

## PROTOCOL

### **Study Title:**

Digital Delivery of Yoga Nidra for Anxiety and Sleep: A Feasibility Study

**Principal Investigator:** Erica Sharpe, PhD

**Co-Investigator(s):** Ryan Bradley, ND, MPH

**Co-Investigator:** Matt Butler, PhD

**Biostatistician:** Doug Hanes, PhD

**IRB #:** ESRB41320

**Version #:** 1

**Initial Document Approval Date:** April 13<sup>th</sup>, 2020

### **A.0 ABSTRACT**

The current COVID-19 pandemic is not only rapidly killing tens of thousands of people, worldwide, but it is heightening worry, anxiety, and uncertainty for many human beings, with 45% of adults reporting that this pandemic has affected their mental health (Kaiser Health Tracking Poll, March 2020). Frequent updates on the virus from the news, family, friends, social media, etc. may induce anxiety, which can lead to difficulty sleeping at night. Poor sleep can decrease immune function and thus, possibly increase risk of poor COVID-19 outcomes, along with a variety of health conditions including depression, stroke, and early death. This current virus is not contained by political, social, or cultural boundaries, and thus, nearly all humans are, or will be, impacted. There is a need for more research into mind/body therapies as alternatives to the standard of care for anxiety and sleep (often consisting of pharmaceuticals, supplements or behavioral interventions). We have begun to study the effects of Yoga Nidra on these outcomes by leading focus groups, as well as conducting a miniature sleep lab study in which we compared relaxation effects of a 90-minute rest period that contained 30-minutes of Yoga Nidra vs. lying quietly. Herein, we propose the study of a Yoga Nidra practice delivered in real-time, to anyone, with internet access, directly before bed, weekly, during the global coronavirus pandemic. Classes do not require registration and will likely contain a mix of new and repeat attendees each week. We will collect data on anxiety and sleep outcomes surrounding each class. Anxiety will be measured directly before and after the practice, and sleep data will be collected the day before and after Yoga Nidra. A feedback survey will be distributed after the 8-week course is complete, before the next 8-week session begins. This is a pilot study of online, live, community yoga practice, and may lead to larger, controlled studies in the future.

### **B.0 SPECIFIC AIMS**

#### **B.1 Specific Aim 1: Feasibility**

We will explore feasibility of live, online offerings by reporting enrollment numbers (target consistent class size would be at least 5 people), number of classes each participant attends (target: 3 of 8 offered), as well as feedback on accessibility (benefits/challenges of using Zoom) and effectiveness (vs. in-person class).

#### **B.2 Specific Aim 2: Effects of Yoga Nidra on Acute Anxiety**

Acute changes in anxiety will be monitored using the State Trait Anxiety Index (STAI) before and after class each week for each eight-week session offered through the Canton Yoga Loft, on Zoom.

### **Protocol**

Study Title: Digital Delivery of Yoga Nidra for Anxiety and Sleep: A Feasibility Study

PI: Erica Sharpe, PhD

IRB #: ESRB41320

Approval Date: April 13<sup>th</sup>, 2020

### **B.3 Specific Aim 3. Effects of Yoga Nidra on Sleep**

We will assess impacts of Yoga Nidra on sleep using six questions from the Post Sleep Questionnaire (PSQ). These questions will be distributed at intake (immediately before the first practice) and then in the morning following Yoga Nidra. In subsequent weeks after intake, these questions will be asked on Wednesday mornings (before Yoga Nidra) and on Thursday mornings (after Yoga Nidra).

**B.4 Exploratory Aim: Compare Agreeability of the Post Sleep Questionnaire (PSQ) to Oura Ring sleep outcomes.** Each question from the PSQ has been compared to polysomnography (PSG)[1]. We selected six questions that significantly correlate with certain sleep outcomes using Spearman correlation coefficients (Q6 (evaluation of sleep), with total sleep time (TST) and sleep efficiency (SE); Q7 (sleepiness), with sleep onset latency (SOL), TST, and SE; and Q8 (refreshment), with wakefulness after sleep onset (WASO)). A population of 80 people in NYC, currently being monitored, through the Oura ring, by their naturopathic doctor, will be invited to participate in Zoom classes and in this study. We will request Oura ring data on sleep, in an effort to determine agreeability between Oura outcomes, the PSQ and therefore, to polysomnography (PSG).

