

# F200: Application for Human Research

**PROJECT TITLE:** Effects of two psychosocial wellness workshops on sleep, stress management and well-being: Exploration of psychophysiological mechanisms

## INVESTIGATOR INFORMATION

Principal Investigator Name, Degree(s): John J.B. Allen, PhD

Affiliation:  UA     B-UMG     Other:

Principal Investigator **UA NetID**: John.JB.Allen

Status/Rank: Distinguished Professor

Center: \_\_\_\_\_

Department: Psychology

College: College of Science

Contact phone: 520-621-7448

Official Institutional Email: John.JB.Allen@arizona.edu

## ADVISOR CONTACT INFORMATION (REQUIRED FOR ALL STUDENTS AND RESIDENTS)

Name, Degree(s), **UA NetID**: \_\_\_\_\_

Contact phone: \_\_\_\_\_

Official University Email: \_\_\_\_\_

## ALTERNATE/COORDINATOR or Co-PI CONTACT INFORMATION

Name, **UA NetID**: Michael R. Goldstein, mgoldstein

Contact phone: 608-208-0016

Official University Email: mgoldstein@email.arizona.edu

## SECTION 1: REQUIRED SIGNATURES

### 1. PRINCIPAL INVESTIGATOR

I will conduct my study according to the University of Arizona HSPP policies and procedures for research with human subjects.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name

### 2. ADVISOR (FOR ALL STUDENTS AND RESIDENTS ACTING AS THE PI)

I will oversee the student researcher according to the University of Arizona HSPP policies and procedures for research with human subjects.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name

### 3. SCIENTIFIC/SCHOLARLY REVIEW (SEE HSPP GUIDANCE ON REQUIREMENTS FOR SCIENTIFIC/SCHOLARLY ASSESSMENT - INCLUDE DOCUMENTATION FOR OPTIONS A AND B WITH SUBMISSION MATERIALS.)

- a.  Nationally based, federal funding organization (NIH, NSF) subject to full peer review  
b.  Nationally based, non-federal funding organization (March of Dimes, Amer Academy of Pediatrics) subject to peer review  
c.  Locally constituted peer review (signature required)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name

### 4. DEPARTMENT/CENTER/SECTION REVIEW

I have reviewed this application and determined that all departmental requirements are met and that the investigator has adequate resources to conduct the Human Research.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name/Email

### 5. RESPONSIBLE PHYSICIAN (PROJECTS INVOLVING MEDICAL PROCEDURES WHICH THE PI IS NOT AUTHORIZED TO CONDUCT)

I am a physician licensed by the State of Arizona (or US license for the SAVAHCS). I will be responsible for ensuring that all procedures that are part of this project and that require the attendance of a licensed physician will have a suitable physician present during the procedures. If at any time this is not possible, I will inform the IRB before any procedures are conducted.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name

### 6. NATIVE AMERICAN OR INTERNATIONAL INDIGENOUS POPULATIONS REVIEW

Signature needed only if research takes place in Indian Country or among international Indigenous populations, actively recruits Native Americans or international Indigenous populations for enrollment, and/or requires stratification of Native Americans or international Indigenous populations as one of the statistical analyses or study aims.

- Contact American Indian Studies, (520) 621-7108

I have examined the proposal cited above and advise that further appropriate tribal/Indigenous approval  is or  is not necessary.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name

## SECTION 2: GENERAL INFORMATION

1. How many Human Research studies does the PI have open?

**8**

2. How many research staff will be involved in the Human Research?

**3**

3. What is the expected length of this project?

**18 months**

4. Retention of study materials before, during, and after completion of the project:

a. Where will original signed consent and PHI Authorization documents be stored (building name and room)? Location:

**Psychology room 312**

How long will consents be maintained after conclusion of the project?

6 years (UA standard)  6 years after child reaches 18  Other (explain):

5. Project funding - If the proposed study is or will be funded, complete below:

a. UAccess

i. Development Proposal #:

ii. Institutional Proposal #: 4206880

b. eDoc # (Required for For-profit sponsored research):

c. Total funding amount **OR** per subject amount: **\$15,000 from the Mind & Life Institute (Varela Award to Michael Goldstein)**

*Submit complete copy, cover-to-cover, of grant or award.*

6. Conflict of Interest (COI):

The Principal Investigator hereby affirms that ALL individuals who meet the definition of [investigator](#) for this project in the current *Policy on Investigator Conflict of Interest in Research* have completed the mandatory [Conflict of Interest training](#) and [Disclosure of Significant Financial Interests](#).

Yes - All individuals who meet the definition of "investigator" have completed COI training and disclosure.

No (explain):

7. Additional requirements:

Certain types of research require additional regulatory documentation. Please identify which of the following apply to your project. Complete the appropriate Appendix and submit as part of the submission materials.

Children (subjects under 18) - Appendix A

Drugs/Devices (A clinical investigation of a drug or device) - Appendix B

Multi-Site study (The UA IRB will review research activities for an investigator or research staff not affiliated with the UA who is 'engaged in the research' (e.g. consenting, collecting data, or analyzing identifiable information) - Appendix C

Pregnant Women/Neonates - Appendix D

Prisoners - Appendix E

Waivers of consent, waiver of a signature, or waiver or alteration of PHI - Appendix F

None apply to the proposed study

8. Location of Research **Check all that apply**

Banner – University Medicine Group:

- Phoenix Campus
- Tucson Campus
- South Campus

- Biological specimens
- Biological specimens
- Biological specimens

- Clinical Data
- Clinical Data
- Clinical Data

University of Arizona Cancer Center:

