Online Education and Gentle Exercise Intervention (MY-Skills)

NCT03440320

Updated March 12, 2021

e-PROTOCOL

PROTOCOL
IRB Form

Protocol # 19-9095H
Date Printed: 06/17/2021

Protocol Title: Merging Yoga and self-management to develop Skills (MY-Skills) for chronic pain (NIH grant title) Education and Gentle Movement Intervention (study title for the purposes of the consent and IRB document)

Protocol Type: IRB Form

Date Submitted: 01/28/2021

Approval Period: 03/12/2021-09/16/2022

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* * * Summary, Purpose, Procedures * * *

Title (Please indicate if the protocol title is different from the proposal title)

Merging Yoga and self-management to develop Skills (MY-Skills) for chronic pain (NIH grant title) Education and Gentle Movement Intervention (study title for the purposes of the consent and IRB document)

Proposed Start Date: 01/01/2018 **Proposed End Date:** 12/31/2021

1. Summary

a) Provide a brief summary of the scope of work of this project, using non-technical terms that would be understood by a non-scientific reader. This summary should be no more than 200 words.Did you know that your consent is a great tool to reference the information for this section?

Legacy protocol number is 17-7581H

Adult caregiving dyads (i.e., caregivers and care recipients) are virtually neglected and ignored in health interventions; especially as programing relates to improving individuals' chronic pain. Further, yoga and self-management are effective and useful modalities for improving pain-related disability and is relevant to the mission of NIH NCCIH. However, yoga and self-management have not been combined for the caregiving dyad. Thus, the goal of this study is to develop and test an intervention to improve pain-related disability and health outcomes for individuals in the caregiving dyad.

Year 1 includes the development of such intervention with subsequent years to include the testing/evaluating of the intervention.

Phase 2: Participants will complete baseline assessments and be randomized to one of two interventions(MY-Skils intervention and control). Both interventions include 60 minutes of light exercise and 45-60 minutes of education. Sessions will be twice a week for 8 weeks (16 sessions=~32 hours). Participants will complete the 8 week intervention and complete follow up assessments.

Due to COVID, all assessments and the MY-Skills intervention and control groups will move from face-to-face to a virtual platform.

2. Purpose

a) Describe the purpose for the proposed project as well as the hypotheses/research questions to be examined. What are your primary, secondary, and tertiary objectives?

Aim 1: Develop and manualize the MY-Skills intervention. Using focus groups, clinical reasoning, literature, and findings from previously tested interventions of yoga and self-management, we will develop, refine, and standardize the MY-Skills intervention for chronic pain. In parallel, we will develop a control group that includes exercise and health and wellness education. Our expected outcomes include MY-Skills intervention workbooks for participants and training and teaching manuals for interventionists leading the MY-Skills intervention groupand control group.

Aim 2: Assess feasibility and acceptability of MY-Skills and research procedures including planned assessments. In this small RCT, we will examine feasibility and acceptability of the 8-week MY-Skills procedures and intervention compared to an exercise and health and wellness education control group. Our primary hypothesis is that MY-Skills will be feasible and acceptable to caregiving dyads, as measured by benchmarks for recruitment, screening, attendance, and completion of assessments and intervention. Surveys will be administered and focus groups will be conducted to understand participant satisfaction and experiences with MY-Skills. After each intervention session, interventionists, caregivers, and care recipients will rate their satisfaction with the session content and activities. To assess change on the primary outcome (pain-related disability) and secondary outcome measures, members of the caregiving dyad will complete pre and post-assessments guided by the Biopsychosocial Model. Additionally, this study is also wanting to examine the data for individuals who are screened during the recruitment process but may not be participating in the study for various reasons. With this, an important research question to be examined is through understanding who the caregivers of people with chronic pain are. We are finding that a majority of caregivers also experience chronic pain themselves.

b) What do the investigators hope to learn from this project?

We expect to learn how the MY-Skills intervention changed participants pain disability and intensity, as well as, if the intervention is feasible and acceptable

c) Please describe your plans to share the results of this study with intentions to influence behavior, practice, theory, future research designs.

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We will share results consistent with NIH guidelines.We will disseminate results through conferences and publications in academic journals.

