Microbreaks and Intraoperative Exercises for Gynecologic Surgeons (MIGS Trial)

August 12, 2022

FORM: IRB Proposal - Standard Submission	
NUMBER	VERSION DATE
HRP-UT901	8/12/2022

The Effect of Intraoperative Exercises on Gynecologic Surgeons

GENERAL STUDY INFORMATION

Use for greater than minimal risk studies and minimal risk studies that fit into one or more expedited categories (see Section 5.3 of our Policies & Procedures for details regarding expedited research).

Do NOT submit this form if the study will qualify for exempt review, instead submit HRP-UT902 IRB Proposal – Exempt Submission Form found in the document Library.

If you are only using secondary data that will not be initially collected solely for this research project, use HRP-UT903 Template IRB Proposal Secondary Use form instead.

For studies following a multi-center or sponsor protocol, please use this guidance to assist in your completion of this form.

For questions regarding definitions, policies, or terms referenced below see the policies and procedures manual.

Please note, Word online does not support Word checkboxes. Please download the file and use your desktop version of Microsoft Word.

1 Review Type (Choose one)

*Click on the check box (or double click and type an "X" if using Google Docs) the **one** review type that in the investigator's opinion applies.*

Please note: Expedited Review does not refer to the timeliness of the review of your protocol, but specific categories of research defined by ORHP. If you would like help determining which type of review is most appropriate for your study please contact the Office of Research Support and Compliance: https://research.utexas.edu/ors/about-ors/contact-us/.

Investigator's assessment of review does not preclude the IRB from alternate determinations. In cases where the investigator and the IRB's determination conflict, the IRB's determination should be considered accurate.

a ☐ **Full Board Review – Greater than Minimal Risk Research**

b ☒ **Expedited Review – Minimal Risk Research**

2 Research Hypothesis

To input text, click in the light grey area below.

Short intraoperative
breaks and exercises will improve work-related discomfort among gynecologic surgeons.

3 Study Background

To input text, click in the light grey area below.

Work-related musculoskeletal disorders (MSDs) are prevalent among surgeons and include cumulative trauma disorders, repetitive strain disorders, repetitive motion disorders and overuse syndromes affecting the muscles, nerves, tendons, ligaments, cartilage, or spinal disks.[1,2] A recent meta-analysis found that prevalence of work-related pain ranged from 35%-60% across surgical subspecialties.[3] The risk of these disorders may be higher depending on the route of surgery.[4] Gynecologists are at risk of developing work-related MSDs. One study found that 86.7% of vaginal surgeons in urogynecology reported ever having work-related MSD.[1] MSDs affect the health of individual surgeons and the stability of the surgeon workforce with up to 12% of surgeons with work-related MSD requiring a leave of absence, work restriction, or early retirement. [3]

Improving surgeon ergonomics and instituting intraoperative "microbreaks" and exercises may prevent work-related MSD among gynecologic surgeons. Prior studies have shown improvement in work-related discomfort or stress among surgeons with intraoperative breaks, but there are no prospective studies evaluating the impact of intraoperative exercises among gynecologic surgeons. One multi-center cohort study found that targeted stretch micro breaks diminished impact of pain on body parts, performance, and mental focus among surgeons in a variety of specialties.[5] Another multi-center cohort study found that intraoperative exercise breaks significantly reduced discomfort with minimal impact on distractions or flow during surgery.[6] A randomized control trial showed that intraoperative work breaks during complex laparoscopic surgeries reduced psychological stress without affecting performance or operative time.[7]

The goal of this study is to evaluate the effect of intraoperative microbreaks and exercises on gynecologic surgeon body discomfort by conducting a randomized trial. We hypothesize that gynecologic surgeons will experience decreased pain on surgery days with intraoperative microbreaks and exercises without compromising overall surgical performance.

4 Design and Methodology

Provide information regarding study design or data collection methodologies. Details regarding protocol specific research procedures will be discussed in a later section.

To input text, click in the light grey area below.

This is a prospective randomized trial to assess the effect of intraoperative microbreaks and exercises on gynecologic surgeon body discomfort. Surgery days among gynecologic surgeons will be randomized to include or not include intraoperative microbreaks with specific exercises. Data on body part discomfort and surgeon task load will be collected on each surgery day.

