STUDY TEAM NOTE: The following document, while in a non-standard format, is the protocol document for this study. At the time of submission, our institution did not require a separate protocol document and the IRB application was permitted to be used as the acting protocol document.

VCU Office of the Vice President for Research and Innovation

Date: Tuesday, April 23, 2024 11:33:33 AM Print Close

ID: HM20025635 **HM20025635** View: SF - Study Identification

HM20025635 - Gisela Chelimsky
A pilot study of auricular microstimulation to determine if it improves vagal modulation

Study Identification

1. * **Select the Principal Investigator:**
   Gisela Chelimsky

2. * **Study Title:**
   A pilot study of auricular microstimulation to determine if it improves vagal modulation

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:**
   Peds - Gastroenterology

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 **Previously submitted versions of this study (closed, withdrawn, auto-withdrawn studies)**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
HM20025242	Pediatric POTS: does a periaqueductal gray – vagus nerve interface malfunction explain the natural history with its numerous co-morbidities?	Gisela Chelimsky
HM20025299	Patient Registry for the Autonomics Center	Gisela Chelimsky

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
Andaya	Andrea-Kayle	andayaa@vcu.edu	8048283793	
Chelimsky	Gisela	grotewoldcg@vcu.edu		
Chelimsky	Thomas	chelimskyt@vcu.edu		
Dave	Bhakti	badave@vcu.edu		
Lessard	Margaret	mklessard@vcu.edu	8046283093	
Maxwell	Madison	maxwellme@vcu.edu		
Minter	Sabrina	scminter@vcu.edu		

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)

HM20025635 - Gisela Chelimsky
A pilot study of auricular microstimulation to determine if it improves vagal modulation

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. * **Indicate the FDA regulated product(s) this study involves:**

- [ ] Drug
- [x] **Medical Device**
- [ ] Biologic
- [ ] Dietary Supplement
- [ ] Food/Food Additive
- [ ] Color Additive
- [ ] Electronic Products for Human Use (radiation producing)
- [ ] Tobacco Product
- [ ] Other

3. * **Is this study supported by the Department of Defense (DoD):**

( ) Yes
(●) **No**

4. * **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
- [x] **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**

HM20025635 - Gisela Chelimsky
A pilot study of auricular microstimulation to determine if it improves vagal modulation

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.**
   - [x] **In-person interactions / interventions with participants**
   - [ ] Remote interactions / interventions with participants
   - [x] **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?**
   No, not possible to 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

ID: HM20025635 **HM20025635** View: SF2 - Initial Setup Complete

HM20025635 - Gisela Chelimsky
A pilot study of auricular microstimulation to determine if it improves vagal modulation

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

HM20025635 - Gisela Chelimsky
A pilot study of auricular microstimulation to determine if it improves vagal modulation

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.**

   The aim of this proposal is to determine if utilizing an affordable tool like microstimulation utilizing a TENs unit and applying the stimulation to the ear though an ear clip does improve vagal modulation. This can be easily done at home by utilizing the microstimulation for 2 hours a day and measuring vagal modulation before and after. Previous research investigating this had participants use the unit for 2 hours as well. (Chelimsky et al., 2019), however the data from this study was inconclusive, and therefore this study aims to demonstrate effectiveness of the unit usage on heart rate variability (HRV).

   Although functional gastrointestinal disorders (FGID) affect 10%-20% of children and adolescents. 1-3 the pathophysiology remains unknown. The multiple current hypotheses include visceral hypersensitivity, altered brain-gut connections, dysbiosis, genetic and epigenetic factors, and increased gut permeability among others. 4 Since the vagus nerve links the brain to the gut, many studies of adult subjects have evaluated the cardiovagal modulation in this group of disorders. The cardiovagal modulation can be measured by heart rate variability (HRV). HRV evaluates the heart rate fluctuation over a period of time. HRV is considered a reliable tool to look at parasympathetic function, baroreflex function, and parasympathetic to sympathetic balance.5, 6 High-frequency (hf) HRV is a marker of vagal modulation. The low-frequency (lf) HRV probably reflects cardiac autonomic outflow from the baroreflex or parasympathetic regulation, rather than sympathetic modulation, although this is still being discussed.6, 7

   A meta-analysis of adult subjects with irritable bowel syndrome (IBS) showed decreased cardiovagal modulation.8 One study compared children aged 7-10 years of age with functional abdominal pain or IBS to healthy subjects. They found no difference in cardiovagal and cardiac sympathetic modulation.9 However, a study of young adolescents with different chronic pain syndromes, including chronic abdominal pain, showed decreased cardiovagal modulation.10 These findings are similar to those in many adult syndromes with chronic pain, such as chronic pelvic pain,11 complex regional pain syndrome,12 fibromyalgia,13 and chronic neck pain.14

   Although future research would aim to investigate vagal modulation in those specifically with FGID, for preliminary data purposes we are testing the unit's effects on heart rate variability regardless of having/not having an FGID diagnosis.

   1Hyams JS, Davis P, Sylvester FA, Zeiter DK, Justinich CJ, Lerer T. Dyspepsia in children and adolescents: a prospective study. J Pediatr Gastroenterol Nutr. 2000; 30: 413- 418.
   2Apley J, Naish N. Recurrent abdominal pains: a field survey of 1,000 school children. Arch Dis Child. 1958; 33: 165-170.
   3Boey C, Yap SB, Goh KL. The prevalence of recurrent abdominal pain in 11-to 16-year-old Malaysian schoolchildren. J Paediatr Child Health. 2000; 36: 114- 116.
   4Enck P, Aziz Q, Barbara G, et al. Irritable bowel syndrome. Nat Rev Dis Prim. 2016; 2: 16014.
   5Riganello F, Garbarino S, Sannita WG. Heart Rate Variability, Homeostasis, and Brain Function. J Psychophysiol. 2012; 26: 178– 203.
   6Goldstein DS, Bentho O, Park M-Y, Sharabi Y. LF power of heart rate variability is not a measure of cardiac sympathetic tone but may be a measure of modulation of cardiac autonomic outflows by baroreflexes. Exp Physiol. 2011; 96: 1255– 1261.
   7Reyes del Paso GA, Langewitz W, Mulder LJ, van Roon A, Duschek S. The utility of low frequency heart rate variability as an index of sympathetic cardiac tone: A review with emphasis on a reanalysis of previous studies. Psychophysiol. 2013; 50: 477– 487.
   8Liu Q, Wang EM, Yan XJ, Chen SL. Autonomic functioning in irritable bowel syndrome measured by heart rate variability: A meta-analysis. J Dig Dis. 2013; 14: 638- 646.
   9Jarrett M, Heitkemper M, Czyzewski D, Zeltzer L, Shulman RJ. Autonomic nervous system function in young children with functional abdominal pain or irritable bowel syndrome. Journal of Pain. 2012; 13: 477- 484.
   10Evans S, Seidman L, Tsao J, Lung K, Zeltzer L, Naliboff B. Heat rate variability as a biomarker for autonomic nervous system response differences between children with chronic pain and healthy control children. J Pain Res. 2013; 6: 449- 457.
   11Williams DP, Chelimsky G, McCabe NP, et al. Effects of chronic pelvic pain on heart rate variability in women. J Urol. 2015; 194: 1289- 1294.
   12Terkelsen AJ, Molgaard H, Hansen J, Finnerup NB, Kroner K, Jensen TS. Heart rate variability in complex regional pain syndrome during rest and mental and orthostatic stress. Anesthesiology. 2012; 116: 133- 146.
   13Mork PJ, Nilsson J, Loras HW, Riva R, Lundberg U, Westgaard RH. Heart rate variability in fibromyalgia patients and healthy controls during non-REM and REM sleep: a case-control study. Scand J Rheumatol. 2013; 42: 505- 508.
   14Kang JH, Chen HS, Chen SC, Jaw FS. Disability in patients with chronic neck pain: heart rate variability analysis and cluster analysis. Clin J Pain. 2012; 28: 797- 803.
   Chelimsky, G., Rausch, S., Bierer, D., Feng, M., Simpson, P., Awe, E., & Chelimsky, T. (2019). Cardiovagal modulation in pediatric functional gastrointestinal disorders. Neurogastroenterology and motility : the official journal of the European Gastrointestinal Motility Society, 31(5), e13564. https://doi.org/10.1111/nmo.13564

2. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
   The overarching hypothesis of this proposal is that auricular vagal micro-stimulation improves vagal modulation.

Based on prior experience, in more than half the subjects, we expect high-frequency heart rate variability (hfHRV) to improve by 10% from baseline to week 4.

3. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
To determine if the auricular microstimulator produces the expected increase in HRV.

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

Potential conclusions would include that the vagal stimulator inhibits the neuroinflammatory cascade and that neuro-inflammation plays a major role in pediatric FGID, a currently open question.

5. * **Describe any potential for direct benefits to participants in this study:**
The TENS unit has the potential to decrease symptoms in participants with FGID. We cannot guarantee this will help, hence why we are doing the study.

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:**
If this auricular TENS unit device produces the expected results, it will:

1) provide a portable, affordable tool to decrease symptoms in FGID
2) corroborate that increasing vagal modulation improves symptoms in FGID