- North Campus
- Orange Grove Clinics
- Phoenix

- Biological specimens
- Biological specimens
- Biological specimens

- Clinical Data
- Clinical Data
- Clinical Data

Other: University of Arizona, Department of Psychology (Biological specimens)

**SECTION 3. PROJECT NARRATIVE**

**1) Background**

The transition from adolescence to adulthood, particularly for college students, is accompanied by several major life changes and challenges. For many individuals, this is a period when one moves away from home, begins interacting with different peer groups, and has greater financial and academic responsibilities. The emotional stress associated with these changes is correlated with less time devoted to sleep,<sup>1</sup> increased alcohol intake,<sup>2</sup> reduced academic performance,<sup>2,3</sup> and increased rates of anxiety disorders and/or depression.<sup>4</sup>

Your Enlightened Side (plus more) (YES+) is a life skills workshop with a strong emphasis on breathing practices for reducing stress and increasing well-being. Additional stress management tools including meditation, yoga, and interpersonal exercises that impart social emotional learning skills and stress reduction strategies complement the breathing techniques.

The central practice taught in YES+ is a unique rhythmical breathing technique called Sudarshan Kriya.<sup>5</sup> It is taught along with two preparatory breathing practices: an advanced form of *Ujjayi* breathing (breathing against airway resistance) and *bhastrika* (forceful nasal breathing). Collectively, these three breathing practices are referred to as Sudarshan Kriya Yoga (SKY).

Prior literature has demonstrated significant improvements in psychological and physiological outcomes of SKY in adults, including decreases in subjective stress,<sup>6</sup> clinical and subclinical depression and anxiety,<sup>6-8</sup> posttraumatic stress symptoms,<sup>9-11</sup> impulsivity,<sup>12</sup> and tobacco use,<sup>13</sup> as well as increases in calm, mental focus,<sup>14</sup> emotion regulation,<sup>15,16</sup> and overall well-being.<sup>6,17</sup>

However, little is known about the effects of SKY specifically taught in the YES+ workshop format designed for college students. One randomized controlled trial has demonstrated attenuated levels of subjective stress and several hematological parameters, including lymphocytes and platelet count, during exam periods following SKY training.<sup>18</sup> These findings have not yet been replicated, and the extent to which the effects of YES+ generalize to other health-related changes such as cardiovascular function remain unclear.

## 2) Purpose

Addressing the gap in the literature described above and to provide further preliminary data on the specific effects of YES+ on well-being and stress physiology, this study aims to evaluate measures of self-reported wellness across a variety of questionnaires, in addition to changes in heart rate variability and salivary cortisol levels with a stress induction task. To control for expectancy effects, overall time spent with the workshop, social contact, and exposure to cognitive stress management strategies that may influence the observed effects of YES+ not specific to the yogic breathing and deep social connectedness at the core of the YES+ targets, a comparison workshop with all of these potential supplementary contributors will be included, titled “Wisdom On Wellness” (WOW!).

## 3) Lay Summary (approximately 400 words)

While efficacy of Sudarshan Kriya Yoga (SKY) has been demonstrated in a number of prior studies, little is known about the effects of SKY taught as part of the Your Enlightened Side (YES+) workshop designed for college students. Thus, this study aims to assess the effects of YES+ on well-being, including sleep patterns, and physiological stress response.

## 4) Setting of the Human Research

Laboratory visits will be conducted in the Respiratory Physiology laboratory of Dr. Fiona Bailey, located in room 44 of the Ina Gittings Building (University of Arizona main campus). This room is set up for human subject experiments and is the site at which the Dr. Bailey has conducted all previous research involving human participants.

Workshops will be conducted on the UofA campus in a room reserved through the Psychology Department or other campus reservation procedures.

## 5) Resources available to conduct the Human Research

Professor Allen’s psychophysiology research laboratory (University of Arizona, Psychology Building, Room 409) has extensive experience with similar research protocols. Additional resources will be provided through collaborations with the Psychology Department’s Sleep Research Laboratory, which has more than 20 Actiwatches, a downloading station, and relevant software, as well as the Physiology Department’s Respiratory Physiology Laboratory, where the necessary resources are available for the laboratory visits. These resources include dedicated computers and software from Grass/Telefactor for electrocardiogram (ECG) data acquisition, processing, and analysis. In addition, the University of Arizona maintains full computer and data analytic processing components available to all university faculty on a fiber-optic network system, with automatic daily backup available on a secure server.

## 6) Study Population

**100 college students** (50% female) will be recruited into the current study. Persons expressing interest in the study will be screened along several health dimensions and invited to participate in the proposed research according to the following criteria:

- a) 18-35 years of age. This age range is recommended for the YES+ workshop to capture qualitative consistencies in the unique challenges that face college students and optimize social connectedness during the workshop.
- b) Current identification with student status, which may include undergraduate, graduate, continuing studies, or post-baccalaureate/pre-doctoral.
- c) No history of panic disorder, psychosis, or mania (with or without psychotic features), which may be risk factors for adverse effects of the yogic breathing intervention. These symptoms will be pre-screened via online questionnaire. The use of psychoactive medication will be monitored via sleep diary.
- d) No current substance dependence, assessed via online self-report pre-screening questionnaire.
- e) No current use of medications with known effects on sleep or stress physiology including antidepressants (SSRI, SNSI, NDRI, atypical, TCA, MAOI), antipsychotics, benzodiazepines, non-benzodiazepine receptor agonists, melatonin and melatonin receptor agonists, orexin/hypocretin receptor antagonists, barbiturates, mood stabilizers, anticonvulsants, anticholinergics, first generation antihistamines, and stimulants including NRI, antihypertensives, opioids, or systemic (non-topical) corticosteroids.