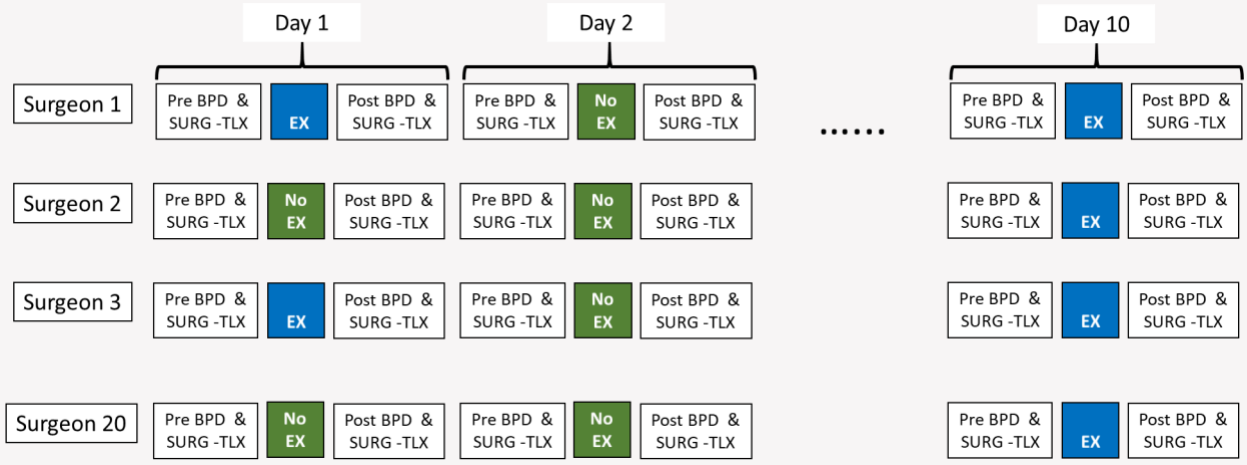
5 Data Analysis

Describe the data analysis plan, including any statistical procedures or power analysis.

To input text, click in the light grey area below.

Design

Describe the design of your study –



Demographic and baseline characteristics

The baseline survey includes information such as surgeon age, gender, weight, height, dominant hand, surgical volume, years practicing surgery, and activity level.

Nordic Musculoskeletal Questionnaire

At the beginning of the study, each participant will complete a baseline questionnaire adapted from the standardized Nordic Musculoskeletal Questionnaire (NMSQ)[8] and a survey developed by Plerhoples et al.[9] The NMSQ is a validated questionnaire for the analysis of musculoskeletal symptoms and assesses for history of trouble (ache, pain, discomfort) in body part regions.

Primary outcome

Body Part Discomfort (BPD) scale

On each of the eligible surgery days, we will collect data on body part discomfort and surgical experience using the Body Part Discomfort (BPD) scale. The BPD scale measures body part discomfort using a 10-point scale (1 corresponds with no discomfort and 10 corresponds to maximum body discomfort) for body part regions. Body part regions include neck, shoulders, arms, wrist/hands, upper back, low back, hips/thighs, knees, ankles/feet. Body part discomfort will be summarized by the mean severity of all ratings by the subjects, known as the Body Part Discomfort Severity (BPDS) index. This summary measure will be calculated from all of the individual BPD ratings for each posture in the present study. We will compare self-reported BPDS at the beginning of the surgery day to the end of the surgery day and calculate the change by subtracting the BPDS reported at the end of day minus beginning of day. When appropriate we will control for the total number of minutes spent in surgery during the day.

Secondary Outcome:

Surgery Task Load Index (SURG-TLX)

Similar to the BPD, we will collect data on a modified SURG-TLX on each of the eligible surgery days. The modified SURG-TLX will be evaluated at the end of each surgery day to assess participant experience throughout the surgery day. The SURG-TLX measures 6 areas: mental demands, physical demands, task complexity, situational stress, and distractions. Each of the 6 areas is rated on a scale of 0 to 100, which is added to generate a sum score. The sum score will then be compared across surgery days with and without the intervention.

Data will also be collected from medical records about each surgery in the study. The following perioperative data will be collected: surgeries performed, operative time, and intraoperative complications (i.e. bladder/bowel injury, large vessel injury, transfusion, allergic reaction, difficulty ventilating, ICU admission).

At the conclusion of the study, an anonymous exit survey will be performed to give all participants an opportunity to provide feedback. Data will be collected on the results of the exit survey. The exit survey with include questions about the participants experience performing the exercises including ease of performing exercises and incorporating into the surgical day.

Randomization

To randomize surgeons, we will first construct Williams squares where exercise follows no exercise (and vice versa) the same number of times.[10] After the Williams squares are constructed and selected, individual sequences are randomly assigned to the surgeon. Sequence randomization will occur according to a predetermined computer-generated scheme prepared by a study statistician.

Statistical Analysis

Descriptive statistics (means, standard deviations, frequencies) will characterize the sample to assess comparability of the intervention and control surgery days.
Chi-square test or Fisher's exact test will be used for categorical variables. Continuous variables will be examined for normality using the Shapiro-Wilk test; normally distributed continuous variables will be compared using the Student's t-test and those non-normally distributed will be compared using the Mann-Whitney U test. We will use linear mixed models to test for an association between BPDS and the targeted micro breaks/exercise intervention across surgery days. We will exclude surgeons who do not provide self-reported BPDS data on both days for a certain body part.

Power analysis:

Sample size estimations were conducted using G*Power. We utilized the research by Park et al (2017) to estimate the effect of intraoperative microbreaks and exercises on surgeon body discomfort. Park et al (2017) reported differences in body discomfort between surgeons who completed the intraoperative microbreaks/exercises and the control group that ranged from d=0.00 to d=0.48. Using G*Power, we computed the required sample size to detect a medium effect with the specified parameters: **power=0.85, α=.05, f=0.25, and measurements = 10**. This yielded a total sample size of at least 20 surgeons, where each surgeon completes 10 surgery days with the intervention and 10 surgery days without the intervention, with a minimal total of 20 surgery days.

