View xForm - Human Subjects Review Protocol

Please use this Human Subjects Review Protocol form when submitting to the IUP IRB.

New protocol data entry
- Submitted 3/12/2018 12:32:35 PM ET by [redacted]

Project Information

Saving Instructions

Each time you click 'Next' or 'Previous' your work is saved. You may click 'Save for Later' to save where you are and leave the form. Finally, if you jump to another page, using the dropdown at the top of the form, your work on each page will be saved. You will not be able to 'Check and Submit' form until all required fields are entered.

Submitter

[redacted]

Email: [redacted]@iup.edu

Project Title

Initial screening study for Somatic symptom disorder: How personality may explain and predict response to treatment.

Project Type

Dissertation Research

**ALL STUDENT PROJECTS MUST BE ACCOMPANIED BY A HUMAN SUBJECTS CITI TRAINING COMPLETION REPORT. PROTOCOLS FROM STUDENTS WILL NOT BE APPROVED UNTIL THIS ITEM IS RECEIVED*

Please enter the email address of the Principal Investigator.

[redacted]

Email: [redacted]@iup.edu

You must enter your official university email address (for example:jdoe@iup.edu or wxyz@iup.edu) Do NOT enter an alias email address (for example Jane.Doe@iup.edu)

Department

Psychology

Please enter the email address of your faculty advisor.

[redacted]

Email: [redacted]@iup.edu

You must enter your faculty advisor's official university email address (for example:jdoe@iup.edu or wxyz@iup.edu) Do NOT enter an alias email address (for example Jane.Doe@iup.edu). If you receive a message that the contact is not found, please ask your faculty advisor to login to IRBManager at least once and that will resolve the issue.

Please add contact and then enter the email address for each Co-Investigator

[redacted]

Email: [redacted]@iup.edu

[redacted]

Email: [redacted]@iup.edu

You must enter the co-investigator's official university email address (for example:jdoe@iup.edu or wxyz@iup.edu). Do NOT enter an alias email address (for example Jane.Doe@iup.edu) ***If the Co-investigator is not found and is a member of the IUP community****, please ask them to login into IRBManager at least once and that will allow you to complete this section. Otherwise click here to add non-IUP individuals to the system.*

Will students be added at a later date.

No

Estimated project start date

3/19/2018 *The project cannot start before IRB approval*

Estimated project end date

5/11/2018 *This date cannot be longer than a year from the start date. If you plan your project to go beyond one year you will need to submit a request for continuing review at the appropriate time.*

Funding Information

Project Funding Source

Non-funded research *Please check all that apply*

Combined Funding Source

Non-funded research

Project Description

Purpose of the study

The purpose of the current study is two-fold: (1) it will provide necessary information regarding the feasibility of utilizing an undergraduate population as the sole sample for the researcher's dissertation and (2) it will aid in determining an appropriate control group for the dissertation.

In a few sentences, describe the purpose of the study. This section need not be elaborate, but does need to clearly indicate the purpose of the study in a way that is clear to persons not familiar with the project.

Background of the study

This section should provide the reader with the administrative and/or scholarly context from which the project emerges. The section should contain enough information to provide Board members with no expertise in your discipline an understanding of how/why the use of human participants is warranted. This can often (but not always) be accomplished in one single spaced typed page or less. It is important to provide relevant citations and complete references so that the Board can conduct any necessary review of these foundations.

Somatic Symptom Disorder is characterized by one or more distressing physical sensations (somatic symptoms) that result in disruption of daily life and the experience of excessive thoughts (i.e. disproportionate and persistent thoughts about the seriousness of their symptoms), feelings (i.e. persistently high level of anxiety about health or symptoms), or behaviors (i.e. excessive time and energy devoted to these symptoms or health concerns) related to the somatic symptoms. Individuals who meet criteria for Somatic Symptom Disorder tend to reject psychological explanations for their symptoms, instead seeking out medical explanations and treatments.

With a prevalence rate of approximately 10% each, depression, anxiety and somatization represent the most common disorders in primary health care (Lowe et al., 2008). In addition, up to 20% of participants in primary care studies meet diagnostic criteria for Somatoform Disorders (DSM-IV terminology for Somatic Symptom Disorder; Korber et al., 2011). Individuals with Somatic Symptom Disorder display comparable functional impairment to those who suffer from anxiety and depression, including significant chronicity of symptoms, severe impairments in everyday living and diminished quality of life (De Waal et al., 2004). Somatic Symptom Disorder has also been linked to excessive healthcare use, with estimates indicating that it is costing the U.S. healthcare system approximately $100 billion per year (Barsky, Orav & Bates, 2005). While symptoms of anxiety and depression sometimes include somatic complaints, Somatic Symptom Disorder is considered a distinct disorder and demonstrates a unique pattern of distress and health care use (Lowe et al., 2008).

Given its prevalence and cost to society, Somatic Symptom Disorder warrants as much attention as is currently given to anxiety and depression. Yet, research regarding treatments and their efficacy for Somatic Symptom Disorder have been largely lacking, and recent meta-analyses have identified that therapeutic interventions have produced only small to moderate effect sizes (Kleinstauber, Witthoft & Hiller, 2011). While researchers have hypothesized as to why treatments that have been found efficacious for other related disorders have not been as effective in treating Somatic Symptom Disorder, data has not yet provided a clear explanation. In

addition, investigations into the personality characteristics of individuals with Somatic Symptom Disorder have not yet been empirically explored despite evidence that specific personality characteristics are present in individuals suffering from known psychological disorders and that personality relates to treatment response and outcome (Bagby et al., 2008, Beauchamp et al., 2010, & Hayward et al., 2013).

Identifying personality characteristics will aid in both explaining the underlying mechanisms of Somatic Symptom Disorder and in working towards the development of more effective treatments for individuals who suffer from the disorder. Thus, the researcher is currently designing a dissertation study aimed at identifying personality characteristics of individuals with Somatic Symptom Disorder. The purpose of the current IRB proposal is to collect pilot data that will be used to inform the development of the researcher's dissertation. The current study has two goals. The first goal is to collect prevalence data on symptoms of Somatic Symptom disorder, which will be used to help determine the feasibility of collecting data on this topic using the subject pool participants vs. in a community sample. The second goal is to identify a feasible control group, which may consist of individuals who score low on measures of somatic symptom distress, individuals with anxiety and/or depressive symptoms without somatic symptom distress, or individuals with no significant psychopathology.

