. The three modules each take approximately 25 minutes to review. Review of content based on study condition will take some sustained attention that will end after the content has been reviewed.

5. * **In the investigator's opinion, is there any reason to think that the participants will find the intervention activity offensive or embarrassing? Explain why or why not.**
   No, the content in the brochure and modules is a review of information covered in standard medical treatment for this patient population. As part of standard prenatal care for people with opioid use disorder, medical providers review information about the pregnancy to postpartum transition, neonatal opioid withdrawal syndrome, and interactions with child welfare. The modules and brochure provide the same information using a different medium. Additionally, the brochure and modules were designed using a process of iterative modification grounded in formative data from both

patients and providers. Preliminary evaluation data indicate the modules and brochure are highly acceptable to patients and feasible to complete in a clinical setting and remotely. Based on our preliminary evaluation, no patients have found the modules or brochure to be offensive or embarrassing. In fact, some patients noted they are more comfortable receiving the information using the modules and brochure rather than being told directly from their medical provider.

Active Internet Data Collection

1. * **Describe the platform/technology chosen for collecting the data and transmitting data securely over the internet. If proposing a non-VCU approved platform, give the rationale for selecting the technology instead of a VCU-approved platform.**
   RedCap, a VCU approved platform, will be used to store/collect all study visit data (surveys, RA questions, chart abstraction).

   The Computerized Intervention Authoring System, Version 3 (CIAS 3.0) is an authoring tool that allows creation or editing of electronic screening and intervention packages without the need of a programmer. Interventions built using CIAS feature a synthetic text to speech engine that reads all questions and speaks aloud to the participant; synchronous interactivity, natural language reflections, branching logic, a clean user interface, and the ability to easily incorporate specific images, graphs, figures, text, or videos. CIAS applications are HIPAA compliant with encryption of all data in transit and at rest, and are hosted on a HIPAA-compliant cloud server. CIAS 3.0 is cross-platform compatible, meaning that it deploys readily on any device including those running the Android or Apple mobile operating systems. CIAS versions 1.0 and 2.0 have been used with thousands of participants, and consistently received extremely high satisfaction ratings (e.g., Naar-King et al., 2013; Ondersma et al., 2005, 2007, 2012), including with high risk and low SES samples.

   For the current study, no identifiable data will be collected using the CIAS 3.0 software. Unique hyperlinks to the CIAS 3.0 modules, associated with participant study ID's, will be provided via email/text by the study RA.

2. * **Describe how data will be linked or unlinked to identifiers including email addresses, names, and/or IP address.**
   A Study ID will be assigned to each participant upon study enrollment. All study visit data (survey, RA questions, chart abstraction) will be stored in RedCap and will only be labelled with participant's Study ID already associated with the study. The key linking the participant information and Study ID will be kept in a separate secure VCU RedCap database.

   The participants will enter their Study ID into the CIAS platform when they complete the modules. Participants will not enter any identifying information into the modules.

   A unique VCU email address used by the research team only will be used to send emails with the links for the RedCap surveys, modules, and the brochure.

3. * **How will you protect your data collection from fraudulent responses:**
   Survey questionnaire links will not be publicly available. Each participant will be sent a RedCap link unique to their study ID to complete study questionnaires. Additionally, the RA will remind the participant that they can skip or not answer any questions that they would prefer not to answer and that they can end the survey at any time.

   During brief RA-led questions, the RA will build rapport with participant to reduce stigma and encourage honest responses. Additionally, the RA will remind the participant that they can skip or not answer any questions that they would prefer not to answer and they can end the interview at any time.

   Data checks for all data collection will be conducted regularly. Identified data irregularities will be discussed immediately with the PI and handled on a case by case basis.

   In the CIAS intervention, attention check questions are included in each module.

4. * **Is there an alternative method for completion of the data collection other than the internet?**
   ○ Yes
   ● **No**

5. * **Describe how individuals will be able to skip or not answer particular questions. If any questions are mandatory, provide justification.**
   Participants will be able to skip or not answer particular questions if they choose by selecting "prefer not to answer."

6. **If not including children, describe any procedures used to verify that research participants are adults.**
   All potential participants will be screened for eligibility (at least 18 years of age) by the research assistant (RA) using the OB MOTIVATE schedule and medical record. For potential participants that are not OB MOTIVATE patients, the RA will screen for eligibility when individuals are contacted. All eligibility criteria will be confirmed by the RA with the potential participant prior to study enrollment.

Secondary Data/Specimen Details

1. * **Describe the source(s) and nature of the information/specimens being obtained. This response should:**

   a. Identify where the data/specimens will come from (e.g., another researcher's registry, pathology lab, commercial source, medical records, etc.); and
   b. List what types of specimens will be obtained (when applicable); and/or
   c. List all data elements that will be obtained (when applicable). A data collection form or other documentation may be uploaded and referenced here.

   OB MOTIVATE patients:
   a. Data will be abstracted from the participants medical record for each study visit.
   b. No specimens will be obtained
   c. See chart abstraction forms (attached) for information to be abstracted from the medical record at each study visit.

   **Community-based addiction treatment:
   No secondary data will be obtained. All data will be self-reported by the participant via survey and interview questions.

2. * **Describe whether any agreement exists between you and data/specimen provider that states you will never have access to the ability to identify the participants (i.e. access to identifiers or the code key) and that you will not attempt to re-identify individuals.**
   Each participant's StudyID will be linked to their medical record number to allow other study visit data to be linked to the protocoled medical record abstraction. This information will be kept in a separate key file within the secure RedCap database. The key linking the Study ID to the participant medical record ID will be destroyed upon completion of the study.

3. * **When the information/specimens were originally collected, did individuals provide consent for secondary research use of their data/specimens (i.e. consent to another research study or to a research registry)?**

   ○ Yes
   ● **No**

Costs to Participants

1. * **Select all categories of costs that participants or their insurance companies will be responsible for:**
   - [x] **Participants will have no costs associated with this study**
   - [ ] Study related procedures that would be done under standard of care
   - [ ] Study related procedures not associated with standard of care
   - [ ] Administration of drugs / devices
   - [ ] Study drugs or devices
   - [ ] Other

Compensation

It is recommended that investigators consult with VCU Procurement Services before proposing a compensation plan (monetary or non-monetary) to the IRB to ensure the plan will comply with VCU policies. Refer to WPP XVII-2 for the IRB's guidelines about compensating research participants.

1. * **Describe any compensation that will be provided including:**
   1. total monetary amount
   2. type (e.g., gift card, research pre-paid card, cash, check, merchandise, drawing, extra class credit)
   3. how it will be disbursed
   4. how you arrived at this amount
   5. What identifiers and tax forms will be required for compensation purposes (i.e. W-9 form, SSN, V#, addresses, etc.)

   Participants will receive $20 for each of the three study visits. Total possible compensation is $60.
   All participants will be offered the option to receive a mailed check or cash following the completion of a study visit OR the option to delay individual visit payments in order to receive a subsequent cumulative payment mailed check or cash after completion of multiple completed study visits.

2. **If compensation will be pro-rated, explain the payment schedule.**
   N/A

Contingency Plan

This page will be used by the IRB in the event that an institution-wide emergency situation arises that requires contingency plans.

A contingency plan describes the alternative procedures that a study would want to use in case of an emergency that prevented normal study activities from occurring. It is a form of adaptive protocol. It enables the VCU IRB to quickly approve alternative study activities along with criteria for when those activities would or would not be put into effect. For example, in 2020, some studies had a COVID-19 Contingency Protocol approved that described alternative remote procedures that they would switch to whenever the University restricted in-person research activities.

In all studies, investigators are strongly encouraged to plan prospectively and build flexibilities into their regular protocols (regardless of whether an emergency situation exists) as well as think about what they would do in an emergency situation. For example, windows for timed study visits, ranges instead of exact values, flexibilities in inclusion criteria, etc. Flexibility and adaptations that are built into the protocol will reduce the number of changes that have to be submitted to the IRB and should reduce the number of incidents of deviations and noncompliance by investigators.

Further instructions and smartform questions on this page will be released from the IRB in the event of such an institution-wide emergency situation.

Research Complete

Protocol Progress:
● **INITIAL SETUP**
● **BACKGROUND, RATIONALE & GOALS**
● **RESEARCH PLAN**
④ CONSENT PLAN
⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

Exempt Information Sheet Upload

While informed consent consistent with federal regulations is not required for exempt studies, VCU strongly advocates, and may require, that participants be provided with an information sheet. Information sheets provide some of the information usually included in a consent document.

At a minimum, the information sheet should indicate in language understandable to the potential participant:

1. **the activity involves research**
2. **brief description of what participants will be asked to do**
3. **the activity is voluntary**
4. **how the participants may ask questions**

Participants should be able to retain a copy of the information sheet, so if provided as a cover sheet to a survey, the ability to print or tear off would be helpful.

A template Exempt Information Sheet can be found at https://research.vcu.edu/forms/ **under IRB Forms.**

1. **Upload information sheets if applicable:**

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Project BETTER Consent Form Community-based recruitment	Community-based recruitment Project BETTER Consent Form_clean IRB 10.25.pdf	0.05	11/7/2022 10:47 AM	Anna Parlier	Consent/Assent/Information Sheet	Yes
View	Community-based Study Interest Form	StudyInterest_ProjectBETTERCom.pdf	0.01	10/31/2022 4:01 PM	Anna Parlier	Recruitment/Advertising	Yes
View	SOP	HM20023314 Project BETTER RCT SOP 10.31.22.docx	0.05	10/31/2022 3:59 PM	Anna Parlier	Research Protocol	Yes
View	Project BETTER Community-based recruitment email template	Project BETTER Community Recruitment Study Notification Email Template.docx	0.01	10/31/2022 3:58 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Project BETTER Community-based recruitment script	Project BETTER Community Remote Recruitment Scripts.docx	0.01	10/31/2022 3:58 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Project BETTER Community-based recruitment flyer	Project BETTER Community-based Flyer.docx	0.01	10/12/2022 5:00 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Project BETTER RA Forms 3 Delivery Questions	Project BETTER Study Visit 3 Delivery Questions.docx	0.01	10/5/2022 2:33 PM	Anna Parlier	Research Measure	Yes
View	Eligibility Form	Revised 7.18.22 Project BETTER Eligibility Form.docx	0.02	7/18/2022 5:45 PM	Anna Parlier	Research Measure	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	In-person Recruitment Script	Revised 7.18.22 Project BETTER In Person Recruitment Scripts.docx	0.04	7/18/2022 5:44 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Remote Recruitment Script	Revised 7.18.22 Project BETTER Remote Recruitment Scripts.docx	0.02	7/18/2022 5:43 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Recruitment Flyer	Revised Project BETTER Flyer 7.18.22.docx	0.02	7/18/2022 5:41 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Consent form	Project BETTER Consent Form_revised 12.15.21.pdf	0.07	12/21/2021 10:35 AM	Anna Parlier	Consent/Assent/Information Sheet	Yes
View	Informatics consult	BETTER_Informatics_Email.pdf	0.01	12/3/2021 9:57 AM	Jessica Lantz	Other	Not Applicable
View	PROC APPROVAL	BETTER_PROC_Approval.pdf	0.01	11/17/2021 1:27 PM	Caitlin Martin	Ancillary Committee Approval	Not Applicable
View	Study Notification Email Template	Project BETTER Study Notification Email Template.docx	0.01	11/17/2021 9:27 AM	Anna Parlier	Recruitment/Advertising	Yes
View	Project Better Module Transcript	Project BETTER Peedy Transcript.docx	0.01	11/17/2021 9:24 AM	Anna Parlier	Research Measure	Yes
View	Project BETTER Module Video Links	Project BETTER Video Links.docx	0.01	11/15/2021 12:02 PM	Anna Parlier	Other	Yes
View	Project BETTER Brochure Webpage	Project BETTER Webpage.pdf	0.01	11/15/2021 12:01 PM	Anna Parlier	Other	Yes
View	Project BETTER Overview	Project BETTER Technology-based Program Overview.pdf	0.01	11/15/2021 12:01 PM	Anna Parlier	Other	Yes
View	Technology-based modules	Project BETTER Technology-based module links.docx	0.01	10/11/2021 7:42 PM	Anna Parlier	Other	Yes
View	Brochure	Project BETTER Brochure.pdf	0.01	10/11/2021 7:41 PM	Anna Parlier	Research Measure	Yes
View	Demographic questions	Project BETTER Demographic Questions .docx	0.01	10/11/2021 7:41 PM	Anna Parlier	Recruitment/Advertising	Yes
View	RA forms 3	Project BETTER Study Visit 3 RA Form.docx	0.01	10/11/2021 7:40 PM	Anna Parlier	Research Measure	Yes
View	RA forms 2	Project BETTER Study Visit 2 RA Form.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes
View	RA forms 1	Project BETTER Study Visit 1 RA Form.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes
View	Follow up survey 2	Project BETTER Follow-up Survey 2.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes
View	Follow up survey 1	Project BETTER Follow-up Survey 1.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes
View	Pre-survey	Project BETTER Pre-Survey.docx	0.01	10/11/2021 7:38 PM	Anna Parlier	Research Measure	Yes
View	Chart abstraction	Project BETTER Study Visit 3 Chart Abstraction Form.docx	0.01	10/11/2021 7:38 PM	Anna Parlier	Research Measure	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	form 3						
View	Chart abstraction form 2	Project BETTER Study Visit 2 Chart Abstraction Form.docx	0.01	10/11/2021 7:37 PM	Anna Parlier	Research Measure	Yes
View	Chart abstraction form 1	Project BETTER Study Visit 1 Chart Abstraction Form.docx	0.01	10/11/2021 7:37 PM	Anna Parlier	Research Measure	Yes
View	Scheduling and Reminder Scripts	Project BETTER Follow Up Scheduling and Reminders Scripts.docx	0.01	10/11/2021 7:36 PM	Anna Parlier	Study reminders/communications	Yes
View	Follow up visit scripts	Project BETTER Follow-up Visits Script.docx	0.01	10/11/2021 7:36 PM	Anna Parlier	Study reminders/communications	Yes
View	Martin CV	CEM_CV_08.15.21_BT.pdf	0.01	10/10/2021 9:23 PM	Caitlin Martin	CV/Biosketch	Yes
View	Parlier CV	Parlier CV .pdf	0.01	10/10/2021 5:44 PM	Anna Parlier	CV/Biosketch	Not Applicable