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

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	FGID Assent/Parental Permission	TENS FGID Assent V10.pdf	0.23	4/23/2024 11:25 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	Healthy Control Assent/Parental Permission	TENS HC Assent V10.pdf	0.23	4/23/2024 11:25 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	Healthy Control Consent	TENS HC Consent V10.pdf	0.22	4/23/2024 11:24 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	FGID Consent	TENS FGID Consent V10.pdf	0.22	4/23/2024 11:24 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	Best Practice Alert MyChart Message Script	Best Practice Alert MyChart Message Script V2.docx	0.03	3/13/2024 3:52 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Flyer	TENS Flyer (Undesigned Language Only) V4.docx	0.07	3/13/2024 3:51 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	REDCap Study Interest & Screening Form	Study Interest & Screening Form V3.pdf	0.04	3/13/2024 3:51 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Daily Recording Diary	Daily Recording Diary V6.pdf	0.06	3/13/2024 3:51 PM	Madison Maxwell	Research Measure	Yes
View	In-Person Recruitment Script	TENS In Person Recruitment Script V5.docx	0.12	3/13/2024 3:46 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Phone Recruitment Script	TENS Phone Recruitment Script V7.docx	0.15	3/13/2024 3:46 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Eligible Interest Form Submission Follow-Up Email Recruitment Script	TENS Eligible Interest Form Submission Follow-Up Email Recruitment Script V3.docx	0.06	3/13/2024 3:44 PM	Madison Maxwell	Recruitment/Advertising	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Participant TENS Instructions	TENS Unit Instructions V6.docx	0.11	1/9/2024 1:31 PM	Madison Maxwell	Other	Yes
View	Screen Fail Contact Information	Screen Fail Contact Information.pdf	0.01	12/6/2023 3:22 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Heart Rate Variability Measurements	HRV Measurements for both study visits (V2).pdf	0.02	8/23/2023 11:31 AM	Madison Maxwell	Research Measure	Yes
View	TENS Unit Manual	TENS Unit Manual (Microcurrent Model).pdf	0.02	8/17/2023 9:07 AM	Madison Maxwell	Drug/Device Brochure	Yes
View	TENS Unit Photo	TENS Unit Photo (Microcurrent Model).png	0.02	8/17/2023 9:07 AM	Madison Maxwell	Other	Yes
View	Symptom Questionnaire	GI Symptom Questionnaire (V1).pdf	0.01	4/13/2023 3:11 PM	Madison Maxwell	Research Measure	Yes
View	Ear Clip Info	TENS Unit Ear Clip Information.docx	0.01	1/20/2023 2:09 PM	Madison Maxwell	Drug/Device Brochure	Yes
View	IDE Documents	TENS Documentation of NSR determination.docx	0.02	11/29/2022 9:41 AM	Madison Maxwell	Other	Yes
View	TENS Unit Ear Clip	TENS Ear Clip.jpg	0.01	11/18/2022 12:35 PM	Madison Maxwell	Other	Yes
View	PROC Approval	TENS PROC Approval.pdf	0.01	10/21/2022 12:45 PM	Madison Maxwell	Ancillary Committee Approval	Not Applicable
View	M. Maxwell Trainings (All Merged)	M Maxwell CITI, Bioraft, MERT Trainings (Merged).pdf	0.01	10/20/2022 11:55 AM	Madison Maxwell	Other	Not Applicable
View	B. Dave CITI Trainings (All Merged)	B Dave CITI Trainings (Merged).pdf	0.01	10/20/2022 11:51 AM	Madison Maxwell	Other	Not Applicable
View	G. Chelimsky CITI Trainings (All Merged)	G Chelimsky CITI Trainings (Merged).pdf	0.01	10/20/2022 11:49 AM	Madison Maxwell	Other	Not Applicable
View	T. Chelimsky CV	T Chelimsky CV Signed.pdf	0.01	10/20/2022 11:43 AM	Madison Maxwell	CV/Biosketch	Yes
View	Basic Participant Information	BasicInformation.pdf	0.01	10/18/2022 3:38 PM	Madison Maxwell	Research Measure	Yes
View	Screening Form	ScreeningForm.pdf	0.01	10/18/2022 3:37 PM	Madison Maxwell	Research Measure	Yes
View	G. Chelimsky CV	G Chelimsky CV.docx	0.01	9/12/2022 4:52 PM	Bhakti Dave	CV/Biosketch	Yes

HM20025635 - Gisela Chelimsky
A pilot study of auricular microstimulation to determine if it improves vagal modulation

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.
   100

2. **If this is a multi-Center Project, what is the maximum anticipated number of subjects across all sites?**
   Not multi-center

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:**
   Our power estimates show that 28 or more measurements/surveys are needed to have a confidence level of 95% that the actual change in HRV d/t TENS unit use is within ±5% of our measurements of HRV. We estimate about a 30% compliance rate, so we arrived at 100 to account for dropouts and screen fails. We are not aiming to recruit an equal number of FGIDs/non-FGID, because our main aim is to figure out if the TENS unit improves vagal modulation in general, not to compare the degree of variability between FGID and non-FGID subjects.

4. * **List the study inclusion criteria:**
   Female

   12 – 21 years old

   Either diagnosed OR not diagnosed with chronic idiopathic nausea, functional abdominal pain, dyspepsia and/or irritable bowel syndrome.

   English speaking

5. * **List the study exclusion criteria:**
   Patients who are unable to stand upright during the heart rate variability recording

   Patients with a known bleeding disorder

   Patients with swollen, infected, inflamed, or other skin eruptions on outer ear

   Patients with epilepsy

   Patients with any implanted cardiac pacemaker or defibrillator

   Patients with serious arterial circulatory problems in the lower limbs

   Patients with abdominal or inguinal hernia

   Patients who are pregnant

   Any unstable medical condition, such as renal disease, uncontrolled diabetes, etc.

   Requires new medication during the 4 weeks of the study that may affect the gastrointestinal symptoms, vagal modulation or immune response.

   Practices over 1 hour of aerobic activity a day

   Daily practice of abdominal breathing (yoga)

6. * **Will individuals with limited English proficiency be included in or excluded from this research?**
   - ○ Included
   - ○ Excluded - safety concerns if participants are unable to communicate with the study team
   - ● **Excluded - instruments/measures only validated in English**
   - ○ Excluded - no prospect of direct benefit to individual participants

- ◯ Excluded - minimal risk study
- ◯ Excluded - lack of budget/resources for translation and interpretation [provide an explanation in next question]
- ◯ Excluded - other reason [provide an explanation in next question]

7. **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.**
   The sex restriction is because there is a disproportionate representation of females having functional disorders. Having male participants in the study may lower the study's external validity and findings may not be generalizable to females with a male population included.

   The TENS unit uses an ear clip and we do not want to disrupt the healing process for ear problems.

   We want to exclude people with the conditions listed above (bleeding disorders, epilepsy, circulatory problems, hernias, pregnancy, any other unstable condition) because it will skew the data by decreasing the ability to properly assess heart rate variability without confounding variables.

   We do not know how the presence of cardiac pacemaker or defibrillators will alter our data nor do we have solid research on the safety of using TENS with these devices, so we are excluding this population.

   We are excluding those who start a medication during the 4 weeks of the study that may affect the gastrointestinal symptoms, vagal modulation or immune response because we do not know how this will alter our data or interact with the TENS unit.

   Participants who engage in over 1 hour of aerobic exercise or daily practice of yoga will be excluded because we will not be able to pinpoint whether HRV changes are due to the use of the TENS unit or the exercise/yoga.

ID: HM20025635 **HM20025635**

View: SF2 - Background, Rationale & Goals Section Complete

HM20025635 - Gisela Chelimsky
A pilot study of auricular microstimulation to determine if it improves vagal modulation

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

HM20025635 - Gisela Chelimsky
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Study Procedures

1. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
The overarching hypothesis of this proposal is that auricular vagal micro-stimulation improves vagal modulation.

Based on prior experience, in more than half the subjects, we expect high-frequency heart rate variability (hfHRV) to improve by 10% from baseline to week 4.

2. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
To determine if the auricular microstimulator produces the expected increase in HRV.

3. * **Choose all types of recruitment materials that may be used and upload them below:**

- [x] **E-mail invitations**
- [ ] Phone Solicitation scripts (i.e. cold calls or random-digit-dialing)
- [x] **Flyers, Mailed Letters or Newspaper/TV/Radio Ads**
- [x] **TelegRAM announcements**
- [ ] Website text
- [ ] Study-specific web sites (provide the design and text)
- [x] **Social Media**
- [x] **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:**
Scripts for individual participants

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.

- Potential participants can contact the study team phone number or email on the study flyer to express interest in their study. The design and formatting of study flyers are subject to change, but all language will remain the same as in the current IRB-approved version.

- Potential participants can scan a QR code on the study flyer to complete a REDCap Study Interest & Screening Form that includes a brief eligibility assessment survey and the option to submit their contact information for study team follow-up if answers to the survey indicate eligibility criteria are met. Otherwise, they will be shown a message that notifies them that they are ineligible and thanking them for their time, and an opportunity to submit their contact

information to be contacted regarding other studies that may be a better fit for their characteristics.

- Participants who are consented to the Registry for the Autonomics Center (HM20025299) and have consented to receiving information about future research studies for which they may be eligible will be contacted via email, phone, or in-person to assess interest in participation with the appropriate script. The design and formatting of email messages are subject to change, but all language will remain the same as in the current IRB-approved script. Potential participants can choose to answer screening questions verbally with a study team member during phone recruitment attempts- if this method is used, a REDCap Study Interest & Screening Form will be filled out by the study team on their behalf for documentation purposes. Study staff will administer screening questions verbally during in-person recruitment attempts. Otherwise, potential participants will fill out the REDCap Study Interest & Screening Form on their own and will be followed up with via the preferred contact method to schedule the first in-person study visit.

- Potential participants may be approached in-person at their clinic visit by a research team member. The PI/clinical staff will not be consenting patients, but they may ask a patient if it is okay if a coordinator talks to them while they are at their appointment if they express interest. Potential participants will answer screening questions verbally with a study team member - a REDCap Study Interest & Screening Form will be filled out by the study team on their behalf for documentation purposes. Eligible participants will be followed up with via the preferred contact method to schedule the first in-person study visit if they would like to proceed with participation.

- EPIC "best practice alerts" (BPA) will be used to notify the study team of potentially eligible participants. This alert will appear if the potential participant meets pre-designated parameters based on the eligibility criteria (e.g., age, sex, ICD-10 codes for diagnoses, medications being taken, etc.). Study team members will receive a message in their InBasket when a potential participant is identified. The study team will then send a MyChart message to the potential participant using the TENS Best Practice Alert MyChart Message Script that includes the REDCap Study Interest & Screening Form link and study team contact information. If interested, they will fill out the REDCap Study Interest & Screening Form at their own discretion and will be followed up with via the preferred contact method to schedule the first in-person study visit if they would like to proceed with participation.

- Potential participant contact information will be stored in a secure REDcap database regardless of recruitment method.

2.

-Study flyers will be posted in VCU/VCUHealth clinics. Study flyers will also be given to clinical staff to directly hand to potential participants. PI/clinical staff will simply be distributing flyers and will not be answering study related questions (unless it is a clinical/health related question beyond the coordinator’s credentials/knowledge) or consent patients. The flyer may also be distributed through the TelegRAM announcements or the VCU Clinical Research Facebook page. The flyer may also be sent via department faculty & staff email messages as permitted.

-Approved coordinators will respond/initiate calls or emails from/to potential participants or approach them in person to schedule an informed consent discussion. PI/clinical staff will only answer clinical/health related questions in relation to participation beyond the coordinator’s credentials/knowledge.

- For in-person recruitment attempts, the coordinator will view the GI clinic schedule on Epic to see when a potential participant’s appointment time is and to review basic eligibility criteria before approaching. A coordinator will approach a patient during their visit to the Gastroenterology Clinic in the private clinic room either before or after their appointment and introduce the study/assess eligibility using the In-Person Recruitment Script. If the potential participant is interested in participating, but is unable to complete an informed consent discussion during the visit, the researcher may collect consent at the study baseline visit in the clinic or pediatric research unit prior to starting study procedures. Only potential participant screening question answers and contact information will be stored on REDcap before the consent discussion. Recruitment discussions with children under 18 will be held with at least one parents/legal guardian present. If recruitment attempts fail for that participant, their contact information will be deleted upon study closure.

- In-person recruitment efforts will be held on all days the PI's clinic is being held. Study staff will be notified upon receiving Study Interest & Screening Form submissions, emails, or phone calls, and will respond to these submissions, emails, or phone calls via preferred contact method within 7 business days. Potential participants who submitted an interest form, sent an email, or made a phone call to our study team may be contacted up to 3 times by email or phone call, once a week.

- During any recruitment discussions, potential participants may be emailed or handed a copy of the consent form for review if requested.

3.

- Eligibility screening will be done via chart review by a study team member, via a REDCap Study Interest & Screening form submission, or via verbal administration of the items on the REDCap Study Interest & Screening Form by a study team member.