3. Procedures

a) Describe in chronological order of event(s) how the activities will be conducted, providing information about all procedures (e.g. interventions/interactions with subjects, data collection, photographing, audio and video recording), including follow up procedures. Please provide details of all research activities that a participant will be involved.

YEAR 1: Adult caregiving dyads (i.e., caregivers and care recipients) are virtually neglected and ignored in health interventions; especially as programing relates to improving individuals' chronic pain. Further, yoga and self-management are effective and useful modalities for improving pain-related disability and is relevant to the mission of NCCIH. However, yoga and self-management have not been combined for the caregiving dyad. Thus, the goal of Phase 1 of this study is to develop an intervention to improve pain-related disability and health outcomes for individuals in the caregiving dyad. The Aim is to develop and manualize the MY-Skills intervention. We will include focus groups and interviews before and after manual development to make sure we are correctly addressing the needs of the caregiving dyad.

Step 1: Using focus groups or interviews, clinical reasoning, literature, and findings from previously tested interventions of yoga and self-management, we will develop, refine, and standardize the MY-Skills intervention for chronic pain. We will include up to 20 participants in focus groups to discuss the unique needs of the caregiving dyad regarding pain-related disability in order to guide the team to further develop content and sequencing of the content for the self-management education.

Step 2: The team will then develop the manual.

Step 3: Once the manual and workbook are developed, we will review them with experts, caregivers, and care recipients. One focus group, including 8 to 10 local experts and clinicians, will examine overall content and delivery. One focus group, including 8 to 10 caregivers, and one focus group, including 8 to 10 care recipients (total N = 24 to 30 participants), will provide feedback about different sessions of the participant workbook. Focus group participants will be asked for their input regarding the self-management education content, (lectures, activities, handouts, worksheets, resources) as well as delivery (sequencing of content, dose, frequency, setting). Interviews will be completed if necessary due to scheduling issues. Additional changes will be made to the manual and workbook as appropriate.

Phase 2: Individuals will be screened for eligibility purposes. Screening data will be used to explore descriptions of caregivers of people with chronic pain. We request that screening data of consented participants as well as those that are not eligible or decline participation in the intervention to be used to explore this question. Our rationale for this request is we have learned in the past 10 months during recruitment that caregivers of people in chronic pain may present themselves differently than what is described in the published literature on family caregiving. Our discovery may have further implications on future research and interventions for people in chronic pain.

Participants eligible and willing to participate will complete baseline assessments and be randomized to one of two interventions. Participants will complete an electronic version of informed consent. All assessments will be completed online. Both interventions include 60 minutes of light exercise and 45-60 minutes of education delivered online. Sessions will be twice a week for 8 weeks (16 sessions=~32 hours). Facilitators will be taking field notes at this time that can later be used during analyses. The treatment intervention includes yoga and self-management education. The control group includes light exercise and health and wellness education.

I) Please take a moment to identify which procedures outlined above are experimental and which are considered standard of care or established practice for the condition or situation in this area.

All outlined procedures are experimental.

b) Explain who will conduct the procedures, where, and when they will take place. Indicate the frequency and duration of visits/sessions as well as the subject's total time commitment for the study. Include how the data will be collected (i.e. in person or online).

Trained research personnel will complete all aspects of assessments, interviews and intervention.

Year 1: The focus group/interview protocol is attached. Topics surround the needs of people with chronic pain, the barriers to best treatment, and the facilitators to best treatment. We will also ask about the needs surrounding the caregiver dyad (caregiver and care receiver) to allow for these needs to be addressed while also treating pain. We expect questions to evolve as new data are collected. Qualitative data will be collected until we meet saturation. Participation should take up to 90 minutes/focus group. Focus groups were completed with trained research assistant in person.

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completed with trained research assistant in person.

Phase 2: This will be an 8-week intervention (2 times a week for 2 hours each time = 32 hours), with baseline (30-60 minutes) and post-assessments (30-60 minutes), and a focus group or interview (60 to 90 minutes). Therefore, approximate time commitment for participants is 35 hours and 30 minutes. Participants will complete assessments online via Qualtrics with an electronic version of informed consent. All interventions will be in a virtual format with trained research personnel.

i) **Indicate if the instruments used are in the public domain or provide appropriate documentation of permission to use each scale.**