Table 1. Power and sample size estimations for a within-subject design

Cohen's f	**f=0.1** small	**f=0.15**	**f=0.20**	**f=0.25** medium	**f=0.30**	**f=0.35**	**f=0.40** large
total sample size	**power**						
10	~~0.12~~	~~0.23~~	~~0.41~~	0.62	**0.8**	**0.9**	**1.0**
15	~~0.16~~	~~0.36~~	~~0.62~~	**0.85**	**1.0**	**1.0**	**1.0**
20	~~0.21~~	~~0.49~~	**0.79**	**0.95**	**1.0**	**1.0**	**1.0**
25	~~0.27~~	~~0.60~~	**0.89**	**0.99**	**1.0**	**1.0**	**1.0**

STUDY ELEMENT IDENTIFICATION

6 Study Elements

Click on the check box (or double click and type an "X" if using Google Docs) each procedure included in your study.

A full description of all study procedures should be provided in the Procedures (Details) section below and/or the applicable supplement form.

☐	Bio-specimens	☐	Biometrics	☐	Registry or Repository
☐	Focus Group	☐	Genetic Analysis	☐	Genomic Data Sharing
☐	International Research	☒	Interview/Survey	☐	MRI
☐	Protected Health Information	☒	Observation	☐	Radioactive Material/PET/Nuc. Med
☒	Record Review	☐	Sensors (Externally Placed)	☐	Sensors (Inserted)
☐	Video/Audio Recording	☐	X-Ray/CT		

7 Study Intervention

Click on the check box (or double click and type an "X" if using Google Docs) if you will implement any of the following interventions.

A full description of all study interventions should be provided in the Procedures (Details) section below and/or the applicable supplement form.

☒	Behavioral	☐	Device	☐	Drug/Biologic

8 Clinical Trial

Click on the following check box (or double click and type an "X" if using Google Docs) if the research meets the below definition of a clinical trial.

☒ **This study meets the definition of a clinical trial according to clinical trials.gov in that it involves one or more human subjects who are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.**

9 Additional Oversight

Click on the check box (or double click and type an "X" if using Google Docs) each activity that requires oversight from additional UT committees.

☐	Energy introduced to the subject (electrical, magnetic, light)	☐	Human embryonic, human induced pluripotent, or human totipotent stem cells; or human gametes or embryos	☐	Radiation exposure without direct clinical benefit

☐ **Biological Samples, Biohazards, Recombinant DNA, or Gene Transfer**

If biological samples are used and stored on UT campus IBC approval is needed.

a ☐ **Biological samples collected will not be stored on UT sites and another agency has responsibility for biospecimen safety.**

b **IBC Protocol Number**

To input text, click in the light grey area below.

10 Alternatives to Participation in This Study

To input text, click in the light grey area below.

Participants are free to not participate in the study.

STUDY PROCEDURE DESCRIPTION

11 Procedure Description

Describe all study procedures, including a step-by-step outline of what participants will be asked to do or how data will be used. Be sure to describe all of the following in detail, as applicable:

- Provide a description of all research procedures being performed and when they are performed, in sequential order.
- All research measures/tests that will be used and state if questions or measures are standardized or published (upload copies of all surveys, scripts and data collection forms)
- Secondary data or specimens that will be obtained, how they will be collected, and how they will be used
- Where each activity will take place, the duration of each, and who will perform each activity
- Include time commitment of participants

To input text, click in the light grey area below.

Potential participants include residents, fellows, and attendings performing gynecologic surgery (including benign gynecologists, gynecologic oncologists, minimally invasive gynecologists, and urogynecologists). We will recruit surgeons from the Department of

Women's Health at the University of Texas at Austin Dell Medical School. Surgeons will need to have operated on average at least 2 days per month over the last 12 months. Written informed consent will be obtained. Eligible surgery days must include at least one surgery with total operative time of at least 2 hours. Surgeons will be excluded if they are unable to perform the exercises.

Upon agreement to participate in the study, surgeons will complete baseline questionnaires adapted from the standardized Nordic Musculoskeletal Questionnaire (NMSQ)[8] and a survey developed by Plerhoples et al.[9] The NMSQ is a validated questionnaire for the analysis of musculoskeletal symptoms and assesses for history of trouble (ache, pain, discomfort) in body part regions. The survey includes information such as surgeon age, gender, weight, height, dominant hand, surgical volume, years practicing surgery, and activity level.

Once participants are enrolled, all participant surgery days will be assessed for inclusion based on the inclusion criteria above. Surgery days will be randomized to surgery days with microbreaks and exercises and surgery days without microbreaks and exercises. The surgeon will be informed of the randomization assignment prior to the surgery day.