In addition, a total of **4 workshop instructors** are expected to enroll in this study to provide questionnaire information regarding expectancy of workshop benefit for participants. All instructors must have prior training with the specific workshop to be led.

## 7) Recruitment Methods and Consenting Process

### a. Recruitment Process:

Potential participants will be recruited primarily through the University of Arizona campus and broader Tucson communities. Potential subjects will be identified through targeted placement of study flyers in campus and community locations (e.g. bookstores, coffee shops, and community centers), and through placements of ads on websites (e.g. Facebook) and University listservs (University of Arizona 3D Memos, Lo Que Pasa, Psychology Department Graduate Student Listserv, etc.). Flyers and other advertisement may include the following language:

--

**Research participants wanted!**  
*Student Wellness Workshops*

With an aim to help students **reduce stress** and **enhance well-being**, the University of Arizona Psychophysiology Research Laboratory is investigating the effects of two innovative workshops on wellness and stress physiology.

Participation involves:

- Online questionnaires
- Three laboratory visits (approximately one hour each)
- Measurement of sleep patterns with a wrist-worn device
- Attendance at one workshop held across four consecutive days (Thurs & Fri evenings, Sat & Sun mid-day)

Compensation provided!

If you are a student 18-35 years of age, you may qualify! Invite friends to participate, too!

E-mail [mgoldstein@email.arizona.edu](mailto:mgoldstein@email.arizona.edu) for more info!

An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

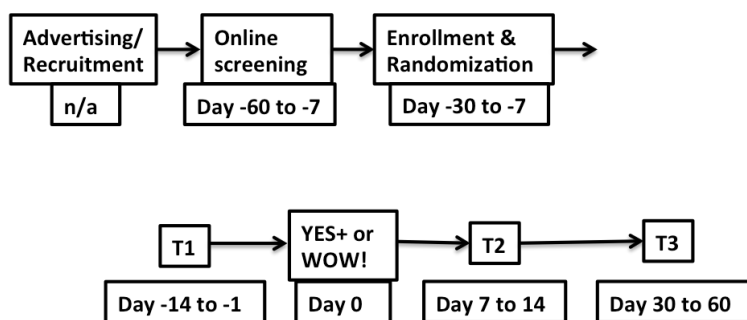
--

**b. Informed Consent:**

All interested individuals who are eligible for the study will undergo an in-person informed consent procedure prior to the first laboratory visit. Subjects, including workshop instructors, will be assigned identifying numbers and the association between the numbers and names will be destroyed upon completion of the study. No minors or individuals incompetent to provide informed consent will participate in the present study. They will be reminded that their participation in the study is entirely voluntarily, they may withdraw at any time, and they will be compensated for their time.

**8) Research procedures involved in the Human Research**

An overview of the study involvement is illustrated in Figure 1. Participation will include three laboratory visits at pre-workshop (T1), post-workshop (T2), and 1-2 month follow-up (T3) time points and four workshop sessions described below.



**Figure 1.** Overview of study timeline for each participant.

*Screening:* Interested participants will first be directed to an online pre-screening survey. The survey will begin with a prompt describing the study and requiring understanding via checkbox that the survey is for screening purposes. The survey will collect information such as name, e-mail address, date of birth, motivation for the study, student status, prior contemplative practice experience, ability to meet the time commitment, panic and bipolar symptoms, and potential affiliation with other

participants. If any of the exclusion criteria indicated above are met, the participant will be notified of ineligibility.

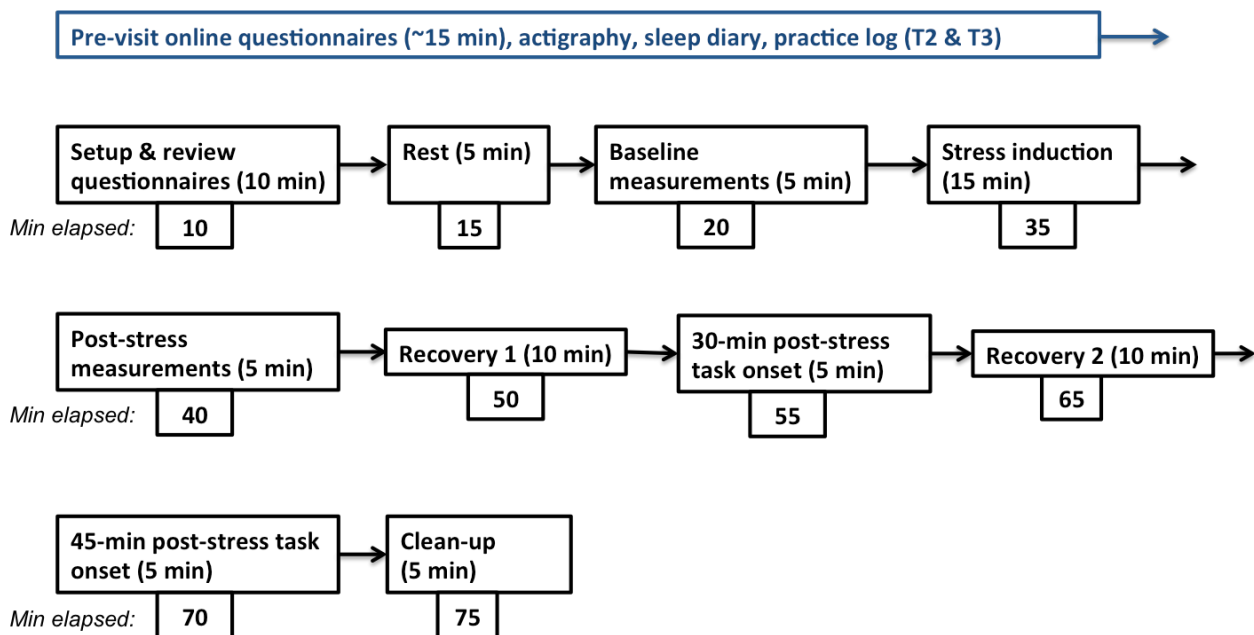
*Enrollment and randomization:* Eligible participants will be first grouped in clusters with any other participants with known affiliations stated in the online screener, in order to minimize possibility of learning about material of the other workshop, then assigned a workshop via random number generator.