SF12v2, paid for 300 copies-please see attached
Canadian Occupational Performance measure, paid for 100 copies, see attached
All other assessments used are in the public domain-please see attached

c) **For school-based activities where class time is used, describe in detail the activities planned for nonsubjects and explain where both subjects and nonsubjects will be located during the activities.**

N/A

d) **State if deception will be used. If so, provide a rationale and describe debriefing procedures. Submit a debriefing script in attachments section**

N/A

e) **Will audio or video taping of individuals occur? Will photographs of individuals be taken? Describe what will become of the tapes/photographs (e.g., shown at scientific meetings, erased, etc.).**

Audio taping will be used during the focus group interviews . No individual identifiers will be used during the focus group.Video taping may be used for assessment of the fidelity of the intervention being delivered as planned. Videos or photos may be used in future research presentations, publications, websites, books, chapters, but names or other identifiers will never be linked to the photo, audio, or video.

f) **Will the proposed research involve the use of existing, identifiable data/specimens?**

- i. **Yes, this research study only involves the analysis of existing, identifiable data/specimens.**
- X ii. **Yes, one of the research activities involved in this research includes the analysis of existing, identifiable data/specimens.**
- iii. **No, there are no research activities proposed that involve existing, identifiable data/specimens.**

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* * * Background and additional procedures * * *

4. Background and additional procedures

a. **Relevant Background: Discuss the present knowledge, appropriate literature and rationale for conducting the research. Include the rationale for the selected subject population.**

Based on our previous work, we found that group yoga was feasible and beneficial to individuals with different chronic conditions. Yoga was modified so people with disabilities could complete the activity and graduated from sitting, to standing, to the floor. Participants demonstrated reductions in pain-related disability. Participants also benefited with improvements in balance, balance self-efficacy, and quality of life scores. Participants with physical disability required assistance to move through postures or to move to the floor. Further, group yoga is feasible and may improve strength, endurance, coping, depressive symptoms, and positive aspects of caregiving. For the best attendance and completion rates in a yoga study, the care recipient needs to be engaged in an intervention or respite care. Finally, caregivers identified specific skills as the most useful, necessary, or important to improve their self-care. Skills included problem solving, action planning, coping skill development, and effective communication and will be included in the MY-Skills intervention.

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b. Do any of the following apply.

i. Will subjects be audio recorded? Y

ii. Will subjects be videotaped? Y

iii. Will subjects be photographed? Y

If yes to i, ii or iii, explain the collection process and use in the context of this research of such media

Audio recordings will only take place during all focus groups. Video recording will take place during the intervention to assess the fidelity of the intervention delivery. Video will be used for fidelity assessment and may be shown at scientific meetings, future research presentations, publications, websites, books, chapters, but names or other identifiers will never be linked to the photo, audio, or video.. All original recordings will be erased from the device and maintained on a CSU secured server

(Explicit consent must be obtained for use of these methods for Expedited and Full Board studies.)

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* * * Subject Population (a-f) * * *

5. Subject Population

a) How many subjects to you intend to enroll and/or how many subject records to you intend to access?

i. At CSU

# of subjects (required, enter 0 if not prospectively enrolling) 111

# of records or data (required, enter 0 if not accessing existing data records) 0

ii. At all sites (if cooperative or multi-site research) N/A

# of subjects (if selected, this is required. Enter 0 if not prospectively enrolling) 111

# of records or data (if selected, this is required. Enter) if not accessing existing data records) 0

b) Inclusion and Exclusion Criteria (e.g., Participants must have 20/20 vision, Participants must be 30-45 years of age, etc.) This should match your screening, consent, and recruitment materials.

i. Identify inclusion criteria.

•At least 18 years old
•Able to speak English
•Ability to stand with or without an assistive device
•Live at home or in the community
•Have home computer for online assessments/interventions
•Have reliable internet connection for online assessments/interventions
•Musculoskeletal pain for a minimum of three months
•Moderately severe pain related disability (BPI ≥ 5)
•Part of caregiving dyad
•Score >4 out of 6 on the short Mini Mental Status Exam (Callahan, et al., 2002)
•Sedentary lifestyle (participate in < two 30-minute organized physical activity sessions each week)
•Completed the PARQ+, and if required completed the ePARMedX for physician clearance into the program

additional inclusion criteria for caregivers: caregiver at least 6 months

ii. Identify exclusion criteria.