What method(s) or design feature(s) do you plan to use in this study? Please choose all that apply

Questionnaire
Survey

This information is used only for internal record keeping and quick identification. Simply mark those methods/design features you currently plan to use.

Subject Population

Age Range

The age range of this study will be 18 years and older.

State the anticipated age range. If it is your intention to exclude minors (those 17 and under), please say so explicitly.

Gender

All

Inclusion Criteria

Participants must be undergraduate students who are currently enrolled in PSYC 101 (General Psychology). They must be age 18 or older.

Exclusion Criteria

Students in PSYC 101 who are under the age of 18 will be excluded from the study. Additionally, students who are not enrolled in PSYC 101 will not be eligible to participate. There are no other exclusion criteria.

Protected population and sensitive subjects: Indicate if any Human Subjects from the following list will be involved in the proposed activity:

No answer provided.

Vulnerable Subjects

There will be no vulnerable subjects used in this study.

If it is your intention to use vulnerable subjects, justify the importance of their use. Here and throughout the protocol discuss how their vulnerability will be matched with appropriate safeguards. The IRB web page discusses vulnerable subjects in more detail.]

Methods and Procedures

Methods and Procedures

This is arguably the most important section of the protocol. You should complete this section in such a way that all of the research procedures are clear. Do not assume that any parts of the procedure can be inferred, and compose this section as though you were writing instructions that someone else could follow to conduct the project.

Method of Subject Selection

Participants will be recruited through the Psychology Subject pool, which includes students enrolled in Introductory Psychology. Participants will utilize the online registration system to select into the current study. In SONA, the title of the study will be "College Students' Experience of Physical and Psychological Distress" and the description will be "The purpose of this study is to gather initial information regarding the prevalence and experience of somatic symptoms (e.g. pain, dizziness, nausea) in college students. Participants will be asked to complete questionnaires that measure experiences of various bodily sensations and differing forms of psychological distress (e.g., anxiety, depression)."

Provide complete information about how research subjects will be identified, recruited, invited to participate, etc. Indicate approximately how many research subjects you will contact and how many you will actually use in your research. Your description of recruitment and selection must include any letters, announcements, advertisements, or other related materials. Any materials used in any selection/recruitment context should be included in the "Attachments" section below. Please see the IRB website for more information regarding how to protect the privacy, dignity, and welfare of potential subjects.

Study Site	
The participant will be completing all measures online using Qualtrics.	*Indicate where the study will be conducted. For sites other than IUP (and sometimes for various offices on the IUP campus), investigators must provide a site approval letter from the outside site. The site approval letter needs to come on the site's own letterhead (i.e., not a plain piece of paper or IUP letterhead for outside sites), contain language that indicates the site understands the nature of the research in question and what their involvement will entail, and be signed by a person from the site with the authority to provide such approval. If the site approval letter is included with the protocol, note this fact in this section, indicate it as one of the "Attachments" (later in this document), and append it to the protocol. If the site approval will arrive under separate cover, state that here.*

Methods and Procedures Applied to Human Subjects

Describe exactly will happen with the subjects from the time of their first contact until the time of their last contact. What will participants actually do while participating in the project?

After consenting to be in the study, participants will be presented with the study questionnaires. This will include a demographics survey, the Patient Health Questionnaire -15 (PHQ-15), Somatosensory Amplification Scale (SSAS), Somatic Symptom Disorder - B Criteria Scale (SSD-12), Beck Depression Inventory -II (BDI-II), Beck Anxiety Inventory (BAI), and the Penn State Worry Questionnaire (PSWQ).

Measures:
Demographics. This survey contains questions about gender, age, race, history of psychiatric/psychological services, and number of medical visits within the past 3 months.

PHQ-15. The Patient Health Questionnaire (PHQ-15) is a 15-item self-report measure of somatic symptom severity that asks participants to rate how much they have been bothered by each symptom during the past month. Response options range from 0 (not bothered at all) to 2 (bothered a lot), and items include "chest pain," "dizziness," "feeling your heart pound in your ear," and "nausea, gas, or indigestion," among others. Scores range from 0 to 30, with cutoffs of 5, 10, and 15 indicating low, medium, and high symptom severity. The PHQ-15 has excellent internal reliability (Cronbach's alpha = 0.80) as well as strong convergent and discriminant validity (Kroenke et al., 2002). In addition, it has been found to demonstrate high sensitivity and specificity in identifying somatic symptom disorder (Kroenke et al., 2010).

SSAS. The Somatosensory Amplification Scale (SSAS) is a 10-item self-report questionnaire that measures characteristics of somatosensory amplification by asking participants to rate the degree to which each statement is "characteristic of you in general." Response options range from 1 (not at all) to 5 (extremely), and items include "When someone else coughs, it makes me cough too," "I have a low tolerance for pain," "I am often aware of various things happening within my body," and "Even something minor, like an insect bite or a splinter, really bothers me," among others. Scores range from 10 to 50, with scores over 30 suggesting the presence of a "highly somaticizing condition." The SSAS has demonstrated acceptable internal consistency (Barsky, Wyshak & Klerman, 1990).

SSD-12. The Somatic Symptom Disorder-B

Criteria Scale (SSD-12) is 12-item self-report questionnaire for the assessment of the psychological features (affective, cognitive, and behavioral aspects) of Somatic Symptom Disorder that asks participants to rate how frequently they experience each emotion, cognition, or behavior. Response options range from 0 (never) to 4 (very often), and items include "I think that my physical symptoms are signs of a serious illness," "My symptoms scare me," and "Due to my physical complaints, I have poor concentration on other things," among others. Scores range from 0 to 48, with varying cutoffs points indicating medium, high, and very high levels of burden based on the participants age and gender. The SSD-12 has demonstrated excellent reliability (Cronbach's alpha = 0.95) (Toussaint et al., 2015).