*Laboratory Visits:* In-person laboratory visits will be conducted at the University of Arizona Respiratory Physiology Laboratory on the main UA campus. Workshops will be conducted in various buildings on the main UA campus depending on reservation availability.

Actigraphy, sleep diary, online questionnaires and practice logs measures will be completely remotely after the instruments are provided to participants during an in-laboratory visit.

In addition to actigraphy, sleep diary, online questionnaires, and home practice logs (for T2 and T3 time points) the following data will be collected during each laboratory visit: electrocardiography (ECG) with concurrent respiratory inductance plethysmography (RIP) and pulse oximetry recordings, as well as salivary cortisol at baseline, post-stress induction task, 30-min post-stress-induction-onset, and 45-min post. ECG, RIP belts, and pulse oximetry will be recorded continuously, in addition to the designated resting recording periods. An overview of the laboratory visit (identical across T1, T2 and T3) is provided in Figure 2.

*Workshop evaluations:* Both workshop participants and instructors will complete a brief questionnaire at two time points (end of Day 1 and end of Day 4) during the workshop to indicate expectation of workshop benefit.



**Figure 2.** Overview of each laboratory visit for data collection.



***Intervention conditions:***

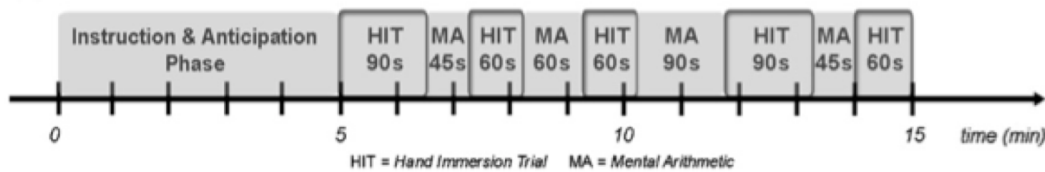
**YES+ workshop.** Your Enlightened Side, plus more (YES+) is an four-day, 15-hour eclectic life skills workshop with a strong emphasis on breathing techniques and social connectedness to enhance stress management, intervene in the potential negative behavioral cycles, and improve overall well-being. In addition to specific contemplative techniques such as yoga, mindfulness meditation, and compassion meditation that help cultivate inner peace, YES+ incorporates discussions and other activities to facilitate social connectedness, leadership, and community service.

During the workshop, participants will have ample time to learn and practice the Sudarshan Kriya Yoga (SKY) technique, as well as to ask questions. SKY has four sequential, form- and rhythm-specific breathing components interspersed with normal breathing while sitting in a relaxed position with eyes closed, followed by Yoga Nidra (tranquil state of rest) for 10-15 minutes in a supine position, yielding a total duration of approximately 30 minutes for the entire home practice. A longer version of SKY will be practiced as a group twice during the workshop. Following the workshop, participants will be instructed to practice SKY at home daily. A certified instructor with a minimum of 1,000 hours of SKY instruction training will lead each workshop.

**WOW! workshop.** A comparison workshop titled “Wisdom On Wellness” (WOW!) will be implemented to control for potential expectancy effects, time commitment, group-based interactions, and wisdom/knowledge of YES+ that is anticipated to have beneficial effects on stress management and well-being, allowing for more rigorous evaluation of the contemplative practices and other activities unique to the YES+ workshop. The material used to guide interactions in WOW! will be similar to the material of YES+ and will be taught by a trained instructor with supervision by the Principal Investigator and Study Coordinator. This workshop differs from YES+ due to the increased focus on cognitive approaches to conceptualizing and managing stress (e.g. thoughts about the past and future versus present moment), and absence of physical or somatic activities. Using a focus group format, whereby the instructor primarily facilitates discussion, a variety of topics will be covered such as the nature of stress for humans, response to stressful events, time management, study skills, alcohol and drug use, personal values, career exploration, sleep habits, and nutrition.

***Experimental manipulations:***

**Stress Induction.** The Maastricht Acute Stress Test (MAST), a previously described and increasingly used stress induction task,<sup>19,20</sup> will be utilized. A research staff member in a white laboratory coat will explain that the session will be video-recorded to then be coded afterwards by trained raters, provide background information regarding performance norms, and express an expected ability of the participant to perform comparably. Next, the researcher will provide instructions for the task that will be guided by a Powerpoint presentation. The MAST consists of a 10 minute acute stress phase that combines elements of both the commonly used Cold Pressor Test and Trier Social Stress Test, adding an element of uncertainty by cycling between these two tests at slightly unpredictable time intervals (Figure 3). For the hand immersion trials (HIT), participants will insert their dominant hand and wrist in a bucket of ice water (approximately 2° C) for up to 90 seconds. Participants are instructed they may remove their hand at any time. Upon removal, participants will place their hand on a towel and immediately begin a serial subtraction task, for which participants will be instructed to count backwards by 13, 17, or 18 from a randomly selected number between 2013 and 2073, with interjections to start over from the beginning if any calculations are incorrect. Neutral or negative feedback will be provided throughout the task, including comments such as “That’s wrong. Start over” and “You’re going too slowly.”



**Figure 3.** Overview of Maastricht Acute Stress Test (MAST). Adapted from Smeets et al., *Psychoneuroendocrinology*, 2012.

