**PROTOCOL TEMPLATE FOR INVESTIGATOR-INITIATED STUDIES**

**INSTRUCTIONS:**

* Sections will expand to fit your responses.
* Keep an electronic copy to modify when making changes either as directed by the IRB, or for amendments/modifications.
* Mark sections “NA” if they are not applicable to your research.
* Please use lay language, avoid professional jargon and define all abbreviations when they first appear.

**PROTOCOL TITLE:**

Response:

Impact of Holistic Wellness Strategies and Techniques on Perceived Stress and Mental Well-Being of Graduate Speech-Language Pathology Students

**PROTOCOL VERSION/AMENDMENT # AND DATE**

Response:

**PRINCIPAL INVESTIGATOR:**

Response: Joy Kling

**1.0** **Objectives**

1.1 Describe the purpose, specific aims, or objectives of this research. Specifically, explain why it is important to do the study.

Response: The purpose of our pretest/posttest study is to assess the impact of implementation of holistic wellness techniques and strategies, including time management strategies, coping strategies, and communication seminars, on the mental well-being of graduate students in speech-language pathology. Impact is operationally defined as an improvement or decrease in self-reported outcomes of students’ perceived stress and mental well-being. Mental well-being is operationally defined as a student’s self-perception of their emotional, social, and physical wellness in regards to graduate program expectations and workload based upon a Qualtrics survey that combines both quantitative and qualitative questions. Perceived stress is operationally defined using the Perceived Stress Scale. A pre-survey, administered prior to implementation of mindfulness seminars, and post-survey, administered at the end of the fall semester, will be examined to determine the impact of implementation of structured holtistic wellness techniques and strategies. A total of 58 students met the criteria to be utilized in this study.

**2.0 Background**

2.1 Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute/fill in gaps to existing knowledge.

Response: Many research studies have highlighted the increased risk of reduced mental well-being, heightened perceived stress, and increased distress amongst graduate student populations in recent years. Many factors, including course load, clinical expectations, lack of mentorship, and time constraints, can contribute to negative feelings of emotional, physical, and social wellness of students in graduate programs. Existing literature has investigated the impact and efficacy of implementation of various strategies, techniques, and programs to increase mental well-being and stress management skills among graduate students, however gaps in the literature exist in the efficacy of these strategies, techniques, and programs on the mental well-being and perceived stress of speech-language pathology students. Investigating the impact of structured intervention in the areas of mindfulness and emotional, social, and physical well-being on speech-language pathology graduate students is critical to gain further insight on intervention models that are effective, what strategies benefit graduate students in competitive programs, and the development of curriculum that involves a focus on mindfulness and wellness.

1. **Mindfulness Interventions for Graduate Students**

Existing research has sought to investigate the impact of mindfulness interventions and practices on student perceptions of stress, mental health, wellness, and other attributes that can impact their social, emotional, and physical well-being. Many studies found that implementation of programs, strategies, or techniques catered to wellness, self-care, or well-being were effective in reducing perceived stress amongst graduate students as well as increasing overall mental well-being.

***A Mindfulness Practice for Communication Sciences and Disorders Undergraduate and Speech-Language Pathology Graduate Students: Effects on Stress, Self-Compassion, and Perfectionism →*** [***https://search.library.stonybrook.edu/permalink/01SUNY\_STB/1ff40p4/cdi\_gale\_infotracacademiconefile\_A509016207***](https://search.library.stonybrook.edu/permalink/01SUNY_STB/1ff40p4/cdi_gale_infotracacademiconefile_A509016207)

Beck et al. (2017) investigated the implications of the implementation of weekly mindfulness practice on undergraduate and graduate level Speech-Language Pathology students’ perceived levels of attention, perfectionism, self-compassion, stress, and biological stress. The results of their between-groups study, consisting of a control and experimental group, demonstrated that implementation of weekly mindfulness practice had positive implications on biological markers of stress and self-compassion, as well as a decrease in perceived stress levels and negative effects of perfectionism. No significantly significant results regarding attention were observed. Mindfulness practices implemented included yoga, posturing, and breath work in 20 minute increments weekly over the course of one academic semester. There were 37 participants in the study, all women, and ages of participants ranged from 18 to 26 years. Perceived stress levels were operationally defined through the use of the 10-item self-reported PSS. Self-compassion was operationally defined through the use of the Self-Compassion Scale, a 26-item self-report scale. Perfectionism was operationally defined through the use of the APS-R, a 23-item self-report scale. This study also consisted of qualitative data analysis of self-reflection journals filled out by participants throughout the academic semester, highlighting important recurrent themes in entries including physical/mental feelings, improvement, and techniques. Limitations included a lack of gender diversity, timing of mindfulness sessions, and that participants volunteered to be part of the experimental group.

***Stronger Together: Group Self-Care Goal-Setting to Support Graduate Nursing Students’ Resilience, Wellness, and Manage Burnout* →** [**https://search.library.stonybrook.edu/permalink/01SUNY\_STB/1anfgvq/cdi\_proquest\_miscellaneous\_3088563652**](https://search.library.stonybrook.edu/permalink/01SUNY_STB/1anfgvq/cdi_proquest_miscellaneous_3088563652)

            Phillips and Corcoran (2024) examined the efficacy of self-care goal setting check-ins on graduate students’ perceived well-being, resilience, and burnout. Well-being, resilience, and burnout were operationally defined utilizing the WHO Well-Being Index, the Brief Resilience Scale, and the Professional Quality of Life Scale, and student perceptions collected via short answer narratives. A secondary research aim was to identify and understand different methods of support to integrate greater self-care practices into a wellness curriculum for nursing graduate students. Results of this pilot study demonstrated moderate resilience, wellness, and burnout. Qualitative data indicated that students felt the self care check-ins were a helpful tool in stress management, however many reported difficulty with implementation of self-care due to factors including time constraints, motivation, and illness. Results of this study demonstrated positive impact of wellness interventions on graduate nursing student populations.