BDI-II. The Beck Depression Inventory (BDI-II) is a 21-item self-report screening tool for depressive symptoms that asks participants to select a statement for each item that best describes the way they have been feeling during the past two weeks. There are four response options for each item ranging from 0 (absence of symptom) to 4 (extreme presentation of symptom), for example item 1 is "sadness," and the responses include "I do not feel sad," "I feel sad much of the time," "I am sad all of the time," or "I am so sad or unhappy that I can't stand it." Other items ask about "loss of pleasure," "irritability," "changes in sleep pattern," and "worthlessness," among others. Scores range from 0 to 63 with scores between 0 and 13 indicating minimal depression, scores between 14 and 19 indicating mild depression, scores between 20 and 28 indicating moderate depression, and scores between 29 and 63 indicating severe depression. The BDI-II has demonstrated excellent reliability (Cronbach's alpha = 0.92) (Dozois, Dobson & Ahnberg, 1998).

BAI. The Beck Anxiety Inventory is a 21-item self-report inventory that measures the severity of anxiety by asking participants to indicate how much they have been bothered by each symptom during the past month. Response options range from 0 (not at all) to 3 (severely - it bothered me a lot), and items include "numbness or tingling," "hands trembling," "fear of worst happening," and "feeling hot," among others. Scores range from 0 to 63, with scores between 0 and 9 indicating minimal anxiety, scores between 10 and 16 indicating mild anxiety, scores between 17 and 29 indicating moderate anxiety, and scores between 30 and 63 indicating severe

anxiety. The BAI has demonstrated excellent reliability (Cronbach's alpha = 0.92) (Beck et al., 1988).

PSWQ. The Penn State Worry Questionnaire (PSQ) is a 16-item questionnaire used to provide a trait assessment of pathological worry (i.e. the typical tendency of the individual to worry, the excessiveness or intensity of worry experience, and the tendency to worry in general without restricting the topic to one or a small number of situations) that asks participants to rate the degree to which each statement is typical of them. Response options range from 1 (not at all typical of me) to 5 (very typical of me). Scores range from 16 to 80, with higher scores indicating more experience of pathological worry. Means and standard deviations are available for many groups including college students. The PSWQ has demonstrated very good to excellent reliability (Cronbach's alpha ranging from 0.88 to 0.95) (Molina & Borkovec, 1994).

Debriefing. After completing the questionnaires, students will click a button to enter the final screen, which will include the information found on the debriefing form. This is also where students will find the link to a second survey asking for their name and email address which they will need to complete should they wish to receive research credit.

Risks/Benefits

Potential Risks

This study involves no more than minimal risk. It is possible that some individuals may experience emotional discomfort while completing the questionnaires, as some people may feel uncomfortable when focusing on personal issues or concerns.

Describe the level of risk of the study to the participants, investigators, and any other group that might be impacted. You should compare the level of risk in your study and the federal definition of "minimal risk". "Minimal risk" is defined in 45 CFR46.1029(i) as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." Visit the IRB website for more detail on this topic.

Protection Against Risks

Participants will have the option to skip any questions they do not wish to answer. They can also opt out of the study at any time by exiting the survey. After completing the questionnaires, participants will be provided with contact information for the IUP Counseling Center if they are interested in talking further about their experiences of bodily sensations or psychological distress.	*Discuss in detail how the investigators will provide safeguards against the identified risks.*

Potential Benefits

There are no direct benefits for the participant. Results from the screening study will allow the researcher to finalize the methods for a main study that aims to improve our understanding of Somatic Symptom Disorder and how to improve the efficacy of its treatment.	*Discuss any potential benefits to the human subjects in the research.*

Compensation for Participation

PSYC 101 students will receive 0.5 research credit for completing the survey, which is estimated to take between 30 and 45 minutes.	*Discuss any and all forms of compensation for participation. This includes payment, extra credit, chances at winning a gift card, etc. Discuss also how the research subject will receive this compensation.*

Alternatives Participation

PSYC 101 students are not required to participate in the study. If they do not wish to participate in the study, they can opt to participate in other research studies available through SONA or they may instead write a paper about a research study to cover their research credit requirements.

Information Withheld

There will be no information withheld from the participants.	*If information will be intentionally withheld from research subjects, discuss this here along with the rationale for doing so.*

Debriefing

N/A (see attached debriefing form)	*If any debriefing will be provided to the research subjects, please discuss it here.*

Privacy/Consent/Nature of Risk

Privacy/Confidentiality

The survey responses are confidential. Once individuals select into the study via SONA they will be taken to a Qualtrics survey where they will be assigned an identification number. The survey will not be tied to their name or any other identifying information. After completing the Qualtrics survey, students will be directed to a separate survey to enter their name and IUP email address in order to receive research credit for their participation. As this is a separate survey, it will not be connected to their survey responses and will allow their answers to remain confidential. All electronic data will be safely stored on a secure, password-protected server that only [redacted] and the research team will be able to access. Data will not be tied to participant names, but instead each participant will be assigned an ID number. Data will be retained for three years per federal regulations.

Define the level of privacy that will be afforded the research subjects (i.e., anonymity, confidentiality, or no expectation of privacy). Indicate how the level of privacy that is defined by the researcher is consistent with the study procedures and how their privacy will be protected within that framework. Federal regulations require researchers to maintain data and consent documents for three years. Please indicate you will do that and where the data will be stored.

The Consent Process

The consent form will be the first page of the Qualtrics survey. Individuals who select the study on SONA will click the link to enter the survey. At this point, they will be presented with the consent form. At the bottom of the consent form, individuals will be instructed that by clicking the next button they are indicating that they have read and understood the information and agree to participate in the study. If after reading the consent form, they prefer to not to continue with the study, they can exit out of the survey.

Every process has some sort of Consent process, whether or not there is a written consent document. This section should describe the Consent Process in detail including, how Consent will be presented to the subjects, how subjects will indicate their Consent. Any relevant documents should be attached in the "Attachments" section of this form. Hard copy consent forms must be printed or copied onto IUP letterhead. If the consent document is provided electronically (e.g., Qualtrics survey), it must be sent from a valid IUP email address. NOTE: The IRB website discusses Informed Consent in detail.

Nature of Risk

No

In your judgment, does your research involve more than minimal risk? Refer back to the definition of minimal risk provided above.