**Measures:**

**Sleep diaries.** Participants will be instructed to fill out a sleep diary for one week at each of the three time points. The sleep diary includes entries for the time that participants go to bed, turn off the lights, awake in the morning, and arise from bed in the morning. Participants also record sleep onset latency, the number and duration of awakenings, and quality of sleep (1 = very restless to 5 = very sound). From these items, the following weekly average sleep summary parameters will be computed: total sleep time (TST), time in bed (TIB), wake time after sleep onset (WASO), number of awakenings, sleep-onset latency (SOL), sleep quality, time of going to bed in the evening, time the lights are turned out with the intention to sleep (lights-out time), wake time in the morning (awakening time), time of getting out of bed in the morning (arising time), and sleep efficiency (SE) which is TST divided by sleep period time; the time from lights out to lights on at arising.

**Actigraphy.** Concurrent with the sleep diaries, participants will be instructed to wear a wrist Actiwatch (Philips Respironics) from the time of getting into bed until the time of getting out of bed for one week. Participants will be instructed to press a button on the face of the Actiwatch that serves as an event marker in the downloaded data on two occasions during each sleep period: when participants intend to fall asleep and when they awaken for the final time at the end of their sleep period. These markers serve as measures of lights-off and lights on times, providing outside boundaries for subsequent calculation of sleep onset and offset. When this is not done, the estimated lights-off and lights-on times given by the participant in their sleep diaries will be used. Sleep onset will be defined as the beginning of the first 5 min of contiguous quiescence with less than 30 sec of any recorded activity counts that occur after lights-off time as used in. Once lights off, lights on, sleep onset, and sleep offset are established, these four values will be entered into a sleep-scoring algorithm to identify WASO, and to calculate the sleep indexes of SOL, TST, and SE. In addition to providing an objective measure of sleep variables, actigraphy has been particularly useful in documenting sleep-wake circadian patterns.

**Questionnaires.** Participants will be asked to complete a custom survey inquiring about information such as GPA and self-rated stress of specific situations, as well as the Morningness-Eveningness Questionnaire (MEQ)<sup>21</sup> with an online format at T1. In addition, participants will be asked to complete a custom survey inquiring about information such as current stress-management techniques, the short-form Mood and Anxiety Symptom Questionnaire (MASQ),<sup>22,23</sup> Perceived Stress Scale (PSS),<sup>24</sup> Pittsburgh Sleep Quality Index (PSQI),<sup>25</sup> Big Five personality inventory (Big-5),<sup>26</sup> Rosenberg Self-Esteem Scale (RSES),<sup>27</sup> Satisfaction With Life Scale (SWLS),<sup>28</sup> and Social Connectedness (SC)<sup>29</sup> measures online for all three time points. During each laboratory visit, participants will also be asked to complete the state-specific items of the State-Trait Anxiety Inventory (STAI).<sup>30</sup>

**Electrocardiogram (ECG) measures.** Individual electrodes will be placed at collarbone and lower ribcage locations to collect ECG recordings. Participants will be instructed to sit quietly for 2 minutes for each of the four resting recordings (baseline, post-stress, 30-min-post, 45-min-post). ECG data will then be processed to determine measures including resting heart rate (HR), heart rate variability (HRV), and

respiratory sinus arrhythmia (RSA). Supplementary HR data will be collected via pulse oximetry, a device consisting of a soft clip placed around the participant's pointer finger. To control for respiration that may influence HR data, respiratory inductance plethysmography will be recorded concurrently via two adjustable belts placed around the participant's abdomen, one passing around the sternum and the other passing around the navel. As an additional covariate of Body Mass Index (BMI) for ECG analysis, height and weight will also be measured at each laboratory visit.

**Salivary cortisol.** In conjunction with the ECG recordings, saliva samples will be collected using Salivettes (Sarstedt, Nümbrecht, Germany). Participants will be instructed to avoid particularly stressful activities or events on the day of the laboratory visit prior to data collection in order to minimize potential effects on cortisol secretion and maximize data specific to the stress-induction task. In addition, participants will be asked to refrain from drinking, eating, and any dental hygiene for the 15 minutes prior to the arriving for the laboratory visit, which will also be confirmed verbally prior to the first sample collection. Following data collection, samples will be stored in a freezer at -70 °C on the University of Arizona campus. Samples will then be de-identified and shipped to an independent site for high sensitivity enzyme-linked immunosorbent assay (ELISA) preparation.

**Visual Analog Scales (VAS).** To assess momentary stress-related ratings, Visual Analog Scale (VAS) measures will be collected throughout each laboratory visit. VAS measures will include items such as "discomfort/pain" and "distress" with a 0-100 scale corresponding to low and high values for each item. One of the two researchers conducting the experimental session will present a whiteboard with the scales to the participant at each measurement point and will ask the participant to simply wipe a single point along the temporarily drawn horizontal line for each scale. The score for analysis will be the nearest 5-pt value on a scale of 0 to 100 (e.g. 35) of the wiped mark, judged by the researcher. The researcher will transfer the two rating scores to a recording sheet, erase both temporary lines, and redraw them using a straight-edged guide to be ready for the next measurement. The whiteboard with each of the participant's ratings (wiped marks) will be visible to the videorecorder in case time between measurements (e.g. during the MAST) does not allow for transfer of the information to the recording sheet while the experiment is in progress.