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. * **Since a separate protocol document is not uploaded, describe the proposed research using language understandable to those IRB committee members whose expertise is not scientific. The description must include:**

1. A statement explaining the study design
2. A detailed description of all the procedures that will be followed to carry out the study, preferably in sequential order, and in sufficient detail that the study's methods could be replicated
3. The schedule and frequency of when and how procedures will be conducted (e.g. in person, online, phone, paper, etc.)
4. A description of all research measures/tests/interventions that will be used, including analyses/tests conducted on specimens/biological samples (if applicable)

See the help text for additional guidance
1.
This study is a clinical trial involving a TENS unit with an IDE.

2.
Week 0 Visit (Baseline): After the signing of the ICF, participants will take a pregnancy test. All other screening questions will have been answered previously in the REDCap Study Interest and Screening Form. If the pregnancy test is negative, the participant will be marked as eligible and assigned a Study ID. Participants will complete the GI Symptom Questionnaire on REDCap via a computer or tablet handed to the participant. Heart rate variability (HRV) will then be collected using a digital HRV device. These devices are commonly used to measure HRV, and this study will not be altering the use of that device for research purposes. To measure HRV, electrode leads connected to the device will be placed on the participant's chest and stomach while they are laying down. HRV will be measured for 15 minutes of supine time and 5 minutes of standing time. Participants will then be hooked up to the TENS microcurrent unit (the unit has a pulse rate from 0.1 - 150 Hz, a pulse width of 2 - 200 mS, and an adjustable pulse amplitude of 0-0.7 mA peak at 1000 ohms- the unit will be set at a pulse rate of 50 and a pulse width of 5ms. The mA will be turned up just until the participant can feel it, and then back down to where they can just not feel it, so specific mA strengths may vary between each participant and session), and heart rate variability will be measured again (supine) for another 30 minutes. The unit will be disconnected and HRV will then again be measured for 15 minutes of supine time and 5 minutes of standing time. The HRV device will continuously measure and the electrodes will not be taken off/the machine will not be turned off in between physical positions and conditions since it gives us information on HRV during episodes of position change. Measurement times, including the start time, time when the participant changes physical position, and end time will be recorded in REDcap. Upon completion of the study visit, HRV data from the device will be exported into software-compatible files on a VCU managed computer. They will then be stored on a VCU managed drive with their Study ID and name of the visit (baseline/follow up) as the title of the file for later use in Kubios, an HRV analysis software. The files generated by the HRV measurement devices include information such as the measurement start and end times and the participants' interbeat intervals (IBI/RR)/ECG during the measurement. Files with this information will only be stored in Kubios and/or the VCU drive until analysis is complete. Following the completion of the HRV measurement, the participant will receive a printout of instructions and a physical demonstration on how to use the unit by an approved study team member and instructed to use it at a consistent time each day for 2 hours daily over 4 weeks. The participant doesn't have to hold the unit the entire time, as long as their ear clip is connected to them and that clip is connected to the machine, they have the freedom to set down the unit near them, hold it, put it in a pocket, or use the belt clip on the device. The ear clip connects to the unit by a cord. The participant will be asked to complete the TENS Microcurrent Unit Daily Recording Diary to document when the device was used and where on their ear, as well as the times of starting/ending sessions. Participants will be emailed daily via REDcap survey distribution for completion. The study coordinator will contact the patient 2 times over the 4 weeks to check in for adverse events that would be promptly recorded and reported and to remind them to keep using the device, but a coordinator contact will be on the instructions printout should they need to report any AEs/device issues prior to the check-in. Problems may also be reported on the daily recording diary, upon which study team members will receive a notification. The next visit will be scheduled, and payment will be processed.

Week 4 Visit: The participant and parent(s)/guardian(s) if applicable, will return to the FGID clinic or PRU and complete heart rate variability measuring using the same procedures as at baseline, return their TENS microcurrent unit, complete the same symptom questionnaire, and return their daily recording diaries if done on paper. Payment will be processed.

3.

Tests: Heart Rate Variability assessment, pregnancy test during screening

Interventions: TENS microcurrent unit usage

Measures: Daily recording diary, GI symptom questionnaire

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

All research activities are being performed exclusively for research purposes.

9. **If applicable, describe alternatives (research or non-research) that are available to potential participants if they choose not to participate in this study:**
No alternatives will be available to potential participants. Participants will be notified that declining to participate will not impact their clinical care and that their participation is totally voluntary.

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	FGID Assent/Parental Permission	TENS FGID Assent V10.pdf	0.23	4/23/2024 11:25 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	Healthy Control Assent/Parental Permission	TENS HC Assent V10.pdf	0.23	4/23/2024 11:25 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	Healthy Control Consent	TENS HC Consent V10.pdf	0.22	4/23/2024 11:24 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	FGID Consent	TENS FGID Consent V10.pdf	0.22	4/23/2024 11:24 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	Best Practice Alert MyChart Message Script	Best Practice Alert MyChart Message Script V2.docx	0.03	3/13/2024 3:52 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Flyer	TENS Flyer (Undesigned Language Only) V4.docx	0.07	3/13/2024 3:51 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	REDCap Study Interest & Screening Form	Study Interest & Screening Form V3.pdf	0.04	3/13/2024 3:51 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Daily Recording Diary	Daily Recording Diary V6.pdf	0.06	3/13/2024 3:51 PM	Madison Maxwell	Research Measure	Yes
View	In-Person Recruitment Script	TENS In Person Recruitment Script V5.docx	0.12	3/13/2024 3:46 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Phone Recruitment Script	TENS Phone Recruitment Script V7.docx	0.15	3/13/2024 3:46 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Eligible Interest Form Submission Follow-Up Email Recruitment Script	TENS Eligible Interest Form Submission Follow-Up Email Recruitment Script V3.docx	0.06	3/13/2024 3:44 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Participant TENS Instructions	TENS Unit Instructions V6.docx	0.11	1/9/2024 1:31 PM	Madison Maxwell	Other	Yes
View	Screen Fail Contact Information	Screen Fail Contact Information.pdf	0.01	12/6/2023 3:22 PM	Madison Maxwell	Recruitment/Advertising	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Heart Rate Variability Measurements	HRV Measurements for both study visits (V2).pdf	0.02	8/23/2023 11:31 AM	Madison Maxwell	Research Measure	Yes
View	TENS Unit Manual	TENS Unit Manual (Microcurrent Model).pdf	0.02	8/17/2023 9:07 AM	Madison Maxwell	Drug/Device Brochure	Yes
View	TENS Unit Photo	TENS Unit Photo (Microcurrent Model).png	0.02	8/17/2023 9:07 AM	Madison Maxwell	Other	Yes
View	Symptom Questionnaire	GI Symptom Questionnaire (V1).pdf	0.01	4/13/2023 3:11 PM	Madison Maxwell	Research Measure	Yes
View	Ear Clip Info	TENS Unit Ear Clip Information.docx	0.01	1/20/2023 2:09 PM	Madison Maxwell	Drug/Device Brochure	Yes
View	IDE Documents	TENS Documentation of NSR determination.docx	0.02	11/29/2022 9:41 AM	Madison Maxwell	Other	Yes
View	TENS Unit Ear Clip	TENS Ear Clip.jpg	0.01	11/18/2022 12:35 PM	Madison Maxwell	Other	Yes
View	PROC Approval	TENS PROC Approval.pdf	0.01	10/21/2022 12:45 PM	Madison Maxwell	Ancillary Committee Approval	Not Applicable
View	M. Maxwell Trainings (All Merged)	M Maxwell CITI, Bioraft, MERT Trainings (Merged).pdf	0.01	10/20/2022 11:55 AM	Madison Maxwell	Other	Not Applicable
View	B. Dave CITI Trainings (All Merged)	B Dave CITI Trainings (Merged).pdf	0.01	10/20/2022 11:51 AM	Madison Maxwell	Other	Not Applicable
View	G. Chelimsky CITI Trainings (All Merged)	G Chelimsky CITI Trainings (Merged).pdf	0.01	10/20/2022 11:49 AM	Madison Maxwell	Other	Not Applicable
View	T. Chelimsky CV	T Chelimsky CV Signed.pdf	0.01	10/20/2022 11:43 AM	Madison Maxwell	CV/Biosketch	Yes
View	Basic Participant Information	BasicInformation.pdf	0.01	10/18/2022 3:38 PM	Madison Maxwell	Research Measure	Yes
View	Screening Form	ScreeningForm.pdf	0.01	10/18/2022 3:37 PM	Madison Maxwell	Research Measure	Yes
View	G. Chelimsky CV	G Chelimsky CV.docx	0.01	9/12/2022 4:52 PM	Bhakti Dave	CV/Biosketch	Yes

HM20025635 - Gisela Chelimsky
A pilot study of auricular microstimulation to determine if it improves vagal modulation

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):**
   - [ ] 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
   - [x] **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
   - [x] **Medical or Surgical Procedures (eg: physical exam, clinical procedures, scans, etc)**
   - [x] **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)
   - [ ] Interviews / Focus Groups / Verbal responses to questions
   - [ ] Audio / Video recording or photographing participants
   - [x] **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)**
   - [ ] 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

Bio-Medical Device Details

1. * **Select the type of device :**
   - [x] **Marketed Device (including 510k device) used as indicated**
   - [ ] Marketed but new indication or intended use
   - [ ] Mobile application or software function with regulatory discretion
   - [ ] Mobile application or software function without regulatory discretion
   - [ ] Investigational device
   - [ ] Humanitarian Use Device (HUD)

2. * **List devices this study will involve:**

Device	Manufacturer	Device Risk	IDE	IDE Holder
Digital TENS Unit	InTENSity	Non-Significant Risk	Abbreviated IDE	VCU Sponsor-Investigator

3. * **Describe how the device will be stored and controlled.**
The device will be stored in a locked room and cabinet with the CRC, the device will be given to the participant after eligibility and consent has been confirmed and the participant has completed their Week 0 HRV measurement session. No identifiable information is stored on the device.

4. A. For each device listed above, **upload documentation of the approved use(s) (operation manual, instructions for use, etc.) or a detailed description of the design, use, and risks of the device.**

B1. If 'Investigational Medical Device' or 'New Use for Marketed Medical Device' was selected above AND the device qualifies for IDE exemption under under 21 CFR 812.2(c), upload one of the following for each applicable device:
- A document explaining how the device's use in this study meets one of the categories for IND exemption under 21 CFR 812.2(c).
- External sponsor's protocol including IDE exemption information
- Communication from the external sponsor verifying the IDE exemption
- Communication from the FDA with verification of IDE exemption

B2. Upload at least one of the following for each Significant Risk medical device:
- External sponsor's protocol including IDE number
- Communication from the external sponsor verifying the IDE number
- VCU sponsor-investigator's FDA IDE protocol including IDE number
- Communication from the FDA with verification of the IDE number

B3. Upload at least one of the following for each Non-Significant Risk medical device:
- External sponsor's protocol including a justification regarding the risk of the device (significant vs. non-significant)
- Communication from the sponsor holding the IDE, which provides a justification regarding the risk of the device (significant vs. non-significant) according to 21 CFR 812.3(m).

