MINIMAL RISK CLINICAL RESEARCH PLAN v. 2/18/2026

Please complete: CPHS# STUDY00032944 **PI: Dr. Diane Gilbert-Diamond**

Important Note: The CPHS Department (Chair & Scientific) Review Form is required with this application. Find the form in the RAPPORT Library or on the CPHS Website.

- **DO NOT USE this form for retrospective chart review studies. Please use the Data Specimens Registries Research Plan.**
- **Respond to each item, even if to indicate N/A or not applicable**
- **Attach and/or upload this form as your 'Investigator Protocol' in Rapport**
- **If you are completing this form on a Mac, indicate your answer to any checkboxes by bolding or highlighting, or by deleting any incorrect options.**

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1. Introduction and Background

College students show rising stress levels and report challenges in maintaining physical and mental health. In a 2018 health survey conducted on 605 undergraduate students at Dartmouth College, 90% responded that they felt overwhelmed by what they had to do, 88% felt exhausted (not from physical activity), and 76% experienced loneliness sometime in the past year (Dartmouth Office of Institutional Research, 2018). Nearly 20% were diagnosed with depression or anxiety. 57% reported experiencing tremendous stress within the last 12 months. Only half of the respondents were able to get three or more servings of vegetables or fruits each day. Every one in four respondents reported having episodes of overeating in the past three months. 50% reported binge or high-risk drinking (having 5+ drinks in one sitting) in the past two weeks. More effective preventative strategies are needed to support college students' well-being.

Mindfulness-based interventions (MBIs) show promise in improving mental and physical health in college student populations (Dawson et al., 2020). A systematic review meta-analyzed 51 randomized controlled trials on MBIs and college student health and found that compared with passive controls, MBIs reduce stress, depression, and trait anxiety and increase self-compassion post-intervention with medium effect sizes (SMD > 0.4 with $p < .00001$) (Dawson et al., 2020). This review and others (Black, 2015; Dawson et al., 2020; Shapiro & Jazaieri, 2015) also highlight the lack of stringent intervention studies that use objective markers to inform training effects on mental and physical health states. Another limitation is the absence of follow-up beyond the conclusion of the interventions to investigate long-term health benefits. Third, as existing literature (88%) primarily assessed health changes, little is known about how MBIs influenced academic outcomes (Dawson et al., 2020). Fourth, the review indicates that 55% of studies used passive controls (i.e., usual care) and recommends further studies to compare mindfulness interventions with active controls, such as health education and nutritional counseling, to examine if MBIs are equally or more efficacious than existing intervention programs (Dawson et al., 2020). Lastly, existing MBIs designed for college students often encounter high attrition rates. In an 8-week mindfulness program adapted for university students in the UK, 41% (127 out of 309) discontinued halfway through the program (Galante et al., 2018). In a review of qualitative studies with college student participants in MBIs, many found it challenging to find time to practice mindfulness (Bamber & Schneider, 2022). It is thus essential to design interventions that adapt to college student lifestyles to encourage consistent practice and investigate intervention efficacy with longer follow-ups beyond course completion.

2. Objectives and Hypotheses

The proposed study aims to evaluate whether integrating mindfulness practice into an undergraduate biology course (Mindful Physiology) will enhance applied mindfulness and stress regulation capacity. We hypothesize completing this ten-week course will (1) increase applied mindfulness, (2) increase trait mindfulness, (3) increase well-being, and (4) decrease physiological stress response to an acute social-evaluative test.

3. Study Design

Describe all study procedures, materials, and methods of data collection:

3.1 Study Design The study is a two-arm randomized controlled trial. The intervention group will consist of students enrolled in the Mindful Physiology course (Biology 3) at Dartmouth College in the spring 2026 term. (3/30/2026-6/3/2026). The control group will enroll students waitlisted for the course over the same period. The waitlist controls will receive university wellness support (i.e., treatment as usual, TAU). TAU includes access to counselors, mental health advisors, and psychiatrists at the university's counseling center, wellness advising at the student wellness center, and campus-wide wellness programs such as weekly group yoga and meditation sessions and a free subscription to the Headspace app. We anticipate enrolling 37 students enrolled in the course and 52 waitlisted students for the study.