**Workshop expectancy evaluations.** To assess potential expectancy effects, both participants and workshop instructors will be asked to complete a short questionnaire at the end of the first and final days of the workshop. Questions will inquire about information such as confidence in anticipated benefit, willingness, credibility, and likelihood to recommend to others. These questionnaires follow a format of previously used and validated expectancy scales.<sup>31-33</sup>

**Home practice logs.** Participants will be asked to track daily practice of any techniques provided from the workshops. In order to maintain consistency across participants and workshops, the same log will be provided to everyone. An example entry for the yogic breathing-based workshop (YES+) may be the use of a specific breathing technique prior to an exam. An example entry for the psychoeducation workshop (WOW!) may be the use of a cognitive strategy such as recognizing that an exam grade is only a portion of a final semester grade.

## 9) Cost to subjects

*There is no monetary cost to the subject, although participation in the study involves time to complete the online screening, measures associated with the three laboratory visits, and workshop.*

## 10) Risks to subjects

*Few risks or complications are posed to the study participants. Participation in either workshop involves interaction with other participants and possible discussion of personal background information that may be uncomfortable for some individuals. Some participants with sensitive skin may experience mild discomfort at the electrode sites for ECG data collection and around the wrist from wearing the Actiwatch. However, the equipment used for ECG recordings is widely used for research and clinical purposes with minimal adverse reactions reported, and the Actiwatch device has been tested for safety and has been FDA approved for use in adults.*

*Subjects will be instructed to report any skin irritations related to study procedures to research personnel and to seek medical care if the irritations persist longer than 24 hours.*

## 11) Potential benefits to subjects and/or society

*Benefit to participants is anticipated from both workshops in terms of stress-management tools and overall well-being, although some may benefit more than others in one workshop or the other. Participants may also benefit by contributing to scientific knowledge stress physiology and well-being in college students and other adults.*

## 12) Provisions to protect the privacy of subjects and the confidentiality of data

### a. Protection of subject privacy:

Participant contact will be conducted through a password-protected e-mail account designated specifically for the study. Information collected via online pre-screening survey will also involve password-protected access. The online nature of the screening survey allows for increased privacy of the participant, as individuals are able to complete the survey at the remote location of their choice without intrusions from study personnel or others from the laboratory. In-person informed consent will be conducted in a private room within the laboratory.

### b. Protection of data confidentiality:

Consent forms will be stored in a locked cabinet in Psychology 409 until the end of the study. Per Psychology Department guidelines, at the end of the study all consent forms will be moved to the Psychology main office, room 312. Each participant will be given a unique participant identifying number that will not be recorded on his or her consent form. This unique participant number only (and not any identifying information) will be recorded on all experimental data collected. Therefore, all of the data in Psychology 409 will be de-identified. The date of the participant's intake will be recorded on the consent form. This date will also be recorded in an excel sheet of de-identified participant data. Consent forms will be stored in the Psychology building for up to six years should data ever need to be re-identified, as requested by the IRB. De-identified data, including questionnaire information, will be secured indefinitely in electronic form on Dr. Allen's secure server. Paper copies, with no identifying information, will be shredded once entered onto the server.

## 13) Subject compensation

The maximum total amount a participant may receive is \$100. Payment will be provided at two points across the study: \$60 upon completion of T2 and an additional \$40 upon completion of T3. This payment plan has been carefully devised to ensure adequate payment that is proportional to the challenge of maintaining commitment through the entire study, while not overly lucrative in order to minimize chance of possible coercion and/or substantial monetary motivation that would be detrimental to the workshop dynamics. To help ensure appropriate attendance at the workshops, which is critical to enable group cohesiveness as part of the workshop benefit for individual participants, payment will not be pro-rated for drop-outs prior to completion of T2.

**14) Medical care and compensation for injury**

There is no expectation of risk for participants. No compensation will be available for medical care. If there should be an unexpected injury, the session will be terminated immediately and the researcher will contact emergency services.

**15) Withdrawal of subjects**

Participants may voluntarily withdraw at any time, as indicated in the consent form. Researchers may ask participants to cease participation in the study if study procedures are not followed (e.g. incomplete workshop attendance). In the event that a participant either undergoes adverse experiences associated with the workshop or voluntarily withdraws while the workshop is in progress, the workshop instructor will follow up with the participant to offer support, if needed, and help facilitate transition out of the study. In the event of withdrawal during laboratory visits, the researchers conducting the visit will likewise follow up with the participant to help facilitate transition out of the study. Withdrawal due to any adverse, study-related circumstances will be reported to the IRB.

**16) Sharing of results with subjects**

Participants may follow up with the research staff upon completion of the study to learn about study results.

**17) Future use and long-term storage of data or specimens**

As described above, de-identified data, including questionnaire information, will be secured indefinitely in electronic form on Dr. Allen’s secure server. Paper copies, with no identifying information, will be shredded once entered onto the server.

**SECTION 4: LIST OF ATTACHMENTS FOR THIS SUBMISSION (REQUIRED) (Items listed here are expected to be attached as separate documents. These documents will appear in the UA HSPP IRB approval letter as 'documents submitted concurrently' with the review.)**

Document Name	Version Date
1. F200 Allen – signature page.pdf	1. 08/19/2015
2. F107 Allen - Student Wellness Workshops 20150915.doc	2. 09/15/2015

3. Allen_biosketch.pdf	3. 08/19/2015
4. SWW_Consent_20150908.doc	4. 09/08/2015
5. 2012 Varela Grant Docs letter Goldstein, Michael.pdf	5. 08/19/2015
6. Actiwatch_510k_approval.pdf	6. 08/19/2015
7. SWW_ScreeningQuestions_20150915.docx	7. 09/15/2015
8. SWW_SleepDiary.docx	8. 07/17/2015
9. SWW_Debrief_20150908.docx	9. 09/08/2015
10. SWW_MAST_20150908.ppt	10. 09/08/2015
11. SWW_T1_QuestionnairePacket.pdf	11. 07/16/2015
12. SWW_T2_QuestionnairePacket.pdf	12. 07/16/2015
13. SWW_T3_QuestionnairePacket.pdf	13. 07/16/2015
14. SWW_Day1_InstructorExpenctancyEval.docx	14. 07/16/2015
15. SWW_Day4_InstructorExpenctancyEval.docx	15. 07/16/2015
16. SWW_Day1_ParticipantExpenctancyEval.docx	16. 07/16/2015
17. SWW_Day4_ParticipantExpenctancyEval.docx	17. 07/16/2015
18. SWW_PracticeLog.docx	18. 07/17/2015
19. SWW_Consent_INSTRUCTORS_20150916.doc	19. 09/16/2015