Exemption Qualification

Exemption Instructions

In your judgment, does your research fall under one of the six exempt categories? If you believe it does, indicate the category under which you are claiming an exemption by choosing yes next to the relevant category.

Will the research be conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods?

No

Will the research be involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Entered: 03/15/18 **By:** Runge, Timothy **Internal:** No

Please select Yes

No

Will the research be involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

No

Will the research be involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

No

Are these research and/or demonstration projects being conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs?

No

Will your research involve taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture?

No

Expedited Review Qualification

Expedited Instructions

In your judgment, does your project fall under one of the nine (9) categories eligible for expedited review (listed below)? If you believe it does, indicate the category of which your claiming expedited review by choosing yes next to the relevant category.

Clinical studies of drugs and medical devices only when condition (a) or (b) is met. a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

No

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or b.from other adults and children2, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

No

Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization

No

Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

No

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

No

Collection of data from voice, video, digital, or image recordings made for research purposes.

No

Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Yes

Continuing review of research previously approved by the convened IRB as follows: a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or b. where no subjects have been enrolled and no additional risks have been identified; or c. where the remaining research activities are limited to data analysis.

No

Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

No

Attachments

Please attach all Informed Consent Documents if applicable

Consent Form - Updated	Consent Form	*A sample consent form can be found by clicking this link Sample Consent Form*

Please attach any site approval letters

No answer provided.	*The site approval letter **must** be on the official letterhead of the site and endorsed by the person responsible for the site.*

Please attach CITI Training Completion Certificates.

Entered: 03/09/18 **By:** [redacted] **Internal:** No

[redacted]

Citi Training Completion Reports	CITI training certificate	*All students submitting a protocol are required to attach their CITI Training Completion Certificate. Student protocols will not be approved without the certificate attached.*

Please click 'Add Attachment' and add all relevant attachments (Questionnaire, Survey, Syllabi, Interview Guide, Focus Group Questions, Debriefing forms, Recruitment Materials)

Demographics Questionnaire	Survey
Physical Health Questionnaire	Survey
Penn State Worry Questionnaire	Survey
Somatic Symptom Disorder Scale	Survey
Somatosensory Amplification Scale	Survey
References	Survey
Debriefing Form	Debriefing form
Beck Depression Inventory	Survey
Beck Anxiety Inventory	Survey

Indiana University of Pennsylvania

www.iup.edu

Department of Psychology Uhler Hall
1020 Oakland Avenue
Indiana, PA 15705-1064

P 724-357-2426
F 724-357-2214

You are invited to participate in this research study being conducted by [redacted], a student in the Indiana University of Pennsylvania (IUP) Doctor of Psychology (PsyD) program, and [redacted], a professor at IUP. The following information is provided in order to help you to make an informed decision whether or not to participate. If you have any questions please do not hesitate to ask (see contact information below).

The purpose of this study is to identify prevalence and experience of somatic symptoms (such as pain, dizziness, nausea) in college students. Participants will be asked to complete questionnaires that measure experiences of various bodily sensations and differing forms of psychological distress (e.g., anxiety, depression). Participation will take approximately 30 minutes of your time and you will earn 0.5 research credit for participating in the study. As an alternative to participation in the current study, you can participate in the other studies listed on SONA or you may do a read and review assignment. By agreeing to participate in the study, you are acknowledging that you are 18 years or older.

If you choose to participate, all information will be held strictly confidential. Questionnaires will be completed using Qualtrics. You will be assigned an identification number that will be associated with your questionnaires. All electronic data will be safely stored on a secure, password-protected server that only [redacted] and the research team will be able to access.

Participation in this study may lead to emotional discomfort, as you will be asked to focus on personal issues and concerns. If you decide to participate, you can always change your mind at any time. You may refuse to answer any questions and you may withdraw at any time by exiting the survey before submitting it. At the end of the survey, you will receive information on how to contact the IUP Counseling Center if you would like to talk further about your experiences of bodily sensations or psychological distress. In the case that you experience distress and discontinue the study, the IUP Counseling Center is located at the Suites on Maple East and can be reached at 724-357-2621.

There are no direct benefits to participating in this study other than receiving research credit for PSYC 101. Upon completing the survey, you will be asked if you would like to earn research credit to your participation. If you answer yes, you will be taken to a separate survey to enter your name and IUP email address. Your answers to the survey questions will remain confidential, as the information from the second survey cannot be linked to your questionnaire responses.

Your participation in this study is voluntary. You are free to decide not to participate in this study or to withdraw at any time by exiting the survey before submitting it. Your decision will not adversely affect your relationship with the investigators or IUP.

If you agree to participate in the study, please click the link to continue with the survey.

You may contact Ms. Quinn or Dr. Davis at any time if you have question about the study.

Student Researcher: [redacted]
Email: [redacted]@iup.edu

Project Advisor: [redacted]
Psychology Department, IUP
[redacted]
Email: [redacted]@iup.edu

THIS PROJECT HAS BEEN APPROVED BY THE INDIANA UNIVERSITY OF PENNSYLVANIA INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS (PHONE 724.357.7730).

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** [redacted]
- **Institution Affiliation:** Indiana University of Pennsylvania (ID: 1711)
- **Institution Unit:** Psychology

- **Curriculum Group:** Human Subjects Research
- **Course Learner Group:** Social, Behavioral, Educational Researchers
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 24511715
- **Completion Date:** 25-Sep-2017
- **Expiration Date:** N/A
- **Minimum Passing:** 80
- **Reported Score*:** 94

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
History and Ethical Principles - SBE (ID: 490)	25-Sep-2017	5/5 (100%)
Defining Research with Human Subjects - SBE (ID: 491)	25-Sep-2017	5/5 (100%)
The Federal Regulations - SBE (ID: 502)	25-Sep-2017	5/5 (100%)
Assessing Risk - SBE (ID: 503)	25-Sep-2017	5/5 (100%)
Informed Consent - SBE (ID: 504)	25-Sep-2017	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	25-Sep-2017	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	25-Sep-2017	5/5 (100%)
Students in Research (ID: 1321)	25-Sep-2017	5/5 (100%)
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID: 14928)	25-Sep-2017	5/5 (100%)
Research and HIPAA Privacy Protections (ID: 14)	25-Sep-2017	2/5 (40%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?k9802567d-fbd9-4250-a135-ea4de14eb221-24511715