3.2 Eligibility Criteria
Students who participated in the 2025 version of the study will not be eligible to enroll, as we are administering the same questionnaires and the same video procedure during the TSST-OL.

3.3 Intervention Description
The intervention, Mindful Physiology, is an undergraduate-level biology course embedded with mindfulness practices. There will be 19 class sessions, each 1 hour and 50 minutes long, over 10 weeks. Students will be taught human physiology through didactic lectures, laboratory activities, and written quizzes typical for a college course. Each class meeting will have ~20 minutes of mindfulness practice in Thích Nhất Hạnh's Plum Village tradition (Hanh, 1992). Students will also be encouraged to practice mindfulness for 15 minutes daily outside the class and to attend a weekly mindfulness event (e.g. Student Wellness Center activities). Students will complete a daily log of their mindfulness practice and be given credit for each log completion regardless of the minutes of mindfulness practice. Students will be asked to download a secure phone application to complete their daily log, as well as self-report their weekly phone screen use. The phone app will only be accessible by students enrolled in the class. The application will also display university wellness resources and mindfulness opportunities on campus. Students will be assigned a weekly written reflection on the physiology course content and/or their mindfulness practice. All students in the class are required to attend a 4.5-hour or a two-day (16-hour) mindfulness retreat. The retreats will also be advertised to and open to all Dartmouth students, including those in the control group. Students in the control arm will receive university wellness resources as usual.

3.4 Data Collection
Trained research staff will email eligible participants with informed consent forms two weeks before the intervention start date and over the first week of classes (3/16/2026 to 4/3/2026). After signing the consent form, participants will receive a baseline survey remotely via RedCap and will be asked to complete the survey no later than the end of the first week of class (3/16/2026 to 4/3/2026). This questionnaire will be administered again at intervention completion (week 10, 6/3/2026 to 6/7/2026).

Over weeks 8 and 9 (5/18/2026 to 5/29/2026), participants will be invited for an in-person lab visit for a Trier Social Stress Test (TSST-OL). Since they have already provided written informed consent, at the beginning of the in-person visit, participants will verbally consent and state whether they still want to engage in the study visit. During the TSST-OL, participants will be invited to give a 5-minute speech in front of a virtual panel of judges to mimic a real-life stressful situation. Perceived stress, heart rate (HR), heart rate variability (HRV), and

respiration rate will be collected to assess physiological reactivity to this acute stressor (please read section 4.1.3. on stress reactivity assessment).

4. Analysis

Describe any qualitative tests and measures as well as quantitative methods:

4.1 Primary Outcomes

4.1.1 Physiological stress response to an acute stressor

At intervention completion, physiological stress reactivity will be evaluated using the online variant of the Trier Social Stress Test (TSST-OL) in our laboratory (Heyers et al., 2025). The TSST-OL is a computerized stress induction protocol with three components: 5 minutes of brief preparation, 5 minutes of public speaking (job interview), and 5 minutes of math test in front of a panel of evaluators online. Our protocol will be modified to use a pre-recorded video of the panel of evaluators to give the impression of a live audience and minimize research assistant time while maintaining the conditions of the established TSST-OL. We will also not administer the math test during the TSST-OL, as our study design does not employ in-person actors administering the math test for real-time feedback.

During the TSST, heart rate will be measured using a chest-worn Polar H10 (Polar Electro Oy, Kempele, Finland) (Schaffarczyk et al., 2022) and video-based photoplethysmography (PPG) (Pirzada et al., 2023). Wrist collected PPG heart rate data will also be measured during the TSST-OL (ActiGraph LEAP; Ametris, Pensacola, Florida). Raw inter-beat intervals will be recorded via a Bluetooth pairing to an accelerometer nearby (ActiGraph wGT3X-BT; Ametris, Pensacola, Florida).