**See HSPP website for submission requirements.**

**Items needed for approval:**

- **F107: Verification of Training Form**
- **Current PI/Co-PI CVs or biosketch**, if not included with copy of grant application
- **Informed Consent/Permission/Assent Form(s)** – including study specific release of information documents, DHHS approved sample consent forms. If consent will not be documented in writing, a script of information to be provided orally to subjects

**Other Items as applicable:**

- **Appendix A - Children**
- **Appendix B - Drug/Device**
- **Appendix C- Multi Site Research**
- **Appendix D- Pregnant Women and Neonates**
- **Appendix E- Prisoners**
- **Appendix F- Waiver of Consent/ PHI**
- **Biosafety Review letter** (for UA - Institutional Biosafety Committee)
- **Certificate of Confidentiality**
- **Compressed Gases Review letter** (for UA – Research Instrumentation)
- **Contract** – complete or draft copy of contract including budget
- **Data Collection Tools** – surveys, questionnaires, diaries not included in the protocol, data abstraction form for records review
- **Data Monitoring Charter and Plan**

- **Drug/Device information** – Investigator's Brochure, drug product sheet, device manual, user's manual, instructions for use, package insert, IND/IDE documentation, FDA 1572 form, 510k indication, FDA exemption, sponsor determination of device risk, etc.
- **Export Control Review**
- **Grant Application(s)** – cover-to-cover copy of grant, regardless of home institution or funding agency, and a copy of the Notice of Grant Award.
- **Other Approval letters** (e.g., school districts, Tribal, other IRB approvals)
- **Participant Materials** – written materials to be provided to or meant to be seen or heard by subjects (e.g. study newsletter, physician to participant letter, wallet cards, incentive items, holiday/birthday cards, certificates, instructional videos/written guides, calendars, certification of achievement, etc.)
- **Payer coverage analysis**
- **PHI Authorization Form(s)**
- **Protocol** – including all amendments/revisions, sub- or extension-studies
- **Radiation Safety Review** letter- needed regardless if the radiation device is approved and used standard of care
- **Recruitment Materials** – telephone scripts, flyers, brochures, websites, email texts, radio/television spots, newspaper advertisements, press releases, etc.
- **Scientific Review Committee** letter (for cancer related projects – AZCC SRC; other units as applicable if the unit has a scientific review committee)
- **Site Authorizations** for research purposes and/or access to administrative records/samples
  - External sites (such as schools, other hospitals or campuses, etc.)
  - B-UMG approval
- **Supplemental site information** (for sites engaged in research where the UA is the IRB of record)
  - Copy of any approvals granted from that site (including determinations if this site has an IRB of its own)
  - Site-specific F107
  - Copy of the site's human subjects training policy
  - CV and medical license (if applicable) of site PI
- **Travel Authorization documentation** (for UA – Office of Global Initiatives)
- **Use of retrospective research samples and/or data** – IRB approval letter, original consent under which samples/data were collected, letter allowing access to samples

## References

1. Ari LL, Shulman S. Pathways of sleep, affect, and stress constellations during the first year of college: transition difficulties of emerging adults. *J Youth Stud.* 2012;15(3):273–292. doi:10.1080/13676261.2011.635196.
2. Park CL, Levenson MR. Drinking to cope among college students: prevalence, problems and coping processes. *J Stud Alcohol.* 2002;63(4):486–497. doi:10.15288/jsa.2002.63.486.
3. Murff SH. The impact of stress on academic success in college students. *ABNF J.* 2005;16(5):102.
4. Rawson HE, Bloomer K, Kendall A. Stress, Anxiety, Depression, and Physical Illness in College Students. *J Genet Psychol.* 1994;155(3):321–330.
5. Brown RP, Gerbarg PL. Sudarshan Kriya yogic breathing in the treatment of stress, anxiety, and depression: part I- neurophysiologic model. *J Altern Complement Med.* 2005;11(1):189–201. doi:10.1089/acm.2005.11.189.
6. Kjellgren A, Bood SA, Axelsson K, Norlander T, Saatcioglu F. Wellness through a comprehensive yogic breathing program - a controlled pilot trial. *BMC Complement Altern Med.* 2007;7:43. doi:10.1186/1472-6882-7-43.