***Do Something Different as an Intervention for Perceived Stress Reduction in Graduate Counseling Students →*** [***https://search.library.stonybrook.edu/permalink/01SUNY\_STB/1anfgvq/cdi\_proquest\_miscellaneous\_3088563652***](https://search.library.stonybrook.edu/permalink/01SUNY_STB/1anfgvq/cdi_proquest_miscellaneous_3088563652)

Quigley et al. (2022) assessed the impact of implementation of a digital behavior change platform, Do Something Different, on the perceived stress, anxiety, depression, and behavioral flexibility on graduate counseling students. 123 graduate counseling students participated in the study, and inclusion criteria included both part-time and full time students majoring in addictions, clinical mental health, and school counseling. Perceived stress was operationally defined using the Perceived Stress Scale. Behavioral flexibility was operationally defined using the Framework for Internal Transformation Profiler’s Behavior Flexibility Rater. Anxiety and depression were operationally defined by the Thoughts and Feelings Scale. Participants were split unevenly into experimental and control groups. DSD online diagnostic questionnaires were completed by participants, allowing for personalized intervention tailored by results of the questionnaire. Results of the pretest/posttest study demonstrated that there was a significant reduction in perceived anxiety and depression levels after implementation of Do Something Different, with no significant change reported in behavioral flexibility. Results also demonstrated that the implementation of Do Something Different had a positive impact on perceived stress levels. Limitations included an imbalance between size of control/treatment groups, limited timeframe for data collection, and self-report bias.

***Perceived stress, coping strategies, and emotional intelligence: A cross sectional study of university students in helping disciplines → <https://search.library.stonybrook.edu/permalink/01SUNY_STB/1anfgvq/cdi_pubmed_primary_30053557>***

           Enns et al. (2018) investigated the relationship between emotional intelligence and perceived stress, as well as the role of coping responses and strategies in the mediation of perceived stress. Emotional intelligence was operationally defined through the use of the SSEIT, a self-report measure consisting of 33 items. Perceived stress was operationally defined through the use of the Perceived Stress Scale. Coping responses and strategies were operationally defined through the use of the Brief COPE, a self-report measure consisting of 28-items. This cross-sectional correlational survey study consisted of 203 undergraduate and graduate students majoring in psychology, nursing, or social work. Results of the study demonstrated that there was a significant direct correlation between emotional intelligence level and perceived stress, as well as a significant indirect effect of adaptive and maladaptive coping on perceived stress. Results highlighted that higher emotional intelligence resulted in lower levels of perceived stress, and that adaptive coping further reduced the levels of perceived stress and increased levels of emotional intelligence. Results of this study provide rationale for the implementation of emotional intelligence based interventions for the mediation of perceived stress amongst graduate students, as well as the importance of instructing graduate students on flexible, adaptive coping methods.

***Meta-Analytic Evaluation of Stress Reduction Interventions for Undergraduate and Graduate Students →*** [***https://search.library.stonybrook.edu/permalink/01SUNY\_STB/1anfgvq/cdi\_proquest\_journals\_2034046153***](https://search.library.stonybrook.edu/permalink/01SUNY_STB/1anfgvq/cdi_proquest_journals_2034046153)

Yusofov et al. (2018) systematically examined the effectiveness of a variety of stress reduction interventions for undergraduate and graduate students. This meta-analysis systematically analyzed results from 43 different studies with an inclusion criteria of a control group as well as pre and post assessment of distress levels. Results of the meta-analysis demonstrated that cognitive-behavioral therapy, coping skills, and social support interventions were effective at reducing perceived stress, whereas relaxation training, mindfulness-based stress reduction, and psychoeducation were effective at reducing perceived anxiety. Across all 6 intervention types, significant reduction of both anxiety and perceived stress was observed in experimental groups when compared to control groups. Results also highlighted the importance of tailoring intervention methods and strategies toward specific outcome targeted as well as group type targeted.

***Interventions to Reduce Perceived Stress Among Graduate Students: A Systematic Review with Implications for Evidence-Based Practice* →** [**https://search.library.stonybrook.edu/permalink/01SUNY\_STB/1anfgvq/cdi\_proquest\_miscellaneous\_1927834637**](https://search.library.stonybrook.edu/permalink/01SUNY_STB/1anfgvq/cdi_proquest_miscellaneous_1927834637)

Stillwell et al. (2024) systematically assessed existing literature and evidence to identify evidence-based self-care interventions for coping with perceived stress for graduate students. Perceived stress was operationally defined through the use of the Perceived Stress Scale. Results of the systematic review, which further investigated the results of eight studies that were predominantly pre-post study designs, demonstrated that across all studies, a reduction of perceived stress was noted following the implementation of evidence-based self-care interventions. Evidence-based self-care interventions included stress management courses and mind-body-stress-reduction techniques.

1. **Mental Wellness of Graduate Students**

Existing literature highlights that graduate students in multiple professions experience increased stress, distress, and decreased mental wellness and overall well-being. Perceived stress and mental wellness are often measured through self-report measures including the Perceived Stress Scale. Understanding the implications of negative mental well-being, reported self-outcomes that demonstrate distress and greater perceived stress, and factors that contribute to the mental wellness of graduate students is crucial for providing rationale for the implementation of wellness-based interventions tailored to the needs of graduate students.