Collaborative Institutional Training Initiative (CITI Program)
Email: support@citiprogram.org
Phone: 888-529-5929
Web: https://www.citiprogram.org

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** [redacted]
- **Institution Affiliation:** Indiana University of Pennsylvania (ID: 1711)
- **Institution Unit:** Psychology

- **Curriculum Group:** Human Subjects Research
- **Course Learner Group:** Social, Behavioral, Educational Researchers
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 24511715
- **Report Date:** 25-Sep-2017
- **Current Score**:** 94

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Students in Research (ID: 1321)	25-Sep-2017	5/5 (100%)
History and Ethical Principles - SBE (ID: 490)	25-Sep-2017	5/5 (100%)
Defining Research with Human Subjects - SBE (ID: 491)	25-Sep-2017	5/5 (100%)
The Federal Regulations - SBE (ID: 502)	25-Sep-2017	5/5 (100%)
Assessing Risk - SBE (ID: 503)	25-Sep-2017	5/5 (100%)
Informed Consent - SBE (ID: 504)	25-Sep-2017	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	25-Sep-2017	5/5 (100%)
Research and HIPAA Privacy Protections (ID: 14)	25-Sep-2017	2/5 (40%)
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID: 14928)	25-Sep-2017	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	25-Sep-2017	5/5 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: www.citiprogram.org/verify/?k9802567d-fbd9-4250-a135-ea4de14eb221-24511715

Collaborative Institutional Training Initiative (CITI Program)
Email: support@citiprogram.org
Phone: 888-529-5929
Web: https://www.citiprogram.org

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** [redacted]
- **Institution Affiliation:** Indiana University of Pennsylvania (ID: 1711)
- **Institution Unit:** Psychology

- **Curriculum Group:** Human Subjects Research
- **Course Learner Group:** Social, Behavioral, Educational Researchers
- **Stage:** Stage 1 - Basic Course

- **Report ID:** 19908295
- **Completion Date:** 06/20/2016
- **Expiration Date:** N/A
- **Minimum Passing:** 80
- **Reported Score*:** 92

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
History and Ethical Principles - SBE (ID: 490)	06/14/16	5/5 (100%)
Defining Research with Human Subjects - SBE (ID: 491)	06/16/16	5/5 (100%)
The Federal Regulations - SBE (ID: 502)	06/16/16	5/5 (100%)
Assessing Risk - SBE (ID: 503)	06/18/16	5/5 (100%)
Informed Consent - SBE (ID: 504)	06/20/16	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	06/20/16	4/5 (80%)
Belmont Report and CITI Course Introduction (ID: 1127)	06/20/16	3/3 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	06/20/16	3/5 (60%)
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID: 14928)	06/16/16	5/5 (100%)
Research with Children - SBE (ID: 507)	06/14/16	4/5 (80%)
Internet-Based Research - SBE (ID: 510)	06/16/16	5/5 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

CITI Program
Email: citisupport@miami.edu
Phone: 305-243-7970
Web: https://www.citiprogram.org

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK TRANSCRIPT REPORT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** [redacted]
- **Institution Affiliation:** Indiana University of Pennsylvania (ID: 1711)
- **Institution Unit:** Psychology

- **Curriculum Group:** Human Subjects Research
- **Course Learner Group:** Social, Behavioral, Educational Researchers
- **Stage:** Stage 1 - Basic Course

- **Report ID:** 19908295
- **Report Date:** 06/20/2016
- **Current Score**:** 92

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
History and Ethical Principles - SBE (ID: 490)	06/14/16	5/5 (100%)
Defining Research with Human Subjects - SBE (ID: 491)	06/16/16	5/5 (100%)
Belmont Report and CITI Course Introduction (ID: 1127)	06/20/16	3/3 (100%)
The Federal Regulations - SBE (ID: 502)	06/16/16	5/5 (100%)
Assessing Risk - SBE (ID: 503)	06/18/16	5/5 (100%)
Informed Consent - SBE (ID: 504)	06/20/16	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	06/20/16	4/5 (80%)
Research with Children - SBE (ID: 507)	06/14/16	4/5 (80%)
Internet-Based Research - SBE (ID: 510)	06/16/16	5/5 (100%)
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID: 14928)	06/16/16	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	06/20/16	3/5 (60%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

CITI Program
Email: citisupport@miami.edu
Phone: 305-243-7970
Web: https://www.citiprogram.org

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** [redacted]
- **Institution Affiliation:** Indiana University of Pennsylvania (ID: 1711)
- **Institution Unit:** Psychology

- **Curriculum Group:** Human Subjects Research
- **Course Learner Group:** Social, Behavioral, Educational Researchers
- **Stage:** Stage 1 - Basic Course

- **Report ID:** 20781221
- **Completion Date:** 19-Sep-2016
- **Expiration Date:** N/A
- **Minimum Passing:** 80
- **Reported Score*:** 89

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
History and Ethical Principles - SBE (ID: 490)	15-Sep-2016	5/5 (100%)
Defining Research with Human Subjects - SBE (ID: 491)	15-Sep-2016	5/5 (100%)
The Federal Regulations - SBE (ID: 502)	15-Sep-2016	4/5 (80%)
Assessing Risk - SBE (ID: 503)	15-Sep-2016	4/5 (80%)
Informed Consent - SBE (ID: 504)	15-Sep-2016	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	19-Sep-2016	4/5 (80%)
Belmont Report and CITI Course Introduction (ID: 1127)	19-Sep-2016	3/3 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	19-Sep-2016	4/5 (80%)
Students in Research (ID: 1321)	19-Sep-2016	4/5 (80%)
Research with Children - SBE (ID: 507)	19-Sep-2016	4/5 (80%)
Research in Public Elementary and Secondary Schools - SBE (ID: 508)	19-Sep-2016	5/5 (100%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: https://www.citiprogram.org/verify/?a5e791f1-6fcb-4696-9d9e-f3a663d2d273

CITI Program
Email: support@citiprogram.org
Phone: 888-529-5929
Web: https://www.citiprogram.org

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** [redacted]
- **Institution Affiliation:** Indiana University of Pennsylvania (ID: 1711)
- **Institution Unit:** Psychology