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	FGID Assent/Parental Permission	TENS FGID Assent V10.pdf	0.23	4/23/2024 11:25 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	Healthy Control Assent/Parental Permission	TENS HC Assent V10.pdf	0.23	4/23/2024 11:25 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
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View	M. Maxwell Trainings (All	M Maxwell CITI, Bioraft, MERT	0.01	10/20/2022 11:55 AM	Madison Maxwell	Other	Not Applicable

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	Merged)	Trainings (Merged).pdf					
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HM20025635 - Gisela Chelimsky
A pilot study of auricular microstimulation to determine if it improves vagal modulation

Sample Collection Details

1. * **Select all of the types of samples that will be collected as part of this study.**
   - [ ] Amniotic Fluid
   - [ ] Blood
   - [ ] Buccal Smears
   - [ ] Saliva
   - [ ] Tissue
   - [x] **Urine**
   - [ ] Stool
   - [ ] Other

2. * **In order to collect urine, will an indwelling catheter be placed solely for the research study:**
   - ○ Yes
   - ● **No**

3. * **Describe how the sample will be collected and the collection schedule. For each type of sample, include information about**

   - The procedures that will be followed to collect the sample
   - The role(s) of the individuals who will collect the sample
   - The volume/size range of the sample
   - The timing and frequency of sample collection
   - Participants will be given a non-labeled specimen cup to urinate in privately. They will hand the cup to an approved study staff member who will conduct a dipstick pregnancy test using good practice. The sample will be immediately disposed of when the test is done and only the result will be recorded on the participant's screening form.
   - Approved and trained study staff will be able to collect the sample (except PI)
   - 6.5oz specimen cups will be used but only about 3oz of urine is needed to perform the test, so it will vary from participant to participant.
   - One sample will be taken after consent at the beginning of the study for screening purposes.

4. * **Will genetic testing or genetic analyses be conducted on any of the samples:**
   - ○ Yes
   - ● **No**

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

2. * **Describe how data will be linked or unlinked to identifiers including email addresses, names, and/or IP address.**
   REDCap Study Interest & Screening Forms will contain names, phone numbers, and emails if this information is provided by the potential participant.

   REDcap daily diary forms will be linked to a separate form with identifying/contact information (name, email, phone number) in the participant's REDcap record. None of the daily recording diary response forms require the input of personal information, but we ask for their initials for consistency and tracking. Symptom questionnaire will be linked in the same way.

3. * **How will you protect your data collection from fraudulent responses:**
   The REDCap Study Interest & Screening Form will have a reCAPTCHA test enabled to protect the form link from fraudulent responses.

   Daily recording diaries will be sent out individually to each participant. Each daily form will have a unique access URL, and once it is completed the answers cannot be changed. Participants will be encouraged to give honest answers on the form, and even if they did not use it we still would like that information to take into account. Symptom questionnaires will be given to the participant via a REDCap survey at their in-person visits via a VCU-managed computer or with the survey link opened on a tablet. These questions are not particularly sensitive or difficult to answer, so we will communicate the importance of honesty, but no survey questions are required.

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

5. * **If yes, describe the alternative(s).**
   Participants can choose to take home paper printouts of the daily diary REDcap form that they can write on and return to study staff at the final in-person visit. They may also choose to be verbally administered questionnaire items by study staff if requested.

6. * **Describe how individuals will be able to skip or not answer particular questions. If any questions are mandatory, provide justification.**
   We will encourage participants to fill out their diaries accurately, honestly, and consistently. Participants may skip any questions they would like, but because the diary and symptom questionnaires are so short, objective, simple, and do not cover any particularly sensitive material, we will encourage them not to skip if possible.

7. **If not including children, describe any procedures used to verify that research participants are adults.**
   Including children

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A pilot study of auricular microstimulation to determine if it improves vagal modulation

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.
   a. Epic
   b. N/A
   c. Name, MRN, medications to confirm eligibility on an ongoing basis (medication information is not recorded, only monitored). Name/MRN stored in REDcap separate from research data.

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.**
   No agreement exists.

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.)

   1. $100 total. $25 for the first visit and $75 for the second visit.
   2. Mailed check
   3. Participants will fill out a W-9 form that will be given to the business office for check processing.
   4. With the current budget and the time it takes to complete the research procedures we believe this is a fair amount of compensation.
   5. W-9 form that includes full name, address, and SSN. No one except the CRC and the business office will have access to these forms. These elements are all required to process checks.

2. **If compensation will be pro-rated, explain the payment schedule.**
   Participants will receive a $25 mailed check after the completion of the Week 0 (Baseline) Visit and a $75 mailed check after the completion of the Week 4 Visit.

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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

ID: HM20025635 **HM20025635** View: SF2 - Consent Process

HM20025635 - Gisela Chelimsky
A pilot study of auricular microstimulation to determine if it improves vagal modulation

Consent Process

1. * **List all consent groups:**

	Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
View	Children (12-17)	Signed Assent by Child or Decisionally Impaired Adult Signed Parent/Guardian Permission or Legally Authorized Representative Consent	No Waivers Requested	Research Coordinator Research Assistant		Not using electronic signature platforms	- Consent will occur at the FGID clinic appointment either before or after the visit or while they are waiting for the physician or at the PRU with parent(s)/guardian(s) present - Study procedures, rights as a participant, risks and discomforts, data privacy, and compensation will be discussed with parent(s) present. - In-person - We will encourage participants/parents to reach out to us with any questions or concerns about the study or if they would like to stop participating and will be following up with them multiple times throughout the study where we can address any needs.	Having a 3rd person (family/friends, another study team member, etc.) present during the consent / assent discussion Sitting down beside the participant instead of standing over them	Until they are outside the age range thus not meeting inclusion criteria	We will contact the participant using recorded contact information via phone, letter, or email to communicate that we need to meet with them for them to re-consent.
View	Adults (18)	Signed Consent by Participant	No Waivers Requested	Research Coordinator Research Assistant		Not using electronic signature platforms	- Consent will occur at the FGID clinic appointment either before or after the visit or while they are waiting for the physician or at the PRU. - Study procedures, rights as a participant, risks and discomforts, data privacy, and compensation will be discussed. - In-person - We will encourage participants to reach out to us with any questions or concerns about the study or if they would like to stop participating and will be following up with them multiple times throughout the study	Sitting down beside the participant instead of standing over them If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to)	Until they are outside of the age range, thus not meeting inclusion criteria	N/A

Group Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
					where we can address any needs.			

2. Upload any consent / assent documents:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	FGID Assent/Parental Permission	TENS FGID Assent V10.pdf	0.23	4/23/2024 11:25 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	Healthy Control Assent/Parental Permission	TENS HC Assent V10.pdf	0.23	4/23/2024 11:25 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	Healthy Control Consent	TENS HC Consent V10.pdf	0.22	4/23/2024 11:24 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	FGID Consent	TENS FGID Consent V10.pdf	0.22	4/23/2024 11:24 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	Best Practice Alert MyChart Message Script	Best Practice Alert MyChart Message Script V2.docx	0.03	3/13/2024 3:52 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Flyer	TENS Flyer (Undesigned Language Only) V4.docx	0.07	3/13/2024 3:51 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	REDCap Study Interest & Screening Form	Study Interest & Screening Form V3.pdf	0.04	3/13/2024 3:51 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Daily Recording Diary	Daily Recording Diary V6.pdf	0.06	3/13/2024 3:51 PM	Madison Maxwell	Research Measure	Yes
View	In-Person Recruitment Script	TENS In Person Recruitment Script V5.docx	0.12	3/13/2024 3:46 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Phone Recruitment Script	TENS Phone Recruitment Script V7.docx	0.15	3/13/2024 3:46 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Eligible Interest Form Submission Follow-Up Email Recruitment Script	TENS Eligible Interest Form Submission Follow-Up Email Recruitment Script V3.docx	0.06	3/13/2024 3:44 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Participant TENS Instructions	TENS Unit Instructions V6.docx	0.11	1/9/2024 1:31 PM	Madison Maxwell	Other	Yes
View	Screen Fail Contact Information	Screen Fail Contact Information.pdf	0.01	12/6/2023 3:22 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Heart Rate Variability Measurements	HRV Measurements for both study visits (V2).pdf	0.02	8/23/2023 11:31 AM	Madison Maxwell	Research Measure	Yes
View	TENS Unit Manual	TENS Unit Manual (Microcurrent Model).pdf	0.02	8/17/2023 9:07 AM	Madison Maxwell	Drug/Device Brochure	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	TENS Unit Photo	TENS Unit Photo (Microcurrent Model).png	0.02	8/17/2023 9:07 AM	Madison Maxwell	Other	Yes
View	Symptom Questionnaire	GI Symptom Questionnaire (V1).pdf	0.01	4/13/2023 3:11 PM	Madison Maxwell	Research Measure	Yes
View	Ear Clip Info	TENS Unit Ear Clip Information.docx	0.01	1/20/2023 2:09 PM	Madison Maxwell	Drug/Device Brochure	Yes
View	IDE Documents	TENS Documentation of NSR determination.docx	0.02	11/29/2022 9:41 AM	Madison Maxwell	Other	Yes
View	TENS Unit Ear Clip	TENS Ear Clip.jpg	0.01	11/18/2022 12:35 PM	Madison Maxwell	Other	Yes
View	PROC Approval	TENS PROC Approval.pdf	0.01	10/21/2022 12:45 PM	Madison Maxwell	Ancillary Committee Approval	Not Applicable
View	M. Maxwell Trainings (All Merged)	M Maxwell CITI, Bioraft, MERT Trainings (Merged).pdf	0.01	10/20/2022 11:55 AM	Madison Maxwell	Other	Not Applicable
View	B. Dave CITI Trainings (All Merged)	B Dave CITI Trainings (Merged).pdf	0.01	10/20/2022 11:51 AM	Madison Maxwell	Other	Not Applicable
View	G. Chelimsky CITI Trainings (All Merged)	G Chelimsky CITI Trainings (Merged).pdf	0.01	10/20/2022 11:49 AM	Madison Maxwell	Other	Not Applicable
View	T. Chelimsky CV	T Chelimsky CV Signed.pdf	0.01	10/20/2022 11:43 AM	Madison Maxwell	CV/Biosketch	Yes
View	Basic Participant Information	BasicInformation.pdf	0.01	10/18/2022 3:38 PM	Madison Maxwell	Research Measure	Yes
View	Screening Form	ScreeningForm.pdf	0.01	10/18/2022 3:37 PM	Madison Maxwell	Research Measure	Yes
View	G. Chelimsky CV	G Chelimsky CV.docx	0.01	9/12/2022 4:52 PM	Bhakti Dave	CV/Biosketch	Yes

ID: HM20025635 **HM20025635** View: SF2 - Consent Plan Complete

HM20025635 - Gisela Chelimsky
A pilot study of auricular microstimulation to determine if it improves vagal modulation

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

ID: HM20025635 **HM20025635**

View: SF2 - Risks, Discomforts, Potential Harms and Monitoring

HM20025635 - Gisela Chelimsky
A pilot study of auricular microstimulation to determine if it improves vagal modulation

Risks, Discomforts, Potential Harms and Monitoring

1. * **Describe the risks of each research procedure to participants or others. For each identified risk, provide an assessment of the anticipated seriousness and likelihood of the risk. Some examples of possible risks include but are not limited to:**
   - **Physical risks (e.g. bodily harms or discomforts, side effects, etc.)**
   - **Psychological risks (e.g. emotional, mental, or spiritual harms or discomforts, changes to thoughts, beliefs, or behaviors, etc.)**
   - **Research data risks (e.g. loss of confidentiality and privacy)**
   - **Social or legal risks (e.g. impacts on relationships or reputation, legal or criminal justice actions for self or others, etc.)**
   - **Financial risks (e.g. impacts on income, employability, or insurability, loss of services, etc.)**
   - **Other risks (e.g. unforeseeable risks of experimental procedures, risks related to particular study designs (randomization, washout, placebo, withholding care/services, deception), etc.)**

   See the help text for additional guidance.