Surgery days randomized to intraoperative microbreaks and exercises will include standardized breaks lasting approximately 1.5-2 minutes. During these breaks, surgeons will perform a set of targeted stretches or exercises while remaining sterile. These exercises were developed with the assistance of a physician specialized in Physical Medicine and Rehab. The exercises will be performed just before surgical time-out, at a surgically safe and convenient time 45-75 mins after the start of the case and at the end of the case. A surgically safe and convenient time means the surgeon feels that it is safe to take an approximately 1.5-2 minute break during the procedure at that time. Surgeons will skip the microbreak if there is no surgically convenient or safe time during the case. Surgeons will stop the microbreak at any point if needed to ensure patient safety. The microbreaks performed during the surgery may add time to the surgery in approximately 1.5-2 minute increments, however prior studies have shown no difference in operative time with addition of microbreaks. Attached is a document outlining the exercises including photos with exercise cues and a video demonstrating the exercises. Participants will have access to these documents before and during the study.

On each surgery day, participating surgeons will complete the "Surgery Day Questionnaire" which will include the Body Part Discomfort (BPD) scale and Surgery Task Load Index (SURG-TLX). The Corlett and Bishop BPD Scale was originally created in 1976 and is a validated technique to assess work-related discomfort by body part regions.[11,12]

Another measure of work-related stress during surgery is the SURG-TLX. This is a validated tool based off the NASA-TLX used to assess overall workload including mental demands, physical demands, temporal demands, task complexity, situational stress, and distractions.[13] At the beginning of all surgery days, the participating surgeon will complete a baseline BPD scale as the first part of the "Surgery Day Questionnaire". Following each surgery day, the surgeon will complete both the BPD scale and the SURG-TLX survey to complete the "Surgery Day Questionnaire" for that day. Participating surgeons are asked to inform the research team if they develop any new work-related injury during the study period.

Data will be collected from medical records about each surgery in the study. The following perioperative data will be collected: surgeries performed, operative time, and intraoperative complications.

At the conclusion of the study, an anonymous exit survey will be performed to give all participants an opportunity to provide feedback. Data will be collected on the results of the exit survey.

All data will be collected and stored in our institution's REDcap, a secure electronic application for research.

<u>Intervention (see PDF document and video attached)</u>
Chest and Shoulder Opener "Elbows in Pockets"
Stand with feet no wider than hip width apart. Extend arms out in front, palms facing forward. Keep the glutes engaged and weight firmly placed through the heels. Take a deep inhale. Then exhale slowly while tilting your head backwards, pulling your elbows towards your glutes as if to place them in your back pockets. As you move, arch your back while pushing up through the sternum to engage your core muscles. As you are doing this, gently guide your elbows down and back, imagining you are placing them "in your pockets". Allow the head to relax backwards. Hold for 2 seconds, remembering to breath, and slowly return back to a standing position. Repeat.

Chin Tuck
Look straight ahead. Pull the chin straight backwards towards the back of the neck while inhaling until a gentle stretch is felt in the back of the neck. Exhale as you come forward. The primary motion is pushing the entire head backwards, with only a slight tilt of the chin downwards. It can be help to practice this out of scrub. Doing this, you can place your finger on your and push straight backwards to guide your head in the appropriate motion.

Neck Rotation
Look straight ahead. Turn head to the right, hold for a moment. Return to center. Turn head to the left, hold for a moment. Return to center.

Squat with Truncal rotation (Chair pose with prayer)
With feet hip width apart, bring palms together in a prayer position. Deeply inhale, then slowly squat down pushing the buttocks back, as if sitting down in a chair while slowly exhaling. Avoid letting the knees in front of the ankles, and go only as low as can be maintained with control. Keep the chest up and slight arch to the back. Then, on an exhale slowly rotate the torso to the left as far as can be comfortably done without moving the hips and continuing to breath. Return to center, then do this motion to the right. Return to center, and rise to a stand.

Forward Bend
Stand straight up, feet hip width apart. Cross arms. Engage the glutes and arch the back. With a slight bend in the knees, inhale and then on your exhale hinge forward at the hips until a stretch is felt in the hamstrings or the low back. Avoid rounding the back and avoid bringing arms close to legs. Stand up slowly keeping the glutes engaged and back straight.

Data Collection Sheet:

Baseline surgeon data:	
Age (years)	
Gender (male/female)	
Weight (lb.)	
Height (in.)	
Dominant hand (right/left)	
Years practicing surgery since residency	
Number of cases performed per year	
Number of hours exercising per week in the past month (hrs)	
Data for each surgery day:	
Surgeon BPDS score at beginning of day	
Surgeon BPDS score at end of day	
Surgeon SURG-TLX score at end of surgery day	
Data for each surgery:	
Hysterectomy performed	

Route of Surgery	
Operative time (surgery start time to surgery stop time)	
Intraoperative complications	
Exit survey:	
The intraoperative exercises helped to reduce discomfort: (strongly disagree/disagree/agree/strongly agree)	
It was easy to understand the exercises as demonstrated in the video: (strongly disagree/disagree/agree/strongly agree)	
It was easy to understand the exercises as demonstrated in the PDF document: (strongly disagree/disagree/agree/strongly agree)	
I had to modify the exercises as demonstrated in the PDF document: (strongly disagree/disagree/agree/strongly agree)	
The intraoperative exercises did NOT disrupt the workflow in the operating room: (strongly disagree/disagree/agree/strongly agree)	
I will perform the intraoperative exercises (or some modification of them) in my future practice (strongly disagree/disagree/agree/strongly agree)	
I developed a work-related musculoskeletal disorder during the course of the study: (No/yes)	
Please provide any comments or suggestions to improve the feasibility of this research protocol from your perspective as a participant	

SUBJECT POPULATION

12 Protected Subject Populations

Click on the check box (or double click and type an "X" if using Google Docs) each population, if they are specifically studied for this research.