***“This program should come with a warning sign!”: Mental wellness in occupational therapy and physical therapy students* →** [**https://search.library.stonybrook.edu/permalink/01SUNY\_STB/1anfgvq/cdi\_proquest\_journals\_2736067707**](https://search.library.stonybrook.edu/permalink/01SUNY_STB/1anfgvq/cdi_proquest_journals_2736067707)

Webber et al. (2022) investigated distress reported in entry-level masters students and compared distress levels to existing data, as well as explored many factors that cause stress amongst students, their effects, and coping strategies. Results of the mixed-methods cross-sectional study, consisting of questionnaires and focus groups, demonstrated that occupational therapy and physical therapy students of one cohort reported higher levels of distress compared to the following cohort as well as undergraduate and general population samples. Cause of stress was attributed to an imbalance of school responsibilities and other aspects of life, which had a negative impact on perceived mental health. Coping strategies included physical activity, peer selection, and modification of expectations. Distress is operationally defined as perceived levels of stress, anxiety, and/or depression through the use of the Depression Anxiety Stress Scale. Student stress was operationally defined through the use of the Occupational Therapy Student Stressor Survey. Coping ability was operationally defined as comprehensibility, manageability, and meaningfulness through the use of the Sense of Coherence tool. 98 participants were utilized in the study and exclusion criteria involved injury or medical condition affecting physical activity. Limitations included small sample size and limited sampling time frame.

***Experience Doesn’t Reduce All Stress: An Exploration of Perceived Stress Among Graduate Students in Speech-Language Pathology →*** [**https://search.library.stonybrook.edu/permalink/01SUNY\_STB/1anfgvq/cdi\_proquest\_journals\_2162378803**](https://search.library.stonybrook.edu/permalink/01SUNY_STB/1anfgvq/cdi_proquest_journals_2162378803)

           Ellis and Briley (2018) assessed perceived stress reported by first and second-year speech-language pathology graduate students. Perceived stress was operationally defined through the use of the Perceived Stress Scale (PSS). 3 open-ended qualitative questions examined source of stress, increase in stress, and faculty strategies to reduce stress. Results of the mixed-methods study demonstrated that more than 35% of students reported moderate levels of stress, and that significantly higher levels of perceived stress were reported by second year students (48%) when compared to levels reported by first year students (25%). Different facilitators of stress were reported amongst both cohorts, with a focus on transition to a new program being the primary cause of stress for first year students and a focus on issues with coping as well as feeling overwhelmed for second year students. Qualitative analysis of open-ended questions revealed that students felt as if better coordination of assignments, limited changes to syllabi, greater communication, reduced workload, greater flexibility, and more personal contacts were strategies that could be implemented by faculty to reduce perceived levels of stress amongst students. Limitations included limited variation in sample, fluctuation of stress levels was not accounted for, and there was limited geographical diversity of participants.

***Positive factors related to graduate student mental health →*** [***https://search.library.stonybrook.edu/permalink/01SUNY\_STB/1anfgvq/cdi\_crossref\_primary\_10\_1080\_07448481\_2020\_1841207***](https://search.library.stonybrook.edu/permalink/01SUNY_STB/1anfgvq/cdi_crossref_primary_10_1080_07448481_2020_1841207)

            Charles et al. (2022) examined positive aspects and factors that can play a role in the attenuation of stress experienced by graduate students to better understand a correlation between positive and negative factors influencing perceived stress. Negative factors are operationally defined as financial distress, poorer psychological functioning, less satisfying mentorships, perceived discrimination, and less contact with advisors reported by graduate students. Positive factors are operationally defined as social support, university and faculty support, optimism, and perceived career advantage reported by graduate students. Both positive and negative factors were operationally defined through web-based survey questions about their graduate school experience as well as a self-report CESD-R depressive symptom survey. Results of the study demonstrated high rates of depressive symptoms among graduate students, with stronger effects on positive perceptions of mental health correlated with positive factors. Although correlation doesn't equal causation, this study provided useful insight into specific factors that contribute to a decline in mental well-being of graduate students and provided an outline for areas of concern for graduate programs to target and remediate to facilitate a more positive environment for graduate students.

***Building a foundation in self-awareness: Genetic counseling students’ experiences with self-care, reflection, and mindfulness →*** [***https://search.library.stonybrook.edu/permalink/01SUNY\_STB/1anfgvq/cdi\_crossref\_primary\_10\_1002\_jgc4\_1539***](https://search.library.stonybrook.edu/permalink/01SUNY_STB/1anfgvq/cdi_crossref_primary_10_1002_jgc4_1539)

             Bulmer et al. (2021) investigated self-awareness of genetic counseling students in the areas of mindfulness, self-care and self-reflection. Self-awareness was operationally defined using the Self-Reflection Insight Scale, the Mindfulness Attention Awareness Scale, and qualitative descriptions of personal experiences regarding self-awareness practice. Results of the mixed-methods study demonstrated that genetic counseling students’ obtained significantly lower mean scores on the Mindfulness Attention Awareness Scale and Self-Reflection Insight Scale when compared to other health professionals, highlighting that genetic counseling students’ had decreased mindfulness. Results also demonstrated that that is a significant positive correlation between levels of self-awareness and mindfulness, and that those who reported having structured practice in self-awareness, which was part of their graduate program curriculum, demonstrated greater mean scores on the Self-Reflection Insight Scale, demonstrating the impact of implementation of mindfulness techniques in graduate curriculum.