7. Katzman MA, Vermani M, Gerbarg PL, et al. A multicomponent yoga-based, breath intervention program as an adjunctive treatment in patients suffering from generalized anxiety disorder with or without comorbidities. *Int J Yoga*. 2012;5(1):57–65. doi:10.4103/0973-6131.91716.
8. Vedamurthachar A, Janakiramaiah N, Hegde JM, et al. Antidepressant efficacy and hormonal effects of Sudarshana Kriya Yoga (SKY) in alcohol dependent individuals. *J Affect Disord*. 2006;94(1-3):249–53. doi:10.1016/j.jad.2006.04.025.
9. Descilo T, Vedamurtachar A, Gerbarg PL, et al. Effects of a yoga breath intervention alone and in combination with an exposure therapy for post-traumatic stress disorder and depression in survivors of the 2004 South-East Asia tsunami. *Acta Psychiatr Scand*. 2010;121(4):289–300. doi:10.1111/j.1600-0447.2009.01466.x.
10. Carter JJ, Gerbarg PL, Brown RP, et al. Multi-Component Yoga Breath Program for Vietnam Veteran Post Traumatic Stress Disorder: Randomized Controlled Trial. *Trauma Stress Disord Treat*. 2013;2(3):1–10.
11. Seppälä EM, Nitschke JB, Tudorascu DL, et al. Breathing-based meditation decreases posttraumatic stress disorder symptoms in U.S. military veterans: a randomized controlled longitudinal study. *J Trauma Stress*. 2014;27(4):397–405. doi:10.1002/jts.21936.
12. Ghahremani DG, Oh EY, Dean AC, Mouzakis K, Wilson KD, London ED. Effects of the Youth Empowerment Seminar on impulsive behavior in adolescents. *J Adolesc Heal*. 2013;53(1):139–41. doi:10.1016/j.jadohealth.2013.02.010.
13. Kochupillai V, Kumar P, Singh D, et al. Effect of rhythmic breathing (Sudarshan Kriya and Pranayam) on immune functions and tobacco addiction. *Ann N Y Acad Sci*. 2005;1056:242–52. doi:10.1196/annals.1352.039.
14. Naga Venkatesha Murthy PJ, Gangadhar BN, Janakiramaiah N, Subbakrishna DK. Normalization of P300 Amplitude following Treatment in Dysthymia. *Biol Psychiatry*. 1997;42(8):740–743. doi:10.1016/S0006-3223(97)00296-5.
15. Gootjes L, Franken IHA, Van Strien JW. Cognitive Emotion Regulation in Yogic Meditative Practitioners. *J Psychophysiol*. 2011;25(2):87–94. doi:10.1027/0269-8803/a000043.
16. Warner A, Wall K, Birk H, Koopman C. Psychological and Spiritual Well-Being of Women with Breast Cancer Participating in the Art of Living Program . In: Hicks NL, Warren RE, eds. *Psychology of Cancer*. Nova Science Publishers; 2012:63–108.
17. Bhatia M, Kumar A, Kumar N, Pandey RM, Kochupillai V. Electrophysiologic evaluation of Sudarshan Kriya: an EEG, BAER, P300 study. *Indian J Physiol Pharmacol*. 2003;47(2):157–63.
18. Subramanian S, Elango T, Malligarjunan H, Kochupillai V, Dayalan H. Role of sudarshan kriya and pranayam on lipid profile and blood cell parameters during exam stress: A randomized controlled trial. *Int J Yoga*. 2012;5(1):21–7. doi:10.4103/0973-6131.91702.
19. Smeets T, Cornelisse S, Quaedflieg CWEM, Meyer T, Jelacic M, Merckelbach H. Introducing the Maastricht Acute Stress Test (MAST): a quick and non-invasive approach to elicit robust autonomic and glucocorticoid stress responses. *Psychoneuroendocrinology*. 2012;37(12):1998–2008. doi:10.1016/j.psyneuen.2012.04.012.
20. Bali A, Jaggi AS. Clinical experimental stress studies: methods and assessment. *Rev Neurosci*. 2015. doi:10.1515/revneuro-2015-0004.
21. Horne JA, Ostberg O. A self-assessment questionnaire to determine morningness-eveningness in human circadian rhythms. *Int J Chronobiol*. 1976;4(2):97–110.
22. Clark LA, Watson D. Tripartite model of anxiety and depression: psychometric evidence and taxonomic implications. *J Abnorm Psychol*. 1991;100(3):316–36.
23. Casillas A, Clark LA. The Mini Mood and Anxiety Symptom Questionnaire (Mini- MASQ). In: *72nd Annual Meeting of the Midwestern Psychological Association*. Chicago, IL.
24. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav*. 1983;24(4):385–96.
25. Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. *Psychiatry Res*. 1989;28(2):193–213.
26. John OP, Srivastava S. The Big-Five trait taxonomy: History, measurement, and theoretical perspectives. In: Pervin LA, John OP, eds. *Handbook of personality: Theory and research*. New York: Guilford Press; 1999:102–138.
27. Rosenberg M. *Society and the adolescent self-image*. Princeton, NJ: Princeton University Press; 1965.
28. Diener E, Emmons RA, Larsen RJ, Griffin S. The Satisfaction With Life Scale. *J Pers Assess*. 1985;49(1):71–5. doi:10.1207/s15327752jpa4901\_13.
29. Lee RM, Draper M, Lee S. Social connectedness, dysfunctional interpersonal behaviors, and psychological distress: Testing a mediator model. *J Couns Psychol*. 2001;48(3):310–318.
30. Spielberger CD, Gorsuch RL, Lushene PR, Vagg PR, Jacobs GA. *Manual for the State-Trait Anxiety Inventory*. Palo Alto, CA: Consulting Psychologists Press, Inc.; 1983.
31. Borkovec T, Nau SD. Credibility of analogue therapy rationales. *J Behav Ther Exp Psychiatry*. 1972;3:247–260.
32. Edinger JD, Wohlgemuth WK, Radtke RA, Marsh GR, Quillian RE. Cognitive Behavioral Therapy for Treatment of Chronic Primary Insomnia. *JAMA*. 2001;285(14):1856. doi:10.1001/jama.285.14.1856.



33. Van Middendorp H, Kox M, Pickkers P, Evers AWM. The role of outcome expectancies for a training program consisting of meditation, breathing exercises, and cold exposure on the response to endotoxin administration: a proof-of-principle study. *Clin Rheumatol*. 2015. doi:10.1007/s10067-015-3009-8.