The mean heart rate (MHR) will be computed during the baseline resting phase and during the TSST (speech preparation and speaking), and during the recovery (Nyklíček et al., 2013). Reactivity to the acute stressor will be operationalized as differences in heart rate parameters during the TSST compared to the baseline.

4.1.2 Well-Being

Psychological well-being will be assessed with the 5-item World Health Organization Well-Being Index (WHO-5) (Topp et al., 2015). Participants will rate five positively phrased items on subjective well-being, i.e., “I have felt cheerful and in good spirits.” Responses are anchored from 0 (none of the time) to 5 (all the time). The total score is the sum of item responses ranging from 0 to 25, with 25 indicating the maximum possible well-being. The index has shown high internal consistency with $\alpha = 0.86$ and test-retest reliability of $r = 0.77$ in 903 college students (Downs et al., 2017).

4.1.3. Applied Mindfulness

Students will complete the Applied Mindfulness Process Scale (AMPS) at baseline and post-intervention completion (Roemer & Medvedev, 2022). The scale consists of 15 questions that quantify the application of mindfulness skills to navigate difficult situations and stressors in life. The AMPS encompasses three subscales: decentering, negative emotion regulation, and positive emotion regulation. The total scores are the sum across items. Total possible scores range from 0 to 60. Higher scores reflect more active use of mindfulness practice in everyday life. The scale showed high internal validity with a Cronbach’s α of 0.91 in 134 adults in the original study (Roemer & Medvedev, 2022). Additionally, lab-observed application of mindfulness in stressful situations will be assessed during the Trier Social Stress Test (TSST). Participants will report whether they have used mindfulness techniques during the stress challenge.

4.1.4. Trait Mindfulness

Trait mindfulness will be assessed with the Five Facet Mindfulness Questionnaire (FFMQ), a 39-item questionnaire evaluating five distinct components of mindfulness (R. Baer, 2019; R. A. Baer et al., 2006). The five facets are observation, description, aware actions, non-judgmental inner experience, and non-reactivity. (7 items). The total score is the average across the five subscales. Possible scores range from 1 to 5, with higher scores indicating higher dispositional mindfulness.

4.2 Other Outcomes

4.2.1. Stress Management Self-Efficacy

Participants will evaluate their confidence in managing stress with the Stress Management Self-Efficacy Scale ($\alpha = 0.86$, N = 2292) (Sawatzky et al., 2012). The scale has four items, e.g., "I believe I have the ability to cope with the demands of my life." All items will be rated on a four-point Likert scale from 1 (strongly disagree) to 4 (strongly agree). A global score will be computed with the mean across the four items (range: 1 to 4), with higher scores indicating greater self-efficacy in identifying and managing stress.

4.2.2. Heart rate variability response to TSST

Heart rate variability response to the TSST will be assessed with the change in the Root Mean Square of Successive Differences (RMSSD) during the presentation task from the baseline.

4.2.3. Harmful Alcohol Consumption

Harmful alcohol consumption behavior will be assessed via the Consumption subscale from the Alcohol Use Disorders Identification Test (AUDIT-C) (Bush et al., 1998). The AUDIT-C has three items on the frequency and quantity of alcohol use (US Preventive Services Task Force, 2018). The total score is the sum across items, which range from 0 to 12, with higher scores indicating a higher risk of alcohol abuse or dependence. A score of 3 and above is indicative of possible risky drinking that warns of clinical concerns. Questions include asking on how often you have a drink containing alcohol, how many alcoholic drinks are consumed on typical day and how often six or more alcoholic drinks are consumed on any occasion. This survey was modified to include the option "I choose to not answer" given the nature of asking about potential illegal behaviors. Responses from these questionnaires are identifiable but will be coded for participant anonymity and stored securely on Dartmouth College's encrypted server.