☐	Active military personnel	☐	Children	☐	Decisionally impaired adults
☐	Emancipated minors	☐	Fetuses	☐	Individuals with limited English proficiency
☐	Neonates	☐	Pregnant Woman	☐	Prisoners
☐	UT Students	☒	UT or Seton Staff/Employees		

13* Research Participant Information

Describe the research population.

**For multiple research populations (e.g., teachers, students, and parents), copy this section as necessary to describe your population.*

a Participant Group Name

To input text, click in the light grey area below.

Potential participants include residents, fellows, and attendings performing gynecologic surgery (including benign gynecologists, gynecologic oncologists, minimally invasive gynecologists, and urogynecologists). We will recruit surgeons from the Department of Women's Health at the University of Texas at Austin Dell Medical School.

b Minimum Age

To input text, click in the light grey area below.

18

c Maximum Age

To input text, click in the light grey area below.

75

d Inclusion Criteria

To input text, click in the light grey area below.

- Residents, fellows, and attendings performing gynecologic surgery (including benign gynecologists, gynecologic oncologists, minimally invasive gynecologists, and urogynecologists) who are able to perform the exercises.
- Surgery days must contain at least one gynecologic surgery with two hours of total operating time in one day.
- Surgeons will need to have operated on average at least 2 days per month over the last 12 months.

e **Exclusion Criteria**

To input text, click in the light grey area below.

Participants will be excluded if they are unable to perform the exercises.

f **Additional Population Information**

To input text, click in the light grey area below.

14 **Total Sample Size**

To input text, click in the light grey area below.

This study will recruit at least 20 surgeons. Each surgeon will complete at least 10 surgery days with the intervention and at least 10 surgery days without the intervention, which will yield at least 20 surgery days.

15 **Sample size rationale**

To input text, click in the light grey area below.

Using G*Power, we computed the required sample size to detect a medium effect with the specified parameters: **power=0.85, α=.05, *f*=0.25,** and measurements = 10. This yielded a total sample size of at least 20 surgeons, where each surgeon completes 10 surgery days with the intervention and 10 surgery days without the intervention, with a minimal total of 20 surgery days.

SCREENING AND RECRUITMENT

16 **Identification and Screening**

Click on the check box (or double click and type an "X" if using Google Docs) if true.

☐ **This study involves obtaining information or biospecimens for the purpose of screening, recruiting or determining eligibility of prospective subjects prior to informed consent by either:**

1. Oral or written communication with the prospective subject or LAR
2. By accessing records containing identifiable private information or stored identifiable biospecimens.

17 **Identification and/or Screening Procedures**

Describe the identification and/or screening procedures below.
To input text, click in the light grey area below.

Surgeons (residents, fellows, and attendings performing gynecologic surgery) will be identified from the Department of Women's Health at the University of Texas at Austin

Dell Medical School. Surgery days for each enrolled surgeon will be screened for inclusion. Surgery days containing at least one gynecologic surgery with two hours of total operating time in one day are eligible for inclusion. The eligible surgery days with then be randomized to standard surgery days or surgery days with the intervention (microbreaks with exercises).

18 **Recruitment Overview**

Click on the check box (or double click and type an "X" if using Google Docs) all recruitment methods utilized for this research.

☒	E-mail	☐	Flyer
☒	In-Person	☐	Letter
☐	Social Media	☐	Research Pool
☒	Telephone/Text	☐	Snowball Sampling
☐	Web-post	☐	Word of Mouth

19 **Describe the recruitment process, including where recruitment will take place.**

Describe the recruitment procedures below.
To input text, click in the light grey area below.

Surgeons (residents, fellows, and attendings performing gynecologic surgery) will be recruited from the Department of Women's Health at the University of Texas at Austin Dell Medical School. Information about the study will be presented to the gynecologic surgeons and all eligible surgeons will be asked to participate. Participation is voluntary and surgeons are not required to participate.

OBTAINING INFORMED CONSENT

20 **Consent Overview**

Click on the check box (or double click and type an "X" if using Google Docs) all applicable items.

☒	Obtaining Written Informed Consent	☐	Requesting a Waiver of Documentation of Informed Consent

☐ **Requesting a Waiver of Informed Consent**

☐ **Requesting an Alteration of the Required Elements of Informed Consent**

☐ **Obtaining Child Assent**

☐ **Obtain Consent Using a Short Form with a Witness**

21 **Consent and Assent Processes**

Provide a detailed description of the consent process including who will obtain consent, where, and when consent will occur in such a manner that participants have sufficient time for adequate consideration.

To input text, click in the light grey area below.

A member of the research team will obtain consent from all participating surgeons. Participants will have adequate time to review the consent form and consider participation.

22 **Consent and Translation**

Click on the check box (or double click and type an "X" if using Google Docs) to indicate that consent will be translated.