## **C.0 BACKGROUND AND SIGNIFICANCE**

The current pandemic is not only projected to kill tens of thousands in the US alone, but is impacting the lives of everyone, as it requires social distancing and increases anxiety and stress about health, employment, the economy, and more. Chronic stress increases risk for a variety of health conditions (e.g., depression, obesity, heart disease, and early death) and contributes to 75-90% of doctor visits [2]. In pre-pandemic statistics, 73% percent of the US population reported regular psychological symptoms of stress, and 48% of people reported lying awake at night due to stress [3, 4]. Therefore unsurprisingly, 40% of the US population reported sleep deprivation, 31% and reported anxiety [5]. These numbers may increase during a global pandemic. Although treatments exist for some these functional disorders (sleep, anxiety, etc.) current pharmaceutical treatments for sleep, for example, have severe effects on daytime cognitive functioning and motor control, which can contribute to workplace absenteeism, suboptimal performance, motor vehicle accidents and increased mortality (hypnotic drugs contribute to 50% of motor vehicle fatalities) [6-10]. There is a strong demand, at this moment, for nonpharmaceutical alternatives and for low-risk, broadly accessible practices that can be implemented at home, digitally, if possible.

Our proposed intervention, Yoga Nidra, is a scripted and reproducible, guided meditation technique that promotes mental, emotional and physical relaxation while also facilitating the transition between waking and sleeping. It is estimated that the average person actually sleeps during 10-50% of a Yoga Nidra practice [11]. Studies has shown the practice to enhance alpha brainwave power, which is indicative of the process of falling asleep. Our own preliminary work at Helfgott supports both of these statistics in the practice we developed, in-house (with an 11% increase in alpha power during Yoga Nidra, and with 78% of participants sleeping for an average of 51% of the practice). Traditionally, Yoga Nidra has been used to treat insomnia by practicing before bed. Treatment includes basic sleep hygiene [12], and physical postures (called asanas) before Yoga Nidra, in order to reduce restlessness, pain, stiffness and tension that could prevent focus during the practice. In similarity to other meditative and progressive relaxation techniques,

### **Protocol**

Study Title: Digital Delivery of Yoga Nidra for Anxiety and Sleep: A Feasibility Study

PI: Erica Sharpe, PhD

IRB #: ESRB41320

Approval Date: April 13<sup>th</sup>, 2020

the practice of Yoga Nidra produces significant physical relaxation characterized by increased parasympathetic response [13] (also confirmed in our pilot study, which observed a 13% decrease in respiration rate during the hour of rest which followed the practice). Unique to Yoga Nidra, however, is the additional release of mental and emotional tensions. During Yoga Nidra, mental tensions are released by rotating awareness throughout the body, following the mapping of the motor homunculus [11, 14, 15]. By sending a signal from body to brain, following the same pattern as this neuronal map, the mind is progressively relaxed [11]. Emotional release is then evoked through systematic arousal of feeling, sensation and experience, followed by guided visualizations.

**The goal of this application** is to collect survey data, indicating the effects of a digital Yoga Nidra practice, delivered real-time, before bed (10pm EST), to a group of students, through Zoom, during the COVID-19 pandemic. We will explore effects on momentary anxiousness, as well as on sleep. Participants will be consented through REDCap during the Yoga Nidra class, then asked to complete an intake form, a sleep questionnaire (composed of questions from the Post Sleep Questionnaire (PSQ)) and a pre/post State Trait Anxiety (STAI) Index, surrounding the practice. Participants will receive an email the next morning, inquiring about their sleep (~2 min survey), and again the following week, the morning of the Yoga Nidra class, in order to remind them about the weekly class offering and also to collect sleep data for a night that did not include pre-bed Yoga Nidra. We will additionally report feasibility measures including enrollment, retention, qualitative feedback, and challenges of using the digital platform. Using this data, we will gain valuable feasibility data for implementation of this type of mind-body practice using digital platforms. We will also gain important data on the effects of this practice on anxiety and sleep, when used as part of a pre-bed routine. Data from this trial will supplement our pilot data that measured relaxation and meditative effects *during* the practice, as well as qualitative feedback on *perceived experience* from focus groups. We will use our data set as a whole to pursue grant funding, to further explore this practice in a larger sample size.