•Alzheimer's disease, dementia
•Expectation of death in the next 12 months
•Receiving or planning to receive cancer treatment in the next 6 months

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- Stroke or TIA in the last 6 months
- Myocardial infarction in the last 3 months
- In physical or occupational therapy specifically for chronic pain and attend ≥ once a week
- Completed self-management education in the last year

c) What is the rationale for studying the requested group(s) of participants?

The caregiving dyad. Caregivers are a critical and important asset in healthcare. In the United States, 65.7 million informal caregivers (i.e., non-paid family members and/or friends) provide on average 20 hours of care a week and complete tasks, such as assisting with activities of daily living (ADLs; bathing, dressing, eating, etc.) and instrumental ADLs (cooking, cleaning, shopping, finances, etc.; Brody, 2003) resulting in an annual savings of $470 billion dollars to the healthcare system (Reinhard, Feinberg et al., 2015). More importantly, when compared to non-caregivers, caregivers experience stress and strain (Pearlin, Mullan et al., 1990), often to the detriment of their own health and well-being (Pinquart et al., 2003; Vitaliano, Zhang et al., 2003), chronic pain experience (Jones et al., 2011), and even leading to their own death (Schulz et al., 1999).
A majority (58%) of care recipients have a chronic physical condition (e.g., arthritis, back problems, cancer, diabetes, heart disease, mobility, and stroke) that result in needing assistance (AARP & National Alliance for Caregiving, 2015). More than half (53%) of care recipients have been hospitalized due to illness in the past year (AARP & National Alliance for Caregiving, 2015); such illness may lead to an increased likelihood of pain, increased pain-related disability (i.e., the intrusion of pain on enjoyment of life and activity), and greater stress and strain. Furthermore, as pain disability and intensity increases, the caregiving dyad may experience challenges in relationship factors including: a decrease in communication and relationship satisfaction, and an increase in relationship strain as pain is experienced in a social context (Mann, LeFort et al., 2013).

Chronic pain and the caregiving dyad. Chronic pain is widely recognized as a significant national public health issue (NIH, 2016) with at least 100 million Americans suffering from chronic pain at any given time. It is well established that chronic pain leads to decreased QoL. Further, healthcare costs and treatments for chronic pain are estimated to annually cost $635 billion a year and pain contributes to decreases in paid work and increases in disability benefits (Gaskin & Richard, 2012). Much of the expenditure is related to opioid use (Manchikanti, Helm II et al., 2012), as we are in the midst of an opioid epidemic, leading to opioid use disorders and overdose deaths (Dart, Surratt et al., 2015). Many patients continue to experience severe, disabling pain despite opioid treatment; others report intolerable side effects from opioids. Primary care providers often struggle with opioid treatment decisions and worry about fostering prescription drug abuse and addiction. Given these controversies, struggles, and lack of convincing data for opioid use, research on innovative non-pharmacological treatments to improve the management of chronic pain is urgently needed.
Chronic pain may be experienced by both individuals in the caregiving dyad and is not simply a physical ailment, but instead a complex interplay of biological, psychological, and social conditions that impact the caregiving relationship (Lyons, Zarit et al., 2002). Informal caregivers are challenged with how to best support care recipients in pain, while also experiencing their own pain (i.e., 74% of caregivers experience chronic pain; Jones, et al., 2011), social isolation, stress and strain, and burden due to the demands of caregiving (Adelman, Tmanova et al., 2014). For example, caregivers and care recipients may experience increased isolation, communication conflict, or may disagree about doctors' orders and/or adherence to doctors' orders. Specific to spousal caregivers, when the care receiver experiences chronic pain, caregivers may act solicitously and enable certain negative pain behaviors (e.g., encourage bed rest instead of activity and movement). This may perpetuate pain-related disability in the care receiver (Flor, Kerns et al., 1987). As a result, there is often increased pain-related disability and strain placed on the caregiving dyad relationship. Therefore, interventions targeting both caregivers and care recipients using a holistic approach are essential for QoL and physical and emotional health (Lyons et al., 2002). Yet, caregivers are often invited to only attend one session or a special session designed for caregivers, but interventions have not been directly designed for the dyad (Lyons et al., 2002; Mann et al., 2013). Including both members of the dyad may improve intervention adherence and attendance (Savini, Buck et al., 2015), improve social supports for each member of the dyad (Boise, Congleton et al., 2005; Savundranayagam, Montgomery et al., 2011), and allow for improved communication and decision making within the caregiving dyad (Braun, Mura et al., 2010; Whitlatch, 2008). Treating the members of the dyad together appears to be feasible and improves outcomes in dementia and stroke studies (Savini et al., 2015; Whitlatch, Judge et al., 2006), but has not been tested for chronic pain. In spite of best-practices in self-management programs addressing chronic pain (Bair, Ang et al., 2015; Mann et al., 2013) or informal caregivers (Boise et al., 2005; Kuhn, Fulton et al., 2003; Lorig, Thompson-Gallagher et al., 2012; Won, Fitts et al., 2008) minimal research has been conducted on non-pharmacological pain interventions for the caregiving dyad (Martire, Schulz et al., 2010; Zarit & Reamy, 2013). Thus, there is a critical need for innovative non-pharmacological pain interventions for both individuals in the caregiving dyad.