4.2.4. Social Connectedness

Social connectedness will be measured via the Social Connectedness Scale, revised (SCS-r) (R. M. Lee & Robbins, 1995). Participants will rate 20 items on a six-point Likert scale from 1 (strongly disagree) to 6 (strongly agree), e.g., "I am able to relate to my peers." A total score will be computed by taking the sum across items. Possible scores range from 20 to 120, with 120 indicating the strongest sense of belongingness.

4.2.5. Learning-Related Anxiety

Anxiety around learning will be assessed with the learning-related anxiety subscale from the Achievement Emotions Questionnaire-Short Form (AEQ-S) (Bieleke et al., 2021). Participants will rate four five-point Likert scales on feelings of anxiousness when studying, e.g., "I get tense and nervous

while studying." The subscale showed adequate internal validity in the original study with an α of 0.72 in 180 adults (71% female, 58% White) (Bieleke et al., 2021).

4.2.6. Social Media Addiction

Social media use will be assessed with the Bergen Social Media Addiction Scale (BSMAS) (Shin, 2022). This is a brief 6-item self-assessed questionnaire evaluating individuals' reliance on social media. The scale has been validated and previously used for understanding young adults' social media use (Meynadier et al., 2023). Participants will also be asked to estimate the minutes spent on social media on a typical weekday and weekend day separately.

4.2.7. Perceived Stress During the Last Month

Subjective stress will be measured with the 10-item Perceived Stress Scale (PSS), which evaluates individuals' perception of how uncontrollable and overloaded their lives have been in the past month (Cohen et al., 1983). Participants will complete the 10-item version at baseline and post-class assessments. Participants will rate items on a five-point Likert scale from 0 (never) to 5 (very often). The possible scores range from 0 to 50; higher scores reflect more perceived stress. The scale has shown strong internal validity ($\alpha > 0.70$) and test-retest reliability ($r > 0.70$) in a systematic review (E.-H. Lee, 2012).

4.2.8. Anxiety

Anxiety will be assessed with the seven-item Generalized Anxiety Disorder Scale (GAD-7) (Spitzer et al., 2006). The scale had high internal validity ($\alpha = 0.92$) and test-retest reliability (interclass correlation = 0.83) in the original study. Item responses are anchored on a four-point Likert scale from 0 (not at all) to 3 (nearly every day). A total score will be computed by taking the sum of item responses. Possible scores range from 0 to 21, with higher scores reflecting more severe anxiety. A score of 8 and above indicates possible cases of GAD with a sensitivity of 83% and specificity of 84% (Plummer et al., 2016).

4.2.9 Emotional Eating

Emotional Eating will be assessed with the 13-item Emotional Eating Subscale from the Dutch Eating Behavior Questionnaire (DEBQ) (Van Strien et al., 1986). The Emotional Eating scale has shown a strong internal validilty ($\alpha > 0.98$) in English speaking populations (Mason et al., 2019). Items are scored on a five-point Likert scale from 1 (never) to 5 (very often). A total score with be computed by taking the average across all items. Possible scores range from 1 to 5, with higher scores indicating higher rates of emotional eating (Mason et al., 2019; Van Strien et al., 1986).

4.3. Covariates

4.3.1. Demographics

Sociodemographic information will be self-reported via a questionnaire, including questions on age, biological sex, gender, race, ethnicity, class year, major, parental education (i.e., highest education attained by either parent: doctoral degree, master's degree, bachelor's degree, or no college degree).

4.3.2. Self-Reported Screen Use

Students will be asked to self-report their daily average screen use over 1 week as posited within their phone "Screen Time" report in the baseline and follow-up questionnaire. Students will have the option to include a screen-capture of this on the survey if they wish but it is not required.

4.3.3. Self-Reported Mindfulness Practice

Students will be asked to self-report their average daily amount of mindfulness practice over 1 week in the baseline and follow-up questionnaire.

4.3.4. Post-Term Question

Students will be asked whether they attended a Plum Village mindfulness retreat hosted by Dartmouth over the spring term in the follow-up questionnaire.

4.3.5. Daily Logs, Weekly Course Material and Attendance, Class

Students in the intervention arm of this study will be asked for their consent to use their course materials and questionnaire data to be used for research purposes. Students in the intervention arm of this study will also be asked for their permission to quote from their submitted writing for research anonymously.

4.4. Statistical Analysis

Participant baseline characteristics will be compared between the intervention and control groups to ensure a balance between the intervention arms. Any demographic variables that significantly differ between the two groups will be adjusted in all models. Second, summary statistics will be computed for primary and other outcomes and covariates. Means with standard deviations will be reported for continuous variables. Counts with proportions will be reported for categorical variables. Normality will be examined for continuous variables via Shapiro-Wilk tests and visual inspections of histograms and quantile-to-quantile (Q-Q) plots. Outcomes that do not follow a normal distribution will be log-transformed in all models.

For the primary outcomes, we will examine the between-group differences in changes in applied mindfulness, trait mindfulness, heart rate response to the TSST, and the WHO-5 Index, using linear regression models with change scores in each outcome as the dependent variable and the group status as the independent variable, adjusted for age and sex. We will report Cohen's *d* to estimate the effect sizes.

As exploratory analyses, we will examine the dose-response relationship between practice time (assessed with self-report practice time) and changes in primary and other outcomes over the term. Further, we will explore any between-group differences in changes in heart rate and heart rate variability during the TSST preparation and speaking task, separately, with linear regression models, adjusted for age and sex. All analyses will consider a p-value > 0.05 as statistical significance.

5. Study Progress Monitoring

Note: appropriate monitoring may include periodic assessment of the following:

- data quality
- timelines
- recruitment and enrollment

Provide a description of the methods which will be used to determine the progress of the study, including periodic assessments of data quality, timelines, recruitment, and enrollment as appropriate:

5.1. Data Management

Trained research staff will download data within two weeks of the data collection period and examine data for incompletion and errors. Data will be de-identified and stored in a private, secure server hosted at Dartmouth College. Data quality will be assessed by examining missingness of questionnaire items and missing heart rate data from study visits.

5.2. Timeline

Study recruitment and enrollment will occur two weeks before the spring term begins and will proceed into the first week of the class (3/16/2026 to 4/3/2026). Baseline questionnaires will be administered online up to one week after enrollment (3/16/2026 to 4/3/2026). In-person lab assessments will occur during weeks 8 and 9 of the intervention period (5/18/2026 to 5/29/2026). Follow-up questionnaires will be administered within a week after intervention completion (6/2/2025 to 6/9/2026).

6. Risks & Benefits

Note: Risks may be physical, psychological, social, legal, economic, to reputation, or others.

a. Describe any potential risks, their likelihood and seriousness:

Psychological distress due to survey questions: Some questionnaires administered screen for mental health disorders. Participants filling out these questionnaires may perceive this as an appropriate avenue to call for help if they are experiencing mental health problems. The likelihood of this is low, provided the informed consent makes it explicitly clear that the surveys administered do not provide a mental health diagnosis, and in the event of certain scores, mental health professionals will not be contacted.

Psychological distress due to in-person stress test: Participants are expected to experience an acute increase in feelings of stress during the virtual Trier Social Stress Test. This amount of stress is expected to be comparable to what students experience during typical public speaking activities in classes or during a job interview. The risk that the TSST-OL impacts participants outside the study visit is low. Participants will be debriefed at the end of data collection, explaining that they were not being judged on their performance of tasks in the virtual setting within the lab. A copy of the written debrief is in the supplementary materials.

Discomfort related to wearing the heart rate monitors: Participants may experience mild skin irritation at the wear site related to the activity tracker or heart rate monitors. Any participants who experience skin irritation because of this is directed to discontinue wearing either device.

Loss of confidentiality: Participants risk a loss of confidentiality. Information collected from surveys, logs, wearables and video will be stored in on a private secure Dartmouth server, with several methods for mitigating this risk of privacy loss, providing some of the data collected in this research is identifiable. To further ensure data security, identifiable video data will be recorded and stored on a secure Dartmouth server in a password protected folder. Some of the questionnaires disclose potentially illegal behaviors related to alcohol use. The likelihood this risk occurs is low, however if loss of confidentiality were to occur it would be serious. When the data is no longer needed, electronic data will be permanently deleted from the database, and any paper files will be securely shredded and destroyed.

b. Confirm that risks to subjects have been minimized, by use of procedures which are consistent with sound research design, and which do not unnecessarily expose subjects to risk:

To reduce the risk of student mental health going unchecked, an overview of all mental health and wellness services available to all Dartmouth students will be provided to all participants at the time of going over the informed consent document, as well as via email after study enrollment. This document provides a comprehensive overview of resources available to students and was developed by the Student Wellness Center at Dartmouth.

Provided some collected data in this research is identifiable to participants, it will be coded and stored with a random study ID, on a secure, encrypted Dartmouth server. Only the research team members who directly contact participants will have access to the information necessary to link them to their identified data from

surveys and other data measures collected. The encrypted database on a secure Dartmouth server will be password protected and only accessed by research staff while connected to the eduroam network on the Dartmouth campus. Further, video data collected that is identifiable will also be securely stored on the Dartmouth server, in a password protected folder.

Health information collected in this research will be kept confidential unless its disclosure is permitted by law. Information created or collected by the study team will only be shared with other researchers after it is stripped of identifiers, and no information can be traced back to participants. Currently, there is no plan to share any data. Additionally, no names will be used in any publications presentations that may come from this research.

A Certificate of Confidentiality from the NIH has been obtained to further protect participants related to any information that is disclosed in this research.

c. Describe why all the risks to subjects are reasonable in relation to both anticipated benefits and the knowledge expected to be gained from the study:

College students experience high levels of stress, which is linked to poor health outcomes, so understanding whether Mindfulness practice integrated into the classroom improves health outcomes in college students can be beneficial to college student populations.

7. Unexpected Events or Incidental Findings

Note: It may be important to consider the potential for certain unanticipated events to occur, for example:

- finding an anomaly in a MRI
- discovering child abuse
- causing distress in interviews of a sensitive nature

Describe potential events and provide a plan of action:

Should any participant experience discomfort during the study, the participant will be encouraged to contact the Committee for the Protection of Human Subjects at Dartmouth College (603) 646-3053. Student participants can receive physical health and mental health support resources that are available to them throughout the study.

In the event of a breach confidentiality, participants and the Dartmouth College IRB would be informed of the context and the extent of the breach.

8. Deception

Does any part of this study involve deception or withholding of information from participants?

☒ Yes ☐ No

If Yes, provide an explanation which addresses the following:

· A description of the deception being used
· Why the deception is necessary

A plan for debriefing, or providing subjects with the pertinent information after participation

Participants are invited to attend an in-person study visit for a stress reactivity assessment (Trier Social Stress Test, TSST-OL) (Heyers et al., 2025). In the consent process, this protocol will be introduced to the participants as a mock interview in front of a live panel of evaluators evaluating their speaking ability and

facial expressions. In fact, the panel of evaluators will be a pre-recorded video to simulate a live audience while reducing research staff effort, and no one will be assessing participants' facial expressions or speaking ability. The deception during the TSST-OL intends to elicit a more natural stress response from the participants. Participants will be informed that the assessment is an established stress induction after all participants have completed the in-person study visit. A copy of the debrief is included in the supplementary materials.

9. Placebo Use or Inconsistency with Standard of Care

Does any part of this study involve the use of a placebo or procedures that are inconsistent with the standard of care?

☒ **No**

If Yes, explain how the use of placebo or non-standard of care therapy may affect risks for participants, addressing the following:

- The safety and efficacy of other available therapies
- The maximum total length of time a participant may receive placebo on study
- The greatest potential harm that may result from not receiving or delaying effective therapy
- Safeguards for the participants receiving placebo or non-standard of care therapy

10. Genetics

Does any part of the study involve genetic analysis of biological specimens?

☒ **No**

☐ **Yes,** the study is based on the premise that a link between a genotype or a biomarker and a specific disease or condition is clinically useful in predicting the development of that specific disease or condition. **Please complete the Genetic Research Form and upload it to the 'Supporting Documents' page in Rapport.**

-OR -

☐ **Yes,** the study is looking for an association between a genotype or a biomarker and a specific disease or condition, but at this point it is not clear if the genetic marker has predictive value. The uncertainty regarding the predictive value of the genetic marker is such that studies in this category will not involve referral of participants to genetic counseling; however, participants will be informed of genetic testing in the consent form. **Please comment:**

11. Equitable Participant Selection

a. Estimated number of participants at Dartmouth CPHS reviewed sites:

89 (control: n = 52; class: n = 37)

b. **Provide a justification of the proposed sample size**

The proposed sample size is based on preliminary data and feasibility. Our preliminary data indicated that the class had statistically significant lower increase in heart rate during TSST preparation and speaking tasks (preparation: Cohen's d = -0.74; speaking: d = -0.73), suggesting medium to large effect sizes. Based on last year's recruitment rate, we expect that 52 students from the control group and 37 from the class would complete both baseline and follow-up assessments. This sample size is powered to detect an effect size of d of 0.61 or above, sufficient to detect a significant effect for our primary outcomes.

c. Define the target population:
College Students

d. Vulnerable populations

Note: Certain populations are considered vulnerable to coercion and undue influence and are provided with additional protections when participating in a research study.

Identify any of the below populations which you plan to recruit for this study. In addition, complete the form(s) linked with each population as necessary and upload on the 'Supporting Documents' page in Rapport.

☐ Pregnant Women, Fetuses and Neonates
☐ Children
☐ People with impaired decision-making capacity

The following populations may also be considered vulnerable to coercion or other undue influence:

- Prisoners
- People who are economically disadvantaged
- The elderly
- People who are illiterate or do not speak English
- Students and employees

Describe any other potentially vulnerable population(s) and the additional protections provided to them:

Students are only being recruited by convenience sampling within the registered waitlists and class lists. The professor will not know the students participating in the study and will not have access to the collected surveys and objective outcome measures until class grades have been submitted.

12. Recruitment

Describe method(s) of recruitment. Associated advertisements and other materials to be used for recruitment should be uploaded to the 'Consent Forms and Recruitment Materials' page in Rapport.

All students who registered in Biology 3: Mindful Physiology at registration were randomly assigned to the class or waitlist by the Dartmouth College registrar. Students on the original class list and waitlist will be contacted up to 5 times via email over 3 weeks during the enrollment phase (3/16/2026 – 4/4/2026). Study recruitment will begin 2 weeks prior to class commencement; students will be sent the recruitment documents provided in the submission. We anticipate enrolling 52 individuals from the class (intervention group), and 37 individuals from the waitlist (control). A research assistant will post flyers around the

Dartmouth campus over the recruitment period of the spring term, which can be viewed in the supplementary materials.

13. Informed Consent, Assent, and Authorization

All forms discussed in this section should be uploaded to the 'Consent Forms and Recruitment Materials' page in Rapport

a. Please describe the consent and/or assent process, addressing the following:

- Who will obtain consent/assent from participants
- Where the consent/assent process will take place
- The timeframe for providing information potential participants about a study, having the consent form signed, and beginning study activities
- Any precautions taken to minimize the possibility of coercion or undue influence
- The forms which will be used as well as any aids used to simplify scientific or technical information
- How comprehension will be ensured

Participants will be offered the opportunity to discuss any questions with a research assistant during the recruitment process. This will be by email request and occur up to two weeks prior to the class beginning. A consent form will be provided to all students who respond to recruitment via RedCAP. Upon a signed informed consent document, a research assistant will administer the baseline survey online via RedCAP.

No mention of the project will occur within the classroom.

Comprehension of the study will be ensured by way of verbal consent before any study activity ensues. Students will be invited to schedule their in-person study visit via email in the middle of the term for an appointment over weeks 8 and 9 (5/18/2026 – 5/29/2026). Trained research staff will debrief the study aims and procedures at the beginning of the lab visit. Participants will verbally state whether they still want to engage in the study activities.

b. Waiver(s) or alteration(s) may be requested for research that involves no more than minimal risk.
Indicate requested waiver(s) or alteration(s) below. In addition, complete the corresponding section of the Waivers and Alterations Request Form and upload it to the 'Consent Forms and Recruitment Materials' page in Rapport.

☐ For the informed consent *process*
☐ For the *documentation* of informed consent
☐ For the HIPAA Authorization to use and/or disclose PHI
☐ For a waiver of the requirement for medical record documentation

14. Financial impact on participants

a. List the tests, visits, and procedures performed for only research purposes and specify who will pay:

Note: Research procedures may not be billed to a health insurance plan

N/A

15. Compensation or Gifts

Please describe any payments, gifts or reimbursements participants will receive for taking part in the study:

Participants will be compensated with a $30 gift card for completing the baseline survey, a $60 gift card for completing an in-person stress induction lab visit, and a $60 gift card for completing the second survey.

Those who complete all three study tasks will be entered into a raffle for an additional $200 gift card.

16. Privacy of Participants

Note: Methods used to obtain information about participants may have an effect on privacy. For example:

- Consent discussions or interviews held in public which concern sensitive subjects or behaviors
- Observations of behavior, especially illicit behavior, in quasi-public settings

Describe any activities or interactions which could lead to a breach of privacy and provide a plan to protect participant privacy:

Since a portion of data is operating out of Dr. Diane Gilbert-Diamond's lab, there is potential of an unforeseen breach of privacy of participants who are enrolled in Biology 3. Because of this, surveys will be administered to participants remotely. The course instructor (D.G.D.) will remove herself from the lab 30 minutes before a study visit to ensure participant privacy and primarily work out of her offices in the Life Sciences Building for visits to be conducted at the lab.

17. Confidentiality of Data

Note: Any person engaged in research collecting information that could cause financial, social or legal harm to participants may apply for a Certificate of Confidentiality. Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They are intended to allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

a. If disclosed, could any of the data collected be considered sensitive, with the potential to damage financial standing, employability, insurability, or reputation?

☐ **No** ☒ **Yes**

If Yes, describe the data or information, the rationale for their collection, and whether a Certificate of Confidentiality will be obtained:

Information relates to potential engagement in illegal activities, specifically alcohol use. Asking this data is necessary, as it may be linked to applied mindfulness. Additionally, alcohol use is a measured health outcome in this study. A certificate of confidentiality has been obtained from the NIH.

b. Describe the safeguards employed to secure, share, and maintain data during the study, addressing any of the following which may apply:

- Administrative, ie. coding of participant data
- Physical, ie. use of locked file cabinets
- Technical, ie. encrypted data systems

Participant data will be coded and stored with a random study ID on the encrypted Dartmouth server. Researchers on this project will only access the Dartmouth server while connected to a secure Dartmouth network or VPN. Additionally, the database where data is stored will be password protected.

c. Describe the plan for storage or destruction of data upon study completion:

All files collected will be in digital format. Physical copies with any data collected will be destroyed after the study is complete. Data in a digital format will be stored on the encrypted, secure Dartmouth College server for a minimum of 5 years.