## **D.0 PERSONNEL AND PRELIMINARY DATA**

**D.1 Erica Sharpe, PhD  
Ryan Bradley, ND, MPH  
Matt Butler, PhD  
Doug Hanes, PhD**

**D.2 Preliminary Data:** Our recent pilot study showed that in a sample of 18 participants reporting mild to moderate insomnia, momentary anxiousness decreased by 20% following Yoga Nidra. We also showed that respiration rate (RR) decreased by 1.4 breaths per minute during the practice of Yoga Nidra, and by 2.1 bpm during an hour rest that followed Yoga Nidra. Conversely, RR increased slightly in the control group, which lay quietly instead of practicing Yoga Nidra. These effects were statistically different between groups.

Furthermore, we displayed an 11% increase in alpha brainwave power from the occipital lobe. This change is consistent with other studies which report increase in alpha

### **Protocol**

Study Title: Digital Delivery of Yoga Nidra for Anxiety and Sleep: A Feasibility Study

PI: Erica Sharpe, PhD

IRB #: ESRB41320

Approval Date: April 13<sup>th</sup>, 2020

brainwave power [16] in response to meditation, thus asserting that our practice successfully modifies the brain in a similar manner to other successful practice, such as mindfulness meditation, and previously studied Yoga Nidra scripts.

We measured sleep in 67% of our control group, and 89% of our intervention group at both visits, with 78% (7/9) of participants in the Yoga Nidra group actually falling asleep *during* the Yoga Nidra practice (average SOL, 9 min), even though they were instructed by the recording to stay awake and focus on the meditation. 43% of these participants (3/7) did not wake up when the practice ended, and all but one of those participants that did wake up, fell back asleep within 10-minutes, and continued sleeping into the hour-long napping period which followed. 86% of the participants who slept during Yoga Nidra fell asleep less than halfway through the 27-min practice, and averaged a total sleep time of 38 minutes, during the 90-minute measurement period.

Our focus group data, which is still being analyzed, supports the hypothesis that for many individuals, Yoga Nidra can induce perceived physical, mental and emotional relaxation, as well as produce what participants recalled as sleep or a sleep-like state, that helps to clear the mind and decrease tension.

These findings support the hypothesis that Yoga Nidra may be a useful pre-bed technique for reducing sleep latency and increasing restfulness.

## **E.0 RESEARCH DESIGN AND METHODS STUDY FLOW**

**E.1. Overview:** In this preliminary study of digital, real-time, Yoga Nidra classes, we will assess acute pre/post changes in anxiety (using the STAI-Y6 survey) and pre/post changes in sleep (using the PSQ following nights with pre-bed Yoga Nidra vs. nights without pre-bed Yoga Nidra). Our sample will broadly include anyone who chooses to sign into this class, which is offered through the Canton Yoga Loft, in Canton, NY (who has moved all of its classes to Zoom, in response to the COVID-19 pandemic). Participants will be informed about the study and will have the opportunity to join and consent using a digital consent process within REDCap. During the 5-10 minutes before the intervention, participants will be asked to complete an intake form and two questionnaires. Participants will then be invited to practice Yoga Nidra, which involves the instructor reading to them for roughly 30-40 minutes. Following this practice, they will complete one final survey. They will then be prompted through email, to complete sleep surveys at two time points in the week that follows class. See the intervention schedule below.

### **Intervention Schedule:**

#### **Yoga Nidra Class via Zoom (Offered through the Canton Yoga Loft, Wednesdays at 10pm EST)**

5 minutes:

- Consent within REDCap
- Complete Intake Survey (with Insomnia Severity Index (ISI))
- Complete State Trait Anxiety Index (STAI-Y6) and 6 questions from the Post Sleep Questionnaire (PSQ)

### **Protocol**

Study Title: Digital Delivery of Yoga Nidra for Anxiety and Sleep: A Feasibility Study

PI: Erica Sharpe, PhD

IRB #: ESRB41320

Approval Date: April 13<sup>th</sup>, 2020

40 Minutes:

- Intro: greeting and sharing of one thing we are grateful for
- Yoga Nidra: listening to the teacher (Erica Sharpe) read a script from the Yoga Nidra book

1 Minute:

- Complete STAI survey

**Sleep Analysis *after* Yoga Nidra (next morning, 10am, email prompt from REDCap)**

1-2 minutes:

- 6 questions from the PSQ

**Sleep Analysis *without* Yoga Nidra (1-week later, Wednesday morning, 10am, email prompt from REDCap)**

1-2 minutes:

- 6 questions from the PSQ
- Reminder that Yoga Nidra is available on Zoom at 10pm

**Recordings:** Weekly Yoga Nidra sessions will be recorded and may be made available through the NUNM Moodle page for additional participants to access, as a non-live experience. Data collected from these participants will be analyzed in comparison to those participants in the live Zoom classes.