   Physical risks: It is possible that participants may develop skin irritation or scab(s) in/on the ear from using the TENS unit. The TENS unit ear clip may become uncomfortable or annoying to wear. Participants may possibly have a skin reaction from electrodes placed during heart monitoring.

   Psychological risks: None

   Research data risks: Loss of confidentiality

   Social/Legal risks: None

   Financial risks: None

   Other risks: None

2. * **Describe how each of the risks/harms/discomforts identified above will be minimized:**
   Physical risks: Participants will be advised to rotate between clipping the unit to their tragus or conchae on their ears for each session to avoid irritation, scabbing, and discomfort. Skin will be properly cleaned and dried before electrode placement during the HRV measurements to avoid reactions and silicone pads will be used which are generally not reactive in most people.

   Research data risks: All data will be kept in a secure REDcap/OnCore/OneDrive database only accessible to approved study team members.

3. * **Describe any potential risks or harms to a community or a specific population based on study findings (e.g. information that could be stigmatizing or derogatory):**
   None

4. **Where appropriate, discuss provisions for ensuring necessary medical, professional, or psychological intervention in the event of adverse events to the subjects:**
   Dr. Gisela Chelimsky will monitor the health of all patients in this study per standard clinical practice.
   If needed, we will contact emergency personnel to assist with emergency episodes that could occur.

   We will clearly tell the participant about all risks during the consent discussion. When CRCs are checking in on the participant during the weeks of using the TENS unit, they will ask the participant if they are experiencing any ear irritation. If severe irritation or scabbing occurs, we will instruct the participant to discontinue the use of the unit.

   If the subject experiences a medical emergency during the Week 0 or 4 in-person visits, the VCU Public Safety emergency response process will be activated. In a situation that calls for an advanced medical response, this process includes the following steps:

   a. VCU public safety working with a 911 dispatcher to direct emergency personnel to the building
   b. Emergency vehicle transporting to VCU emergency department

5. * **Describe criteria for when the investigator would withdraw an individual participant from the study; such as safety or toxicity concerns, emotional distress, inability to comply with the protocol, etc.:**
If the participant is not able to wear the TENS unit due to physical discomfort, severe irritation/scabbing, or they cannot commit to using the unit for 2 hours a day for the duration of the study, they will be withdrawn from the study.

Should the participant require new medication during the duration of the study that may affect gastrointestinal symptoms, vagal modulation or immune response, or their HRV measurement indicates an abnormality, the PI may withdraw the participant. The Epic build of this study will send the study team an alert for new medications for FGID participants. New medication usage will be assessed on a case-by-case basis by the PI and they will make a decision on whether to keep or withdraw the participant. All participants will also be asked to detail the start or plans to start a new medication.

6. * **Summarize any pre-specified criteria that would trigger the investigator/sponsor/monitoring committee to stop or change the study protocol due to safety concerns:**
The stopping points for the study include the request to stop by the patient as well as the inability to recruit participants or unexpected adverse events that might result in stopping the study.

Data and Safety Monitoring
Data and safety monitoring is a system for checking the study's data at regular intervals over the study period to identify and address issues that could affect the safety of research participants. This requirement is in accordance with 45 CFR 46.111.

The purpose of data and safety monitoring plan is to set forth study team procedures for monitoring/addressing:
- Participant safety (physical, psychological, etc.)
- Data validity
- Early stopping (termination) based upon changes in risks and benefits.

7. * **Indicate if this study will have a Data Safety Monitoring Board (DSMB) or a Data Safety Monitoring Plan (DSMP): [Required for all greater than minimal risk studies]**

- [x] **DSMB**
- [ ] DSMP
- [ ] No DSMB/DSMP [Note: This response is not applicable for greater than minimal risk studies]

8. * **Describe the composition and affiliations of the DSMB:**
Henry J. Rozycki, M.D., CHRI
Brad McQuilkin, M.D., CHoR

9. * **Describe the frequency or schedule for DSMB review of data:**
Before study kickoff, then every 6 months

10. * **Describe what data (blinded or unblinded) the DSMB will review.:**
Protocol before study kickoff. Blinded adverse events/safety issues, serious non-compliance, vagal modulation data (when data is available/members have bandwidth to review for any concerning trends) every 6 months.

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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**
   - [ ] Asking the participant if they are comfortable with having other people present (if any)
   - [ ] Moving away from other people when conducting activities in public spaces or offering a private space
   - [ ] Offering other options of ways to respond to sensitive questions (i.e. pointing, clicking, or writing) if uncomfortable verbally responding
   - [x] **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**
- [ ] 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
- [ ] Offering other options of ways to complete the activity (i.e. online, paper, phone) if more privacy is desired
- [ ] 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:**

- [ ] Obtaining permission to mail study materials
- [ ] Confirming/verifying the accuracy of addresses before mailing items
- [ ] 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)
- [ ] Using return address labels and document headers that avoid study identifiers, such as study names, clinics, study topics, etc.
- [ ] 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
- [x] **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)**
- [ ] 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
- [x] **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*.

We will be using a secure REDcap database and OnCore to store data. The eligibility screening form/consent form will have the participants' name and will be stored in a binder in a locked cabinet separate from the participant's study data, which will only have a study ID on it. REDcap data forms will be stored in a separate form than the forms with participants' name and eligibility information. The heart rate variability assessment will be in a private room. The HRV measurements will be stored with no identifiers. The data collection diaries will have no identifiable information on them. The TENS unit poses no privacy risks as it does not collect data or personal information.

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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**
   - [ ] 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:**
   - [x] **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
   - [x] **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
   - [ ] 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 provided to participants 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.):

- [ ] Transferring data promptly from the device/app given to the participant to a VCU storage location
- [ ] 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
- [x] **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**
- [ ] 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.
Paper diary documents will be copied into the corresponding REDcap forms for the participant and immediately shredded upon entry and verification.
Pregnancy test strips and urine samples will be immediately disposed of after reading.
The TENS unit does not record or store data.

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:
N/A

8. * Select all identifiers that will be collected at any time as part of this study (including for recruitment, data gathering, data analysis, etc.), even if the data will eventually be anonymized:

- [x] **Names**
- [x] **Geographic Locators Below State Level**
- [x] **Social Security Numbers**
- [ ] 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.
Study IDs will be generated sequentially in REDcap. A key with participant identifiers will be stored in a separate form in REDcap. Only approved research personnel will be able to access this key. This key will be stored until the study is closed. Some participants will give us permission to use their contact information to contact them for future studies. We will not keep the code key or any link to the data from this study upon its closing, but we will be keeping a separate, unlinked list of names and contact info for those who consent to contact for future studies.

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)
   - [ ] Store until the end of study & then destroy
   - [x] **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. * **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

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/

   - (●) **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.)**

- [x] **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)**
- [ ] 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

ID: HM20025635 **HM20025635**

View: SF2 - Pertinent Results and Incidental Findings

HM20025635 - Gisela Chelimsky
A pilot study of auricular microstimulation to determine if it improves vagal modulation

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.**
   Pregnancy (collected only for screening).

   Arrhythmia on HRV measurement

3. * **Explain what actions or procedures research personnel should take to inform the PI of such a discovery :**
   Pregnancy findings will not constitute contacting the PI and the participant will not be able to participate further in the study since we are not aware of the long-term effects of using a TENS unit while pregnant.

   Upon review of the HRV measurements, the PI will contact participants/parents and engage in proper referral procedures if there is evidence of arrhythmia.

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

5. * **Describe a communication plan addressing:**
   1. What criteria will be used to determine which pertinent and/or incidental findings will be communicated, including the following for health related findings:
   --- The reliability of the tests/images, such as being done in a CLIA-certified lab,
   --- Whether the meaning and significance of the findings are known,
   --- Whether the findings reveal a significant risk of a serious health condition,
   --- Whether there is an accepted treatment for the health condition revealed by the findings, and
   --- The risks both of knowing and not knowing the findings, including risks to family members from genetic testing results.
   2. What information will be provided during the consent process about the plans for communicating pertinent and/or incidental findings;
   3. Whether the participants will be given the option of refusing communication of some or all types of pertinent and/or incidental findings to themselves, their family members, and/or any other individuals or groups; and
   4. To whom and by whom the findings will be communicated, when, and how.
   Pregnancy findings:

   1. -Pregnancy tests are generally reliable. We will be using a urine test purchased through a trusted clinical manufacturer.
   -the meaning and significance of a positive pregnancy test is known, the participant will no longer be eligible to participate in the study.
   -the findings of a positive pregnancy test does not reveal a significant risk of a serious health condition
   -there are resources and treatment for taking a pregnancy to term or not.
   -the risk of a positive pregnancy test could cause potential mental and emotional issues, as well as health concerns to the participants if they have other conditions. the risk of not knowing is that participation in the study and using the TENS unit may cause harm to an embryo/fetus. We do not have solid information on the risks of TENS units on pregnant people.

   2. If a participant has a positive pregnancy test, we will only be telling the participant whether they are a child or an adult, which we note in the ICFs.

   3. Participants will not have the option to refuse communications for safety reasons. If we identify a situation that requires mandatory reporting (ie child abuse in the context of the pregnancy), we will follow the normal procedures for mandatory reporting.

   4. Positive pregnancy tests will be verbally communicated to the adult or child participant by a member of the study team, preferably the PI. The study doctor will be notified so they are aware of the participant's ineligibility to continue with the study. If the parent asks why their child is ineligible, we will tell them that we have many different criteria and

can only tell them/the participant if they are eligible or not, and not the reason why.

Arrhythmia findings:
1. - HRV measurement is generally reliable. HRV measurement will be conducted by study team members will sufficient training to operate the devices. HRV measurements done by a coordinator will be reviewed by the PI for evidence of arrhythmia during the data analysis portion of the study.

- The full meaning and significance of an arrhythmia cannot be concluded with a single test. Proper referral will be given, and it will be the responsibility of the participant and/or their parents to seek specialized testing/care to further analyze.

- Arrhythmia findings may reveal a significant risk of a serious health condition, but further testing and analysis is needed for conclusive results.

- There are a variety of accepted treatments for arrhythmia such as medications, therapies such as vagal maneuvers, cardioversion, catheter procedures or heart surgery.

- The risk of knowing the findings is that participants and/or parents could become distressed upon learning the finding.

- The risk of not knowing the finding is that we would not be able to properly measure HRV which is essential to answering our research questions.