☐ **The study population will likely include participants whose limited English speaking status requires translation of the consent form.**

Translation Process

Click on the check box (or double click and type an "X" if using Google Docs) that best describes the translation process, either 21 or 22.

23 ☐ **The consent documents will be translated by a certified translator.**

24 ☐ **A non-certified translator will translate the consent documents.**

If selected, complete the next two questions below.

i **Describe the translator's qualifications**

To input text, click in the light grey area below.

ii ☐ **Another individual will confirm that the translation is accurate and appropriate.**

Waiver of Documentation of Informed Consent

To approve a waiver of documentation of informed consent, one of the following options below must be justified by the researcher.

Only complete the sections below if requesting a waiver of documentation of informed consent. *If not requesting a waiver of documentation of consent, skip to 27.*

Please choose one waiver option and provide additional information as prompted. The Office of Research Support and Compliance recommends using Waiver Option 2 in most cases.

25 Waiver Option 1

Provide confirmation for the following criteria and follow the additional instructions.

Additional Instructions:
1. Include this choice in the informed consent form.
2. Articulate the destruction process for signed consent forms in the privacy and confidentiality section.

Click on the check box (or double click and type an "X" if using Google Docs).

a ☐ **The only record linking the subject and the research would be the consent document.**

b ☐ **The principal risk would be potential harm resulting from a breach of confidentiality.**

c ☐ **Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.**

26 Waiver Option 2

Provide confirmation for the following criteria and follow the additional instructions.

Click on the check box (or double click and type an "X" if using Google Docs).

a ☐ **The study is minimal risk.**

b ☐ **Written consent would not be required outside the research context.**

27 Waiver Option 3

Provide confirmation for the following criteria and provide additional information as requested.

Click on the check box (or double click and type an "X" if using Google Docs).

a ☐ **The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm**

b **Describe the cultural group or community.**

To input text, click in the light grey area below

c ☐ **The research presents no more than minimal risk of harm to subjects.**

d ☐ **There is an appropriate alternative mechanism for documenting that informed consent was obtained.**

e **Describe mechanism for documenting that informed consent was obtained**

To input text, click in the light grey area below

Waiver or Alteration of Informed Consent

To approve a waiver or alteration of informed consent all of the following criteria below must be justified by the researcher.

Only complete the sections below if requesting a waiver of informed consent. *If not requesting a waiver or alteration of consent, skip to 31.*

28 **The research involves no more than minimal risk to the subjects.**

To input text, click in the light grey area below

29 **The waiver or alteration will not adversely affect the rights and welfare of the subjects.**

To input text, click in the light grey area below

30 **The research could not practicably be carried out without the waiver or alteration (it is impracticable to perform the research if obtaining informed consent is required and not just impracticable to obtain consent).**

To input text, click in the light grey area below

31 **If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.**

To input text, click in the light grey area below.

Deception and Debriefing

Only complete the sections below if requesting an alteration of informed consent that involves deceiving research participants. *If this study does not involve deception, skip to 35.*

See IRB Policies and Procedures Section 15 for a description of deception.

Click on the check box (or double click and type an "X" if using Google Docs).

32 ☐ **It is appropriate to provide additional pertinent information to the subject after research activities are complete (e.g., the researcher needed to deceive to subject to the nature of the study).**

33 ☐ **Research participants will have the opportunity to withdrawal their data during the debriefing.**

34 **Describe the nature of deception and why it is necessary to conduct the research.**

To input text, click in the light grey area below.

35 **Describe debriefing procedures.**

To input text, click in the light grey area below.

BENEFITS

36 **Benefits to Society**

Describe the scientific and societal benefit(s) below.

To input text, click in the light grey area below.

This study may provide a model for intraoperative breaks and exercises that gynecologic surgeons can use to decreased work-related discomfort. This could potentially mitigate the risk of work-related musculoskeletal disorders and the impact these conditions have on the workforce.

Benefits to Participants

Click on the applicable check box (or double click and type an "X" if using Google Docs).

37 ☐ **There is no anticipated direct benefit to participants.**

38 ☒ **There are anticipated benefits to participants.**

39 **If applicable, describe the potential direct benefits to participants.**

To input text, click in the light grey area below.

Participants may directly benefit from the intervention and may experience decreased work-related pain or discomfort.

RISKS

40 **Describe the risks associated with each activity in this research**

To input text, click in the light grey area below.

Participants are at risk for musculoskeletal injury from the exercises and stretches that are performed in this study.

Surgeries performed during this study may include a surgical lasting approximately 1.5-2 minutes. This could potentially increase the operative time of procedures, although prior studies have shown that there is no significant difference in operative time with the institution of microbreaks[7].

41 **Describe how each risk is mitigated/minimized.**

To input text, click in the light grey area below.

The risk of musculoskeletal injury are mitigated by ensuring that exercises and stretches included in this study are gentle and can be performed with minimal strain and exertion. The exercises were developed with the assistance of a physician specialized in Physical Medicine and Rehab.

To ensure that surgical microbreaks do not interfere with patient safety, microbreaks with exercises will only be performed if it is safe. Surgeons will remain sterile during the microbreak and can respond promptly to any patient concerns during the microbreak. The surgeon can stop or skip microbreaks at any point in the study if it is deemed unsafe.