**E.2 Recruitment:** Anyone with access to the internet and Zoom, will be allowed to join this group class. Recruitment will take place using the Canton Yoga Loft webpage and social media pages, as this course is one of their offerings. Where possible, we may choose to advertise using TV, radio, and other online/digital means offered through our marketing department.

**E.3 Description of Participant Population:**

**E.3.1 Inclusion Criteria** Adult males and females, who speak English and can listen to a recording while resting comfortably.

**E.3.2 Exclusion Criteria** If a participant does not speak English, or cannot hear, they must be excluded from this intervention.

**E.3.3 Considerations:** Participants who are unable to lay on their back can assume another comfortable position.

**E.7 Informed Consent:** At the start of class, the instructor will describe the study to attendees, and go over the consent form through Zoom, while allowing time for prospective participants to read and sign, digitally. The only identifying piece of information we will collect is an email address, so surveys can be sent out as described in the protocol. Questions will be answered by the PI (also the Yoga Nidra instructor) and necessary accommodations will be made during this time as well. For their reference, participants will receive a Dropbox link to a PDF of the Consent Form by email, the next morning, as part of the prompt to complete their post-yoga sleep survey.

**E.8 Data Collection and Sources**

**Protocol**

Study Title: Digital Delivery of Yoga Nidra for Anxiety and Sleep: A Feasibility Study

PI: Erica Sharpe, PhD

IRB #: ESRB41320

Approval Date: April 13<sup>th</sup>, 2020

**5.8.1 Confidentiality and Data Storage:** All surveys and questionnaires will be stored in the encrypted REDCap server, and only email addresses will be collected, reducing risk.

**5.8.2 Data Integrity:** Every effort will be made to ensure confidentiality, including asking participants to refrain from using names, in discussion; and to keep any shared personal health information confidential.

#### **E.9 Risks and Benefits:**

**E.9.1 Risks:** In this study, we only collect email addresses, and no names or other identifying information. This session will be recorded in case other participants wish to participate remotely. We will crop out any portions of the recording that contain student video or voice. Although we will make every effort to protect identity, there is a minimal risk of loss of confidentiality. Yoga Nidra is a mind/body meditative practice, which involves mental, physical and emotional release and relaxation. Risks may include bringing up possibly upsetting memories, or emotions. If suddenly woken, participants may become startled, dizzy upon standing, and/or disoriented. There could be additional risks that we are unaware of at the time of the study. Participants are encouraged, if they experience any side effects while in the study, to contact Erica Sharpe at [esharpe@nunm.edu](mailto:esharpe@nunm.edu) as soon as possible.

**E.9.2 Benefits:** There is no guarantee that participants will receive any benefit from this study. However, participation will help us learn more about Yoga Nidra as a possible intervention to address poor sleep and anxiety in adults and will also be useful for assessing feasibility of this intervention as a whole, and particularly, when offered virtually. It is possible to may receive benefit from the practice of Yoga Nidra. These practices may have mental, physical and emotional benefits including relaxation, emotional release, and mental relaxation.

**E.10 Data Analysis:** Pre and post-practice surveys will be collected and analyzed by the PI and the biostatistician.

#### **F.0 Conclusion, Summary and/or Benefits of the Knowledge Gained**

With this study we will gain useful information that will help inform our study design for larger studies on digital execution of mind-body practices, and specifically, digital Yoga Nidra delivery for insomnia and anxiety during the COVID-19 pandemic. We will also understand more about feasibility challenges, such as how participants view online Yoga Nidra vs. face-to-face, as well as any challenges that arise from using Zoom for delivery, or when practicing at home vs. in a studio. Moving forward, we aim to further explore the effectiveness of Yoga Nidra as a self-administered, digital treatment for insomnia and anxiety. The mind/body practice of Yoga Nidra is a very accessible technique, with a history of use in reducing sleep onset latency and stress. We propose that this practice can be easily integrated into a sleep routine to produce immediate and measurable effects in the general American population. Further, we posit that this is a very valuable time to implement such as study, due to the tremendous challenge faced by all of humanity, in overcoming the novel coronavirus.