d) State if any of the subjects are students, employees, or laboratory personnel. Please explain how subjects will be protected from coercion and undue influence **N/A**

If someone does fit this description, we will treat them the same as all other participants.

e) Please describe the expertise you have, or have access to, which prepares you to conduct research in this location and/or with this

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subject population, including specific qualifications (e.g., relevant coursework, background, experience, and training). Also, explain your knowledge of local community attitudes and cultural norms and cultural sensitivities necessary to carry out the research (e.g., differences with U.S. culture).

Three of our most recent studies directly support this proposal. In our recent yoga and chronic pain study, we recruited 83 participants in five months for the RCT comparing yoga to usual care. We found that eight weeks of yoga led to decreased pain-related disability, as measured with the Brief Pain Inventory (BPI) (Cleeland, 1989), for individuals with chronic pain (effect size = .34) (Schmid et al., in review). In a separate study of self-management for chronic pain, we recruited 241 participants for the RCT comparing stepped care (self-management, analgesics, cognitive behavioral therapy) to usual care. We found stepped care led to decreased pain related-disability (BPI) (effect size = .26) (Bair et al., 2015). Finally, we merged yoga and self-management for 14 people with stroke and fall risk in a single arm intervention pilot study. We found that merged yoga and self-management is feasible and beneficial (Schmid, Van Puymbroeck et al., 2016b) and improved balance and balance confidence, and decreased fall risk factors. Of note, we invited caregivers to attend. Caregivers had a 47% reduction in perceived burden, compared to a 2% decrease in burden in caregivers who did not participate (Hinsey et al., 2015). Table 1 includes a summary of our additional supporting research.
Collectively, our team has demonstrated an ability to work together and access the desired patient populations. Our team is uniquely suited to address the needs of the caregiving dyad with chronic pain by merging yoga with self-management skills (see Figure 1). While we have created and tested a yoga and self-management intervention for individuals with stroke and a history of falls (Schmid et al., 2016b) MY-Skills is a new intervention for the caregiving dyad with chronic pain. Based on our previous research, this is the next logical step as there are no studies merging yoga and self-management to address chronic pain, particularly for the caregiving dyad.

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* * * Recruitment Process, Subject Compensation and Costs * * *

6. Recruitment Process:

a) Describe the step-by-step procedures for identifying and recruiting potential research subjects or requesting pre-existing data or materials. All recruitment materials must be uploaded in Attachment section, and have IRB approval prior to use.

- **List any specific agencies or institutions that will provide access to prospective subjects.**
- **Identify who will contact prospective subjects and how.**

We will recruit broadly for this study, using social media and email blasts to appropriate parties. Due to COVID, all recruitment will be virtual to ensure safety of potential participants and the research team. Twenty-seven individuals have been screened, are eligible, and prior to COVID, were scheduled for assessments and randomization. We have kept in contact with these individuals to maintain communication and interest in participating in the study.

Other recruitment strategies for online delivery will involve individuals/staff at local pain clinics, aging centers, community centers, independently living facilities, in and out-patient rehabilitation or medical centers, hospitals, and colleagues within the community via phone and email. Online advertisements may be run in the online versions of local newspapers and community outreach newsletters. More specifically we will also use approved flyers in emails sent to the local pain clinic, Poudre Valley Hospital and/or the Larimer County Office on Aging - National Family Caregiver Support Coordinator. If individuals are interested in participating in MY-Skills, they will then call or email study staff to set-up a time to discuss the study and eligibility criteria via phone or email.