2. Participants will be told during the consent discussion that the investigator will contact them/their parents upon the instance of abnormal findings.

3. Participants will not have the option to refuse communications for safety reasons.

4. Abnormal HRV measurements will be communicated by the PI verbally or by phone/email to the participant and/or their parents upon review of the measurements. The participant will be withdrawn from the study by the study staff if this finding is revealed during their participation, but analysis of these measurements will not happen immediately upon collection, so this is an unlikely occurrence.

ID: HM20025635 **HM20025635** View: SF2 - Risk Benefit Complete

HM20025635 - Gisela Chelimsky
A pilot study of auricular microstimulation to determine if it improves vagal modulation

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

ID: HM20025635 **HM20025635**

View: SF2 - Populations with Special Considerations

HM20025635 - Gisela Chelimsky
A pilot study of auricular microstimulation to determine if it improves vagal modulation

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
- [ ] Pregnant women or fetuses
- [ ] 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

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.**
Parents will provide informed consent for their child's participation by signing the consent form. Any questions will be answered. A copy of the informed consent will be given to the parents for their records.

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).**
Children will provide informed assent by signing the form. The form will use lay language so the participant knows what the study procedures entail. Any questions will be answered. The study will be explained in a developmentally and age appropriate manner by using "smaller" words to describe the procedures after it is read verbatim. For example, the section in the consent that describes the TENS units sending electrical signals and communications to the brain will be read that way, but will then be elaborated in more age-appropriate language. Study staff would say something like "and by that, we mean the TENS units help your brain talk to the other parts of your body more clearly, and they work by sending a little bit of electricity through your skin. It is not something that will hurt you- you might just feel like someone is tapping your skin a little bit or you may feel a little twitch". Study staff will ask the child if they feel worried or scared about anything we talked about, and will encourage them to ask questions and let them know they are safe to tell us anything they are thinking during the discussion.

ID: HM20025635 **HM20025635**

View: SF2 - Populations with Special Considerations Section Complete

HM20025635 - Gisela Chelimsky
A pilot study of auricular microstimulation to determine if it improves vagal modulation

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

HM20025635 - Gisela Chelimsky
A pilot study of auricular microstimulation to determine if it improves vagal modulation

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
- ☑ **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:

- ☐ 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:**
   - [x] **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**
   - [x] **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	FGID Assent/Parental Permission	TENS FGID Assent V10.pdf	0.23	4/23/2024 11:25 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	Healthy Control Assent/Parental Permission	TENS HC Assent V10.pdf	0.23	4/23/2024 11:25 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Healthy Control Consent	TENS HC Consent V10.pdf	0.22	4/23/2024 11:24 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	FGID Consent	TENS FGID Consent V10.pdf	0.22	4/23/2024 11:24 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	Best Practice Alert MyChart Message Script	Best Practice Alert MyChart Message Script V2.docx	0.03	3/13/2024 3:52 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Flyer	TENS Flyer (Undesigned Language Only) V4.docx	0.07	3/13/2024 3:51 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	REDCap Study Interest & Screening Form	Study Interest & Screening Form V3.pdf	0.04	3/13/2024 3:51 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Daily Recording Diary	Daily Recording Diary V6.pdf	0.06	3/13/2024 3:51 PM	Madison Maxwell	Research Measure	Yes
View	In-Person Recruitment Script	TENS In Person Recruitment Script V5.docx	0.12	3/13/2024 3:46 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Phone Recruitment Script	TENS Phone Recruitment Script V7.docx	0.15	3/13/2024 3:46 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Eligible Interest Form Submission Follow-Up Email Recruitment Script	TENS Eligible Interest Form Submission Follow-Up Email Recruitment Script V3.docx	0.06	3/13/2024 3:44 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Participant TENS Instructions	TENS Unit Instructions V6.docx	0.11	1/9/2024 1:31 PM	Madison Maxwell	Other	Yes
View	Screen Fail Contact Information	Screen Fail Contact Information.pdf	0.01	12/6/2023 3:22 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Heart Rate Variability Measurements	HRV Measurements for both study visits (V2).pdf	0.02	8/23/2023 11:31 AM	Madison Maxwell	Research Measure	Yes
View	TENS Unit Manual	TENS Unit Manual (Microcurrent Model).pdf	0.02	8/17/2023 9:07 AM	Madison Maxwell	Drug/Device Brochure	Yes
View	TENS Unit Photo	TENS Unit Photo (Microcurrent Model).png	0.02	8/17/2023 9:07 AM	Madison Maxwell	Other	Yes
View	Symptom Questionnaire	GI Symptom Questionnaire (V1).pdf	0.01	4/13/2023 3:11 PM	Madison Maxwell	Research Measure	Yes
View	Ear Clip Info	TENS Unit Ear Clip Information.docx	0.01	1/20/2023 2:09 PM	Madison Maxwell	Drug/Device Brochure	Yes
View	IDE Documents	TENS Documentation of NSR determination.docx	0.02	11/29/2022 9:41 AM	Madison Maxwell	Other	Yes
View	TENS Unit Ear Clip	TENS Ear Clip.jpg	0.01	11/18/2022 12:35 PM	Madison Maxwell	Other	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	PROC Approval	TENS PROC Approval.pdf	0.01	10/21/2022 12:45 PM	Madison Maxwell	Ancillary Committee Approval	Not Applicable
View	M. Maxwell Trainings (All Merged)	M Maxwell CITI, Bioraft, MERT Trainings (Merged).pdf	0.01	10/20/2022 11:55 AM	Madison Maxwell	Other	Not Applicable
View	B. Dave CITI Trainings (All Merged)	B Dave CITI Trainings (Merged).pdf	0.01	10/20/2022 11:51 AM	Madison Maxwell	Other	Not Applicable
View	G. Chelimsky CITI Trainings (All Merged)	G Chelimsky CITI Trainings (Merged).pdf	0.01	10/20/2022 11:49 AM	Madison Maxwell	Other	Not Applicable
View	T. Chelimsky CV	T Chelimsky CV Signed.pdf	0.01	10/20/2022 11:43 AM	Madison Maxwell	CV/Biosketch	Yes
View	Basic Participant Information	BasicInformation.pdf	0.01	10/18/2022 3:38 PM	Madison Maxwell	Research Measure	Yes
View	Screening Form	ScreeningForm.pdf	0.01	10/18/2022 3:37 PM	Madison Maxwell	Research Measure	Yes
View	G. Chelimsky CV	G Chelimsky CV.docx	0.01	9/12/2022 4:52 PM	Bhakti Dave	CV/Biosketch	Yes

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A pilot study of auricular microstimulation to determine if it improves vagal modulation

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	Gisela Chelimsky	Principal Investigator		Data Analysis Project Coordination Data Collection - Direct Observation Data Management Data Collection - Clinical Participant Identification Data Entry Study Design Clinical Services		Experience - Research Experience - Related Skills Experience - Clinical Education and/or Professional Preparation		yes
View	Thomas Chelimsky	Co/Sub-Investigator		Data Analysis Project Coordination Data Collection - Direct Observation Data Collection - Clinical Participant Identification Study Design Clinical Services		Experience - Research Experience - Related Skills Experience - Clinical Education and/or Professional Preparation		yes
View	Madison Maxwell	Research Coordinator		Data Analysis Project Coordination Data Collection - Direct Observation Participant Consent Data Management		Experience - Research Experience - Related Skills Education and/or Professional Preparation		yes

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
				Data Collection - Clinical Participant Identification Data Entry Study Design Data Coding Participant Recruitment				
View	Bhakti Dave	Research Coordinator		Data Analysis Project Coordination Data Collection - Direct Observation Participant Consent Data Management Data Collection - Clinical Participant Identification Data Entry Study Design Data Coding Participant Recruitment		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:**
N/A

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	FGID Assent/Parental Permission	TENS FGID Assent V10.pdf	0.23	4/23/2024 11:25 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	Healthy Control Assent/Parental Permission	TENS HC Assent V10.pdf	0.23	4/23/2024 11:25 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	Healthy Control Consent	TENS HC Consent V10.pdf	0.22	4/23/2024 11:24 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	FGID Consent	TENS FGID Consent V10.pdf	0.22	4/23/2024 11:24 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Best Practice Alert MyChart Message Script	Best Practice Alert MyChart Message Script V2.docx	0.03	3/13/2024 3:52 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Flyer	TENS Flyer (Undesigned Language Only) V4.docx	0.07	3/13/2024 3:51 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	REDCap Study Interest & Screening Form	Study Interest & Screening Form V3.pdf	0.04	3/13/2024 3:51 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Daily Recording Diary	Daily Recording Diary V6.pdf	0.06	3/13/2024 3:51 PM	Madison Maxwell	Research Measure	Yes
View	In-Person Recruitment Script	TENS In Person Recruitment Script V5.docx	0.12	3/13/2024 3:46 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Phone Recruitment Script	TENS Phone Recruitment Script V7.docx	0.15	3/13/2024 3:46 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Eligible Interest Form Submission Follow-Up Email Recruitment Script	TENS Eligible Interest Form Submission Follow-Up Email Recruitment Script V3.docx	0.06	3/13/2024 3:44 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Participant TENS Instructions	TENS Unit Instructions V6.docx	0.11	1/9/2024 1:31 PM	Madison Maxwell	Other	Yes
View	Screen Fail Contact Information	Screen Fail Contact Information.pdf	0.01	12/6/2023 3:22 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Heart Rate Variability Measurements	HRV Measurements for both study visits (V2).pdf	0.02	8/23/2023 11:31 AM	Madison Maxwell	Research Measure	Yes
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View	IDE Documents	TENS Documentation of NSR determination.docx	0.02	11/29/2022 9:41 AM	Madison Maxwell	Other	Yes
View	TENS Unit Ear Clip	TENS Ear Clip.jpg	0.01	11/18/2022 12:35 PM	Madison Maxwell	Other	Yes
View	PROC Approval	TENS PROC Approval.pdf	0.01	10/21/2022 12:45 PM	Madison Maxwell	Ancillary Committee Approval	Not Applicable
View	M. Maxwell Trainings (All	M Maxwell CITI, Bioraft, MERT	0.01	10/20/2022 11:55 AM	Madison Maxwell	Other	Not Applicable

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	Merged)	Trainings (Merged).pdf					
View	B. Dave CITI Trainings (All Merged)	B Dave CITI Trainings (Merged).pdf	0.01	10/20/2022 11:51 AM	Madison Maxwell	Other	Not Applicable
View	G. Chelimsky CITI Trainings (All Merged)	G Chelimsky CITI Trainings (Merged).pdf	0.01	10/20/2022 11:49 AM	Madison Maxwell	Other	Not Applicable
View	T. Chelimsky CV	T Chelimsky CV Signed.pdf	0.01	10/20/2022 11:43 AM	Madison Maxwell	CV/Biosketch	Yes
View	Basic Participant Information	BasicInformation.pdf	0.01	10/18/2022 3:38 PM	Madison Maxwell	Research Measure	Yes
View	Screening Form	ScreeningForm.pdf	0.01	10/18/2022 3:37 PM	Madison Maxwell	Research Measure	Yes
View	G. Chelimsky CV	G Chelimsky CV.docx	0.01	9/12/2022 4:52 PM	Bhakti Dave	CV/Biosketch	Yes

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 am aware that I may need to establish a research account with VCUHS Department of Pathology for specimen processing:**
   - (●) **Yes**
   - ( ) No
2. * **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.**
3. * **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**

Based upon your responses, this study will be routed to the VCU Scientific Review Committee (SRC) when it is submitted. After SRC review is completed, the IRB will receive the study.

16. Upload any documents requested in the questions above:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	FGID Assent/Parental Permission	TENS FGID Assent V10.pdf	0.23	4/23/2024 11:25 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	Healthy Control Assent/Parental Permission	TENS HC Assent V10.pdf	0.23	4/23/2024 11:25 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
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View	B. Dave CITI Trainings (All Merged)	B Dave CITI Trainings (Merged).pdf	0.01	10/20/2022 11:51 AM	Madison Maxwell	Other	Not Applicable
View	G. Chelimsky CITI Trainings (All Merged)	G Chelimsky CITI Trainings (Merged).pdf	0.01	10/20/2022 11:49 AM	Madison Maxwell	Other	Not Applicable
View	T. Chelimsky CV	T Chelimsky CV Signed.pdf	0.01	10/20/2022 11:43 AM	Madison Maxwell	CV/Biosketch	Yes
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View	Screening Form	ScreeningForm.pdf	0.01	10/18/2022 3:37 PM	Madison Maxwell	Research Measure	Yes
View	G. Chelimsky CV	G Chelimsky CV.docx	0.01	9/12/2022 4:52 PM	Bhakti Dave	CV/Biosketch	Yes

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.**
   PHI: Name, MRN, medications (to confirm eligibility on an ongoing basis)

   RHI: Screening questions, pregnancy test (screening purposes only), HRV recording data, daily recording diary entries

3. * **Describe the source(s) of the protected health information (e.g. Informatics or which clinical databases):**
   EPIC, via information submitted on the secure REDCap eligibility screening survey

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

HM20025635 - Gisela Chelimsky
A pilot study of auricular microstimulation to determine if it improves vagal modulation

Partial Waiver of Authorization

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

2. * **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?).
   This waiver requests access to the electronic medical record so study staff can briefly review eligibility criteria and send recruitment messages or approach patients referred via the Best Practice Alert or patients who are scheduled for a clinical visit at the PI's clinic. Those potential participants who are consented to the Registry for the Autonomics Center have already provided consent for the study team to access their full medical record. The privacy risks are similar than those experienced in everyday life as names, phone numbers and emails are often collected and used without additional authorization for recruitment & advertising purposes both in and outside the context of research. Chart review for any patients will only include items directly related to eligibility criteria, and that information will only be recorded upon a voluntary completion of the screening questions by the potential participant. Any personal information, like contact information, would also be stored on a secure REDcap database which has strict access requirements (ie can only view if manually added to the project with identifier viewing permissions, must be on a VPN to access, password protected) that are similar to protections in place for EMR information storage. None of this information would ever be shared with unauthorized individuals who do not have a key role in the study.

3. * **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

4. * **Other than the PI and research personnel identified in this research application, who else will have access to the Protected Health Information?**
   No one

5. * **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?)
   Recruiting only patients who are under the care of the PI will create bias in the sample and gives scarce opportunity to identify non-FGID group participants (since this is the PI's primary patient population). Using the BPA and MyChart allows for more widespread recruitment across a more diverse population.
   Attempting to recruit at different VCUHS clinics in-person for a more varied sample would also disrupt clinical flow for these departments who are not set up to accommodate research recruitment efforts.

6. * **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

ID: HM20025635 **HM20025635**

View: SF2 - Institutional Requirements Complete

HM20025635 - Gisela Chelimsky
A pilot study of auricular microstimulation to determine if it improves vagal modulation

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

HM20025635 - Gisela Chelimsky
A pilot study of auricular microstimulation to determine if it improves vagal modulation

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.

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View	Healthy Control Consent	TENS HC Consent V10.pdf	0.22	4/23/2024 11:24 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	FGID Consent	TENS FGID Consent V10.pdf	0.22	4/23/2024 11:24 AM	Madison Maxwell	Consent/Assent/Information Sheet	Yes
View	Best Practice Alert MyChart Message Script	Best Practice Alert MyChart Message Script V2.docx	0.03	3/13/2024 3:52 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Flyer	TENS Flyer (Undesigned Language Only) V4.docx	0.07	3/13/2024 3:51 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	REDCap Study Interest & Screening Form	Study Interest & Screening Form V3.pdf	0.04	3/13/2024 3:51 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Daily Recording Diary	Daily Recording Diary V6.pdf	0.06	3/13/2024 3:51 PM	Madison Maxwell	Research Measure	Yes
View	In-Person Recruitment Script	TENS In Person Recruitment Script V5.docx	0.12	3/13/2024 3:46 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Phone Recruitment Script	TENS Phone Recruitment Script V7.docx	0.15	3/13/2024 3:46 PM	Madison Maxwell	Recruitment/Advertising	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Eligible Interest Form Submission Follow-Up Email Recruitment Script	TENS Eligible Interest Form Submission Follow-Up Email Recruitment Script V3.docx	0.06	3/13/2024 3:44 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Participant TENS Instructions	TENS Unit Instructions V6.docx	0.11	1/9/2024 1:31 PM	Madison Maxwell	Other	Yes
View	Screen Fail Contact Information	Screen Fail Contact Information.pdf	0.01	12/6/2023 3:22 PM	Madison Maxwell	Recruitment/Advertising	Yes
View	Heart Rate Variability Measurements	HRV Measurements for both study visits (V2).pdf	0.02	8/23/2023 11:31 AM	Madison Maxwell	Research Measure	Yes
View	TENS Unit Manual	TENS Unit Manual (Microcurrent Model).pdf	0.02	8/17/2023 9:07 AM	Madison Maxwell	Drug/Device Brochure	Yes
View	TENS Unit Photo	TENS Unit Photo (Microcurrent Model).png	0.02	8/17/2023 9:07 AM	Madison Maxwell	Other	Yes
View	Symptom Questionnaire	GI Symptom Questionnaire (V1).pdf	0.01	4/13/2023 3:11 PM	Madison Maxwell	Research Measure	Yes
View	Ear Clip Info	TENS Unit Ear Clip Information.docx	0.01	1/20/2023 2:09 PM	Madison Maxwell	Drug/Device Brochure	Yes
View	IDE Documents	TENS Documentation of NSR determination.docx	0.02	11/29/2022 9:41 AM	Madison Maxwell	Other	Yes
View	TENS Unit Ear Clip	TENS Ear Clip.jpg	0.01	11/18/2022 12:35 PM	Madison Maxwell	Other	Yes
View	PROC Approval	TENS PROC Approval.pdf	0.01	10/21/2022 12:45 PM	Madison Maxwell	Ancillary Committee Approval	Not Applicable
View	M. Maxwell Trainings (All Merged)	M Maxwell CITI, Bioraft, MERT Trainings (Merged).pdf	0.01	10/20/2022 11:55 AM	Madison Maxwell	Other	Not Applicable
View	B. Dave CITI Trainings (All Merged)	B Dave CITI Trainings (Merged).pdf	0.01	10/20/2022 11:51 AM	Madison Maxwell	Other	Not Applicable
View	G. Chelimsky CITI Trainings (All Merged)	G Chelimsky CITI Trainings (Merged).pdf	0.01	10/20/2022 11:49 AM	Madison Maxwell	Other	Not Applicable
View	T. Chelimsky CV	T Chelimsky CV Signed.pdf	0.01	10/20/2022 11:43 AM	Madison Maxwell	CV/Biosketch	Yes
View	Basic Participant Information	BasicInformation.pdf	0.01	10/18/2022 3:38 PM	Madison Maxwell	Research Measure	Yes
View	Screening Form	ScreeningForm.pdf	0.01	10/18/2022 3:37 PM	Madison Maxwell	Research Measure	Yes
View	G. Chelimsky CV	G Chelimsky CV.docx	0.01	9/12/2022 4:52 PM	Bhakti Dave	CV/Biosketch	Yes

ID: HM20025635 **HM20025635** View: SF2 - Documents Complete

HM20025635 - Gisela Chelimsky
A pilot study of auricular microstimulation to determine if it improves vagal modulation

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

Bio-Medical Devices

1. * **Name:**
   Digital TENS Unit

2. * **Manufacturer:**
   InTENSity

3. * **What risk has the sponsor or sponsor-investigator designated the device:**
   Non-Significant Risk

4. * **Indicate the device's IDE number if a protocol was submitted to the FDA for any investigational device or new use of a marketed device (regardless of what the FDA's determination was).**

   Or, if a protocol was not submitted to the FDA:
   - Enter "Abbreviated IDE" if the sponsor or sponsor-investigator has designated the device as a Non-Significant Risk device
   - Enter "IDE Exempt" if the sponsor or sponsor-investigator has determined that the device qualifies for IDE exemption
   - Enter "Regulatory Discretion" for a mobile application with regulatory discretion
   - Enter the FDA-provided HDE number if a HUD is being used in a clinical investigation for the HDE-approved indication(s).

   Abbreviated IDE

5. * **Select who holds the Investigational Device Exemption (FDA-granted IDE or Abbreviated IDE) for the device:**

   - ○ External to VCU Sponsor or Investigator
   - ● **VCU Sponsor-Investigator**
   - ○ VCU Sponsor who is not the Investigator
   - ○ Not Required

6. **If someone other than the PI is the sponsor for the IDE, name the entity or individual who will be the IDE sponsor.**

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   FGID Assent/Parental Permission
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   TENS FGID Assent V10.pdf(0.23)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Healthy Control Assent/Parental Permission
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   TENS HC Assent V10.pdf(0.23)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Healthy Control Consent
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   TENS HC Consent V10.pdf(0.22)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   FGID Consent
2. * **Type:**
   Consent/Assent/Information Sheet
3. * **File:**
   TENS FGID Consent V10.pdf(0.22)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Best Practice Alert MyChart Message Script
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   Best Practice Alert MyChart Message Script V2.docx(0.03)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Flyer
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   TENS Flyer (Undesigned Language Only) V4.docx(0.07)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   REDCap Study Interest & Screening Form
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   Study Interest & Screening Form V3.pdf(0.04)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Daily Recording Diary
2. * **Type:**
   Research Measure
3. * **File:**
   Daily Recording Diary V6.pdf(0.06)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   In-Person Recruitment Script
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   TENS In Person Recruitment Script V5.docx(0.12)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Phone Recruitment Script
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   TENS Phone Recruitment Script V7.docx(0.15)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Eligible Interest Form Submission Follow-Up Email Recruitment Script

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

3. * **File:**
   TENS Eligible Interest Form Submission Follow-Up Email Recruitment Script V3.docx(0.06)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Participant TENS Instructions
2. * **Type:**
   Other
3. * **File:**
   TENS Unit Instructions V6.docx(0.11)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Screen Fail Contact Information
2. * **Type:**
   Recruitment/Advertising
3. * **File:**
   Screen Fail Contact Information.pdf(0.01)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Heart Rate Variability Measurements
2. * **Type:**
   Research Measure
3. * **File:**
   HRV Measurements for both study visits (V2).pdf(0.02)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   TENS Unit Manual
2. * **Type:**
   Drug/Device Brochure
3. * **File:**
   TENS Unit Manual (Microcurrent Model).pdf(0.02)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   TENS Unit Photo
2. * **Type:**
   Other
3. * **File:**
   TENS Unit Photo (Microcurrent Model).png(0.02)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Symptom Questionnaire
2. * **Type:**
   Research Measure
3. * **File:**
   GI Symptom Questionnaire (V1).pdf(0.01)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Ear Clip Info
2. * **Type:**
   Drug/Device Brochure
3. * **File:**
   TENS Unit Ear Clip Information.docx(0.01)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   IDE Documents
2. * **Type:**
   Other
3. * **File:**
   TENS Documentation of NSR determination.docx(0.02)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   TENS Unit Ear Clip
2. * **Type:**
   Other
3. * **File:**
   TENS Ear Clip.jpg(0.01)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   PROC Approval
2. * **Type:**
   Ancillary Committee Approval
3. * **File:**
   TENS PROC Approval.pdf(0.01)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   M. Maxwell Trainings (All Merged)

2. * **Type:**
   Other

3. * **File:**
   M Maxwell CITI, Bioraft, MERT Trainings (Merged).pdf(0.01)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   B. Dave CITI Trainings (All Merged)

2. * **Type:**
   Other

3. * **File:**
   B Dave CITI Trainings (Merged).pdf(0.01)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   G. Chelimsky CITI Trainings (All Merged)
2. * **Type:**
   Other
3. * **File:**
   G Chelimsky CITI Trainings (Merged).pdf(0.01)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   T. Chelimsky CV
2. * **Type:**
   CV/Biosketch
3. * **File:**
   T Chelimsky CV Signed.pdf(0.01)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Basic Participant Information
2. * **Type:**
   Research Measure
3. * **File:**
   BasicInformation.pdf(0.01)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Screening Form
2. * **Type:**
   Research Measure
3. * **File:**
   ScreeningForm.pdf(0.01)

ID: HM20025635 **HM20025635** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   G. Chelimsky CV
2. * **Type:**
   CV/Biosketch
3. * **File:**
   G Chelimsky CV.docx(0.01)

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
Children (12-17)

2. * **Select all that apply to this consent / assent group:**

	Name
☐	Signed Consent by Participant
☑	**Signed Parent/Guardian Permission or Legally Authorized Representative Consent**
☑	**Signed Assent by Child or Decisionally Impaired Adult**
☐	Verbal/Other Indication of Assent by Child or Decisionally Impaired Adult
☐	Short Form Consent (limited applicability)
☐	None of the Above (select waiver below)

3. * **Select all electronic signature platforms that apply to this consent / assent group:**
- ☑ **Not using electronic signature platforms**
- ☐ DocuSign Part 11 (FDA regulated studies)
- ☐ DocuSign (standard platform for non-FDA regulated studies)
- ☐ REDCap e-Consent
- ☐ iMedConsent (Veterans Affairs studies)
- ☐ Other electronic signature platform

4. **If Other is selected, explain:**

5. * **Select any waivers that apply to this consent / assent group:**

☑	**No Waivers Requested**
☐	Waiver of All Consent or Some Elements in Consent Form
☐	Waiver of Parental Permission or Legally Authorized Representative Consent
☐	Waiver of All Assent by Child or Decisionally Impaired Adult
☐	Waiver of Signature on Consent/Permission Forms (waiver of documentation of consent)
☐	Exception from Informed Consent (for emergency research only)

6. * **Select all study team role(s) that will obtain consent / assent from this group:**

☐	Principal Investigator
☐	Co/Sub-Investigator

- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [x] **Research Coordinator**
- [ ] Research Nurse
- [ ] Consultant
- [x] **Research Assistant**
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other
- [ ] N/A: Requesting Waiver of Consent

7. * **Describe the consent procedures used for this group. Address each point below:**

   - When and where consent will occur
   - What will be covered during the consent discussion
   - How the consent discussion will occur (e.g. in-person, phone, video conference)
   - How you will reconfirm consent on an ongoing basis, if applicable

   - Consent will occur at the FGID clinic appointment either before or after the visit or while they are waiting for the physician or at the PRU with parent(s)/guardian(s) present
   - Study procedures, rights as a participant, risks and discomforts, data privacy, and compensation will be discussed with parent(s) present.
   - In-person
   - We will encourage participants/parents to reach out to us with any questions or concerns about the study or if they would like to stop participating and will be following up with them multiple times throughout the study where we can address any needs.

8. * **Select the processes for minimizing any potential perception of undue influence to participate, particularly when there is a pre-existing relationship between the participant and the researcher (e.g. treatment provider/patient; instructor/student; supervisor/employee, etc.):**
   - [x] **Having a 3rd person (family/friends, another study team member, etc.) present during the consent / assent discussion**
   - [ ] Having an independent advocate (e.g. advocate for decisionally impaired adults, wards) present during the consent / assent discussion
   - [ ] Removing physical symbols of authority like white coats or police badges
   - [x] **Sitting down beside the participant instead of standing over them**
   - [ ] If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to)
   - [ ] Moving to a more neutral location like a conference room
   - [ ] Obtaining consent / assent after other services/interactions have been completed (e.g. after school or the clinic visit)
   - [ ] Having a mandatory wait period for the participant to go home and think before they sign consent /assent
   - [ ] Sharing the consent / assent discussion between two people (i.e. a clinician might be the best person to explain study procedures and risks, but then they could step out and let a research assistant finish the consent process)
   - [ ] Other protection(s) not listed here – describe below
   - [ ] N/A: Requesting Waiver of Consent

9. * **Describe the other ways the study team will minimize any potential perception of undue influence to participate:**
   We will ensure participants understand their participation is voluntary. Questions and concerns will be answered from the child and parent(s)/guardian(s). No staff involved in the patient's clinical care or the PI will be present for the discussion.

10. * **How much time will participants be given to make a decision:**
    Until they are outside the age range thus not meeting inclusion criteria

11. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**
    We will contact the participant using recorded contact information via phone, letter, or email to communicate that we need to meet with them for them to re-consent.

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
Adults (18)

2. * **Select all that apply to this consent / assent group:**

	Name
☑	**Signed Consent by Participant**
☐	Signed Parent/Guardian Permission or Legally Authorized Representative Consent
☐	Signed Assent by Child or Decisionally Impaired Adult
☐	Verbal/Other Indication of Assent by Child or Decisionally Impaired Adult
☐	Short Form Consent (limited applicability)
☐	None of the Above (select waiver below)

3. * **Select all electronic signature platforms that apply to this consent / assent group:**

- ☑ **Not using electronic signature platforms**
- ☐ DocuSign Part 11 (FDA regulated studies)
- ☐ DocuSign (standard platform for non-FDA regulated studies)
- ☐ REDCap e-Consent
- ☐ iMedConsent (Veterans Affairs studies)
- ☐ Other electronic signature platform

4. **If Other is selected, explain:**

5. * **Select any waivers that apply to this consent / assent group:**

☑	**No Waivers Requested**
☐	Waiver of All Consent or Some Elements in Consent Form
☐	Waiver of Parental Permission or Legally Authorized Representative Consent
☐	Waiver of All Assent by Child or Decisionally Impaired Adult
☐	Waiver of Signature on Consent/Permission Forms (waiver of documentation of consent)
☐	Exception from Informed Consent (for emergency research only)

6. * **Select all study team role(s) that will obtain consent / assent from this group:**

☐	Principal Investigator
☐	Co/Sub-Investigator

- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [x] **Research Coordinator**
- [ ] Research Nurse
- [ ] Consultant
- [x] **Research Assistant**
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other
- [ ] N/A: Requesting Waiver of Consent

7. * **Describe the consent procedures used for this group. Address each point below:**

   - When and where consent will occur
   - What will be covered during the consent discussion
   - How the consent discussion will occur (e.g. in-person, phone, video conference)
   - How you will reconfirm consent on an ongoing basis, if applicable

   - Consent will occur at the FGID clinic appointment either before or after the visit or while they are waiting for the physician or at the PRU.
   - Study procedures, rights as a participant, risks and discomforts, data privacy, and compensation will be discussed.
   - In-person
   - We will encourage participants to reach out to us with any questions or concerns about the study or if they would like to stop participating and will be following up with them multiple times throughout the study where we can address any needs.

8. * **Select the processes for minimizing any potential perception of undue influence to participate, particularly when there is a pre-existing relationship between the participant and the researcher (e.g. treatment provider/patient; instructor/student; supervisor/employee, etc.):**

- [ ] Having a 3rd person (family/friends, another study team member, etc.) present during the consent / assent discussion
- [ ] Having an independent advocate (e.g. advocate for decisionally impaired adults, wards) present during the consent / assent discussion
- [ ] Removing physical symbols of authority like white coats or police badges
- [x] **Sitting down beside the participant instead of standing over them**
- [x] **If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to)**
- [ ] Moving to a more neutral location like a conference room
- [ ] Obtaining consent / assent after other services/interactions have been completed (e.g. after school or the clinic visit)
- [ ] Having a mandatory wait period for the participant to go home and think before they sign consent /assent
- [ ] Sharing the consent / assent discussion between two people (i.e. a clinician might be the best person to explain study procedures and risks, but then they could step out and let a research assistant finish the consent process)
- [ ] Other protection(s) not listed here – describe below
- [ ] N/A: Requesting Waiver of Consent

9. * **Describe the other ways the study team will minimize any potential perception of undue influence to participate:**
   Participants will be given ample time to consider their participation and have any questions answered about the research activities. No staff involved in clinical care or the PI of the study will be present during the discussion.

10. * **How much time will participants be given to make a decision:**
    Until they are outside of the age range, thus not meeting inclusion criteria

11. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**
    N/A

Personnel

1. * **Name:**
   Gisela Chelimsky

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**

- [ ] Data Collection - Interviews/Surveys
- [x] **Data Collection - Direct Observation**
- [x] **Clinical Services**
- [ ] Intervention Services
- [x] **Data Entry**
- [ ] Data Coding
- [x] **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:**
   Thomas Chelimsky

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

- [ ] Data Collection - Interviews/Surveys
- [x] **Data Collection - Direct Observation**
- [x] **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:**
   Madison Maxwell

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

- [ ] Data Collection - Interviews/Surveys
- [x] **Data Collection - Direct Observation**
- [ ] Clinical Services
- [ ] Intervention Services
- [x] **Data Entry**
- [x] **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**
- [ ] Experience - Clinical
- [x] **Experience - Related Skills**
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**

Personnel

1. * **Name:**
   Bhakti Dave

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)
   - [x] **Research Coordinator**
   - [ ] Research Nurse
   - [ ] Consultant
   - [ ] Research Assistant
   - [ ] Pharmacist
   - [ ] Statistician
   - [ ] Regulatory Coordinator
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   - [x] **Study Design**
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- [x] **Experience - Clinical**
- [x] **Experience - Related Skills**
- [ ] Trainee
- [ ] Student
- [ ] Other

7. **Additional or Emergency Phone:**