#### **Protocol**

Study Title: Digital Delivery of Yoga Nidra for Anxiety and Sleep: A Feasibility Study

PI: Erica Sharpe, PhD

IRB #: ESRB41320

Approval Date: April 13<sup>th</sup>, 2020

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## Protocol

Study Title: Digital Delivery of Yoga Nidra for Anxiety and Sleep: A Feasibility Study

PI: Erica Sharpe, PhD

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Approval Date: April 13<sup>th</sup>, 2020

## 1.0 Participant Informed Consent

**Title of Study:** Digital Delivery of Yoga Nidra for Anxiety and Sleep: A Feasibility Study

**Principal Investigator:** Erica Sharpe, PhD

**Co-Investigators:** Ryan Bradley, ND, MPH; Matt Butler, PhD; Doug Hanes, PhD

An Investigator in the Helfgott Research Institute at NUNM is conducting this research study. The study is supported by funding from the R90 Building Research across Inter-Disciplinary Gaps (BRIDG) clinical research training program, hosted at the National University of National Medicine, and funded by the National Center for Complementary and Integrative Health (NCCIH), of the National Institutes of Health (NIH).

### 2.0 What is the study about?

This study is being conducted in order to understand feasibility of online community delivery of Yoga Nidra, and also to explore its possible effects on stress and sleep during the COVID-19 pandemic.

### 3.0 How long will I be in the study?

Your part in the study will consist of filling out surveys online for roughly 5 minutes before and after Yoga Nidra class, as well as roughly 2 minutes the morning after class, and the morning of the next class.

### 4.0 What will happen in the study?

**Intake:** If you choose to participate, you will be asked to give consent and then complete an intake form, and provide your email address, which will be used to deliver two 2-minute follow up surveys.

**Yoga Nidra:** You will be invited to participate in a guided meditation practice called Yoga Nidra. You will be asked to lie on your back during this practice, close your eyes, and listen to a voice. This practice takes 30-40 minutes.

**Questionnaires:** After intake, you will be invited to complete two surveys before and after Yoga Nidra (a survey assessing anxiety will be given directly before and directly following Yoga Nidra, and a sleep survey will be administered directly before Yoga Nidra, and also emailed to you tomorrow morning, and again a week from today).

**Expectations of you:** Please perform any/all activities you are comfortable with, and complete any/all surveys you are comfortable completing. We ask that you give your full attention to the practice of Yoga Nidra and answer all surveys honestly. For the rigor of our research study, we truly appreciate a willingness to answer all surveys.

#### Protocol

Study Title: Digital Delivery of Yoga Nidra for Anxiety and Sleep: A Feasibility Study

PI: Erica Sharpe, PhD

IRB #: ESRB41320

Approval Date: April 13<sup>th</sup>, 2020



If you are over 18, and wish to join the study, you must consent by indicating “Yes” below (this is a REDCap checkbox).

**Intervention Schedule:** This class will be offered weekly, for 8-weeks at a time.

**Yoga Nidra Class via Zoom (Offered through the Canton Yoga Loft, Wednesdays at 10pm EST)**

5 minutes (before Yoga Nidra):

- Consent within REDCap
- Complete Intake Survey (Demographics and Insomnia Severity Index (ISI))
- Complete State Trait Anxiety Index (STAI-Y6)
- Complete 6 questions from the Post Sleep Questionnaire (PSQ)

40 Minutes (Yoga Nidra):

- Intro: greeting and sharing of one thing we are grateful for that day
- Yoga Nidra: listening to the teacher (Erica Sharpe) read a script from the Yoga Nidra book

1 Minute (after Yoga Nidra):

- Complete STAI survey

**Sleep Analysis *after* Yoga Nidra (next morning, 10am, email prompt from REDCap)**

1-2 minutes:

- 6 questions from the PSQ

**Sleep Analysis *without* Yoga Nidra (1-week later, Wednesday morning, 10am, email prompt from REDCap)**

1-2 minutes:

- 6 questions from the PSQ
- Reminder that Yoga Nidra is available on Zoom at 10pm

**Feedback Survey (following the 8-week session)**

- Effectiveness and Challenges of the practice through Zoom
- Optional comments from you

**Recordings:** Weekly Yoga Nidra sessions will be recorded and may be made available through the NUNM Moodle page for additional participants to access, as a *non-live* experience. For your privacy, we will cut out any portions of this class, before and after the practice, that include participant communication and on-screen interaction.