- **Curriculum Group:** Human Subjects Research
- **Course Learner Group:** Social, Behavioral, Educational Researchers
- **Stage:** Stage 1 - Basic Course

- **Report ID:** 20781221
- **Report Date:** 19-Sep-2016
- **Current Score**:** 89

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Students in Research (ID: 1321)	19-Sep-2016	4/5 (80%)
History and Ethical Principles - SBE (ID: 490)	15-Sep-2016	5/5 (100%)
Defining Research with Human Subjects - SBE (ID: 491)	15-Sep-2016	5/5 (100%)
Belmont Report and CITI Course Introduction (ID: 1127)	19-Sep-2016	3/3 (100%)
The Federal Regulations - SBE (ID: 502)	15-Sep-2016	4/5 (80%)
Assessing Risk - SBE (ID: 503)	15-Sep-2016	4/5 (80%)
Informed Consent - SBE (ID: 504)	15-Sep-2016	5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505)	19-Sep-2016	4/5 (80%)
Research with Children - SBE (ID: 507)	19-Sep-2016	4/5 (80%)
Research in Public Elementary and Secondary Schools - SBE (ID: 508)	19-Sep-2016	5/5 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	19-Sep-2016	4/5 (80%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

Verify at: https://www.citiprogram.org/verify/?a5e791f1-6fcb-4696-9d9e-f3a663d2d273

Collaborative Institutional Training Initiative (CITI Program)
Email: support@citiprogram.org
Phone: 888-529-5929
Web: https://www.citiprogram.org

Demographic Questionnaire

Gender Identity: (choose one)
___Female ___Male

Age: (choose one)
___18-21 ___22-25 ___26-30 ___30-40 ___40-50 ___>50

Race: (choose any)
___American Indian or Alaska Native
___Asian
___Black of African American
___Native Hawaiian or Other Pacific Islander
___White
___Hispanic/Latino

History of psychiatric/psychological services: (choose any)
___Yes – Counseling/Therapy
___Yes – Psychological Testing
___Yes – psychopharmacological medication from primary care physician
___No

Frequency of medical visits within past 3 months: (choose one)
___0-2
___3-5
___6-9
___10-15
___>16

PHQ-15

Prompt:

During the *last 4 weeks*, how much have you been bothered by any of the following problems?

Response Options:

Not Bothered (0) Bothered a little (1) Bothered a lot (2)

Items:

1. Stomach pain
2. Back pain
3. Pain in your arms, legs, or joints (knees, hips, etc.)
4. Feeling tired or having little energy
5. Trouble falling or staying asleep, or sleeping too much
6. Menstrual cramps or other problems with your periods
7. Pain or problems during sexual intercourse
8. Headaches
9. Chest pain
10. Dizziness
11. Fainting spells
12. Feeling your heart pound or race
13. Shortness of breath
14. Constipation, loose bowels, or diarrhea
15. Nausea, gas, or indigestion

Scoring Cut-points:

0-4 = no-minimal
5-9 = mild / low symptom burden
10-14 = moderate / medium symptom burden
15 and above = severe / high symptom burden

Alternate: 3 or more 2-point responses “is a pointer towards” somatoform disorders

Patient Name:_____ Date:_____

The Penn State Worry Questionnaire (PSWQ)

Instructions: Rate each of the following statements on a scale of 1 ("not at all typical of me") to 5 ("very typical of me"). Please do not leave any items blank.

	Not at all typical of me				Very typical of me
1. If I do not have enough time to do everything, I do not worry about it.	1	2	3	4	5
2. My worries overwhelm me.	1	2	3	4	5
3. I do not tend to worry about things.	1	2	3	4	5
4. Many situations make me worry.	1	2	3	4	5
5. I know I should not worry about things, but I just cannot help it.	1	2	3	4	5
6. When I am under pressure I worry a lot.	1	2	3	4	5
7. I am always worrying about something.	1	2	3	4	5
8. I find it easy to dismiss worrisome thoughts.	1	2	3	4	5
9. As soon as I finish one task, I start to worry about everything else I have to do.	1	2	3	4	5
10. I never worry about anything.	1	2	3	4	5
11. When there is nothing more I can do about a concern, I do not worry about it any more.	1	2	3	4	5
12. I have been a worrier all my life.	1	2	3	4	5
13. I notice that I have been worrying about things.	1	2	3	4	5
14. Once I start worrying, I cannot stop.	1	2	3	4	5
15. I worry all the time.	1	2	3	4	5
16. I worry about projects until they are all done.	1	2	3	4	5

Scoring the PSWQ

In scoring the PSWQ, a value of 1, 2, 3, 4, and 5 is assigned to a response depending upon whether the item is worded positively or negatively. The total score of the scale ranges from 16 to 80.

Items 1, 3, 8, 10, 11 are reverse scored as follows:

- Very typical of me = 1 (circled 5 on the sheet)
- Circled 4 on the sheet = 2
- Circled 3 on the sheet = 3
- Circled 2 on the sheet = 4
- Not at all typical of me = 5 (circled 1 on the sheet)

For items 2, 4, 5, 6, 7, 9, 12, 13, 14, 15, 16 the scoring is:

- Not at all typical of me = 1
- Ratings of 2, 3, and 4 are not transformed
- Very typical of me = 5

Citation: Meyer TJ, Miller ML, Metzger RL, Borkovec TD: Development and Validation of the Penn State Worry Questionnaire. Behaviour Research and Therapy 28:487-495,1990

Supplementary Material A: SSD-12 – English Version

	never	rarely	sometimes	often	very often
1. I think that my physical symptoms are signs of a serious illness (I).	☐	☐	☐	☐	☐
2. I am very worried about my health (II).	☐	☐	☐	☐	☐
3. My health concerns hinder me in everyday life (III).	☐	☐	☐	☐	☐
4. I am convinced that my symptoms are serious (I).	☐	☐	☐	☐	☐
5. My symptoms scare me (II).	☐	☐	☐	☐	☐
6. My physical complaints occupy me for most of the day (III).	☐	☐	☐	☐	☐
7. Others tell me that my physical problems are not serious (I).	☐	☐	☐	☐	☐
8. I'm worried that my physical complaints will never stop (II).	☐	☐	☐	☐	☐
9. My worries about my health take my energy (III).	☐	☐	☐	☐	☐
10. I think that doctors do not take my physical complaints seriously (I).	☐	☐	☐	☐	☐
11. I am worried that my physical symptoms will continue into the future (II).	☐	☐	☐	☐	☐
12. Due to my physical complaints, I have poor concentration on other things (III).	☐	☐	☐	☐	☐

(I) = sub-criterion I (cognitive aspects); (II) = sub-criterion II (affective aspects); (III) = sub-criterion III (behavioral aspects)

The cutoff points for a male person aged 50 are 13, 19 and 25 representing medium, high and very high levels of burden. Increasing (decreasing) age by five years roughly increases (decreases) each cutoff by one point. Moreover, cutoff points for females of the same age are increased by three points.

SSAS

Prompt:

Rate the degree to which each statement is *characteristic of you in general*.

Response Options:

1 “not at all” 2 3 4 5 “extremely”

Items:

1. When someone else coughs, it makes me cough too.
2. I can’t stand smoke, smog, or pollutants in the air.
3. I am often aware of various things happening within my body.
4. When I bruise myself, it stays noticeable for a long time.
5. Sudden loud noises really bother me.
6. I can sometimes hear my pulse or my heartbeat throbbing in my ear.
7. I hate to be too hot or too cold.
8. I am quick to sense the hunger contractions in my stomach.
9. Even something minor, like an insect bite or a splinter, really bothers me.
10. I have a low tolerance for pain.

Scoring Cut-points:

Over 30 = may reflect highly somaticizing condition

REFERENCES

Bagby, R. M., Quilty, L. C., Segal, Z. V., McBride, C. C., Kennedy, S. H., & Costa, P. T. (2008). Personality and differential treatment response in major depression: A randomized controlled trial comparing cognitive-behavioural therapy and pharmacotherapy. *The Canadian Journal of Psychiatry, 53(*6), 361-370.

Barsky, A. J., Wyshak, G., & Klerman, G. L. (1990). The somatosensory amplification scale and its relationship to hypochondriasis. *Journal of Psychiatric Research, 24*(4), 323-334.

Beauchamp, M., Lecomte, T., Lecomte, C., Leclerc, C., & Corbiere, M. (2011). Personality traits in early psychosis: relationship with symptom and coping treatment outcomes. *Early Intervention in Psychiatry, 5*, 33-40.

Beck, A. T., Epstein, N., Brown, G., & Steer, R. A. (1988). An inventory for measuring clinical anxiety: Psychometric properties. *Journal of Consulting and Clinical Psychology, 56*(6), 893-897.

Dozois, D. J. A., Dobson, K. S., & Ahnberg, J. L. (1998). A psychometric evaluation of the Beck Depression Inventory-II. Psychological Assessment, 10, 83-89.

Hayward, R. D., Taylor, W. D., Smoski, M. J., Steffens, D. C., & Payne, M. E. (2013). Association of five-factor model personality domains and facets with presence, onset, and treatment outcomes of major depression in older adults. *American Journal of Geriatric Psychiatry, 21*(1), 88-96.

Kroenke, K., Spitzer, R. L., & Williams, J. B. W. (2002). The PHQ-15: Validity of a new measure for evaluating the severity of somatic symptoms. *Psychosomatic Medicine, 64*, 258-266.

Kroenke, K., Spitzer, R. L., Williams, J. B. W., & Lowe, B. (2010). The patient health questionnaire somatic, anxiety, and depressive symptom scales: a systematic review. *General Hospital Psychiatry, 32*, 345-359.

Lowe, B., Spitzer, R. L., Williams, J. B. W., Mussell, M., Schellberg, D., & Kroenke, K. (2008). Depression, anxiety and somatization in primary care: syndrome overlap and functional impairment. *General Hospital Psychiatry, 30*, 191-199.

Mander, J., Schaller, G., Bents, H., Dinger, U., Zipfel, S., & Junne, F. (2017). Increasing the treatment motivation of patients with somatic symptom disorder: applying the URICA-S scale. *BMC Psychiatry, 17*, 240.

Molina, S., & Borkovec, T. D. (1994). The Penn State Worry Questionnaire: Psychometric properties and associated characteristics. In G. C. L. Davey & F. Tallis (Eds.), *Wiley series in clinical psychology. Worrying: Perspectives on theory, assessment and treatment* (pp. 265-283). Oxford, England: John Wiley & Sons.

Rodic, D., Meyer, A. H., Lieb, R., & Meinlschmidt, G. (2016). The association of sensory responsiveness with somatic symptoms and illness anxiety. *International Journal of Behavioral Medicine, 23*, 39-48.

Toussaint, A., Murray, A. M., Voigt, K., Herzog, A., Gierk, B., Kroenke, K., Rief, W., Henningsen, P., & Lowe, B. (2016). Development and validation of the somatic symptom disorder – B criteria scale (SSD-12). *Psychosomatic Medicine, 78*, 5-12.

Debriefing Form

The purpose of this study is to identify how often college students experience somatic symptoms (e.g., pain, dizziness, nausea) in addition to symptoms of psychological distress (such as anxiety and depression). The results of this study will be used to determine whether there are enough students who experience varying degrees of somatic symptoms that the the primary investigator can collect her dissertation data using the subject pool.

If you would like to further discuss this study, please contact:

[redacted]: Primary investigator [redacted]@iup.edu
[redacted]: Investigator and advisor [redacted]@iup.edu

If you would like to read more on this topic, we recommend the following articles:

Chaturvedi, S. K. (2013). Many faces of somatic symptom disorders. *International Review of Psychiatry, 25*(1), 1-4.

Lowe, B., Spitzer, R. L., Williams, J. B.W., Mussel, M., Schellberg, D., & Kroenke, K. (2008). Depression, anxiety and somatization in primary care: syndrome overlap and functional impairment. *General Hospital Psychiatry, 30*, 191-199.

If you would like to talk to someone about difficulties related to anxiety, depression, or somatic symptoms, counseling services are available at:

The Counseling Center in the Center for Health and Wellbeing
Suites on Maple East
(724) 357-2621

Thank you again for your participation!

BDI®-II

Date:

Name: _____ Marital Status: _____ Age: _____ Sex: _____

Occupation: _____ Education: _____

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully, and then pick out the **one statement** in each group that best describes the way you have been feeling during the **past two weeks, including today**. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Pattern) or Item 18 (Changes in Appetite).

1. Sadness

0 I do not feel sad.
1 I feel sad much of the time.
2 I am sad all the time.
3 I am so sad or unhappy that I can't stand it.

2. Pessimism

0 I am not discouraged about my future.
1 I feel more discouraged about my future than I used to be.
2 I do not expect things to work out for me.
3 I feel my future is hopeless and will only get worse.

3. Past Failure

0 I do not feel like a failure.
1 I have failed more than I should have.
2 As I look back, I see a lot of failures.
3 I feel I am a total failure as a person.

4. Loss of Pleasure

0 I get as much pleasure as I ever did from the things I enjoy.
1 I don't enjoy things as much as I used to.
2 I get very little pleasure from the things I used to enjoy.
3 I can't get any pleasure from the things I used to enjoy.

5. Guilty Feelings

0 I don't feel particularly guilty.
1 I feel guilty over many things I have done or should have done.
2 I feel quite guilty most of the time.
3 I feel guilty all of the time.

6. Punishment Feelings

0 I don't feel I am being punished.
1 I feel I may be punished.
2 I expect to be punished.
3 I feel I am being punished.

7. Self-Dislike

0 I feel the same about myself as ever.
1 I have lost confidence in myself.
2 I am disappointed in myself.
3 I dislike myself.

8. Self-Criticalness

0 I don't criticize or blame myself more than usual.
1 I am more critical of myself than I used to be.
2 I criticize myself for all of my faults.
3 I blame myself for everything bad that happens.

9. Suicidal Thoughts or Wishes

0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.

10. Crying

0 I don't cry anymore than I used to.
1 I cry more than I used to.
2 I cry over every little thing.
3 I feel like crying, but I can't.

_____ Subtotal Page 1

Continued on Back

THE PSYCHOLOGICAL CORPORATION®
Harcourt Brace & Company
SAN ANTONIO
Orlando • Boston • New York • Chicago • San Francisco • Atlanta • Dallas
San Diego • Philadelphia • Austin • Fort Worth • Toronto • London • Sydney

0154018392

11. Agitation

0 I am no more restless or wound up than usual.

1 I feel more restless or wound up than usual.

2 I am so restless or agitated that it's hard to stay still.

3 I am so restless or agitated that I have to keep moving or doing something.

12. Loss of Interest

0 I have not lost interest in other people or activities.

1 I am less interested in other people or things than before.

2 I have lost most of my interest in other people or things.

3 It's hard to get interested in anything.

13. Indecisiveness

0 I make decisions about as well as ever.

1 I find it more difficult to make decisions than usual.

2 I have much greater difficulty in making decisions than I used to.

3 I have trouble making any decisions.

14. Worthlessness

0 I do not feel I am worthless.

1 I don't consider myself as worthwhile and useful as I used to.

2 I feel more worthless as compared to other people.

3 I feel utterly worthless.

15. Loss of Energy

0 I have as much energy as ever.

1 I have less energy than I used to have.

2 I don't have enough energy to do very much.

3 I don't have enough energy to do anything.

16. Changes in Sleeping Pattern

0 I have not experienced any change in my sleeping pattern.

1a I sleep somewhat more than usual.

1b I sleep somewhat less than usual.

2a I sleep a lot more than usual.

2b I sleep a lot less than usual.

3a I sleep most of the day.

3b I wake up 1–2 hours early and can't get back to sleep.

17. Irritability

0 I am no more irritable than usual.

1 I am more irritable than usual.

2 I am much more irritable than usual.

3 I am irritable all the time.

18. Changes in Appetite

0 I have not experienced any change in my appetite.

1a My appetite is somewhat less than usual.

1b My appetite is somewhat greater than usual.

2a My appetite is much less than before.

2b My appetite is much greater than usual.

3a I have no appetite at all.

3b I crave food all the time.

19. Concentration Difficulty

0 I can concentrate as well as ever.

1 I can't concentrate as well as usual.

2 It's hard to keep my mind on anything for very long.

3 I find I can't concentrate on anything.

20. Tiredness or Fatigue

0 I am no more tired or fatigued than usual.

1 I get more tired or fatigued more easily than usual.

2 I am too tired or fatigued to do a lot of the things I used to do.

3 I am too tired or fatigued to do most of the things I used to do.

21. Loss of Interest in Sex

0 I have not noticed any recent change in my interest in sex.

1 I am less interested in sex than I used to be.

2 I am much less interested in sex now.

3 I have lost interest in sex completely.

14 15 16 17 18 19 20 A B C D E

_____ Subtotal Page 2

_____ Subtotal Page 1

_____ Total Score

BAI®

NAME _____ **DATE** _____

Below is a list of common symptoms of anxiety. Please carefully read each item in the list. Indicate how much you have been bothered by each symptom during the PAST WEEK, INCLUDING TODAY, by placing an X in the corresponding space in the column next to each symptom.

	NOT AT ALL	MILDLY It did not bother me much.	MODERATELY It was very unpleasant, but I could stand it.	SEVERELY I could barely stand it.
1. Numbness or tingling.				
2. Feeling hot.				
3. Wobbliness in legs.				
4. Unable to relax.				
5. Fear of the worst happening.				
6. Dizzy or lightheaded.				
7. Heart pounding or racing.				
8. Unsteady.				
9. Terrified.				
10. Nervous.				
11. Feelings of choking.				
12. Hands trembling.				
13. Shaky.				
14. Fear of losing control.				
15. Difficulty breathing.				
16. Fear of dying.				
17. Scared.				
18. Indigestion or discomfort in abdomen.				
19. Faint.				
20. Face flushed.				
21. Sweating (not due to heat).				

THE PSYCHOLOGICAL CORPORATION®
Harcourt Brace & Company
SAN ANTONIO
Orlando • Boston • New York • Chicago • San Francisco • Atlanta • Dallas
San Diego • Philadelphia • Austin • Fort Worth • Toronto • London

29 30 31 32 33 34 35 A B C D E
0154018422