Consent Plan Complete

Protocol Progress:
● **INITIAL SETUP**
● **BACKGROUND, RATIONALE & GOALS**
● **RESEARCH PLAN**
● **CONSENT PLAN**
⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

Privacy

Privacy refers to an individual's right to control how others view, record, or obtain information about them. When privacy is violated it can involve such things as

- Being asked personal questions in a public setting;
- Being publicly identified as having a particular characteristic or diagnosis;
- Being seen entering a place that might be stigmatizing;
- Being photographed, videotaped or observed without consent;
- Disclosure of personal information to unauthorized people

Privacy is not the same as confidentiality because privacy protections apply to people, and confidentiality protections apply to data. Confidentiality protections should be described on the Data Confidentiality page of this form, not here.

Instructions for this page:

Select all the applicable ways that the research team will protect participants' privacy throughout the course of the study. The options listed include some of the most common best practices. Not all will be applicable to every study.

****The IRB will expect studies to operationalize all selected checkboxes into the conduct of the research.**

To elaborate on any response, also click the "Other Protections" checkbox to provide further explanation in the last free-text question.

Read the entire page before filling out the form.

1. * **Protections when conducting one-on-one in-person interventions or interactions (for groups see Q2 below):**
   - [x] **Conducting study activities in locations that maximize privacy (limited people around, closing doors, drawing drapes around beds, monitoring voice volume, etc.)**
   - [x] **Verifying identity before discussing personal information.**
   - [x] **Asking the participant if they are comfortable answering questions in that location**
   - [x] **Asking the participant if they are comfortable with having other people present (if any)**
   - [x] **Moving away from other people when conducting activities in public spaces or offering a private space**
   - [x] **Offering other options of ways to respond to sensitive questions (i.e. pointing, clicking, or writing) if uncomfortable verbally responding**
   - [ ] Using generic signs on research rooms and spaces, particularly for research on stigmatizing or sensitive topics
   - [ ] Other protections not listed in this question – describe below
   - [ ] N/A – study has no in-person interventions or interactions with participants

2. * **Protections when conducting group interventions or interactions:**
   - [ ] Conducting study activities in locations that maximize privacy (limited people passing by, closing doors, monitoring voice volume, etc.)
   - [ ] Moving to a more private area to answer questions or to discuss concerns
   - [ ] Discussing privacy with the participants and the importance of not talking outside the group about what other people say during the group session
   - [ ] Allowing participants to use a pseudonym or limiting use of individuals' names during the group activity
   - [ ] Asking everyone in a public group setting (e.g. classrooms, workshops) to turn something in (blank or filled) so participants do not have to self-identify when turning in materials
   - [ ] Collecting paper forms in a closed box or envelope rather than passing to others or leaving in an open area
   - [ ] Limiting participant identifiers that would be visible on paper documents (i.e. using study IDs instead of direct identifiers)
   - [ ] Allowing people to distance themselves from other participants during group activities

- [ ] Offering other options of ways to respond to sensitive questions (i.e. pointing, clicking, or writing instead of speaking)
- [ ] Using generic signs on research rooms and spaces, particularly for research on stigmatizing or sensitive topics
- [ ] Ensuring non-participating individuals are not captured on recordings or in photos
- [ ] Other protections not listed in this question – describe below
- [x] **N/A – study has no group interventions or interactions**

3. * **Protections when conducting remote interventions or interactions (e.g. phone, text, email, video-conference, tele-health, online, etc.):**
   - [x] **Conducting study activities in locations where study staff can maximize their own privacy (limited people around, closing doors, monitoring voice volume, etc.)**
   - [x] **Leaving/sending generic messages that avoid using study and participant identifiers, such as names, study titles, clinics, study topics, etc.**
   - [x] **Obtaining permission prior to sending text messages**
   - [x] **Advising the participant to move to a location where they are comfortable answering questions and will not be overheard - incorporate this instruction into your study materials**
   - [x] **Advising online participants to complete the activity at a time and location where they will be comfortable answering questions - incorporate this instruction into your study materials**
   - [ ] Ensuring non-participating individuals are not captured on recordings or in photos
   - [x] **Offering other options of ways to complete the activity (i.e. online, paper, phone) if more privacy is desired**
   - [x] **Offering a way to save and return later to the online activity if privacy is compromised**
   - [ ] Other protections not listed in this question – describe below
   - [ ] N/A – study has no remote interventions or interactions with participants

4. * **Protections when mailing study materials to/from participants:**
   - [x] **Obtaining permission to mail study materials**
   - [x] **Confirming/verifying the accuracy of addresses before mailing items**
   - [x] **Ensuring the participant is able to personally receive mailed materials and has a way to protect their own privacy if they do not want others to know they are receiving research communications (i.e. notifying participants of when to expect it)**
   - [x] **Using return address labels and document headers that avoid study identifiers, such as study names, clinics, study topics, etc.**
   - [x] **Avoiding or limiting use of participant identifiers and health information on mailed documents (i.e. using study IDs instead of direct identifiers)**
   - [ ] Providing a return mailing address label or pre-addressed envelope to ensure returned items are sent to the correct address
   - [ ] Communicating receipt of mail from participants and/or asking them to notify you when they mail it to ensure study documents are not lost in transfer
   - [ ] Offering other options of ways to complete the activity (i.e. by phone or online) if desired
   - [ ] Other protections not listed in this question – describe below
   - [ ] N/A – not mailing any materials to/from participants

5. * **Protections when analyzing or disseminating study data** *Applicable to all studies*:
   - [x] **Working only in locations where the study team can ensure privacy (not working in close proximity to non-study personnel, closing doors, closing/putting away documents/files before leaving, etc.)**
   - [x] **Securing physical materials only in locations that ensure privacy (access limited to authorized study personnel)**
   - [x] **Only sharing data/specimens in accordance with the Sharing Plan outlined in this smartform**
   - [ ] Obtaining explicit parental permission before disseminating or sharing recordings or photos of children
   - [ ] Blurring/redacting/hiding faces and other identifiable features/marks (tattoos, scars, birthmarks, distinctive voice, etc.) in recordings or photos prior to disseminating or sharing
   - [ ] Only publishing or presenting aggregate results or findings (i.e. no individual-level information)

- [ ] Taking additional steps to protect participant identities when publishing or presenting individual-level information, quotations, results, images – describe below
- [ ] Other protections not listed in this question – describe below

6. **Describe any other way(s) that the research team will protect participants' privacy. *See the help text for additional guidance*.**
   N/A

Data Confidentiality and Storage

Confidentiality refers to the way private, identifiable information about a participant or defined community is maintained and shared. It describes how the study's research materials (data, specimens, records, etc.) are protected from unauthorized access.

Instructions for this page:
Select all the ways that the research team will keep the study materials and data confidential throughout the course of the study. Not all will be applicable to every study.
To elaborate on any response, also click the "Other Protections" checkbox to provide further explanation in the last free-text question.

Read the entire page before filling out the form.

1. * **Protections for paper research materials:**
   - [x] **Maintaining control of paper documents at all times, including when at an off-campus location**
   - [x] **Limiting or avoiding use of participant identifiers on paper documents (i.e. using study IDs instead of direct identifiers)**
   - [x] **Storing paper documents in a secure location accessible only to authorized study personnel**
   - [x] **Promptly transcribing, scanning, or abstracting data from paper into electronic platforms with destruction of the paper copy**
   - [x] **Proper destruction of paper records (and obtaining prior permission when required) in accordance with VCU Records Management policies**
   - [ ] Other protection not listed in this question – describe below
   - [ ] N/A – no paper research materials

2. * **Protections for research specimens:**
   - [ ] Maintaining control of specimens at all times, including when at an off-campus location
   - [ ] Storing specimens in a secure location accessible only to authorized study personnel
   - [ ] Labeling specimens with subject ID or other coded information instead of direct identifiers
   - [ ] Final destruction of specimens will be in accordance with VCU policies and specimen containers will be devoid of any identifiable information
   - [ ] Other protection not listed in this question – describe below
   - [x] **N/A – no research specimens**

3. * **Protections for electronic files/data - See https://ts.vcu.edu/about-us/information-security/data-management-system/**
   - [x] ***Required for all studies* Use VCU-approved methods of data storage, transmission, and transfer (see https://dms.vcu.edu)**
   - [x] **Remotely accessing VCU network storage to store data when at off-campus locations**
   - [x] **Ensuring unauthorized individuals who might share a device do not have access to study materials (e.g. individual logins, separate accounts)**
   - [x] **Using VCU-approved data collection tools and apps (e.g. REDCap) and storing exported analysis files in VCU-approved storage locations (see https://dms.vcu.edu)**
   - [x] **When using non-VCU-approved electronic data collection tools, storage locations, data transfer platforms, and mobile apps (e.g. Dropbox, Box, Survey Monkey, Fitbits, novel apps, multi-site data collection platforms):**
     • consulting with VCU Information Security on proper data management (see https://ts.vcu.edu/askit/essential-computing/information-security/);
     • advising participants about the terms of use and privacy policies of those sites/apps;
     • limiting or avoiding use of identifiers; and
     • removing data promptly from the external location after transferring it to a VCU storage location
   - [x] **De-identifying the research data by replacing subjects' names with assigned subject IDs**
   - [x] **Storing the study's linkage key in a password-protected and VCU-approved storage location (see https://dms.vcu.edu)**
   - [ ] When analyzing particularly sensitive information, using computers that are unconnected from the internet.