Data Safety Monitoring

For additional information regarding data safety monitoring boards and data safety monitoring plans, please see Section 21 of our Policies and Procedures.

Click on the check box (or double click and type an "X" if using Google Docs).

42 ☒ **In the investigator's opinion, this study is minimal risk and does not require a Data Safety Monitoring Plan (DSMP) or a Data Safety Monitoring Board (DMSB).**

PLEASE NOTE: The IRB may determine minimal risk studies do require data safety monitoring under certain circumstances (e.g., if there is a known risk with an expected frequency).

43 ☐ **This study does not have a Data Safety Monitoring Board, but researchers have an internal plan/policy to monitor for safety.**

Complete Data Safety Monitoring Details (44-51).

44 ☐ **This study has a Data Safety Monitoring Board (DSMB).**

Complete Data Safety Monitoring Details (44-51) or upload this study's Data Safety Monitoring Board's charter.

Data Safety Monitoring (Details)

45 **How is safety information collected?**

To input text, click in the light grey area below.

46 **When will safety data collection start (for each participant or for the whole study, as applicable)?**

To input text, click in the light grey area below.

47 **How frequently will safety data be collected?**

To input text, click in the light grey area below.

48 **Who will review the data for safety?**

To input text, click in the light grey area below.

49 **How frequently will data be monitored for safety concerns?**

To input text, click in the light grey area below.

50 **What data will be reviewed?**

To input text, click in the light grey area below.

51 **State the frequency or periodicity of the review of cumulative data?**

To input text, click in the light grey area below.

52 **State any conditions that would trigger an immediate suspension of the research.**

To input text, click in the light grey area below.

Early Withdrawal

Only complete this section if there are planned conditions under which a participant will be withdrawn from the study. *If not applicable, skip to 56.*

Include this information in your consent form.

53 **List the criteria for withdrawing individual participants from the study (e.g., safety or toxicity concerns, emotional distress, inability to comply with the protocol, or requirements from study sponsor).**

To input text, click in the light grey area below.

Participants that develop a work-related or sports-related injury during study period must withdraw to prevent worsening of injury from exercises/stretches required as part of the study.

54 **Describe any necessary procedures for ensuring the safety of a participant who has withdrawn early.**

To input text, click in the light grey area below.

If a participant develops a work-related or sports-related injury as defined by the above criteria, he or she should withdraw from the study and follow-up with a provider regarding the injury.

55 **Describe any pre-specified criteria for stopping or changing the study protocol due to safety concerns.**

To input text, click in the light grey area below.

There is no pre-specified criteria.

REQUIRED DISCLOSURES

Required Consent Disclosures

Identify each element below that may require additional information to be disclosed in the consent form.

Click on the check box (or double click and type an "X" if using Google Docs).

56 ☐ **It is reasonable that researchers could discover or suspect child or elder abuse.**

57 ☐ **It is reasonable that researchers could learn of an incident that could require reporting under Title IX.**

58 ☐ **It is reasonable that researchers could discover incidental findings or other information of medical interest about a participant's previously unknown condition.**

59 **Articulate methods for addressing and reporting incidental findings, if applicable.**

To input text, click in the light grey area below.

PRIVACY AND CONFIDENTIALITY

60 **Privacy**

Describe how you will protect the identity and privacy of study participants during each phase of research. Privacy focuses on the individual participants rather than data. In this section, researchers should focus on issues such as where research activities take place and how participant involvement is protected from non-participants.

Describe methods to ensure participants' privacy during identification, recruitment, screening, the consent process, the conduct of the study, and dissemination of data.

To input text, click in the light grey area below.

Surgeons (residents, fellows, and attendings performing gynecologic surgery) will be identified from the Department of Women's Health at the University of Texas at Austin Dell Medical School. Participants with be introduced to the study and interested participants will be assessed for inclusion. Written informed consent will be obtained by the PI.

Data will be collected and stored in our institution's REDcap, a secure electronic application for research.

UT Austin policies for Protected Health Information will be followed. There will not be any patient PHI data collected in this study however. There will be a spreadsheet source to de-identify the participants that will be kept on a password protected, encrypted USB drive with access only by the fellow collecting the data. All participant data will be deidentified as it is stored in REDcap. Note, the participants are not patients. The data will be kept for the required 6 years after completion of the study and then destroyed.

Confidentiality and Data Security Plan

Click on the check box (or double click and type an "X" if using Google Docs) that best describes the confidentiality and data security plan and provide additional details regarding how you will protect the confidentiality of data or address confidentiality concerns.

61 ☒ **Identifiers will be coded to protect confidentiality.**

61a If true, state how data is coded and where identifiers are stored.

To input text, click in the light grey area below.

UT Austin policies for Protected Health Information will be followed. There will not be any patient PHI data collected in this study, however. There will be a spreadsheet source to de-identify the participants that will be kept on a password protected, encrypted USB drive with access only by the fellow collecting the data. All participant data will be deidentified as it is stored in REDcap. Note, the participants are not patients. The data will be kept for the required 6 years after completion of the study and then destroyed.

62 ☒ **Identifiable data will be destroyed.**

62a If true, describe destruction plan and timeline

To input text, click in the light grey area below.