2.2 Include complete citations or references:

Response: References:

Beck, A. R., Verticchio, H., Seeman, S., Milliken, E., & Schaab, H. (2017). A mindfulness practice for Communication Sciences and disorders undergraduate and speech-language pathology graduate students: Effects on stress, self-compassion, and perfectionism. *American Journal of Speech-Language Pathology*, *26*(3), 893–907. <https://doi.org/10.1044/2017_ajslp-16-0172>

Briley, P.M, Ellis, C. (2018). Experience Doesn’t Reduce All Stress: An Exploration of Perceived Stress Among Graduate Students in Speech-Language Pathology. *Journal of Allied Health*, 47(4), 277-281.

Bulmer, L., Stanley, C., Loffredo, L., Mills, R., & Doyle, L. (2021). Building a foundation in self‐awareness: Genetic counseling students’ experiences with self‐care, reflection, and mindfulness. *Journal of Genetic Counseling*, *31*(3), 722–734. <https://doi.org/10.1002/jgc4.1539>

Charles, S. T., Karnaze, M. M., & Leslie, F. M. (2021). Positive factors related to graduate student mental health. *Journal of American College Health*, *70*(6), 1858–1866. <https://doi.org/10.1080/07448481.2020.1841207>

Enns, A., Eldridge, G. D., Montgomery, C., & Gonzalez, V. M. (2018). Perceived stress, coping strategies, and emotional intelligence: A cross-sectional study of university students in helping disciplines. *Nurse Education Today*, *68*, 226–231. <https://doi.org/10.1016/j.nedt.2018.06.012>

Phillips, K. E., & Corcoran, K. J. (2024). Stronger together: Group self-care goal-setting to support graduate nursing students’ resilience, Wellness, and Manage Burnout. *Nursing Education Perspectives*, *45*(5), 310–312. <https://doi.org/10.1097/01.nep.0000000000001314>

Quigley, J. L., Schmuldt, L., Todd, S., & Bender, S. (2021). Do something different as an intervention for perceived stress reduction in graduate counseling students. *Journal of Technology in Human Services*, *40*(1), 1–24. <https://doi.org/10.1080/15228835.2021.1904324>

Stillwell, S. B., Vermeesch, A. L., & Scott, J. G. (2017). Interventions to reduce perceived stress among graduate students: A systematic review with implications for evidence‐based practice. *Worldviews on Evidence-Based Nursing*, *14*(6), 507–513. <https://doi.org/10.1111/wvn.12250>

Webber, S. C., Wener, P., MacDonald, L. L., Tittlemier, B. J., Hahn, F., & Cooper, J. E. (2021). “this program should come with a warning sign!”: Mental wellness in occupational therapy and physical therapy students. *Journal of American College Health*, *70*(8), 2491–2498. <https://doi.org/10.1080/07448481.2020.1865983>

Yusufov, M., Nicoloro-SantaBarbara, J., Grey, N. E., Moyer, A., & Lobel, M. (2019). Meta-analytic evaluation of stress reduction interventions for undergraduate and graduate students. *International Journal of Stress Management*, *26*(2), 132–145. <https://doi.org/10.1037/str0000099>

**3.0 Study Design**

3.1 Describe and explain the study design (e.g., case-control, cross-sectional, ethnographic, experimental, interventional, longitudinal, and observational). Indicate if there is randomization, blinding, control group, etc. If randomizing, explain how this will be achieved.

Response: A QR code will be shared during the first day and last day of participation in the holistic wellness initiative for the speech-language pathology program at Stony Brook University, as well as via email. This QR code will lead to the Perceived Stress Scale (PSS) 10-item and Qualtrics Survey. This is a pretest/posttest study in the form of a PSS and Qualtrics Survey, with pretesting occurring prior to the implementation of holistic wellness seminars, and posttesting occurring following the completion of mindfulness seminars at the end of the academic year.

All surveys will be sent at the same time with a possible three week return window for the pre-survey and six week return window for the post survey. All surveys returned within the survey window will be collected for data. After three weeks the pre-survey will no longer be accessible through the QR code and after six weeks the post survey will no longer be accessible through the QR code.

3.2 Include the number of subjects and the power analysis. If applicable, indicate your screen failure rate, i.e., how many subjects you expect to screen to reach your target sample.

Response: There are 26 students in our second year cohort and 32 students in our first year cohort of the Stony Brook University graduate speech-language pathology program.

3.3 Indicate the duration of the subject participation including long-term follow-up.

Response: Subject participation is estimated to be about 4 months. The study will begin the first week of classes in the fall semester and end the last week of classes in the fall semester.

3.4 Indicate whether you are specifically recruiting or targeting any of the following special populations in your study using the checkboxes below.

Response: No

Minors (under 18 years old)

Adults unable to consent

Pregnant women

Prisoners

3.5 Indicate if you will include minorities (American Indians, Alaskan Native, Asian, Native Hawaiian, Pacific Islander, Black [not of Hispanic origin] and Hispanic) as Federal mandates require that you include minorities unless you can justify their exclusion.

Response:

Yes

No, Justify:

3.6 Indicate whether you will include non-English speaking individuals in your study. Provide justification if you will specifically exclude non-English speaking individuals. Review <https://www.stonybrook.edu/research-compliance/Human-Subjects/sops> for the SBU policy on inclusion of non-English speakers (section 17.8). Following approval of the English version, you must submit the translated version of the materials with the attestation of the translation.

Response: No

3.7 Describe the data analysis plan, including any statistical procedures.

NOTE: If we are a lead site for a multi-site study include the total number of subjects that will be enrolled or records that will be reviewed across all sites. This section applies to both quantitative and qualitative analysis.