- [x] **Proper destruction of electronic records (and obtaining prior permission when required) in accordance with VCU Records Management policies**
- [ ] Other protection not listed in this question – describe below

4. * **Protections for computers and research devices/apps that are <u>provided to participants</u> for use in the study and taken out of the lab (i.e., giving participants a phone or iPad to take home, wearable trackers, apps, etc.):**
   - [x] **Transferring data promptly from the device/app given to the participant to a VCU storage location**
   - [x] **Setting strong passwords on computers and research devices (when applicable) that leave VCU with participants**
   - [ ] Device/app set up by VCU Information Security
   - [ ] When providing devices or mobile apps to children, informing parents about the settings and how to manage them (if applicable), internet access, and any other installed apps on the device
   - [ ] Other protection not listed in this question – describe the device/app and protection below
   - [ ] N/A – no computers or devices/apps being provided for participant use outside the lab

5. * **Protections for email/online communications**
   - [x] **Only using VCU/VCU Health email addresses for study-related communications**
   - [x] **Only using VCU/VCU Health–approved methods of teleconferencing or video conferencing (e.g. Zoom) (for studies involving HIPAA, contact VCU or VCU Health Information Security [as appropriate] about HIPAA-compliant systems)**
   - [ ] Other protection not listed in this question – describe below
   - [ ] N/A – no email/online communications

6. **Specify any other places where this study's paper and electronic research data and/or physical specimens will be stored and any other ways they will be secured from improper use and disclosure.**

   See the help text for additional guidance.
   N/A

7. * **If research data/specimens will be sent/released to person(s) or group(s) outside of the VCU study team or the PI's department for the conduct of this protocol (not for future sharing),**
   1) identify the data/specimen recipient(s) along with their VCU department or other institutional or organizational affiliation(s).
   2) give a description of what identifiers and/or codes will accompany the data/specimens.
   If data/specimens are not being sent/released outside of the VCU study team or the PI's department, state that:
   There are no plans to release patient level data/identifiers to anyone outside of VCU. If this changes, we will revise the submission accordingly, prior to any release of information

8. * **Select all identifiers that will be collected <u>at any time</u> as part of this study (including for recruitment, data gathering, data analysis, etc.), even if the data will eventually be anonymized:**
   - [x] **Names**
   - [ ] Geographic Locators Below State Level
   - [ ] Social Security Numbers
   - [x] **Dates (year alone is not an identifier)**
   - [ ] Ages over 89 (age under 89 is not an identifier)
   - [x] **Phone Numbers**
   - [ ] Facsimile Numbers
   - [x] **E-mail Addresses**
   - [x] **Medical Record Numbers**
   - [ ] Device Identifiers
   - [ ] Biometric Identifiers
   - [ ] Web URLs

- [ ] IP Addresses
- [ ] Account Numbers
- [ ] Health Plan Numbers
- [ ] Full Face Photos or Comparable Images
- [ ] License/Certification Numbers
- [ ] Vehicle ID Numbers
- [ ] Other Unique Identifier
- [ ] No Identifiers
- [ ] Employee V#

9. * **If the study will code (i.e. de-identify) the research data by replacing subjects' names and/or other identifiers with assigned subject IDs, explain the following aspects of the coding process:**

- The process for how subject IDs will be generated/assigned (e.g. random, sequential)
- Whether there will be a key that links the subject ID with direct identifiers. If there will be no linkage key, state that.

If a key will be created, describe
- The place where the key will be stored
- The role(s) of all individuals who will have access to the key
- When the key will be destroyed

See the help text for guidance.
A study ID will be assigned in sequential order for all study participants and will not be related to participant information. A key with the participant identifier (e.g., MRN) linked to study ID numbers will be kept in a document within RedCap separate from the research data and consent forms. Only key study personnel involved in study procedures will have access to the key. Patient identifying information will be kept (linked to study ID numbers) to facilitate contact for follow up study visits within the study. The key will be destroyed when the study is complete and the study manuscripts are published.

Data Retention

1. * **Select all of the ways that individually identifiable information obtained during pre-screening and/or screening will be handled for individuals who DO NOT qualify for the study:**
   - [ ] N/A - study does not require screening procedures
   - [ ] Immediately destroy the information and identifiers (no data collected)
   - [ ] Immediately destroy the identifiers connected with the data (anonymization)
   - [x] **Store until the end of study & then destroy**
   - [ ] Use as "screening failure" data by members of the study team
   - [ ] Provide to others outside of the research team (with the participant's permission)
   - [ ] Request permission from participant to maintain and use the identifiable information
   - [ ] Other

2. * **Will participants be able to withdraw their data (paper, electronic, or specimens) from the study (e.g. ask that it be destroyed or returned) if they no longer wish to participate? (FDA-regulated studies should select No – see help text)**
   - (●) **Yes**
   - ( ) No

3. * **If Yes , describe the process (oral, written, email, letter, etc.) that participants should use to request withdrawal of their data/specimens. Identify if there is a timepoint when withdrawal will no longer be an option and/or if the amount of data that can be withdrawn is reduced at different points in the study.**
   Participants will be given contact information (phone number) for study personnel with their copy of the consent form and be informed to contact the study team if they would like their data withdrawn. Data used in published findings cannot be withdrawn.

4. * **What will happen to the research materials (e.g. data, specimens, documents, etc.) when the research has been completed?**
   - ( ) Stored indefinitely with identifiers removed
   - ( ) Stored indefinitely with identifiers attached
   - (●) **Destroyed at the end of study once the minimum time required for data retention has been met per VCU Data Retention Policy and/or sponsor retention requirements**
   - ( ) Destroyed when notified by sponsor but not less than the minimum time required for data retention per VCU Data Retention Policy
   - ( ) Other

HM20023314 - Caitlin Martin

Project BETTER: Bringing Education Through Technology, Empathic listening, and Research - A Feasibility Randomized Controlled Trial

Sharing Plan

This page addresses times when investigators may be required to share information about participants or may desire to share their research information/specimens with the aim of advancing science. This page creates a plan for when and how information/specimens could be shared.

Try to anticipate all reasonably foreseeable sharing so that the consent document can also reflect that information. However, it is acceptable to amend this page later and explain either how re-consent of previously and currently enrolled participants will occur or why re-consent should not be required.

The IRB reviews this page against the consent document (if one exists) to demonstrate the ethical principle of Respect for Persons by confirming that plans for sharing do not go against what participants would understand about the use of their data/specimens.

The IRB also ensures there are adequate protections for the privacy of participants and the confidentiality of participants' data/specimens when data is shared with others.

1. * **Is it likely investigators could discover information about child/elder abuse or neglect that would require mandatory reporting by the investigators or staff?**

   The Code of Virginia requires that most medical personnel and all employees of institutions of higher education report suspected child/elder abuse or neglect.

   - (●) **Yes**
   - ( ) No

2. * **Is it likely investigators could discover a previously unknown reportable disease or condition that would require mandatory reporting by the investigators or staff (i.e., HIV , coronavirus, hepatitis, etc.)?**

   ( ) Yes (●) **No**

3. * **Will the sponsor or investigator obtain a Certificate of Confidentiality for this study?**

   Certificates of Confidentiality (CoC) are issued by the National Institutes of Health (NIH), the FDA and CDC to protect identifiable research information from forced disclosure. All human subject research studies regardless of funding can qualify to receive a CoC. A CoC is automatically issued for research that was ongoing on December 13, 2016. or initiated after that date. For more information, see https://humansubjects.nih.gov/coc/

   - (●) **Yes – Plan to submit request for CoC and will amend study/ICF once status of request is known**
   - ( ) No – Will not obtain CoC for this study
   - ( ) Yes – CoC has been obtained or issued automatically
   - ( ) Yes – CoC request is pending

4. * **Select the way(s) that information or biospecimens (including DNA) may be used <u>by the VCU PI or VCU study team for other future research projects</u> (i.e. analyses beyond/apart from the aims of this study)?**
   See help text for definitions.

   - [ ] Will use directly identifiable information or specimens.

   ('Directly identifiable' means that identifiers like name, medical record number, social security number, etc. are included in/attached to the dataset/specimens. Maintaining identifiable data for future research is treated as a registry by the VCU IRB. The IRB must approve the new research use in an amendment to this study or as part of a new study before the project is initiated. VCU IRB studies will be asked more questions about this on a later page)

Will use de-identified or indirectly identifiable information or specimens.

☐ *('De-identified' means that a linkage/key code exists that links identifiers to data/specimens. When the researcher holds both the data and the key, the VCU IRB considers the subjects to be readily identifiable. Maintaining identifiable data for future research uses is treated by the IRB as a registry. The IRB must approve the new research use in an amendment to this study or as part of a new study before the project is initiated. VCU IRB studies will be asked more questions about this on a later page)*

Will use anonymized information or specimens.

☑ *('Anonymized' means that 1) no linkage/key codes exist that link identifiers to data/specimens; and 2) subjects cannot be readily identified, i.e. no direct or indirect identifiers or identifiable combinations of variables. The VCU IRB considers uses of anonymized data/specimens to not be human subject research.)*

Will use aggregate results (summary-level results), not individual-level information or specimens.

☑ *(The VCU IRB considers uses of aggregate data to not be human subject research because there are no individual subjects.)*

Will contribute to an existing registry or repository

☐ *(VCU IRB studies will be asked more questions about this on a later page.)*

☐ Will not use information/specimens for purposes beyond this study.

☐ Not sure and will submit an amendment when known

☐ Other use(s) of individual-level information in a way not listed above

5. * **Select the way(s) the VCU PI/study team may share information or biospecimens (including DNA) with other researchers who are not on this study team (i.e. for analyses beyond/apart from the aims of this study).**
See help text for definitions.

Will share directly identifiable information or specimens with other researchers.

☐ *('Directly identifiable' means that identifiers like name, medical record number, social security number, etc. are included in/attached to the dataset/specimens. Maintaining identifiable data for future research uses is treated by the VCU IRB as a registry. The data recipient's use of identifiable data would require them to obtain IRB review. VCU IRB studies will be asked more questions about this on a later page.)*

Will share de-identified or indirectly identifiable information or specimens with other researchers.

☐ *('De-identified' means that a linkage/key code exists that links identifiers to data/specimens. The VCU researcher maintains the key but does not share it with any other researchers. The recipient's use of de-identified data/specimens may not be human subject research if there is documentation that the key will never be shared with the recipient, but they should check with their own IRB about review requirements. VCU IRB studies will be asked more questions about this on a later page.)*

Will share anonymized information or specimens with other researchers.

☑ *('Anonymized' means that 1) no linkage/key codes exist that link identifiers to data/specimens; and 2) subjects cannot be readily identified (i.e. no direct or indirect identifiers or identifiable combinations of variables). The VCU IRB considers uses of anonymized data/specimens by other researchers to not be human subject research, but the recipient should check with their own IRB about review requirements.)*

Will only share aggregate results (summary-level results), not individual-level information or specimens.

☐ *(The VCU IRB considers uses of aggregate data to not be human subject research because there are no individual subjects. The data recipient should check with their own IRB about review requirements.)*

- [ ] Will contribute to an existing registry or repository (VCU IRB studies will be asked more questions about this on a later page.)
- [ ] Will submit data to an NIH genomic data repository (VCU IRB studies will be asked more questions about this on a later page.)
- [ ] Will not share information/specimens with other researchers.
- [ ] Not sure and will submit an amendment when known
- [ ] Other sharing of individual-level information with other researchers

6. * **Since you responded in a question above that you may use or share anonymous, individual level data, indicate why the proposed use or sharing of anonymous data/specimens is not inconsistent with what participants would have reasonably understood from the consent document about the uses of their information. (Select all that apply.)**

- [ ] The consent form states that after identifiers are removed, information or specimens could be used for future research studies without additional informed consent from the subject (this is a new element of consent included in consent templates as of May 2018)
- [x] **The consent form or exempt information sheet is silent about whether/how information or specimens could be used for future research studies.**
- [ ] The information or specimens were/will be obtained under a waiver of informed consent, waiver of HIPAA authorization, or an exempt study that did not use an information sheet.
- [ ] Other reason why anonymous use/sharing is not inconsistent with the consent document

7. * **The Principal Investigator certifies that prior to releasing an anonymized dataset or anonymized specimens the following conditions will all be met:**

- all 18 HIPAA identifiers (including all dates) will be removed;
- all indirectly identifiable data elements (unusual, rare, uncommon data) will be removed, grouped, suppressed, or otherwise transformed to no longer be readily identifiable;
- a different subject ID will be assigned than the one used for the main study and a linkage key will not be kept; and
- the PI will review the dataset/specimens to confirm that the remaining information could not be used alone or in combination with any other information to re-identify the participants represented in the data.