### 5.0 What if I have questions?

If you have questions about the study, you can contact the principal investigator, Erica Sharpe, PhD at [esharpe@nunm.edu](mailto:esharpe@nunm.edu), or our clinical co-investigator, Ryan Bradley, ND, MPH at [rbradley@nunm.edu](mailto:rbradley@nunm.edu).

### 6.0 Do I have to be in the study?

You decide if you want to be in the study, and this study is completely voluntary. You can leave the study at any time and you do not have to give a reason. If you are an NUNM student or employee, deciding not to take part, or deciding to leave will not affect your relationship with

#### Protocol

Study Title: Digital Delivery of Yoga Nidra for Anxiety and Sleep: A Feasibility Study

PI: Erica Sharpe, PhD

IRB #: ESRB41320

Approval Date: April 13<sup>th</sup>, 2020

NUNM. As a student in this Yoga Nidra class, deciding not to participate will not affect your ability to participate in Yoga Nidra itself: survey feedback is entirely voluntary.

### **7.0 What if I don't want to be in the study?**

You can choose not to be in the study, and you do not have to give a reason, just indicate "No", below, and then close the window.

### **8.0 Are there any costs?**

No, all study-related activities are free of charge.

### **9.0 Will I be paid for being in the study?**

You will not be paid for being in the study.

### **10.0 Are there any risks?**

Although we will make every effort to protect identity, there is a minimal risk of loss of confidentiality. Yoga Nidra is a mind/body meditative practice, which involves mental, physical and emotional release and relaxation. Risks may include bringing up possibly upsetting memories, or emotions. If suddenly woken, you may become startled, dizzy upon standing, and/or disoriented. There could be additional risks that we are unaware of at the time of the study. You are encouraged, if you experience any side effects while in the study, to contact Erica Sharpe at [esharpe@nunm.edu](mailto:esharpe@nunm.edu) as soon as possible.

### **11.0 What if I feel I've been hurt by taking part in the study?**

If you feel you have been injured or harmed by taking part in this study, please contact Erica Sharpe at [esharpe@nunm.edu](mailto:esharpe@nunm.edu). NUNM does not offer to pay the cost of being treated for harm.

If you feel your rights have been violated or you have been harmed by this study, please contact the NUNM Institutional Review Board Chair, Dr. Richard Barrett, at 503-552-1758.

### **12.0 Are there any benefits?**

There is no guarantee that participants will receive any benefit from this study. However, participation will help us learn more about Yoga Nidra as a possible intervention to address poor sleep and anxiety in adults and will also be useful for assessing feasibility of this intervention as a whole, and particularly, when offered virtually. It is possible to may receive benefit from the practice of Yoga Nidra. These practices may have benefits including physical relaxation, emotional release, and mental relaxation.

### **13.0 Your privacy is important**

Your name will not be collected or stored. We will use a study number instead of your name, and we will only use your collected email address to deliver surveys to you. We will, with your consent, also store your email address in a secure location, in case you would like to be notified about other study opportunities. Because we are collecting minimal identifiable information, and storing it in an encrypted and secure digital server (REDCap) used for research, there is little chance of breach of confidentiality. Your voice and video will be recorded, during our class. However, this recording will only be used by study staff, and all video and sound from participants will be cut out

#### **Protocol**

Study Title: Digital Delivery of Yoga Nidra for Anxiety and Sleep: A Feasibility Study

PI: Erica Sharpe, PhD

IRB #: ESRB41320

Approval Date: April 13<sup>th</sup>, 2020

before sharing the Yoga Nidra recording from class with any future students who wish to participate in the meditation. Any personal health information you choose to share will be kept anonymous to the best of our ability, and we ask that members of our group keep our discussion confidential. You may decline to answer any of the questions asked.

#### **14.0 Consent**

By checking “Yes” below, you are indicating the following:

- I am over 18 years old
- I know my rights have not been waived by agreeing to participate in this study.
- I have had all of my questions answered and/or I know whom to ask if I have more.
- I have read this form and understand it.
- I want to join the study.
- I know I can leave the study at any time and do not have to give a reason.

**\*\*\*After consenting, please expect to receive a copy of this form by email, tomorrow morning, when you receive your follow-up survey link. Thank you for participating in our research study! \*\*\***

#### **Protocol**

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