Response:

**4.0 Inclusion and Exclusion Criteria**

NOTE: If your study is more than minimal risk, you must also upload (in the myResearch IRB smartform) a copy of your inclusion/exclusion checklist to be completed at time of enrollment of each subject.

4.1 Describe, in bullet points, the criteria that define who will be included in this study.

Response:

* Participants must be a graduate student in Speech-Language Pathology at Stony Brook Southampton
* Participants must be 18+ years old.
* Participate in the department holistic wellness initiative

4.2 Describe, in bullet points, the criteria that define who will be excluded from this study.

Response: Schools that are:

* Does not read or understand English
* Faculty

4.3 Describe how individuals will be screened for eligibility. Upload all relevant screening documents with your submission (screening protocol, script, questionnaire). Identify who will certify that subjects meet eligibility requirements. (Upload these documents in the myResearch IRB smartform.)

Response: Individuals will be screened by asking if they are participating in the holistic wellness initiative for the Stony Brook University graduate speech-language pathology program.

**5.0 Vulnerable Populations**

5.1 For research that specifically recruits/targets minors (under 18 years), review, complete and upload Supplemental Form F: Minors.

Confirmed

N/A: This research does not involve persons who have not attained the legal age for consent to treatments or procedures (“children”).

5.2 For research that specifically recruits/targets adults who cannot consent for themselves, you will be asked additional information in Section 25 (“Informed Consent”).

Confirmed

N/A: This research does not involve this population.

5.3 For research that specifically recruits/targets pregnant women, review, complete and upload Supplemental Form A: Pregnant Women, Fetuses, Non-Viable Neonates, or Neonates of Uncertain Viability.

Confirmed

N/A: This research does not involve pregnant women.

5.4 For research that specifically recruits/targets neonates of uncertain viability or non-viable neonates, review, complete and upload Supplemental Form A: Pregnant Women, Fetuses, Non-Viable Neonates, or Neonates of Uncertain Viability.

Confirmed

N/A: This research does not involve non-viable neonates or neonates of uncertain viability.

5.5 For research that specifically recruits/targets prisoners, review, complete and upload Supplemental Form B: Prisoners.

Confirmed

N/A: This research does not involve prisoners.

5.6 Consider if other specifically targeted populations such as students, employees of a specific firm, or educationally or economically disadvantaged persons are vulnerable. Provide information regarding their safeguards and protections, including safeguards to eliminate coercion or undue influence.

Safeguards include: Yes, vulnerable populations such as students will be included in this study. Safeguards and protections used to eliminate coercion or undue influence include informed consent and withdrawal without penalization.

**6.0 Recruitment Methods**

N/A: This is a records review only, and subjects will not be recruited.

NOTE: If you select this option, please make sure that all record review procedures and inclusion/exclusion screening are adequately described in other sections, including date range for records that will be reviewed.

6.1 Describe source of subjects: When, where, and how potential subjects will be recruited. In order to approach patients in the clinic/hospital setting you must have a treatment relationship with these individuals.

NOTE: Recruitment refers to how you are identifying potential participants and introducing them to the study.

Response: Participants recruited for this study include graduate students of the Speech-Language Pathology Program at Stony Brook Southampton. They will be recruited via a QR code that will be shared during the first day and last day of participation in the holistic wellness initiative for the speech-language pathology program at Stony Brook University, as well as via email.

6.2 Describe how you will protect the privacy of prospective subjects during the recruitment process.

NOTE: Examples of appropriate responses may include: “participant only meets with a study coordinator in a private office setting where no one can overhear”, “the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering.”

Response: Confidentiality will be maintained by converting all personally identifiable data into nominal data for comparison over time. The participant will select a 5-digit code to link there pre and post PSS and Survey without any personally identifiable information. Demographic questions will be limited to asking student’s year in the program and employment status as to not identify any of the students in the cohort. Participants will be reminded that they are free to refuse to answer any questions or stop participating at any time.

**7.0 Research Procedures**

7.1 Provide a detailed description of all research procedures or activities being performed on the research subjects. **This should serve as a blueprint for your study and include enough detail so that another investigator could pick up your protocol and replicate the research.** For studies that have multiple or complex visits or procedures, consider the addition of a schedule of events table in in your response. Be sure to include:

* Procedures being performed to monitor subjects for safety or to minimize risks.
* All drugs and devices used in the research and the purpose of their use, and their regulatory status

Response:

Research procedures will be as follows:

1. Creation of Qualtrics survey inclusive of qualitative and quantitative questions regarding perceived stress, stress management techniques, coping strategies, and perceived mental well-being
2. Administration of pre-survey prior to implementation of wellness seminars. This should take 20 minutes.
3. Administration of post-survey following the completion of the fall semester. This should take 20 minutes.
4. Data analysis
   1. Conduct a pretest and posttest analysis of data to demonstrate impact of implementation of holistic wellness seminars and examine statistical findings related to research question.
   2. Conduct qualitative analysis to identify recurrent themes amongst participants.
5. Interpret data and explore, if any, relationships between the variables exist.
6. Draw conclusions about the impact of holistic wellness seminars, propose methods for future research, discuss limitations

7.2 Describe what data, including long-term follow-up data, will be collected.

NOTE: For studies with multiple data collection points or long-term follow up, consider the addition of a schedule or table in your response.

Response: Quantitative and qualitative data will be collected at two points in time, pre and post implementation of holistic wellness seminars. All data will be collected via Qualtrics.

7.3 List any instruments or measurement tools used to collect data (e.g., surveys, scripts, questionnaires, interview guides, validated instruments, data collection forms). Upload these materials in the myResearch IRB smartform.