***See help text for more information*.**

- (●) **Yes**
- ( ) No

8. * **The Principal Investigator certifies that after the study has been closed with the VCU IRB, the following conditions will be met whenever individual level research information and/or specimens are used or shared:**

- The identities of participants who are represented in the dataset/specimens will not be readily ascertainable or otherwise re-identifiable by the recipient;
- If a linkage/code key is created, it will be maintained at VCU and not shared with the recipient under any circumstances;
- The PI will have no knowledge that the remaining information could be used alone or in combination with any other information to identify the individuals represented in the data; and
- The PI agrees to abide by this sharing plan even after the study has been closed with the VCU IRB.

- (●) **Yes**
- ( ) No
- ( ) N/A - No sharing will occur

Pertinent Results and Incidental Findings

1. * **Is it likely investigators could discover a participant's previously unknown condition (e.g. pregnancy, disease, suicidal thoughts, wrong paternity, genetic results, or other findings that may be of importance to health or well-being) or if a participant is engaging in illegal or reportable activities:**
   - (●) **Yes**
   - ( ) No

2. * **Describe what possible pertinent results or incidental findings stemming from research-only procedures may be discovered.**
   The RA-led questions at each study visit ask about substance use which may include use of illicit substances.

3. * **Explain what actions or procedures research personnel should take to inform the PI of such a discovery :**
   No additional actions will be taken if participants do disclose substance use.

4. * **Will findings be disclosed to participants and/or any other person/group outside of the study team?**
   - ( ) Yes
   - (●) **No**

5. **If pertinent and/or incidental findings will not be disclosed, explain why not:**
   Because the research is centered around women in recovery from substance use disorder and being conducted in clinics where these women are receiving care for their substance use disorder, there is not a necessity to take any action if participants do disclose substance use.

Risk Benefit Complete

Protocol Progress:
- **INITIAL SETUP**
- **BACKGROUND, RATIONALE & GOALS**
- **RESEARCH PLAN**
- **CONSENT PLAN**
- **RISKS, PRIVACY & CONFIDENTIALITY**

⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

Populations with Special Considerations

1. * **Check all participant groups that will be either**

   a) Specifically included in this study or

   b) Discernable in the research data/specimens.

   (Selections will branch)

- [x] **Children**
- [ ] Emancipated minors
- [ ] Wards of the State
- [x] **Pregnant women or fetuses**
- [x] **Neonates or Post-delivery Materials**
- [ ] Prisoners
- [ ] Decisionally Impaired Adults
- [ ] VCU / VCUHS students or trainees
- [ ] VCU / VCU Health System employees
- [ ] Individuals with limited English proficiency
- [ ] Active military personnel
- [ ] Student populations in K-12 educational settings or other learning environments
- [ ] Members of a federally recognized American Indian and Alaska Native tribe
- [ ] None of the Above

2. * **Check all of the following categories that apply to this research:**

[x]	**45 CFR 46.204**	**Research involving pregnant women or fetuses.**
[ ]	45 CFR 46.205(a) and (b)	Research involving neonates of uncertain viability.
[ ]	45 CFR 46.205(a) and (c)	Research involving nonviable neonates
[x]	**45 CFR 46.205(d)**	**Research involving viable neonates.**
[ ]	45 CFR 46.206	Research involving, after delivery, the placenta, the dead fetus, or fetal material.
[ ]	45 CFR 46.207	Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

Children

1. * **Check all that apply to the study:**

☑	**45 CFR 46.404**	**Research involving no greater than minimal risk to children, with adequate provisions for soliciting the assent of the children and permission of their parents or guardians, as set forth in Sec. 46.408**
☐	45 CFR 46.405	Research involving greater than minimal risk but presenting the prospect of direct benefit to individual participants
☐	45 CFR 46.406	Research involving greater than minimal risk and no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition
☐	45 CFR 46.407	Research not otherwise approvable which presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children. (Research in this category must be reviewed and approved by the Secretary of the Department of Health & Human Services)

2. **If multiple categories are selected above, explain which study groups are covered by each selected category (e.g. treatment vs. control groups):**
   N/A

3. * **Describe how you plan to obtain permission of parents or legal guardians. If you have indicated this study will fall into categories 406 or 407, please describe here how you will obtain permission from both parents.**
   Pregnant females will be consented and enrolled in this study. For OB MOTIVATE patients, consent will include chart abstraction of information about their babies after birth

4. * **Describe how children will be assented to participate in the study (i.e. what will the study team do during the assent process to ensure the child understands what the research involves).**
   We will not be including children, just abstracting data about newborn health right after birth for OB MOTIVATE patients.

Pregnant Women or Fetuses

1. * **When scientifically appropriate, briefly describe any preclinical studies (including studies on pregnant animals) and clinical studies (including studies on nonpregnant women) that have provided data for assessing potential risks to pregnant women and fetuses [45 CFR 46.204(a)].**
   N/A

2. * **Select the condition that is applicable to this study [45 CFR 46.204(b)]:**
   - ○ The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus.
   - ● **If there is no prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.**

3. * **Provide protocol-specific information to support the selected condition above [45 CFR 46.204(b)].**
   Surveys and interviews are widely utilized in day-to-day life, in clinical settings, etc. Additionally, because participants are in substance use disorder treatment, the information provided in the study condition materials is already being provided as part of standard medical care.

4. * **Describe how the risk is the least possible for achieving the objectives of the research [45 CFR 46.204(c)].**
   Participants will be informed of their right to refuse or stop study participation at any time, and their right to refuse to answer any questions that make them uncomfortable. All participant data will be kept confidential. Participants will be able to complete the study in person at their clinic visit or virtually to reduce time burden.

5. * **Describe how consent will be obtained from the pregnant woman if the research may:**
   _directly benefit the pregnant woman,
   _directly benefit the pregnant woman and the fetus, or
   _offer no benefit for the woman nor the fetus (when risk to the fetus is not greater than minimal) and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means [45 CFR 46.204(d)].
   Consent will be obtained from the mother only, as the study is no greater than minimal risk and offers no prospect of benefit for the woman nor the fetus.

6. **If the research may directly benefit the fetus only, describe how the consent of the pregnant woman and the father will be obtained. [45 CFR 46.204(e)]**

   Note: The father's consent is not required if he is unable to consent because he is unavailable, incompetent, temporarily incapacitated, or the pregnancy resulted from rape or incest.

   N/A

7. * **Describe how each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate [45 CFR 46.204(f)].**
   it is anticipated that the research will have no impact on the fetus or neonate.

8. **For children who are pregnant, describe how you will obtain assent from the child and permission from the parent(s) of the pregnant child [45 CFR 46.204(g)].**
   No one under 18 years of age will be enrolled in the study.

9. * **Will inducements, monetary or otherwise, be offered to terminate a pregnancy [45 CFR 46.204(h)]?**
   - ○ Yes
   - ● **No**

10. * **Will individuals engaged in the research have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy [45 CFR 46.204(i)]?**

- ○ Yes
- ● **No**

11. * **Will individuals engaged in the research have any part in determining the viability of a neonate [45 CFR 46.204(j)]?**
    - ○ Yes
    - ● **No**

Populations with Special Considerations Section Complete

Protocol Progress:

- **INITIAL SETUP**
- **BACKGROUND, RATIONALE & GOALS**
- **RESEARCH PLAN**
- **CONSENT PLAN**
- **RISKS, PRIVACY & CONFIDENTIALITY**
- **POPULATIONS WITH SPECIAL CONSIDERATIONS**

⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

Study Funding

1. * **Have you applied for funding:**
   - (●) **Yes**
   - ( ) No

2. **Is this study already funded:**
   - (●) **Yes**
   - ( ) No

3. * **Select all funding sources for this study (pending or awarded):**
   - [ ] Industry
   - [ ] Direct Federal
   - [ ] Indirect Federal
   - [ ] State/Local Government
   - [ ] Non-Profit - Sponsored Project
   - [ ] Non-Profit - Gift
   - [x] **Internal Grant**
   - [ ] Investigator/Departmental Funds
   - [ ] None
   - [ ] Other

4. * **In addition to providing funding support, what is the funding source's role in this study? Select all that apply:**
   - [x] **Solely providing funding support**
   - [ ] Providing resources (e.g. study drug, device)
   - [ ] Providing guidance to the researcher but does NOT make decisions about study design
   - [ ] Study design/Creation of the study protocol
   - [ ] Collaborator in the research (helps design and/or conduct the study) [list the funder as a site on the Types of Sites page]
   - [ ] Data or sample analysis regardless of identifiability

5. **Select all related funding proposals and contracts that have been submitted through the Division of Sponsored Programs (DSP):**

RAMS-SPOT ID# (FP/PT/PD#)	Direct Sponsor	PI	Title	Status	Start	End

There are no items to display

Types of Sites

VCU Site Information

1. * **Select all VCU sites that will be utilized in this study:**
   - [ ] Children's Hospital of Richmond at VCU
   - [ ] Clinical Research Services Unit (CRSU)
   - [ ] Massey Cancer Center
   - [ ] VCU Health Community Memorial Hospital
   - [ ] VCU Health Tappahannock Hospital
   - [x] **VCU Medical Center**
   - [ ] Other VCU Health Location
   - [ ] VCU Monroe Park Campus
   - [ ] VCU Qatar
   - [x] **Other VCU Site**

   Non-VCU Site Information

   Non-VCU sites should be selected whenever any of the following situations apply:
   a) Non-VCU sites that will be collaborating on a VCU-led study (i.e. involved in conducting the research, including being involved in the study interpretation or analysis of data and/or authorship of presentations or manuscripts related to the research.)
   b) Non-VCU sites that will be deferring to the VCU IRB for IRB review
   c) Non-VCU sites where VCU investigators will be overseeing study interventions or interactions
   d) Non-VCU sites/locations where VCU investigators will conduct study activities

2. * **Select any of the following non-VCU sites utilized in this study:**
   - [ ] McGuire VAMC
   - [ ] Foreign Sites
   - [ ] Other Non-VCU Sites
   - [x] **No Non-VCU Sites**

3. * **Is this a multi-center study being led by VCU?**
   ○ Yes ● **No**

4. **For Non-VCU Sites: For each site or institution listed as "Site Engaged -- Requests to Rely on VCU IRB Review," upload:**

   - Completed Local Context Form for Relying on VCU's IRB
   - Site specific informed consent form(s) and HIPAA authorization(s), if applicable