The data will be kept for the required 6 years after completion of the study and then destroyed.

63 ☐ **Identifiable data will not be destroyed.**

63a If true, provide rationale for retaining identifiable data indefinitely.

To input text, click in the light grey area below.

64 Data Access

Click on the check box (or double click and type an "X" if using Google Docs) for each group of individuals that will have access to study data.

If you plan on creating a repository, complete the repository form as well.

☒	Study Team Members	☐	External Collaborators	☐	Data coordinating center
☐	Sponsor	☐	Future Sharing with other researchers		

☐ **Others**

Describe below. To input text, click in the light grey area below.

65 Describe data sharing plan for each group checked above and state whether researchers plan on sharing identifiable, coded, or de-identified data

To input text, click in the light grey area below.

Study team members will have access to deidentified data. Data will not be shared with any other institution or non-study team members.

Certificate of Confidentiality

Click on the check box (or double click and type an "X" if using Google Docs) to identify each element below that may require additional information to be disclosed in the consent form.

If a Certificate of Confidentiality is not applicable for this study, skip to 68.

66 ☐ **The study requires a Certificate of Confidentiality.**

67 ☐ **NIH has issued a Certificate of Confidentiality for this study.**

68 ☐ **A Certificate of Confidentiality has not been obtained, but there are plans to apply for one.**

COMPENSATION AND COSTS

Compensation

Click on the check box (or double click and type an "X" if using Google Docs).

69 ☐ **Subjects receive compensation.**

70 ☒ **Subject will not receive compensation.**

Skip to question 74 if subjects will not receive compensation.

71 **Total Amount of Compensation**

To input text, click in the light grey area below.

72 **Type of Compensation**

Click on the check box (or double click and type an "X" if using Google Docs) for each form of compensation that will be provided.

☐ Cash	☐ Check	☐ Gift Card
☐ Course Credit	☐ ClinCard	☐ Tango Card

☐ **Other**

Describe, To input text, click in the light grey area below.

73 **Proration Schedule**

To input text, click in the light grey area below.

74 ☐ **Amount of compensation and its form is reasonable for this population for the activities requested of them.**

75 **Costs**

Click on the check box (or double click and type an "X" if using Google Docs) each applicable item regarding costs.

☒ **Participants will have no costs associated with this study**

☐	Standard of care procedures contributing to study data	☐	Research procedures not associated with standard of care
☐	Administration of drugs / devices	☐	Study drugs or devices
☐	Transportation and parking		

76 **Describe all costs below.**

To input text, click in the light grey area below.

References:

1. Kim-Fine S, Woolley SM, Weaver AL, Killian JM, Gebhart JB. Work-related musculoskeletal disorders among vaginal surgeons. Int Urogynecol J. 2013;24(7):1191-1200.
2. Catanzarite T, Tan-Kim J, Menefee SA. Ergonomics in gynecologic surgery. Curr Opin Obstet Gynecol. 2018;30(6):432-440.
3. Epstein S, Sparer EH, Tran BN, et al. Prevalence of work-related musculoskeletal disorders among surgeons and interventionalists: a systematic review and meta-analysis. JAMA Surg. 2018;153(2):e174947
4. Plerhoples TA, Hernandez-Boussard T, Wren SM. The aching surgeon: a survey of physical discomfort and symptoms following open, laparoscopic, and robotic surgery. J Robotic Surg. 2012;6(1):65-72.
5. Park AE, Zahiri HR, Hallbeck MS, et al. Intraoperative “micro breaks” with targeted stretching enhance surgeon physical function and mental focus: a multicenter cohort study. Ann Surg. 2017;265(2):340-346.
6. Hallbeck MS, Lowndes BR, Bingener J, et al. The impact of intraoperative microbreaks with exercises on surgeons: A multi-center cohort study. Appl Ergon. 2017;60:334-341.
7. Englemann C, Schneider M, Kirschbaum C, et al Effects of intraoperative breaks on mental and somatic operator fatigue: a randomized clinical trial. *Surg Endosc* 2011; 25:1245–1250.
8. Kuorinka I, Jonsson B, Kilbom A, et al. Standardised Nordic questionnaires for the analysis of musculoskeletal symptoms. Appl Ergon. 1987;18(3):233-237.
9. Plerhoples TA, Hernandez-Boussard T, Wren SM. The aching surgeon: a survey of physical discomfort and symptoms following open, laparoscopic, and robotic surgery. J Robotic Surg. 2012;6(1):65-72.
10. Jones B, Kenward MG. Design and analysis of cross-over designs, 2nd edn. Chapman and Hall, London. 2003
11. Corlett EN, Bishop RP. A technique for assessing postural discomfort. Ergonomics. 1976;19(2):175-182.
12. Olendorf MR, Drury CG. Postural discomfort and perceived exertion in standardized box-holding postures. Ergonomics. 2001;44(15):1341-1367.
13. Wilson MR, Poolton JM, Malhotra N, Ngo K, Bright E, Masters RSW. Development and validation of a surgical workload measure: the surgery task load index(Surg-tlx). World J Surg. 2011;35(9):1961-1960.