In our prior studies we used the Physical Activity Readiness Questionnaire+ (PAR-Q+) (Arraiz, Wigle et al., 1992) and will use it with all potential participants before enrollment in the study. Any participant responding 'yes' to an item will require a doctor's approval to enter the study, using the ePARMedX. If potential participants do not meet all criteria the research staff will keep note and follow-up with potential participants as eligibility may change. Once found eligible, participants will be scheduled for online baseline assessments that will be completed within one week prior to the start of each cohort. The potential participant will be given a time, online delivery information, and contact information for the CSU research staff to complete the baseline visit.

b) Planned Subject Identification Methods:

- N/A
- Chart/database review
- Class participants
- X Direct advertising
- Living conditions (e.g., nursing home residents)
- From PI's own practice/clinic/class

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Circumstance (e.g., homelessness)
X Organization mailing lists
Other (please specify):

X Referrals
CSU Subject Pool

c) Planned Recruitment Materials/Methods:

N/A
X Phone Scripts
Television ads
Letters to prospective subjects
X Oral Scripts
X Internet ads/postings
X Face to face interactions
X Other (please specify):

X Flyers/posters
Letters to providers/schools/organizations
X Newspaper ads
Radio ads
X PowerPoint presentations
X Email
X CSU Subject Pool

emails to prospective subjects

(All advertising must be submitted for review in its final printed/recorded form)

Note: Attach copies of ALL recruitment materials in the attachment Section

7. Subject Compensation and Costs:

a) Will subjects receive compensation for participation? Y

Total amount (in dollars or equivalent) $100

b) Form of Compensation:

X Cash
Check
X Gift card/certificate
Voucher

Raffles/lotteries
Course/extra credit
Reimbursement only
Other (please specify)

c) Describe the remuneration plan (Include when subjects will be paid, whether payment will be prorated and whether a 1099 will be issued.)

Phase 1 A $50 gift card will be provided to all focus group and interview participants

Phase 2
$50 at the completion of each assessment (up to 2 assessments, $100 total)

d) For raffles include the number of prizes, nature and value of each prize.If possible, include odds of winning.

N/A

e) If extra course credit is offered be sure to address the alternative means by which students can accrue extra course credit should they not wish to participate in the study.

N/A

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* * * Consent Information * * *

11. **What is Consent? The consent process is intended to fully inform participants of their involvement in your research project. This should describe what a participant will be expecting when they are involved in your activities. Nothing should surprise them. The basic elements of informed consent can be found at 46.116This may include, but not limited to screening consents, consent scripts, main study consent, reconsenting materials. Informed consent can be obtained through varied processes: Consent (formal, signed consent)Waiver of Documentation (verbal, cover letter, 'Click to Consent' or implied consent)Waiver (waiver of parental permission or participant consent)Alteration (formal, signed consent with deception or exempt qualifying research)Debriefing (post participation providing addt'l information)Screening ConsentPlease label each item appropriately so your IRB reviewers understand what purpose/population each document is aiming to address.**

11 a & b apply ONLY to Exempt applications.NOTE: If you are completing an Exempt application, please upload all your consent, recruitment, and supporting documentation in the Attachments section of the application.

a) **How will subjects be informed of procedures, intent of the study, and potential risks to them?**

Via online on REDCap or written consent

Due to COVID, online via Qualtrics or eConsent

b) **How will subjects be informed they may withdraw at any timewithout penalty?**

Via online on REDCap or written consent

Due to COVID, online via Qualtrics or eConsent

Note: Attach, in the Attachments Section, written and/or verbal instructions the subject will receive.

See sample consent forms at https://www.research.colostate.edu/ricro/irb/templates//

Please provide consent process background information below.

Informed Consent

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Title	Consent Type	Attached Date	Submitted Date
COVID-online version Virtual Format Signed eConsent For Federally Funded Research MYSkills	Consent	07/02/2020	07/02/2020
New Format_IRB_SignedConsentForFederallyFundedResearch_MYSkills 11.14.19	Consent	08/19/2020	08/26/2020
Recruitment Disclosure Reconsent.2	Continued Participation Consent	10/13/2020	10/13/2020