Response: Qualtrics Survey, Perceived Stress Scale

7.4 Describe any source records that will be used to collect data about subjects (e.g., school records, electronic medical records) and include the date range for records that will be accessed.

Response: N/A

7.5 Indicate whether or not the results for individual subjects, such as results of investigational diagnostic tests, genetic tests, or incidental findings will be shared with subjects or others (e.g., the subject’s primary care physician) and if so, describe how these will be shared.

Response: Results will not be shared with subjects or others. Data is confidential.

**8.0 Research Setting**

8.1 Describe all facilities/sites/locations where you will be screening and conducting research procedures.

Example: “A classroom setting in the Department of Psychology equipped with a computer with relevant survey administration software,” “The angiogram suite at Stony Brook University Hospital, a fully accredited tertiary care institution within New York State with badge access,” etc.

Response: A classroom at Stony Brook Southampton campus where the department of Speech-Language Pathology program is located.

8.2 For research procedures being conducted internationally), Supplemental Form C must be completed and uploaded.

Response:

N/A: This study is not conducted outside of SBU or its affiliates.

8.3 For research procedures conducted externally to Stony Brook University (e.g. other institutions, schools, other states), attach applicable approval letter(s) in the myResearch IRB smartform.

Response:

**9.0 Resources and Qualifications**

9.1 The Principal Investigator (PI) must confirm, in consultation with Chair and Dean as applicable, that adequate resources are present to conduct and complete the study compliantly and safely. Specifically:

NO YES The proposed subject population(s) are available in sufficient numbers to meet the study requirements.

NO YES Sufficient funds are available to conduct and complete the study compliantly and safely.

NO YES The PI and study team have sufficient time to conduct and complete the study compliantly and safely.

NO YES The PI has determined that the named study team is qualified to conduct the research compliantly and to monitor the safety and welfare of the enrolled research subjects effectively.

NO YES The PI ensures that the study team is fully aware of his/her involvement in this study and the details of the study protocol.

NO YES The PI ensures that the study teams will only be involved in research procedures for which they have been trained, and are currently certified and/or licensed, if required.

NO YES The PI ensures that all study team members are updated on the progress of the research and the regulatory requirements (including enrolled subjects, unanticipated problems, etc.).

Response: All members of the research team are invited to participate in the weekly discussions with the PI and any additional meetings if necessary.

**10.0 Other Approvals**

10.1 List approvals that will be obtained prior to commencing the research (e.g., University Hospital sign-offs per the UH Application, Cancer Center Scientific review, external site, funding agency, laboratory, Radiation Safety, IBC, SCRO, IACUC, RDRC).

Response:

N/A: This study does not require any other approvals.

**11.0 Provisions to Protect the Privacy Interests of Subjects**

11.1 Describe how you will protect subjects’ privacy interests during the course of this research.

NOTE: Privacy refers to an individual’s desire/right to control access to or to place limits on whom they interact with or whom they provide personal information. Privacy applies to the person. Examples of appropriate responses include: “participant only meets with a study coordinator in a private office setting where no one can overhear”, or “the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering.”

Response: All surveys are conducted anonymously online, no participants will be asked for any identifying information.

**12.0 Confidentiality**

**A. Confidentiality/Security of Study Data**

Describe the local procedures for maintenance of security and confidentiality of study data and any records that will be reviewed for data collection.

NOTE: Confidentiality refers to how data collected about individuals for the research will be protected by the researcher from release. Confidentiality applies to the data.

12.1 Where and how will all data and records be stored? Include information about: locked cabinet/locked office, authorization of access, certificates of confidentiality, and separation of identifiers and data, as applicable. Include physical (e.g., paper) and electronic files (e.g., storage of data in REDCap) password protection, encryption.

Response: All data will be stored on secure Stony Brook serves and share drives. No PHI or person data will be collected. The raw data will be downloaded from SBU Qualtrics into SPSS data file and will be stored in the SBU SINC site folded of Joy Kling.

12.2 Who will have access to the data?

Response: The primary research team will have access to the data.

NOTE: If there are plans to share datasets with unrestricted access, adjust language in the consent form to reflect this. Consider including the phrase: “*Your data and biospecimens will be shared in a way where anybody around the world can gain access to them without review.”*

12.3 How will the data be transported/transmitted (if applicable)?

Response: Data will be transported via survey and remain digital in our archives.

12.4 Describe if identifiers will be retained, deidentification of the data is not feasible, or whether there are circumstances in which re-identification may be possible.

Response: The surveys will be identified only through cohort year. All surveys will be collected anonymously.

12.5 If this study includes data collected from individuals, groups, or populations with unique attributes (e.g., Tribal Nations, international sites ) that may increase the risk of re-identification, describe how sensitive information regarding potentially stigmatizing traits, illegal behaviors, or other information that could be perceived as causing group harm or used for discriminatory purposes will be protected.

Response: N/A

12.6 Describe circumstances under which a code key may be used to re-link identifying information to data/specimens?

Response: A Unique ID code (A loved ones birthday month, 1st 2 letters of a childhood friend, and loved ones birthday day) will be selected by the participant to re-link pre and post survey

**B. Confidentiality of Study Specimens**

Describe the local procedures for maintenance of confidentiality of study specimens.

N/A: No specimens will be collected or analyzed in this research.

12.7 Where and how will all specimens be stored? Include information about: locked freezers, locked laboratory, authorization of access, and labeling of specimens, as applicable.

Response:

12.8 Are there limits for the future use of biospecimens in any way? Such as controlled access to the data based on laws, regulations, policies, and agreements.