   For Foreign Sites: For each Cultural Consultant upload a CV/Biosketch that includes a clear description of cultural expertise:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Project BETTER Consent Form Community-based recruitment	Community-based recruitment Project BETTER Consent Form_clean IRB 10.25.pdf	0.05	11/7/2022 10:47 AM	Anna Parlier	Consent/Assent/Information Sheet	Yes
View	Community-based Study Interest Form	StudyInterest_ProjectBETTERCom.pdf	0.01	10/31/2022 4:01 PM	Anna Parlier	Recruitment/Advertising	Yes
View	SOP	HM20023314 Project BETTER RCT SOP 10.31.22.docx	0.05	10/31/2022 3:59 PM	Anna Parlier	Research Protocol	Yes
View	Project BETTER Community-based recruitment email template	Project BETTER Community Recruitment Study Notification Email Template.docx	0.01	10/31/2022 3:58 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Project BETTER Community-based recruitment script	Project BETTER Community Remote Recruitment Scripts.docx	0.01	10/31/2022 3:58 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Project BETTER Community-based recruitment flyer	Project BETTER Community-based Flyer.docx	0.01	10/12/2022 5:00 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Project BETTER RA Forms 3 Delivery Questions	Project BETTER Study Visit 3 Delivery Questions.docx	0.01	10/5/2022 2:33 PM	Anna Parlier	Research Measure	Yes
View	Eligibility Form	Revised 7.18.22 Project BETTER Eligibility Form.docx	0.02	7/18/2022 5:45 PM	Anna Parlier	Research Measure	Yes
View	In-person Recruitment Script	Revised 7.18.22 Project BETTER In Person Recruitment Scripts.docx	0.04	7/18/2022 5:44 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Remote Recruitment Script	Revised 7.18.22 Project BETTER Remote Recruitment Scripts.docx	0.02	7/18/2022 5:43 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Recruitment Flyer	Revised Project BETTER Flyer 7.18.22.docx	0.02	7/18/2022 5:41 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Consent form	Project BETTER Consent Form_revised 12.15.21.pdf	0.07	12/21/2021 10:35 AM	Anna Parlier	Consent/Assent/Information Sheet	Yes
View	Informatics consult	BETTER_Informatics_Email.pdf	0.01	12/3/2021 9:57 AM	Jessica Lantz	Other	Not Applicable
View	PROC APPROVAL	BETTER_PROC_Approval.pdf	0.01	11/17/2021 1:27 PM	Caitlin Martin	Ancillary Committee Approval	Not Applicable
View	Study Notification Email Template	Project BETTER Study Notification Email Template.docx	0.01	11/17/2021 9:27 AM	Anna Parlier	Recruitment/Advertising	Yes
View	Project Better	Project BETTER Peedy Transcript.docx	0.01	11/17/2021 9:24 AM	Anna Parlier	Research Measure	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	Module Transcript						
View	Project BETTER Module Video Links	Project BETTER Video Links.docx	0.01	11/15/2021 12:02 PM	Anna Parlier	Other	Yes
View	Project BETTER Brochure Webpage	Project BETTER Webpage.pdf	0.01	11/15/2021 12:01 PM	Anna Parlier	Other	Yes
View	Project BETTER Overview	Project BETTER Technology-based Program Overview.pdf	0.01	11/15/2021 12:01 PM	Anna Parlier	Other	Yes
View	Technology-based modules	Project BETTER Technology-based module links.docx	0.01	10/11/2021 7:42 PM	Anna Parlier	Other	Yes
View	Brochure	Project BETTER Brochure.pdf	0.01	10/11/2021 7:41 PM	Anna Parlier	Research Measure	Yes
View	Demographic questions	Project BETTER Demographic Questions .docx	0.01	10/11/2021 7:41 PM	Anna Parlier	Recruitment/Advertising	Yes
View	RA forms 3	Project BETTER Study Visit 3 RA Form.docx	0.01	10/11/2021 7:40 PM	Anna Parlier	Research Measure	Yes
View	RA forms 2	Project BETTER Study Visit 2 RA Form.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes
View	RA forms 1	Project BETTER Study Visit 1 RA Form.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes
View	Follow up survey 2	Project BETTER Follow-up Survey 2.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes
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View	Pre-survey	Project BETTER Pre-Survey.docx	0.01	10/11/2021 7:38 PM	Anna Parlier	Research Measure	Yes
View	Chart abstraction form 3	Project BETTER Study Visit 3 Chart Abstraction Form.docx	0.01	10/11/2021 7:38 PM	Anna Parlier	Research Measure	Yes
View	Chart abstraction form 2	Project BETTER Study Visit 2 Chart Abstraction Form.docx	0.01	10/11/2021 7:37 PM	Anna Parlier	Research Measure	Yes
View	Chart abstraction form 1	Project BETTER Study Visit 1 Chart Abstraction Form.docx	0.01	10/11/2021 7:37 PM	Anna Parlier	Research Measure	Yes
View	Scheduling and Reminder Scripts	Project BETTER Follow Up Scheduling and Reminders Scripts.docx	0.01	10/11/2021 7:36 PM	Anna Parlier	Study reminders/communications	Yes
View	Follow up visit scripts	Project BETTER Follow-up Visits Script.docx	0.01	10/11/2021 7:36 PM	Anna Parlier	Study reminders/communications	Yes
View	Martin CV	CEM_CV_08.15.21_BT.pdf	0.01	10/10/2021 9:23 PM	Caitlin Martin	CV/Biosketch	Yes
View	Parlier CV	Parlier CV .pdf	0.01	10/10/2021 5:44 PM	Anna Parlier	CV/Biosketch	Not Applicable

Personnel

1. * **List all VCU/VCUHS personnel who are key study personnel.**

Key personnel are defined as including:

- Conflict of interest investigators, including
- the PI
- the Lead Student/Trainee Investigator,
- medically/Psychologically responsible investigator(s)
- FDA Form 1572 investigators, and
- Other personnel whose roles are essential to the conduct of the research.

Note: Individuals who are not key personnel are not required to be listed here, but PIs still bear the responsibility to document the delegation of responsibilities in the study records.

PIs may elect to use the Study Roster activity button in RAMS-IRB (available after approval) as an alternative way to document study staff involvement and delegation of responsibilities. Personnel changes made to the non-key personnel listed in the separate Study Roster activity do not require an amendment.

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
View	Caitlin Martin	Principal Investigator		Data Analysis Project Coordination Participant Identification Study Design		Experience - Research Experience - Related Skills Experience - Clinical Education and/or Professional Preparation		yes
View	Anna Parlier	Research Coordinator		Data Analysis Project Coordination Participant Consent Data Management Data Collection - Clinical Participant Identification Data Entry Study Design Participant Recruitment Data Collection - Interviews/Surveys		Experience - Research Experience - Clinical Education and/or Professional Preparation Student		no
View	Andrea-Kayle Andaya	Research Assistant		Participant Consent Data Collection - Clinical Participant Identification		Experience - Research Education and/or Professional Preparation		no

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
				Data Entry Participant Recruitment Data Collection - Interviews/Surveys				
View	Sarah Martin	Trainee/Student(working on project)		Participant Consent Data Collection - Clinical Participant Identification Data Entry Participant Recruitment Data Collection - Interviews/Surveys		Experience - Clinical Education and/or Professional Preparation Student		no
View	Michelle Eglovitch	Trainee/Student(working on project)		Data Analysis Participant Consent Data Management Data Collection - Clinical Participant Identification Data Entry Participant Recruitment Data Collection - Interviews/Surveys		Experience - Research Education and/or Professional Preparation Student		no
View	Dace Svikis Pickens	Co/Sub-Investigator		Study Design		Experience - Research Experience - Related Skills Experience - Clinical Education and/or Professional Preparation		yes

2. **Identify all independent investigators and key personnel at non-VCU sites who will be engaged in this study AND who DO NOT have IRB approval for this study from their own institution.**

Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator

There are no items to display

3. If independent investigators or community engaged investigators are listed above,**describe the human subjects training these individuals will complete and the process that will be used to ensure that all persons assisting with the research are adequately informed about the protocol and their research related duties and functions:**

4. * **Upload a CV or Biosketch for the PI, Medically/Psychologically Responsible Investigators and the lead Student/Trainee Investigators. Do not upload CVs or Biosketches for other individuals.**

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Project BETTER Consent Form Community-based recruitment	Community-based recruitment Project BETTER Consent Form_clean IRB 10.25.pdf	0.05	11/7/2022 10:47 AM	Anna Parlier	Consent/Assent/Information Sheet	Yes
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View	Parlier CV	Parlier CV .pdf	0.01	10/10/2021 5:44 PM	Anna Parlier	CV/Biosketch	Not Applicable

Conflict of Interest

The PI should ask the questions on this page of all research personnel who are engaged in the research, including subrecipient investigators and personnel.

1. * **To the best of your knowledge, do you (as PI) or any other engaged individual have a financial interest related to this study?**
   Financial interest include utilizing your licensed intellectual property in the study; serving as a paid consultant, or advisory board member, or officer/director with a related entity; and equity or business ownership in a company that is related to this project
   ◯ Yes ● **No**

2. * **To the best of your knowledge, do you (as PI) or any other engaged individual have a non-financial interest related to this study?**
   Non-financial Interests could include such things as:
   - utilizing your unlicensed intellectual property in the study,
   - serving as an unpaid advisory board member or officer/director with a related entity, and
   - equity or business ownership in a company that has yet to make a profit and is related to this project
   - conflict of time/effort,
   - personal and professional relationships/affiliations,
   - intellectual passions or personal beliefs
   - other factors that could create bias in the study
   ◯ Yes ● **No**

3. **Describe any institutional conflict of interest that you or any member of the research team are aware of that pertains to this research:**

   An institutional conflict of interest is a situation in which financial interests of the University or University leadership may affect research activities at VCU.
   N/A

Other VCU Requirements

This page asks questions on behalf of other ancillary offices, committees and departments at VCU regarding institutional requirements that could apply to this research. In some cases, these requirements could also impact the consent process or other aspects of the IRB's review.

Based upon answers provided earlier in this form, certain ancillary sections below may not have questions displayed if those requirements are not applicable to this study.

1. Cost Coverage Analysis

Information on coverage analysis requirements and processes can be found through VCU's Clinical Research Compliance Program at https://research.vcu.edu/human-research/clinical-research/vcu-clinical-research-coverage-analysis/

1. * **VCU requires that all clinical research studies be evaluated to determine if a Coverage Analysis is required. Has your study been evaluated by an institutionally designated Coverage Analysis Specialist?**
   - ○ Yes
   - ○ No
   - ● **Not Applicable**

2. ClinicalTrials.gov Program & OnCore

For guidance, see https://cctr.vcu.edu/support/consultation/clinical-trials-gov/ or email CCTRCTGOV@vcu.edu

1. * **Is this a Clinical Trial?**
   - ● **Yes** ○ No
2. * **ThePI acknowledges awareness of the following requirements for posting clinical trial consent forms:**

   - Each clinical trial under the 2018 Common Rule that is conducted or supported by a Federal department or agency must post one IRB-approved consent form that was used to enroll subjects on a publicly available Federal website [45 CFR 46.116(h)].
   - When engaged in multi-site research, the VCU PI is responsible for confirming with the lead site who is responsible for posting the informed consent form.
   - When VCU is the lead site, the VCU PI is responsible for posting the informed consent form (unless the federal department or agency will post it).
   - ● **Yes** ○ No

3. Community Engagement

For more information, see https://community.vcu.edu/

1. * **Is this a community engaged research study? (See help text for definitions)**
   - ○ Yes
   - ● **No**

4. Family Educational Rights and Privacy Act (FERPA) Requirements

For guidance, see https://rar.vcu.edu/records/family-educational-rights-and-privacy-act/

1. * **Does this study involve obtaining information from VCU students' educational records (see help text)?**
   - ○ Yes
   - ● **No**

5. Research Data Privacy Requirements
Contact the VCU Research Data Privacy Office with questions: https://research.vcu.edu/integrity-and-compliance/compliance/research-data-privacy/

1. * **Does this study involve the VCU site (regardless of the IRB of record), or any sites under the VCU IRB"s oversight, obtaining data in, or from, a foreign country?**
   ○ Yes ● **No**

6. Information Security
For guidance, see https://ts.vcu.edu/askit/essential-computing/information-security/

1. * **Using the VCU Data Classification Tool, please determine the appropriate data classification category for the data that will be collected or used in this research.**

   Note: if the data falls into Category 1, a data security management plan is required by University Information Security Office.

   See help text for information on accessing the VCU Data Classification Tool, and for information on creating a data security management plan at https://dms.vcu.edu**.**
   ● **Category 1: all data that require breach notifications in the event of improper release, including personally identifiable information covered by HIPAA and Commonwealth of Virginia regulations.**
   ○ Category 2: all proprietary data that if improperly released has the potential to cause harm to the institution, its mission or its reputation that do not require breach notifications.

2. * **I confirm use of the VCU Data Classification Tool at** https://go.vcu.edu/dataclassification **in determining the data classification category selected in Question 1:**
   ● **Yes**
   ○ No

3. * **The PI is aware that if the study's data is classified as Category 1, a Data Management Plan must be submitted to and approved by VCU Information Security prior to IRB approval. See** https://ts.vcu.edu/askit/essential-computing/information-security/data-management-system/
   ● **Yes** ○ No

4. * **I confirm that any use of external technology has been submitted to Information Security in the study's Data Management Plan. If this study uses any technology platforms, apps, services, etc. that are maintained external to VCU or hosted by another institution and are NOT currently listed in the DMS system as an approved service for the storage, processing, or transmission of VCU data, I am required to have VCU Information Security conduct a security review of that technology. I may contact infosec@vcu.edu with questions.**

   I also confirm that if the study involves use of external technology and VCUHS HIPAA data, I must also seek security review from the VCUHS Data Governance group (contact Mary Harmon at mary.harmon@vcuhealth.org):
   ● **Yes**
   ○ No
   ○ N/A - not using external technology

7. Massey Cancer Center Protocol Review and Monitoring Committee (PRMC)
For guidance, see https://www.masseycancercenter.org/research/~/link.aspx?_id=ee49e95faa8b44d09b6e89d8e3b48b57&_z=z

1. * **Does this study involve any of the following?**
   - Research involving patients with cancer, their families or their health care providers
   - Research involving cancer screening, diagnosis or prevention
   - Secondary data collected from cancer patients or their medical records
   - Cancer-related surveys (e.g., attitudes about risk, prevention and treatment) of the

general population

◯ Yes

● **No**

8. **VCU ONETRAC Protocol Review Oversight Committees (PROCs) For guidance, see** https://onetrac.vcu.edu/

1. * **Does this study involve research with any of the following?**

- VCU Health System patients

- VCU Health System facilities

- VCU Health System data ● **Yes**

◯ No

If Yes, upload documentation of approval or review by the PROC or PRMC in this study's topic area. If you do not have PROC or PRMC approval, please visit onetrac.vcu.edu for additional information and to submit your project for review.

9. **VCU Health Department of Patient Centered Services**

1. * **Does your study involve a satisfaction survey administered to VCUHS patients (*See Help Text):**

◯ Yes

● **No**

◯ Not Applicable

10. **VCU Faculty-Held IND or IDE**

For guidance, see **https://research.vcu.edu/human-research/regulatory-affairs/**.

Questions related to if you need an IND or IDE for your study should be emailed to: indide@vcu.edu. Please submit a copy of your FDA
submission prior to submitting to the FDA to https://redcap.vcu.edu/surveys/?s=NR7K7LR4JW.

11. **VCU Health System locations**

1. * **Will research activities occur in patient care areas of the VCU Health System (including at CHoR, Community Memorial Hospital, Tappahannock Hospital, VCU Medical Center and Massey Cancer Center)?**

● **Yes**

◯ No

2. * **The PI has reviewed and agreed to comply with the VCU Health System Research in Patient Care Areas policy (https://research.vcu.edu/compliance_program/vcuhs_policies.htm):**

● **Yes**

◯ No

12. **VCUHS Department of Pathology**

Learn more about requesting and establishing an account with Pathology here: See https://pathology.vcu.edu/research-services/

1. * **I have contacted VCUHS Department of Pathology to determine feasibility if my study involves the following:**
- Storage of Microbiology isolates
- New instrumentation provided by clinical trial/study sponsor, or
- Non-routine specimen processing (examples include but aren't limited to the following: addition of reagents to samples/aliquots, buffy coat processing, DNA sample processing)

◯ Yes

○ No

● **N/A - my study does not involve any of the listed processes.**

2. * **If my study involves specimen retrieval from the Pathology laboratory, I have established a process with Pathology to deidentify and retrieve specimens.**

○ Yes

○ No

● **N/A - my study won't involve specimen retrieval from Pathology**

13. VCU Institutional Biosafety Committee (IBC)

To contact the Biosafety Office see their website at: https://research.vcu.edu/integrity-and-compliance/compliance/regulatory-committees/

1. * **Does this project involve any of the following hazardous biological agents ("biohazardous agents") that have NOT been FDA approved? These may include, but are not limited to, any of the following. If you are unsure, please contact the Biosafety Office:**

- Any functional recombinant viruses (especially viruses that may integrate into the patients' genome).

- Expression or administration of biological toxins.

- Live pathogenic or potentially pathogenic organisms of plants or animals (bacteria, fungi, wild-type viruses, parasites, etc.), that are, or potentially may be, in experimental products.

- Introduction or expression of rDNA or synthetic nucleic acids

- Use of a product (e.g., monoclonal antibodies, recombinant cytokines) produced from virally infected mammalian cells.

- Use of a product (purified growth factors, cytokines) produced from mammals or their cells.

○ Yes ● **No**

14. VCU Radiation Safety Committee (RSC)

To contact the Radiation Safety Section see their website at: https://research.vcu.edu/integrity-and-compliance/compliance/regulatory-committees/

1. * **Does this study involve radiation exposure and/or scans involving radiation (e.g.: PET, MRA, CT, DXA, nuclear medicine, etc.)?**

○ Yes

● **No**

15. VCU Scientific Review Committee (SRC)

For guidance, see https://cctr.vcu.edu/support/consultation/scientific-review-committee/

1. * **Has this human subjects protocol (not the grant application) already been reviewed by the funder of a sponsored project (e.g. a federal, state or non-profit funding sponsor)?**

○ Yes

● **No**

16. Upload any documents requested in the questions above:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Project BETTER Consent Form Community-based recruitment	Community-based recruitment Project BETTER Consent Form_clean IRB 10.25.pdf	0.05	11/7/2022 10:47 AM	Anna Parlier	Consent/Assent/Information Sheet	Yes
View	Community-based Study Interest Form	StudyInterest_ProjectBETTERCom.pdf	0.01	10/31/2022 4:01 PM	Anna Parlier	Recruitment/Advertising	Yes
View	SOP	HM20023314 Project BETTER RCT SOP 10.31.22.docx	0.05	10/31/2022 3:59 PM	Anna Parlier	Research Protocol	Yes
View	Project BETTER Community-based recruitment email template	Project BETTER Community Recruitment Study Notification Email Template.docx	0.01	10/31/2022 3:58 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Project BETTER Community-based recruitment script	Project BETTER Community Remote Recruitment Scripts.docx	0.01	10/31/2022 3:58 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Project BETTER Community-based recruitment flyer	Project BETTER Community-based Flyer.docx	0.01	10/12/2022 5:00 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Project BETTER RA Forms 3 Delivery Questions	Project BETTER Study Visit 3 Delivery Questions.docx	0.01	10/5/2022 2:33 PM	Anna Parlier	Research Measure	Yes
View	Eligibility Form	Revised 7.18.22 Project BETTER Eligibility Form.docx	0.02	7/18/2022 5:45 PM	Anna Parlier	Research Measure	Yes
View	In-person Recruitment Script	Revised 7.18.22 Project BETTER In Person Recruitment Scripts.docx	0.04	7/18/2022 5:44 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Remote Recruitment Script	Revised 7.18.22 Project BETTER Remote Recruitment Scripts.docx	0.02	7/18/2022 5:43 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Recruitment Flyer	Revised Project BETTER Flyer 7.18.22.docx	0.02	7/18/2022 5:41 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Consent form	Project BETTER Consent Form_revised 12.15.21.pdf	0.07	12/21/2021 10:35 AM	Anna Parlier	Consent/Assent/Information Sheet	Yes
View	Informatics consult	BETTER_Informatics_Email.pdf	0.01	12/3/2021 9:57 AM	Jessica Lantz	Other	Not Applicable
View	PROC APPROVAL	BETTER_PROC_Approval.pdf	0.01	11/17/2021 1:27 PM	Caitlin Martin	Ancillary Committee Approval	Not Applicable
View	Study Notification Email Template	Project BETTER Study Notification Email Template.docx	0.01	11/17/2021 9:27 AM	Anna Parlier	Recruitment/Advertising	Yes
View	Project Better	Project BETTER Peedy Transcript.docx	0.01	11/17/2021 9:24 AM	Anna Parlier	Research Measure	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	Module Transcript						
View	Project BETTER Module Video Links	Project BETTER Video Links.docx	0.01	11/15/2021 12:02 PM	Anna Parlier	Other	Yes
View	Project BETTER Brochure Webpage	Project BETTER Webpage.pdf	0.01	11/15/2021 12:01 PM	Anna Parlier	Other	Yes
View	Project BETTER Overview	Project BETTER Technology-based Program Overview.pdf	0.01	11/15/2021 12:01 PM	Anna Parlier	Other	Yes
View	Technology-based modules	Project BETTER Technology-based module links.docx	0.01	10/11/2021 7:42 PM	Anna Parlier	Other	Yes
View	Brochure	Project BETTER Brochure.pdf	0.01	10/11/2021 7:41 PM	Anna Parlier	Research Measure	Yes
View	Demographic questions	Project BETTER Demographic Questions .docx	0.01	10/11/2021 7:41 PM	Anna Parlier	Recruitment/Advertising	Yes
View	RA forms 3	Project BETTER Study Visit 3 RA Form.docx	0.01	10/11/2021 7:40 PM	Anna Parlier	Research Measure	Yes
View	RA forms 2	Project BETTER Study Visit 2 RA Form.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes
View	RA forms 1	Project BETTER Study Visit 1 RA Form.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes
View	Follow up survey 2	Project BETTER Follow-up Survey 2.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes
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View	Chart abstraction form 3	Project BETTER Study Visit 3 Chart Abstraction Form.docx	0.01	10/11/2021 7:38 PM	Anna Parlier	Research Measure	Yes
View	Chart abstraction form 2	Project BETTER Study Visit 2 Chart Abstraction Form.docx	0.01	10/11/2021 7:37 PM	Anna Parlier	Research Measure	Yes
View	Chart abstraction form 1	Project BETTER Study Visit 1 Chart Abstraction Form.docx	0.01	10/11/2021 7:37 PM	Anna Parlier	Research Measure	Yes
View	Scheduling and Reminder Scripts	Project BETTER Follow Up Scheduling and Reminders Scripts.docx	0.01	10/11/2021 7:36 PM	Anna Parlier	Study reminders/communications	Yes
View	Follow up visit scripts	Project BETTER Follow-up Visits Script.docx	0.01	10/11/2021 7:36 PM	Anna Parlier	Study reminders/communications	Yes
View	Martin CV	CEM_CV_08.15.21_BT.pdf	0.01	10/10/2021 9:23 PM	Caitlin Martin	CV/Biosketch	Yes
View	Parlier CV	Parlier CV .pdf	0.01	10/10/2021 5:44 PM	Anna Parlier	CV/Biosketch	Not Applicable

HIPAA

In order for VCUHS to meet HIPAA regulations regarding accounting of disclosures, data retention, and data destruction requirements for PHI data obtained without patient authorization, members of the study team (including principal investigators) are directed to consult with VCU Informatics to obtain any VCUHS data. This does not include obtaining data for which the study team has patient authorization. [VCU Health System Authority and Affiliates Policy COMP-014]

For data requests, including preparatory to research and research with decedents, submit a request for the desired PHI, or for a consultation on alternate methods to obtain the data, at https://informatics.vcu.edu.

HIPAA Privacy Board Requirements

For guidance, see https://www.vcuhealth.org/our-story/who-we-are/compliance-services/compliance-services

1. * **Select the source of the Individually Identifiable Health Information. See help text for definitions.**
   - [x] **PHI associated with or derived from (i.e. obtained from or entered into) VCU Health medical records or VCU Dental Care records**
   - [x] **Research Health Information (RHI) created or received by a study and kept solely in study records (e.g. self reported or the result of research tests and not entered into health records)**
   - [ ] PHI associated with or derived from (i.e. obtained from or entered into) a non-VCU HIPAA covered entity's health records

2. * **Summarize the types of health information that will be obtained or used in this research. Do not describe only the identifiers that you will collect or use during the study.**
   For OB MOTIVATE patients: Medical record data will be abstracted for each participant including physician notes (e.g., substance use and treatment history) and test results (e.g., urine drug testing). All medical record chart abstraction items are included in the attached chart abstraction forms. Each participant's study ID will be linked with patient identifiers in a key kept in a secure database to facilitate this data abstraction.

   Phone numbers and email addresses will be used to contact participants to schedule and complete study visits.

   Community-based addiction treatment: All health information will be self-reported by participants using surveys and RA-led questions.

3. * **Describe the source(s) of the protected health information (e.g. Informatics or which clinical databases):**
   OB MOTIVATE patients: The source will be VCU Cerner/EPIC electronic medical record.

   Community-based addiction treatment: Participant self report

4. * **Does the PI certify that this study's access to and use of the protected health information is limited to the minimum amount necessary to be able to effectively conduct the research?**
   - (●) **Yes** ( ) No

5. * **Select all pathways this research will employ to use or access PHI (selections will branch):**
   - [ ] De-Identified Data (none of the 18 identifiers are recorded or associated with the research data)
   - [ ] Limited Data Set
   - [ ] Waiver of Authorization
   - [x] **Partial Waiver of Authorization (temporary waiver for recruitment purposes and/or waiver of some elements of Authorization)**
   - [x] **Signed Authorization Combined with Consent Form**
   - [ ] Signed Authorization as Stand-Alone Form

Partial Waiver of Authorization

1. * **Select the purpose for requesting the partial waiver of authorization:**
   - [x] **Identify possible participants to recruit for the study**
   - [x] **Waive some elements of authorization (such as signature)**

2. * **If you selected "Waive some elements of authorization" above, list the elements you want to waive (see the help text) and explain why:**
   Signatures are requesting to be waived to facilitate remote study procedures, such as consent, and to utilize IRB approved REDCap e-consent procedures. A signature will be obtained from participants recruited and completing research procedures in person.

3. * **Explain how the partial waiver of authorization poses no greater than minimal risk to participants' privacy:**
   (Alternative question phrasing: How do the risk(s) of this use of identifiable health information compare to the risks to privacy a person might reasonably experience in normal everyday life?).
   Regarding waiving the signature, participants are provided with all other elements of HIPAA authorization in their informed consent process, and their PHI remains protected as described in the authorization, regardless of whether a signature is obtained.

   OB MOTIVATE patients: Regarding the partial waiver to review the clinic schedules and medical record for basic eligibility criteria, in order to approach eligible participants in their private exam rooms (or over the phone in case of virtual apts), this will pose no greater than minimal risk to participants' privacy - first the RA is part of the study team and no information about the potential participant will be shared, second all patients coming to the OB MOTIVATE clinic have a substance use disorder so the RA reviewing the schedule for potential participants would not reveal anything new about their alcohol/drug use history given that is already the 'norm' at the OB MOTIVATE clinics.

4. * **If you selected "Identify possible participants to recruit" above, describe when will the 18 HIPAA identifiers be destroyed for those who do not eventually enroll in the study?**
   - [ ] Following Participant Contact
   - [x] **Upon Reaching Study Accrual Objectives**
   - [ ] Other

5. * **Other than the PI and research personnel identified in this research application, who else will have access to the Protected Health Information?**
   None.

6. * **Explain why the study cannot practicably be conducted without the partial waiver of authorization:**
   (Alternative question phrasing: Why is this partial waiver necessary to make the study achievable or viable?)
   Waiving the signature on the consent form is necessary to make the study practical and feasible for study participants to complete all study procedures remotely. A signature will be obtained from participants recruited and completing research procedures in person.

   OB MOTIVATE patients: In order to approach potential participants while they are in a private area, in their exam rooms while presenting for routine prenatal care or over the phone (eg, if the potential participant had a virtual apt with their provider), the clinic schedule will need to be assessed so participants are not screened for eligibility in the public waiting area space. Also, the study would not be achievable if the RA had to approach every patient presenting to the OB MOTIVATE clinic, as that would take substantial time and effort; review of the clinic schedule and medical record (solely for eligibility criteria) will allow the RA to only approach potentially eligible participants, making the study feasible.

7. * **In applying for a partial waiver of authorization, the PI agrees to the following:**

   A) The identifiers used for this research study will not be used for any other purpose or disclosed to any other person or entity (aside from members of the research team identified in this application), except as required by law.

B) If at any time I want to reuse this information for other purposes or disclose the information to other individuals, I will seek approval from the IRB/Privacy Board.

C) I will comply with VCU HIPAA policies and procedures and to the use and disclosure restrictions described above.

D) I assume responsibility for all uses and disclosures of the PHI by members of my study team.

- (●) **Yes**
- ( ) No

Institutional Requirements Complete

Protocol Progress:

- **INITIAL SETUP**
- **BACKGROUND, RATIONALE & GOALS**
- **RESEARCH PLAN**
- **CONSENT PLAN**
- **RISKS, PRIVACY & CONFIDENTIALITY**
- **POPULATIONS WITH SPECIAL CONSIDERATIONS**
- **INSTITUTIONAL REQUIREMENTS**
- ⑧ DOCUMENTS

Click Continue below to go to the next section

HM20023314 - Caitlin Martin
Project BETTER: Bringing Education Through Technology, Empathic listening, and Research - A Feasibility Randomized Controlled Trial

Documents

1. **Upload any documents that the VCU IRB will need to conduct a review of this submission: A list of potential documents is given in the help text.**

NOTE: The delete function should only be used if an incorrect document is uploaded or added to the system AND that document has not been reviewed and approved by the IRB. Do NOT delete documents that the IRB previously reviewed and approved.

Once you have uploaded a document to RAMS-IRB, any changes to that document (i.e. different versions of the same document) should be added to the IRB submission by using the Update button. To provide updated documents, follow these steps:

- Click the Update button located to the left of the document to be updated.
- In the Add Document window, click the Choose File or Browse button, select the file you are adding, and click on the Open button.
- Click OK to close the Add Document window, and the system will upload the revised document. RAMS-IRB will automatically provide a version number for the document.

To access previous versions of a document in RAMS-IRB you must use the History link associated with the document.
- Click the View or Update button located to the left of the document you wish to access.
- In the Add/View Document window, click the "History" hyperlink located to the right of the file name.
- A separate window will open that shows all versions of the document that have been added to RAMS-IRB. Click on any file name to download and view the document.

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Project BETTER Consent Form Community-based recruitment	Community-based recruitment Project BETTER Consent Form_clean IRB 10.25.pdf	0.05	11/7/2022 10:47 AM	Anna Parlier	Consent/Assent/Information Sheet	Yes
View	Community-based Study Interest Form	StudyInterest_ProjectBETTERCom.pdf	0.01	10/31/2022 4:01 PM	Anna Parlier	Recruitment/Advertising	Yes
View	SOP	HM20023314 Project BETTER RCT SOP 10.31.22.docx	0.05	10/31/2022 3:59 PM	Anna Parlier	Research Protocol	Yes
View	Project BETTER Community-based recruitment email template	Project BETTER Community Recruitment Study Notification Email Template.docx	0.01	10/31/2022 3:58 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Project BETTER Community-based recruitment script	Project BETTER Community Remote Recruitment Scripts.docx	0.01	10/31/2022 3:58 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Project BETTER Community-based recruitment flyer	Project BETTER Community-based Flyer.docx	0.01	10/12/2022 5:00 PM	Anna Parlier	Recruitment/Advertising	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Project BETTER RA Forms 3 Delivery Questions	Project BETTER Study Visit 3 Delivery Questions.docx	0.01	10/5/2022 2:33 PM	Anna Parlier	Research Measure	Yes
View	Eligibility Form	Revised 7.18.22 Project BETTER Eligibility Form.docx	0.02	7/18/2022 5:45 PM	Anna Parlier	Research Measure	Yes
View	In-person Recruitment Script	Revised 7.18.22 Project BETTER In Person Recruitment Scripts.docx	0.04	7/18/2022 5:44 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Remote Recruitment Script	Revised 7.18.22 Project BETTER Remote Recruitment Scripts.docx	0.02	7/18/2022 5:43 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Recruitment Flyer	Revised Project BETTER Flyer 7.18.22.docx	0.02	7/18/2022 5:41 PM	Anna Parlier	Recruitment/Advertising	Yes
View	Consent form	Project BETTER Consent Form_revised 12.15.21.pdf	0.07	12/21/2021 10:35 AM	Anna Parlier	Consent/Assent/Information Sheet	Yes
View	Informatics consult	BETTER_Informatics_Email.pdf	0.01	12/3/2021 9:57 AM	Jessica Lantz	Other	Not Applicable
View	PROC APPROVAL	BETTER_PROC_Approval.pdf	0.01	11/17/2021 1:27 PM	Caitlin Martin	Ancillary Committee Approval	Not Applicable
View	Study Notification Email Template	Project BETTER Study Notification Email Template.docx	0.01	11/17/2021 9:27 AM	Anna Parlier	Recruitment/Advertising	Yes
View	Project Better Module Transcript	Project BETTER Peedy Transcript.docx	0.01	11/17/2021 9:24 AM	Anna Parlier	Research Measure	Yes
View	Project BETTER Module Video Links	Project BETTER Video Links.docx	0.01	11/15/2021 12:02 PM	Anna Parlier	Other	Yes
View	Project BETTER Brochure Webpage	Project BETTER Webpage.pdf	0.01	11/15/2021 12:01 PM	Anna Parlier	Other	Yes
View	Project BETTER Overview	Project BETTER Technology-based Program Overview.pdf	0.01	11/15/2021 12:01 PM	Anna Parlier	Other	Yes
View	Technology-based modules	Project BETTER Technology-based module links.docx	0.01	10/11/2021 7:42 PM	Anna Parlier	Other	Yes
View	Brochure	Project BETTER Brochure.pdf	0.01	10/11/2021 7:41 PM	Anna Parlier	Research Measure	Yes
View	Demographic questions	Project BETTER Demographic Questions .docx	0.01	10/11/2021 7:41 PM	Anna Parlier	Recruitment/Advertising	Yes
View	RA forms 3	Project BETTER Study Visit 3 RA Form.docx	0.01	10/11/2021 7:40 PM	Anna Parlier	Research Measure	Yes
View	RA forms 2	Project BETTER Study Visit 2 RA Form.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes
View	RA forms 1	Project BETTER Study Visit 1 RA Form.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes
View	Follow up survey 2	Project BETTER Follow-up Survey 2.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Follow up survey 1	Project BETTER Follow-up Survey 1.docx	0.01	10/11/2021 7:39 PM	Anna Parlier	Research Measure	Yes
View	Pre-survey	Project BETTER Pre-Survey.docx	0.01	10/11/2021 7:38 PM	Anna Parlier	Research Measure	Yes
View	Chart abstraction form 3	Project BETTER Study Visit 3 Chart Abstraction Form.docx	0.01	10/11/2021 7:38 PM	Anna Parlier	Research Measure	Yes
View	Chart abstraction form 2	Project BETTER Study Visit 2 Chart Abstraction Form.docx	0.01	10/11/2021 7:37 PM	Anna Parlier	Research Measure	Yes
View	Chart abstraction form 1	Project BETTER Study Visit 1 Chart Abstraction Form.docx	0.01	10/11/2021 7:37 PM	Anna Parlier	Research Measure	Yes
View	Scheduling and Reminder Scripts	Project BETTER Follow Up Scheduling and Reminders Scripts.docx	0.01	10/11/2021 7:36 PM	Anna Parlier	Study reminders/communications	Yes
View	Follow up visit scripts	Project BETTER Follow-up Visits Script.docx	0.01	10/11/2021 7:36 PM	Anna Parlier	Study reminders/communications	Yes
View	Martin CV	CEM_CV_08.15.21_BT.pdf	0.01	10/10/2021 9:23 PM	Caitlin Martin	CV/Biosketch	Yes
View	Parlier CV	Parlier CV .pdf	0.01	10/10/2021 5:44 PM	Anna Parlier	CV/Biosketch	Not Applicable

HM20023314 - Caitlin Martin

Project BETTER: Bringing Education Through Technology, Empathic listening, and Research - A Feasibility Randomized Controlled Trial

Documents Complete

Protocol Progress:

- **INITIAL SETUP**
- **BACKGROUND, RATIONALE & GOALS**
- **RESEARCH PLAN**
- **CONSENT PLAN**
- **RISKS, PRIVACY & CONFIDENTIALITY**
- **POPULATIONS WITH SPECIAL CONSIDERATIONS**
- **INSTITUTIONAL REQUIREMENTS**
- **DOCUMENTS**

End of Application

Click Continue below to exit and submit this project

Personnel

1. * **Name:**
   Caitlin Martin

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   - (●) **Yes**
   - ( ) No

3. * **Roles:**

   - [x] **Principal Investigator**
   - [ ] Co/Sub-Investigator
   - [ ] Medical or Psychological Responsible Investigator
   - [ ] Lead Student/Trainee Investigator (leading their own project)
   - [ ] Research Coordinator
   - [ ] Research Nurse
   - [ ] Consultant
   - [ ] Research Assistant
   - [ ] Pharmacist
   - [ ] Statistician
   - [ ] Regulatory Coordinator
   - [ ] Trainee/Student(working on project)
   - [ ] Other

4. * **Study related responsibilities:**

   - [x] **Study Design**
   - [ ] Data Collection - Lab
   - [ ] Data Collection - Clinical

- [ ] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [ ] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [x] **Data Analysis**
- [x] **Project Coordination**
- [x] **Participant Identification**
- [ ] Participant Recruitment
- [ ] Participant Consent
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Yes

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [x] **Experience - Clinical**
- [x] **Experience - Related Skills**
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Anna Parlier

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   ○ Yes
   ● **No**

3. * **Roles:**

- ☐ Principal Investigator
- ☐ Co/Sub-Investigator
- ☐ Medical or Psychological Responsible Investigator
- ☐ Lead Student/Trainee Investigator (leading their own project)
- ☑ **Research Coordinator**
- ☐ Research Nurse
- ☐ Consultant
- ☐ Research Assistant
- ☐ Pharmacist
- ☐ Statistician
- ☐ Regulatory Coordinator
- ☐ Trainee/Student(working on project)
- ☐ Other

4. * **Study related responsibilities:**

- ☑ **Study Design**
- ☐ Data Collection - Lab
- ☑ **Data Collection - Clinical**

- [x] **Data Collection - Interviews/Surveys**
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [x] **Data Entry**
- [ ] Data Coding
- [x] **Data Management**
- [x] **Data Analysis**
- [x] **Project Coordination**
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [x] **Experience - Clinical**
- [ ] Experience - Related Skills
- [ ] Trainee
- [x] **Student**
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Andrea-Kayle Andaya

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

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   ○ Yes
   ● **No**

3. * **Roles:**

- [ ] Principal Investigator
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant
- [x] **Research Assistant**
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other

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- [ ] Data Collection - Lab
- [x] **Data Collection - Clinical**

- [x] **Data Collection - Interviews/Surveys**
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
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- [ ] Data Management
- [ ] Data Analysis
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- [ ] Regulatory Management
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   Individual has no clinical responsibilities

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- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Sarah Martin

2. * **Is this individual a 'COI Investigator'?**

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   ○ Yes
   ● **No**

3. * **Roles:**

- ☐ Principal Investigator
- ☐ Co/Sub-Investigator
- ☐ Medical or Psychological Responsible Investigator
- ☐ Lead Student/Trainee Investigator (leading their own project)
- ☐ Research Coordinator
- ☐ Research Nurse
- ☐ Consultant
- ☐ Research Assistant
- ☐ Pharmacist
- ☐ Statistician
- ☐ Regulatory Coordinator
- ☑ **Trainee/Student(working on project)**
- ☐ Other

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- ☐ Data Collection - Lab
- ☑ **Data Collection - Clinical**

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- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [x] **Data Entry**
- [ ] Data Coding
- [ ] Data Management
- [ ] Data Analysis
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- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
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- [x] **Education and/or Professional Preparation**
- [ ] Experience - Research
- [x] **Experience - Clinical**
- [ ] Experience - Related Skills
- [ ] Trainee
- [x] **Student**
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Michelle Eglovitch

2. * **Is this individual a 'COI Investigator'?**

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   ○ Yes
   ● **No**

3. * **Roles:**

- ☐ Principal Investigator
- ☐ Co/Sub-Investigator
- ☐ Medical or Psychological Responsible Investigator
- ☐ Lead Student/Trainee Investigator (leading their own project)
- ☐ Research Coordinator
- ☐ Research Nurse
- ☐ Consultant
- ☐ Research Assistant
- ☐ Pharmacist
- ☐ Statistician
- ☐ Regulatory Coordinator
- ☑ **Trainee/Student(working on project)**
- ☐ Other

4. * **Study related responsibilities:**

- ☐ Study Design
- ☐ Data Collection - Lab
- ☑ **Data Collection - Clinical**

- [x] **Data Collection - Interviews/Surveys**
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [x] **Data Entry**
- [ ] Data Coding
- [x] **Data Management**
- [x] **Data Analysis**
- [ ] Project Coordination
- [x] **Participant Identification**
- [x] **Participant Recruitment**
- [x] **Participant Consent**
- [ ] Regulatory Management
- [ ] Other

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- [x] **Experience - Research**
- [ ] Experience - Clinical
- [ ] Experience - Related Skills
- [ ] Trainee
- [x] **Student**
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Dace Svikis Pickens

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

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   - (●) **Yes**
   - ( ) No

3. * **Roles:**

   - [ ] Principal Investigator
   - [x] **Co/Sub-Investigator**
   - [ ] Medical or Psychological Responsible Investigator
   - [ ] Lead Student/Trainee Investigator (leading their own project)
   - [ ] Research Coordinator
   - [ ] Research Nurse
   - [ ] Consultant
   - [ ] Research Assistant
   - [ ] Pharmacist
   - [ ] Statistician
   - [ ] Regulatory Coordinator
   - [ ] Trainee/Student(working on project)
   - [ ] Other

4. * **Study related responsibilities:**

   - [x] **Study Design**
   - [ ] Data Collection - Lab
   - [ ] Data Collection - Clinical

- [ ] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [ ] Data Entry
- [ ] Data Coding
- [ ] Data Management
- [ ] Data Analysis
- [ ] Project Coordination
- [ ] Participant Identification
- [ ] Participant Recruitment
- [ ] Participant Consent
- [ ] Regulatory Management
- [ ] Other

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- [x] **Experience - Research**
- [x] **Experience - Clinical**
- [x] **Experience - Related Skills**
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

Add Document

1. * **Document Name:**
   Project BETTER Consent Form Community-based recruitment

2. * **Type:**
   Consent/Assent/Information Sheet

3. * **File:**
   Community-based recruitment Project BETTER Consent Form_clean IRB 10.25.pdf(0.05)

Add Document

1. * **Document Name:**
   Community-based Study Interest Form

2. * **Type:**
   Recruitment/Advertising

3. * **File:**
   StudyInterest_ProjectBETTERCom.pdf(0.01)

Add Document

1. * **Document Name:**
   SOP

2. * **Type:**
   Research Protocol

3. * **File:**
   HM20023314 Project BETTER RCT SOP 10.31.22.docx(0.05)

Add Document

1. * **Document Name:**
   Project BETTER Community-based recruitment email template

2. * **Type:**
   Recruitment/Advertising

3. * **File:**
   Project BETTER Community Recruitment Study Notification Email Template.docx(0.01)

Add Document

1. * **Document Name:**
   Project BETTER Community-based recruitment script

2. * **Type:**
   Recruitment/Advertising

3. * **File:**
   Project BETTER Community Remote Recruitment Scripts.docx(0.01)

Add Document

1. * **Document Name:**
   Project BETTER Community-based recruitment flyer

2. * **Type:**
   Recruitment/Advertising

3. * **File:**
   Project BETTER Community-based Flyer.docx(0.01)

Add Document

1. * **Document Name:**
   Project BETTER RA Forms 3 Delivery Questions

2. * **Type:**
   Research Measure

3. * **File:**
   Project BETTER Study Visit 3 Delivery Questions.docx(0.01)

Add Document

1. * **Document Name:**
   Eligibility Form

2. * **Type:**
   Research Measure

3. * **File:**
   Revised 7.18.22 Project BETTER Eligibility Form.docx(0.02)

Add Document

1. * **Document Name:**
   In-person Recruitment Script

2. * **Type:**
   Recruitment/Advertising

3. * **File:**
   Revised 7.18.22 Project BETTER In Person Recruitment Scripts.docx(0.04)

Add Document

1. * **Document Name:**
   Remote Recruitment Script

2. * **Type:**
   Recruitment/Advertising

3. * **File:**
   Revised 7.18.22 Project BETTER Remote Recruitment Scripts.docx(0.02)

Add Document

1. * **Document Name:**
   Recruitment Flyer

2. * **Type:**
   Recruitment/Advertising

3. * **File:**
   Revised Project BETTER Flyer 7.18.22.docx(0.02)

Add Document

1. * **Document Name:**
   Consent form

2. * **Type:**
   Consent/Assent/Information Sheet

3. * **File:**
   Project BETTER Consent Form_revised 12.15.21.pdf(0.07)

Add Document

1. * **Document Name:**
   Informatics consult

2. * **Type:**
   Other

3. * **File:**
   BETTER_Informatics_Email.pdf(0.01)

Add Document

1. * **Document Name:**
   PROC APPROVAL

2. * **Type:**
   Ancillary Committee Approval

3. * **File:**
   BETTER_PROC_Approval.pdf(0.01)

Add Document

1. * **Document Name:**
   Study Notification Email Template

2. * **Type:**
   Recruitment/Advertising

3. * **File:**
   Project BETTER Study Notification Email Template.docx(0.01)

Add Document

1. * **Document Name:**
   Project Better Module Transcript

2. * **Type:**
   Research Measure

3. * **File:**
   Project BETTER Peedy Transcript.docx(0.01)

Add Document

1. * **Document Name:**
   Project BETTER Module Video Links

2. * **Type:**
   Other

3. * **File:**
   Project BETTER Video Links.docx(0.01)

Add Document

1. * **Document Name:**
   Project BETTER Brochure Webpage

2. * **Type:**
   Other

3. * **File:**
   Project BETTER Webpage.pdf(0.01)

Add Document

1. * **Document Name:**
   Project BETTER Overview

2. * **Type:**
   Other

3. * **File:**
   Project BETTER Technology-based Program Overview.pdf(0.01)

Add Document

1. * **Document Name:**
   Technology-based modules

2. * **Type:**
   Other

3. * **File:**
   Project BETTER Technology-based module links.docx(0.01)

Add Document

1. * **Document Name:**
   Brochure

2. * **Type:**
   Research Measure

3. * **File:**
   Project BETTER Brochure.pdf(0.01)

Add Document

1. * **Document Name:**
   Demographic questions

2. * **Type:**
   Recruitment/Advertising

3. * **File:**
   Project BETTER Demographic Questions .docx(0.01)

Add Document

1. * **Document Name:**
   RA forms 3

2. * **Type:**
   Research Measure

3. * **File:**
   Project BETTER Study Visit 3 RA Form.docx(0.01)

Add Document

1. * **Document Name:**
   RA forms 2

2. * **Type:**
   Research Measure

3. * **File:**
   Project BETTER Study Visit 2 RA Form.docx(0.01)

Add Document

1. * **Document Name:**
   RA forms 1

2. * **Type:**
   Research Measure

3. * **File:**
   Project BETTER Study Visit 1 RA Form.docx(0.01)

Add Document

1. * **Document Name:**
   Follow up survey 2

2. * **Type:**
   Research Measure

3. * **File:**
   Project BETTER Follow-up Survey 2.docx(0.01)

Add Document

1. * **Document Name:**
   Follow up survey 1

2. * **Type:**
   Research Measure

3. * **File:**
   Project BETTER Follow-up Survey 1.docx(0.01)

Add Document

1. * **Document Name:**
   Pre-survey

2. * **Type:**
   Research Measure

3. * **File:**
   Project BETTER Pre-Survey.docx(0.01)

Add Document

1. * **Document Name:**
   Chart abstraction form 3

2. * **Type:**
   Research Measure

3. * **File:**
   Project BETTER Study Visit 3 Chart Abstraction Form.docx(0.01)

Add Document

1. * **Document Name:**
   Chart abstraction form 2

2. * **Type:**
   Research Measure

3. * **File:**
   Project BETTER Study Visit 2 Chart Abstraction Form.docx(0.01)

Add Document

1. * **Document Name:**
   Chart abstraction form 1

2. * **Type:**
   Research Measure

3. * **File:**
   Project BETTER Study Visit 1 Chart Abstraction Form.docx(0.01)

Add Document

1. * **Document Name:**
   Scheduling and Reminder Scripts

2. * **Type:**
   Study reminders/communications

3. * **File:**
   Project BETTER Follow Up Scheduling and Reminders Scripts.docx(0.01)

Add Document

1. * **Document Name:**
   Follow up visit scripts

2. * **Type:**
   Study reminders/communications

3. * **File:**
   Project BETTER Follow-up Visits Script.docx(0.01)

Add Document

1. * **Document Name:**
   Martin CV

2. * **Type:**
   CV/Biosketch

3. * **File:**
   CEM_CV_08.15.21_BT.pdf(0.01)

Add Document

1. * **Document Name:**
   Parlier CV

2. * **Type:**
   CV/Biosketch

3. * **File:**
   Parlier CV .pdf(0.01)