Response: N/A

12.9 Who is responsible for receipt or transmission of the specimens (if applicable)? If you are transporting specimens to another location not affiliated with Stony Brook University, you must have a Material Transfer Agreement.

Response: N/A

12.10 Banking Data or Specimens for Future Unspecified Use

N/A: This study is not storing data or specimens for research outside the scope of the present protocol. This section does not apply.

NOTE: If you are proposing to bank specimens for future use, you may be subject to licensure requirements under the NYS Department of Health and must be covered under the SBU license. See SOPs section 17.2 at <https://www.stonybrook.edu/research-compliance/Human-Subjects/sops>.

12.11 If data will be banked for research outside of the scope of the present protocol, describe where the data will be stored, how long they will be stored, and who will have access to the data.

NOTE: Your response here must be consistent with the information provided to subjects in your Consent Documents

Response: N/A

12.12 Will specimens be obtained from specific cultural groups? Consider whether your study will include specimens collected from individuals, groups or populations with unique attributes (e.g., Tribal Nations, international groups) that may increase the risk of re-identification. Describe how sensitive information regarding potentially stigmatizing traits, illegal behaviors, or other information that could be perceived as causing group harm or used for discriminatory purposes will be protected.

Also, consider cultural sensitivities around the return and/or destruction of biospecimens when research participants withdraw their consent for the storage and sharing of data and biospecimens or when data and biospecimens need to be maintained.

NOTE:

In general, participants should be given the choice about whether or not they wish to have their data and biospecimens stored and shared for future use. Providing options for participants to agree to data and biospecimen storage and sharing is particularly important in studies that offer the prospect of direct benefit to the participant. Requiring storage and sharing may be considered undue influence if the participant does not want to agree to sharing of data and biospecimens but feels compelled to agree anyway to join a possibly beneficial research study.

If the primary research study offers no prospect of direct benefit, it may be reasonable to consider requiring storage and sharing in the primary protocol (e.g., if the primary protocol is a repository protocol with the sole purpose being to collect data and/or biospecimens for future use). In this case, there is no reason to participate if the participant does not want to provide consent for storage and sharing.

NIH Funded Research: Upload a copy of the Data Management and Sharing Plan

Response: N/A

**13.0 Withdrawal of Subjects**

N/A: This study is not enrolling subjects. This section does not apply.

13.1 Describe anticipated circumstances under which subjects may be withdrawn from the research without their consent.

Response: Participant does not meet the inclusion criteria. Participant abandons the survey.

13.2 Describe any procedures for orderly termination.

NOTE: Examples may include return of study drug, exit interview with clinician. Include whether additional follow up is recommended for safety reasons for physical or emotional health.

Response: N/A

13.3 Describe procedures that will be followed when subjects withdraw from the research, including retention of already collected data, and partial withdrawal from procedures with continued data collection, as applicable.

Response: If participants withdraw from the study, the already collected data will not be used and further data collection will stop.

13.4 Describe what will happen to data already collected.

Response: Any data collected from participants that do not meet the inclusion criteria and are withdrawn from the study will be removed and not considered in the research.

**14.0 Risks to Subjects**

14.1 Describe if any subjects will be withdrawn from therapeutic procedures or drugs (e.g., washout periods) prior to, or during, their participation in the study.

Response: N/A

14.2 List the reasonably foreseeable risks, discomforts, to the subjects related to their participation in the research. Consider physical, psychological, social, legal, and economic risks.

NOTE: Breach of confidentiality is always a risk for identifiable subject data.

Response: N/A

14.3 Describe the probability, magnitude, duration, and reversibility of the risks and the procedures to minimize these risks.

Response: N/A

14.4 Describe procedures being performed to monitor subjects for safety.

Response: There will be no identifying information collected during this study

14.5 If the study poses risks to an embryo or fetus should the subject be or become pregnant, how will you minimize the risk of a pregnancy occurring during the course of the study? (Select all that apply.)

Counseling on birth control and /or abstinence

Pregnancy test during the study

Pregnancy test prior to initiation of the study

Other \_\_\_\_\_

14.6 If applicable, describe possible risks to others who are not subjects (e.g., partner of a subject who is administered a study drug).

Response: N/A

14.7 Provisions to Monitor the Data to Ensure the Safety of Subjects

N/A: This study is not enrolling subjects OR is limited to records review procedures only OR is a minimal risk study. See SBU SOPs section 3.6 for a list of the procedures that are generally considered to be minimal risk: <https://www.stonybrook.edu/research-compliance/Human-Subjects/sops>).

Response: N/A

14.8 Provide information about the Data and Safety Monitoring Plan.

Response: N/A

14.9 Provide information if a medical monitor will be used to monitor the safety of the study.

Response: N/A

14.10 Provide information if a Data and Safety Monitoring Committee/Board will be used to monitor the safety of a study that is greater than minimal risk. Provide justification if a Data and Safety Monitoring Committee/Board will not be used.

N/A:

Response:

14.11 Describe what data are reviewed, including safety data, and efficacy data.

Response:

14.12 Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).

Response:

14.13 Describe the frequency of safety data collection, including when safety data collection starts.

Response:

14.14 Describe who will review the safety data.

Response:

**15.0 Potential Benefits to Subjects**

15.1 Describe the potential benefits that individual subjects may experience by taking part in the research.

Response: Participants may show a reduce in stress or increase in coping mechanisms.

15.2 Indicate if there is no direct benefit.

NOTE: Compensation cannot be stated as a benefit.

Response:

15.3 Indicate if there is a potential benefit to others, future science, or society.

Response: There is the potential benefit of adding to information around holistic wellness for college students.

**16.0 Economic Burden to Subjects**

N/A: This study is not enrolling subjects, or is limited to records review procedures only.

16.1 Describe any costs that subjects may be responsible for because of participation in the research.

NOTE: Some examples include transportation or parking, insurance co-payments, study drugs.

Response:

**17.0 Compensation for Participation**

N/A: There is no compensation for participation. This section does not apply.

17.1 Describe the amount/nature and timing/scheduling of any compensation to subjects, including monetary, course credit, or gift card compensation. Describe any prorated payments based on participation. Add IRS tax information to the consent form per template.

Response:

NOTE: If using West Campus Departmental pools, participation in studies may be offered for credit in class but students MUST be given other options for fulfilling the research component that are comparable in terms of time, effort, and education benefit. Please indicate the alternative activity/related contact information in the consent form.

**18.0 Informed Consent**

18.1 Will you be obtaining consent from subjects?

Yes (If yes, provide responses to each question in this section, and upload your consent documents where indicated in the electronic submission system.)

No (If no, skip to the next section.)

18.2 Describe how the capacity to consent will be assessed for all subjects. Review SBU SOPs section 5.5 for guidance: <https://www.stonybrook.edu/research-compliance/Human-Subjects/sops>).

Response:

18.3 Describe the consent process that will be conducted to ensure that the subject is fully informed regarding study details and subject rights. Include where the consent process will take place, with consideration of the need to protect the subject’s right to privacy.

Response:

18.4 Describe how you will ensure that subjects are provided with sufficient time to consider taking part in the research study. Detail if there is there any time period expected between informing the prospective subject and obtaining the consent.

NOTE: It is required that the prospective subject receive sufficient time to have their questions answered and to consider their participation

Response: A QR code will be shared and participants have 1 week for the pre survey consent and 6 weeks for the post survey consent

18.5 Describe the process to ensure the subject’s ongoing willingness to continue participation for the duration of the research study.

Response: N/A

Non-English Speaking Subjects

N/A: This study will not enroll Non-English speaking subjects.

18.6 Indicate which language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.

Response:

18.7 If subjects who do not speak English will be enrolled, describe the process to consent the subjects, as well as the process to be used to ensure their understanding of research procedures throughout the conduct of the study. Review SOPs section 17.8 for important policies in this regard: <https://www.stonybrook.edu/research-compliance/Human-Subjects/sops>).

Response:

Adults Unable to Consent

N/A: This study will not enroll adults unable to consent.

18.8 Justify why it is necessary to include adult subjects who are unable to consent.

Response:

18.9 Describe how you will identify Legally Authorized Representatives (LAR) for the subjects that will be consistent with the NYS Family Health Care Decisions Act (FHCDA; see SBU SOPs section 5.2 at <https://www.stonybrook.edu/research-compliance/Human-Subjects/sops>).

Response:

18.10 For research conducted outside of New York State, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research.

Response:

18.11 Describe the process for obtaining assent from the adult subjects

Indicate whether assent will be obtained from all, some, or none of the subjects. If some, indicate which adults will be required to assent and which will not.

Response:

18.12 Describe whether assent of the adult subjects will be documented and the process to document assent.

Response:

18.13 Describe how you will obtain consent from a subject to use their data if they later become capable of consent. Include information regarding how competence will be assessed.

Response:

**19.0 Waiver or Alteration of Consent Process**

N/A: A waiver or alteration of consent is not being requested.

**Complete this section if:**

* Informed consent will not be obtained at all
* Informed consent will be obtained, but not documented, or
* Informed consent will be obtained, but not all required information will be disclosed (e.g., in deception research)

A waiver is requested. Complete and upload Supplemental Form G.

19.1 If the research involves a waiver of the consent process for planned emergency research, please contact the Office of Research Compliance for guidance regarding assistance in complying with federal regulations governing this activity (see: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/exception-informed-consent-requirements-emergency-research>

**20.0 Drugs and Devices**

N/A: This study does not involve drugs or devices. This section does not apply.

20.1 Does this study involve use of radiopharmaceuticals?

Yes

No

20.2 For investigational devices, provide the following information below:

Where will the device(s) be stored? Note that the storage area must be within an area under the PI’s control. Describe the security of the storage unit/facility. Provide full detail regarding how the dispensing of the device(s) will be controlled (accountability of removal/return of used devices, and disposition of remaining devices at the conclusion of the investigation) and documented (accounting records/logs).

Response:

20.3 For investigational drugs (including marketed drugs being used off label), will the services of the Investigational Drug Pharmacy be used for storage, dispensing, accounting the drug (required for research conducted at UH, HSC, Cancer Center, and Ambulatory Surgery Center)?

Yes

No → Provide the following information below:

* Where will the drugs/biologics be stored? Note that the storage area must be within an area under the PI’s control
* Describe the security of the storage unit/facility:
* Provide full detail regarding dispensing of the drugs(s), how labeled, controlled (accountability, disposition of unused drug at the conclusion of the investigation) and documented (accounting records/logs):

Response:

**21.0 Sharing of Results with Subjects**

21.1 Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject’s primary care physicians) and if so, describe how it will be shared.

Response: N/A

**22.0 Collaboration**

N/A: This study does not include any collaborations.

22.1 Internal Collaboration

Response:

22.2 External Collaboration

Response:

**22.3 Community Based Participatory Research (CBPR)**

Does this project include community based participatory research? (Also referred to as community-based research (CBR), CBPR is a partnership-based approach to research that takes place in community settings and involves community members in the project’s design and implementation and dissemination of results.)

N/A: This study does not include CBPR.

Response: