Office for Research Protections
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APPLICATION FOR THE USE OF HUMAN PARTICIPANTS
EXPEDITED & FULL REVIEWS

OFFICE USE ONLY

IRB NO._____

Form Instructions:
- To complete the form, press TAB or SHIFT TAB between boxes and enter an 'X' or text. For assistance, contact the Office for Research Protections.
- This application will ask general questions about your study. Depending on your response, additional appendices may need to be completed in order to provide more detailed information. For example, if you indicate that your study involves prisoners, Appendix 4 will also need to be completed and submitted.
- Submit recruitment materials, informed consent forms, and all other materials as attachments to the application. Do NOT include within the application.
- Handwritten applications will NOT be accepted.

Project Title: Counseling and Psychological Services (CAPS) Data Contribution to the Center for the Study of Collegiate Mental Health (CSCMH)

Principal Investigator: Benjamin Locke	PSU User ID (e.g., abc123): bdl10
University Status (Faculty, Staff, Student, etc.): Staff	Telephone Number: (814) 863-0395
Email Address: bdl10@psu.edu	Dept: Counseling and Psychological Services
College:	Campus: University Park
Mailing Address: 501 Student Health Center University Park, PA 16802	

Faculty Advisor, if PI is a student:	PSU User ID (e.g., abc123):
Email Address:	Telephone Number:
Dept:	College:
Mailing Address:	Campus:

Is there anyone you wish to include on correspondence related to this study (e.g., a study coordinator, etc.)?

Name:	PSU User ID (e.g., abc123):
University Status (Faculty, Staff, Student, etc.):	Telephone Number:
Email Address:	Dept:

College:	Campus:
Mailing Address:	Role in this study: Choose one of the following

A. Funding:

1. Is this research study internally or externally funded?
   - ☐ Yes → Answer Questions 2 – 4
   - ☒ No → Skip to Question 6
   - ☐ Pending → Answer Questions 2 – 5

2. Provide the name and mailing address of internal and external sources of funding. Provide a copy of your grant proposal with the application. If a copy of the grant proposal is not included, explain.

3. Is the sponsor providing the drug, device, etc. free of charge? ☐ Yes ☐ No ☐ N/A

4. Has the sponsor agreed to pay for direct costs of treating injuries? ☐ Yes ☐ No

5. If funding is not awarded, will the research still be conducted? ☐ Yes ☐ No ☐ N/A

B. Conflict of Interest:

6. Do any of the investigator(s), key personnel, and/or their spouses or dependent children have a conflict of interest (COI), as defined by PSU Policy RA20, "Individual Conflict of Interest," associated with this research?
   - ☐ Yes → Complete & Submit Appendix 1, Section A
   - ☒ No

7. Does PSU have an ownership or royalty interest in any intellectual property related to this study?
   - ☐ Yes → Complete & Submit Appendix 1, Section B
   - ☒ No

8. Are there are other significant conflicts that could possibly affect or be perceived to affect this study?
   - ☐ Yes → Complete & Submit Appendix 1, Section C
   - ☒ No

C. Class Projects:

9. Is this a class project?
   - ☐ Yes → Provide the following information:
     - Instructor's Name:

       Course Title and Number:

       Semester course is being offered:
   - ☒ No

D. Review Level:

10. What level of review do you expect this research to need?
    - ☒ Expedited Review → Answer Question 11
    - ☐ Full Review → Skip to Question 12

11. Expedited Research Categories: Read the following categories and choose one or more that apply to your research. Your research must fit in at least one category and be no more than minimal risk in order to be considered for an expedited review.

    ☐ Category 1: 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 312) is not required. *(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 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.

☐ Category 2: Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows:

(a) From healthy, non-pregnant adults who weigh at least 100 pounds. For these participants, 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 children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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.

☐ Category 3: Prospective collection of biological specimens for research purposes by non-invasive means. Examples include:

- Hair and nail clippings in a non-disfiguring manner;
- Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- Permanent teeth if routine patient care indicates a need for extraction;
- Excreta and external secretions (including sweat);
- 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;
- Placenta removal at delivery;
- Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- 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;
- Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- Sputum collected after saline mist nebulization

☐ Category 4: Collection of data through non-invasive 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 include:

- 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 participant or an invasion of the participant's privacy;
- Weighing or testing sensory acuity;
- Magnetic resonance imaging;
- Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
- Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ Category 5: Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

☐ Category 6: Collection of data from voice, video, digital, image recordings made for research purposes.

☒ Category 7: 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.

E. Research Personnel:

NOTE:

- The Principal investigator is responsible for ensuring that <u>all</u> individuals conducting procedures described in this application are trained adequately prior to involving human participants.

- All personnel listed on this application who (1) are responsible for the design/conduct of the study, (2) will have access to the human participants (i.e., will consent participants, conduct the study), or (3) will have access to identifying AND confidential information must successfully complete the IRB's Training on the Protection of Human Participants or provide verification of training from their home institution. PSU's training may be located at http://www.research.psu.edu/orp/education/modules/irb/index.asp. Approval will NOT be granted until all individuals have successfully completed the training. Verification of training does NOT need to be sent in if the individual completed the Penn State's training.
- As personnel change, you must submit a *Modification Request Form – Expedited & Full Review* to add or remove personnel.

12. Provide the name of the other individual(s) assisting with this study who (1) will be responsible for the design/conduct of the study, (2) have access to the human participants (i.e., will consent participants, conduct the study), or (3) have access to identifying AND confidential information. If the individual does not have a PSU Access User ID, please provide some other form of contact information. If additional space is needed, attach a separate sheet containing the same information.

Name	Email Address	PSU User ID (e.g., abc 123)	Mailing Address	Role in this Study
Jeff Hayes	jxh34@psu.edu	jxh34	307A Cedar	Co-investigator
Louis Castonguay	lgc3@psu.edu	lgc3	333 Moore	Co-investigator
Amy Crane	alc374@psu.edu	alc374	307Cedar	Research assistant
				Choose one of the following
				Choose one of the following
				Choose one of the following
				Choose one of the following

13. Identify (1) the procedures/techniques each person (including advisors) listed in Question 12 and on the first page of the application will perform and (2) describe their level of research experience.

Dr. Locke is a licensed psychologist in Pennsylvania with more than 10 yeas of experience conducting psychotherapy research. He is an affiliate faculty member in the Department of Psychology as well as the Department of Counselor Education, Counseling Psychology, and Rehabilitation Services. Dr. Locke also is the Assistant Director for Research and Technology at CAPS. Dr. Locke will oversee data collection efforts at CAPS. Dr. Hayes is a professor of Counseling Psychology with more than 20 years of experience conducting psychotherapy research. He will be responsible for assisting in the design of the study, overseeing graduate assistant responsibilities, and data analysis. Dr. Castonguay is a professor of Psychology with more than 20 years of experience conducting psychotherapy research. He will assist with the conceptualization of the study and with data analysis. Amy Crane has a master's degree in Counseling Psychology from Ball State University and is completing the first year of the doctoral program in Counseling Psychology at Penn State. Amy has 3 years of research experience, including working with large data sets as part of her assistantship responsibilities at Ball State's Office for Institutional Research. Amy has taken a research design course at the master's level and has taken a second one at Penn State. She has co-authored two refereed journal articles.

14. Explain how the persons assisting with this research are kept adequately informed about the study and their research-related duties and functions.

The individuals identified above have been meeting, and will continue to meet, at least twice a month to discuss the project and their associated roles and responsibilities. In addition, Dr. Hayes and Amy Crane meet on a weekly basis to supervise her graduate assistantship.

F. Purpose & Procedures:

15. Provide a detailed description of the research that includes (1) the background, (2) aims/objectives [hypothesis], and (3) a description of how the research will be conducted [methodology – what participants will be asked to do].

Background: College student mental health has become a key concern during the last several years. The Center for the Study of Collegiate Mental Health (CSCMH), which is a collaborative effort among more than 100 university counseling centers, was established to document and study issues related to college students' mental health and the treatment they receive. The long-term vision for CSCMH is to develop a national infrastructure to aggregate de-identified, anonymous data from participating counseling centers for the purposes of improving services, identifying trends, and influencing policy decisions.
Details about CSCMH can be found online at: http://www.sa.psu.edu/caps/research_center.shtml.

Aims/Objectives: This IRB proposal seeks permission for Penn State's Center for Counseling and Psychological Services (CAPS) to contribute data to CSCMH on a regular basis. By doing so, CAPS would contribute to a nationally representative data set on college students' mental health. The data that CAPS would contribute is drawn from two instruments: the Standardized Data Set (SDS) and the Counseling Center Assessment of Psychological Symptoms (CCAPS). The SDS consists of client demographic and mental-health history questions. The CCAPS contains 70 Likert-type items pertaining to clients' symptoms and distress. The CCAPS does not ask for or provide psychiatric diagnoses. The SDS and CCAPS are attached to this application for your reference. To be clear, data from the CCAPS and SDS are collected at CAPS from all clients as a part of routine clinical practice. However, these data are not currently uploaded to CSCMH. We would like to obtain clients' permission to have their data, in de-identified form, become part of the national CSCMH database.

Methods: Clients will be asked to complete the SDS and CCAPS immediately prior to their initial intake appointment at CAPS on a private and secure computer located in the reception area of CAPS (5th floor, Student Health Center). Completion of the SDS and CCAPS, it should be noted, is already part of daily, routine, standard clinical practice at CAPS. After clients complete the SDS and CCAPS, they will be presented with the following choice:

CAPS participates in a national research project designed to improve our services and expand the knowledge about college student mental health. We participate by contributing anonymous, numeric data provided by those who use our services (and are over 18 years old) to a database managed by researchers at Penn State University. Data is stripped of all personally identifying information and then combined with anonymous, numeric data from other colleges nationwide for statistical analysis. Because data cannot be linked to specific individuals, there are virtually no risks contributing data. With your permission, we would like to contribute anonymous, numeric data from the questionnaires you just completed. Your decision is voluntary and will not affect the services you receive. If you have questions or concerns, you may contact Dr. Ben Locke at bdl10@psu.edu.

Will you allow your anonymous, numeric responses to be contributed?
Yes
No

The Yes/No question represents a field of data which will be stored in the client's record in Titanium and which can be updated at any time. Data will only be uploaded if a client responded "yes". Data will not be uploaded if they responded "no" or skipped the question.In order to contribute this de-identified anonymous SDS and CCAPS data, Titanium Software has created a function within its software which will upload data from participating centers to CSCMH, following specific actions from administrators at each center. In order to make sure the data is anonymous while also allowing longitudinal research, each client will be assigned a unique alpha-numeric identification number when the data are uploaded to CSCMH. This number will be generated using a one-way encryption process such that a given client will consistently be given the same new national ID#, but the new ID# cannot be reverse-engineered to determine their identity within the counseling center. At no time will it be possible to connect this identification number with clients' names or other personally identifying information. The exported data will be completely anonymous such that it will not include any form of identifying information about the clients. (Even date of birth will be translated to age, by Titanium, prior to export.) Once exported, there will be no way to link the exported data back to a specific individual. This data will be uploaded on an ongoing basis at least once per semester.

16. How long will participants be involved in this research study? Include the number of sessions and the duration of each session.
PARTICPANTS ARE NOT INVOLVED IN THIS RESEARCH ANY LONGER THAN IT TAKES FOR THEM TO CHECK THE OPT-OUT BOX MENTIONED ABOVE. THEIR SDS AND CCAPS DATA IS BEING COLLECTED REGARDLESS OF WHETHER OR NOT THEY CONSENT TO HAVE THEIR DATA UPLOADED INTO THIS DATABASE FOR RESEARCH PURPOSES.

17. Where will this research study take place? Choose all that apply.
☒ University Park → Specify the building and room number. If not yet known, indicate such. 501 SHC
☐ GCRC at University Park

☐ Other PSU Campus Location → Specify the campus, building and room number. If not yet known, indicate such.
☐ Hershey Medical Center → Specify the building and room number. If not yet known, indicate such.

☐ GCRC at the Hershey Medical Center

☐ Mt. Nittany Medical Center

☐ Other Site(s) → Explain:

NOTE: For other sites such as schools, doctor offices, businesses, etc., the IRB requires that research conducted at these sites be approved by an individual in a decision making position at the site. Documented approval (i.e., a letter of agreement) is required.

18. Is this a multi-center study outside of PSU?
Yes → Answer Question 19
x No → Skip to Question 22

19. Is any Penn State investigator on this application the lead investigator (project director) of this multi-center study?
Yes → Answer Questions 20 – 21
☐ No → Skip to Question 22

20. Provide the name and location of all other centers. Copies of IRB approval letters from each site will be required with the supporting documentation for this application.

21. Describe the plan for the management and communication of multi-site information that may be relevant to the protection of participants (e.g., unanticipated problems, adverse events, interim analyses, modifications).

22. How will the data be analyzed?
SPSS will be used to conduct descriptive and inferential statistical analyses.

23. List criteria for inclusion of participants.
CLIENTS WHO COME TO CAPS, COMPLETE THE INTAKE INSTRUMENTS (SDS AND CCAPS), AND WHO GIVE PERMISSION TO HAVE THEIR DATA USED FOR RESEARCH PURPOSES.

24. List criteria for exclusion of participants.
CLIENTS WHO COME TO CAPS, COMPLETE THE INTAKE INSTRUMENTS, AND WHO DO NOT GIVE PERMISSION TO HAVE THEIR DATA USED FOR RESEARCH PURPOSES

G. Participants:

25. Maximum number of participants/samples/charts to be enrolled at this institution (Enter one number – not a range): Data from approximately 2,000 clients at CAPS will be contributed each year.

26. Was a statistical/power analysis conducted to determine the adequate sample? ☐ Yes ☒ No

27. Does this research exclude any particular:

Gender Identity	☐ Yes	☒ No	If Yes, please explain.
Racial/ethnic groups	☐ Yes	☒ No	If Yes, please explain.
Sexual Orientation	☐ Yes	☒ No	If Yes, please explain.

28. Age range – Choose all that apply.
☐ Less than 1 year ☐ 7 – 12 years ☒ 18 – 25 years ☒ 40 – 65 years

☐ 1 – 6 years ☐ 13 – 17 years ☒ 26 – 40 years ☒ 65+ years

29. Choose all categories of participants who will be involved in this research study.

☐ Healthy volunteers
☒ Penn State students
☐ Subject Pool Students – Indicate the subject pool: ☐ CAS 100A ☐ Psychology – UP ☐ Psychology – Behrend
↳ Will all participants involved in this study be from the subject pool? ☐ Yes ☐ No
☐ Children – Individuals under the age of 18 — Complete & Submit Appendix 2
☐ International Research – participants live outside of the U.S. — Complete & Submit Appendix 3
☐ Prisoners — Complete & Submit Appendix 4
☐ Pregnant Women
☐ Women of reproductive potential at the time of this research – Choose one of the following:
☐ The research poses no added risk associated with pregnancy and/or lactation
☐ Precautions against pregnancy and/or lactation, and pregnancy tests are addressed in the research proposal and consent form
☒ Patients — Complete & Submit Appendix 5
☐ Individuals with a decisional impairment who are targeted for this study (e.g., research on Alzheimer's enrolling only individuals with Alzheimer's) — Complete & Submit Appendix 6
☐ Individuals with a decision impairment who are NOT targeted for this study (e.g., decisionally compromised person eligible for a study on a new treatment for breast cancer) — Complete & Submit Appendix 6
☐ Institutionalized individuals (e.g., patients in state hospitals or nursing homes) — Complete & Submit Appendix 7
☐ Fetus, embryo, fetal material in vitro fertilization
☐ None of the above categories will be used in this research

30. Will participants be currently enrolled in a course/class of any personnel listed on this application?

☐ Yes → Describe the measures taken to avoid coercion & undue influence:
☒ No

31. Will participants be employees of any personnel listed on this application?

☐ Yes → Describe the measures taken to avoid coercion & undue influence:
☒ No

32. Could some or all participants be vulnerable to coercion or undue influence due to special circumstances? Do not include children, decisionally impaired persons, and prisoners in your answer.

☐ Yes → Describe the measures taken to protect these individuals:
☒ No

H. Recruitment:

33. Indicate the types of recruitment that will be done for this research & attach copies of the materials. Choose all that apply:

☐ Newspaper/magazine ads
☐ Radio/TV ads
☐ Letters/Emails to potential participants
↳Explain how potential participants contact information was obtained:
☐ Letters/Emails to healthcare professionals for recruitment purposes
↳Which healthcare groups will receive these letters?
☐ Flyers/posters – Where will the items be displayed/distributed?
☐ Brochures – Where will the items be displayed/distributed?
☐ Web sites – List the sites the recruitment materials will be posted:
☐ Email via Listserv – Has permission been obtained from the listserv administrator? ☐ Yes ☐ No

☐ Script – Verbal (i.e., telephone, face-to-face, classroom)
☐ Subject Pool → Indicate which subject pool will be used:
↳ ☐ CAS 100A ☐ Psychology – UP ☐ Psychology – Behrend
Note: If you are not a member of the subject pool's department, a permission letter will be needed.
☒ Other → Explain: Participants will be given the opportunity to opt out of having their information from the SDS and CCAPS anonymously pooled in a national data base via a yes/no question. Clients who answer "no" or skip the question will be excluded from the data pooling. The language for this statement was provided in response to question 15 and is attached as well.

34. Who will approach and/or respond to potential participants?
All clients will be informed and given the opportunity to opt out during the standard intake process at CAPS. The standard intake process involves clients filling out the SDS and CCAPS at a computer station and then meeting with a staff counselor. Clients will be given the opportunity to contribute or not contribute their anonymous data to a national data set by reading and responding to information that is provided on a computer monitor after they complete the SDS and CCAPS.

35. Before potential participants sign a consent form, are there any screening questions that will be asked to determine whether an individual is appropriate for the study?
☐ Yes → Answer Question 36
☒ No → Skip to Question 37

36. During screening questions, will identifiable information about these individuals be recorded?
☐ Yes → Complete & Submit Appendix 8
☐ No

NOTE: Please attach, as appropriate, a procedure and script for the screening questions. Also, attach a copy of the screening question data collection sheet.

37. Will investigators access medical charts and/or hospital/clinic databases for recruitment purposes?
☐ Yes → Answer Question 38
☒ No → Skip to Question 39

38. Has a waiver of authorization to access protected health information been requested?
☐ Yes
☐ No → Explain why a waiver of authorization has NOT been requested:

39. Will physicians/clinicians provide identifiable, patient information (e.g., name, telephone number, address) to investigators for recruitment purposes?
☐ Yes → Provide a copy of the written authorization release form for review.
☒ No

I. Consent:
40. When and where will participants be approached to obtain informed consent/assent [include the timing of obtaining consent in the response]? If participants could be non-English speaking, illiterate or have other special circumstances, describe. Attach a copy of the informed consent/assent form(s).
We are seeking permission to waive the standard process of obtaining informed consent. We believe that having clients read and sign an informed consent form would compromise the anonymity of their data. Furthermore, given the high volume of intakes conducted at CAPS, the limited amount of time available at each computer station for clients to complete the routine intake paperwork, and the fact that a significant portion of clients are coming to CAPS in distress, we believe that many clients will not read the entire language of the standard implied consent form. Therefore, we believe that a brief opt out statement will more effectively communicate the purposes of data collection and allow clients to more effectively make decisions about participation. Please see our attached Opt-out text which provides a "yes/no" response option. Clients who answer "no" or skip the question will be excluded from the data pooling.

41. Who will be responsible for obtaining informed consent/assent from participants?
See 40 and 43.

42. Do the people listed in Question 41 above speak the same language as the participants?
n/a

☐ No → Explain how consent will be obtained.

43. What type of consent will be obtained? Choose all that apply.

☐ Signed consent – participant will sign consent form
☐ Implied consent – participant will not sign consent form (e.g., mail survey, email, on-line survey)
↳Complete & Submit Appendix 9, Section A
☐ Verbal consent – participant gives consent verbally (e.g., in-person interview, telephone interview)
↳Complete & Submit Appendix 9, Section A
☒ Passive/Opt Out consent – participant only required to act if they do not want to participate
↳Complete & Submit Appendix 9, Section B
☐ Complete waiver of informed consent
↳Complete & Submit Appendix 9, Section B
☐ Other → Describe:

44. If multiple groups of participants are being utilized (i.e., teachers, parents, children, people over 18), who will and will not sign the assent/consent form? Specify for each group of participants.
N/A

45. Participants are to receive a copy of the informed consent form with the approval box/statement on it. Describe how participants will receive a copy of the informed consent form to keep for their records.
N/A

J. Payment for Participation:

46. Indicate the type and amount of payment for participation that will be offered. Choose all that apply.

☐ Money	Amount:	Skip to Question 48
☐ Gift Certificate	Amount:	Skip to Question 48
☐ Extra/Class Credit (e.g., 5 points, 1% of final grade)	Amount:	Skip to Question 47
☐ Drawing	Explain:	Skip to Question 48
☐ Other (e.g., merchandise)	Explain:	Skip to Question 48
☒ Compensation will NOT be offered		Skip to Question 49

47. An alternative, equal in time and effort, must be offered in place of participating in the research. Describe the alternative available for earning the extra/class credit. The description should include the length of time it will take to complete the alternative as well as how undue influence will be prevented.

48. Will compensation be pro-rated? NOTE: Pro-rating is required for FDA-regulated studies.

☐ Yes → Explain how payment will be pro-rated:
☐ No

K. Data Collection Measures/Instruments:

49. Choose any of the following data collection measures/instruments that will be used in this study. Attach a copy of all instruments/measures, interview and focus group topics/questions to the application.

☐ Biological Specimens – blood, urine & other human derived samples

- ☐ Biomedical Devices – EEG, EKG, MRI
- ☐ Diaries/Journals completed by the participants
- ☐ Focus Groups
- ☐ Individual Interviews
- ☐ Knowledge/Cognitive Tests
- ☐ Observations
- ☐ Physical Testing Measures – Height, Weight, Body Mass Index, Blood Pressure
- ☒ Questionnaires/Surveys – Mail, Internet, Telephone, Email, Paper/Pencil
- ☐ Other → Explain:

50. Will participants be assigned to groups?
- ☐ Yes → Answer Questions 51 – 52
- ☒ No → Skip to Question 54

51. Will a control group(s) be used?
- ☐ Yes → Choose one of the following:
  - ☐ Placebo control
  - ☐ Standard therapy control
  - ☐ Other control method → Explain:
- ☒ No

52. Is the research a blinded (masked) study?
- ☐ Yes → Answer Question 53
- ☒ No → Skip to Question 54

53. Is emergency unblinding permitted?
- ☐ Yes
- ☐ No → Explain why emergency unblinding is NOT permitted:

L. Recordings – Audio, Video, Photographs

54. Will any type of recordings (audio or video) or photographs be made during this study?
- ☐ Yes → Complete & Submit Appendix 10
- ☒ No

M. Computer/Internet

55. Will any participant interaction in this study be conducted on the Internet or via email (e.g., on-line surveys, observations of chat rooms or blogs, on-line interviews)?
- ☒ Yes → Complete & Submit Appendix 11, Section A
- ☐ No

56. Will a commercial server (i.e., SurveyMonkey, Psych Data, Zoomerang) be used to collect data or for data storage?
- ☐ Yes → Complete & Submit Appendix 11, Section B
- ☒ No

N. Discomforts and Risks

57. List all of the potential discomforts and risks (physical, psychological, legal, social or financial) and describe the likelihood or seriousness of the discomforts/risk. If there are no discomforts/risks, state such.

This project contributes anonymous and de-identified data to CSCMH. Although data is sensitive, it is gathered during and contained within routine clinical practice.

The contribution of data from clients at CAPS imposes no risk or discomfort beyond routine clincial practice because the data is de-identified and anonymous.

58. Describe how risks will be minimized and/or how participants will be protected against potential risks throughout the study.

The requested data is collected as part of routine clinical practice. Therefore, any discomfort related to the questions will be addressed as part of routine clinical practice. That is, clients have the opportunity to discuss their concerns with a staff member at CAPS, during their intake interview.

Regarding the de-identification of data, the technology for handling these processes has been developed by Titanium Software, which is the largest manufacturer and distributor of electronic medical records software for university counseling centers in the United States. CSCMH has worked closely and in collaboration with the President and CEO of Titanium, Karl Zercoe, so that the software used by CAPS and other counseling centers will be specifically designed to ensure the security and anonymity of the data. After stripping all identifying information, clients will be assigned a new unique ID# which cannot be reverse engineered, data will be encrypted for secure transmission, and it will not be possible to trace transferred data back to a specific client. A pilot test of this process was successfully executed during the winter of 2009 in which archival data from more than 28,000 clients from 66 counseling centers, including CAPS, were anonymously and securely uploaded to CSCMH.

59. Does this research involve greater than minimal risk to the participants?

☐ Yes → Answer Questions 60 – 61 → Study must be reviewed by the Full IRB at a convened meeting.

☒ No → Skip to Question 62

60. Will medical or psychological care be available for participants who may require it as a result of the study?

☐ Yes → Identify the source of medical or psychological care available – include address & telephone number:

☐ No → Explain why medical or psychological care will NOT be available:

61. Does the research protocol have a plan for routine analysis or monitoring of the data and safety of this research study?

☐ Yes → Complete & Submit Appendix 17

☐ No → For studies involving greater than minimal risk, a plan will need to be developed for review and approval at the convened IRB meeting.

O. Benefits

62. What are the potential benefits to the individual participants? If none, state such. PLEASE NOTE: Payment for participation cannot be considered a benefit.

Clients' individual psychological treatment may be enhanced by providing nationally standardized information to counseling center staff about clients' demographic characteristics and problems for which they are seeking psychological care.

63. What are the potential benefits to society? If none, state such.

Contributing data to CSCMH will assist in the vision of providing accurate, national data regarding the scope and severity of presenting concerns among college students and student usage of campus mental health systems. In addition, contributing data will assist with making improvemnets to research, treatment, and evaluation of college student mental health.

64. Explain how the benefits outweigh the risks.

Because risks are minimal and potential gains are substantial and likely, it is believed that the benefits clearly outweigh the risks.

P. Reporting

65. Is it possible investigators will discover a participant's previously unknown condition (e.g., disease, suicidal thoughts, wrong paternity) as a result of study procedures?

☐ Yes → Explain how and when such a discovery will be handled:

☒ No

66. Is it possible investigators will discover a participant is engaging in illegal activities (e.g., drug use, domestic violence, child abuse/neglect, underage drinking) as a result of study procedures?

☐ Yes → Explain how and when such a discovery will be handled:

☒ No

Q. Deception

67. Does this study involve giving false or misleading information to participants or withholding information from them such that their "informed" consent is in question?

☐ Yes → Complete & Submit Appendix 12

☒ No

R. Confidentiality and Privacy

68. Describe the provisions made to maintain confidentiality of the data. Choose all that apply.

☒ Password protected computer files ☒ Locked offices

☐ Locked file cabinets ☒ Other → Explain: De-identified, anonymous data

☒ Identification code (i.e., code numbers, pseudonyms) – data will NOT be associated w/personal identifiers

69. Describe the provisions made to protect participants' privacy interests.

As described above, all data will be anonymous and de-identified. Individuals' identities cannot be determined from within the national dataset. Regarding the de-identification of data, the technology for handling these processes has been developed by Titanium Software, which is the largest manufacturer and distributor of electronic medical records software for university counseling centers in the United States. CSCMH has worked closely and in collaboration with the President and CEO of Titanium, Karl Zercoe, so that the software used by CAPS and other counseling centers will be specifically designed to ensure the security and anonymity of the data. After stripping all identifying information, clients will be assigned a new unique ID# which cannot be reverse engineered, data will be encrypted for secure transmission, and it will not be possible to trace transferred data back to a specific client. A pilot test of this process was successfully executed during the winter of 2009 in which archival data from more than 28,000 clients from 66 counseling centers, including CAPS, were anonymously and securely uploaded to CSCMH. There will not be any form of cross-reference, decipher key, or master list linking clients and their new national identifier.

70. Who will have access to the data?

Only the investigators listed on this proposal.

71. Will identifiers be disclosed to a sponsor or collaborators at another institution?

☐ Yes → List the identifiers that will be disclosed and explain why this is necessary:

☒ No

72. Will a list containing a code (i.e., code numbers, pseudonyms) and participants' identity be used in this study?

☐ Yes → Answer Questions 73 – 75

☒ No → Skip to Question 76

73. Where will the list linking the code to participants' identity be stored and how will the list be secured?

74. Who will have access to the list linking the code to participants' identity?

75. Will the list linking the code to participants' identity be destroyed?

☐ Yes → When will the list be destroyed?

☐ No

76. What will happen to the research records when the research has been completed? Choose only one.

☒ Stored indefinitely with identifiers removed

☐ Stored indefinitely with identifiers attached

↳ List the identifiers that will be attached to the data:

↳ Explain why the data must be stored indefinitely with identifiers:

☐ Stored for length of time required by federal regulations/funding source & then destroyed (minimum of 3 years)

☐ Destroyed after a number of years (minimum of 3 years) → Specify the number of years:

☐ Destroyed when notified by sponsor

☐ Other → Explain:

77. Could the information being collected for this study have adverse consequences for participants or be damaging to their financial standing, employability, insurability or reputation?

☐ Yes → Indicate the type of information being collected:

- ☐ Substance abuse or other illegal risk behaviors
- ☐ Determination of HIV status for the research
- ☐ Genetic information about inheritable diseases
- ☐ Other → Explain:

☒ No

78. Will a "Certificate of Confidentiality" be obtained from the federal government?

Yes → Indicate who will obtain the Certificate of Confidentiality

- ☒ Sponsor
- Principal Investigator (NIH)
- ☐ Other → Explain:

☐ No

S. Health Insurance Portability & Accountability Act (HIPAA) – Use of protected health information

79. Will participant's protected health information (PHI) be obtained for this study?

☐ Yes → Complete & Submit Appendix 13

☒ No

T. Drugs, Medical Devices, and Other Substances

80. Does this research study involve drugs or biologics?

☐ Yes → Complete & Submit Appendix 14, Section A

☒ No

81. Does this research study involve a device?

☐ Yes → Go to Question 82

☒ No → Skip to Question 83

82. Does the device meet the FDA's definition of a medical device?

☐ Yes → Complete & Submit Appendix 14, Section C

☒ No → Go to Question 83

FDA's Definition of a Medical Device: If a product is labeled, promoted or used in a manner that meets the following definition in section 201(h) of the Federal Food Drug and Cosmetic (FD&C) Act it will be regulated by the Food and Drug Administration (FDA) as a medical device and is subject to pre-marketing and post-marketing regulatory controls. A device is:

- "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
  - Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
  - Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

U. Biological Specimens

83. Will biological specimens (including blood, urine and other human-derived samples) be used in this study?

☐ Yes → Complete & Submit Appendix 15

☒ No

NOTE: If the response to Question 83 is YES, an application must be submitted to the Institutional Biosafety Committee (IBC). The IBC Applications may be located at http://www.research.psu.edu/orp/areas/biohazardous/applications/index.asp.

V. Other Biomedical Procedures – Diagnostic Radiation Procedures, Physical Activity, Diet Modifications

84. Will participants be asked to undergo diagnostic radiation procedures while enrolled in this study?

☐ Yes → Complete & Submit Appendix 16

☒ No

85. Will participants be required to engage in or perform any form of physical activity?

☐ Yes → Describe the nature and extent of the physical activity:

☒ No

86. Will any type of electrical equipment other than audio headphones be attached to the participants (e.g., EMG, EKG)?

☐ Yes → Submit a letter describing the most recent safety check of the equipment with the supporting documents for this application.

☒ No

87. Will there be any diet modifications or restrictions?

☐ Yes → Describe:

☒ No

W. Assurances

As the principal investigator on this research study, I assure that…

1. this application, if funded by an extramural source, accurately reflects all procedures involving human participants described in the grant proposal to the funding agency previously noted or an explanation is given for any differences.

2. I will obtain approval from the Institutional Review Board (IRB) before initiating any changes to the approved study, including changes in procedures, personnel, documents, instruments, etc., except where necessary to eliminate apparent immediate hazards to participants. In the latter instance, the IRB must be notified by the next workday.

3. I am familiar with and will comply with all pertinent institutional, local, state, and Federal regulations and policies. I will adhere to the policies and procedures described in Penn State's Federalwide Assurance with the Office for Human Research Protections as well as Federal regulations for the protection of human participants involved in research (45CFR46; 21CFR parts 50 & 56). Copies of these documents are available in the ORP upon request or on their website – http://www.research.psu.edu/orp/.

4. the information provided in this application reasonably summarizes the nature and extent of the proposed use of human participants.

5. I will notify the IRB within 5 business days regarding any significant adverse events that impact human participants.

6. all individuals listed on this form are competent and have been properly trained. I also assure that all individuals will complete the required training for the protection of human participants available on-line prior to contact with human participants.

7. any individual associated with or responsible for the design, the conduct, or the reporting of this research will comply with Penn State's Conflict of Interest Policy, RA-05.

Signature of Principal Investigator, REQUIRED | Date

I hereby confirm that I have read this application and my signature denotes the completeness and accuracy of the information provided.

PRINT Name of Faculty Advisor, REQUIRED IF PI IS A STUDENT

SIGNATURE of Faculty Advisor, REQUIRED IF PI IS A STUDENT | Date

I hereby confirm that I have read this application and my signature denotes departmental/unit approval of this project. To the best of my knowledge, the information in the attached application relating to members of my department is correct.

The investigator(s) who are members of my department are qualified to perform the roles proposed for them in this application. Any novice researchers from my department will be supervised by qualified investigators.

PRINT Name of PI's Department/Unit Head, REQUIRED

SIGNATURE of PI's Department/Unit Head, REQUIRED | Date

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201 Kern Building
University Park, PA 16802
814-865-1775
Fax: 814-863-8699
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APPENDIX 5
INVOLVEMENT OF PATIENTS IN RESEARCH

Form Instructions:
- This Appendix must be completed and submitted if Question 29 the *Application for the Use of Human Participants* indicates patients will be involved in this research study.
- To complete the form, press TAB or SHIFT TAB between boxes and enter an 'X' or text. For assistance, contact the Office for Research Protections.
- Handwritten applications will NOT be accepted.

Project Title: Counseling and Psychological Services (CAPS) Data Contribution to the Center for the Study of Collegiate Mental Health (CSCMH)

Principal Investigator: Dr. Ben Locke PSU User ID (e.g., abc123): bdl10

Email Address: bdl10@psu.edu

1. Specify the disease category of the patient(s):
   Students seeking services at Penn State's Center for Counseling and Psychological Services

2. Are any of these participants patients of the investigator(s)?
   ☒ Yes – Explain the measures implemented to avoid coercion & undue influence when recruiting your own patients:
   Patients will decide whether or not to contribute their intake data to a national data base BEFORE meeting with an intake counselor at CAPS (e.g., Dr. Locke). For this reason, the possibilitiy of coercion is minimal.
   ☐ No

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APPENDIX 9
WAIVERS OF INFORMED CONSENT

Form Instructions:
- To complete the form, press TAB or SHIFT TAB between boxes and enter an 'X' or text. For assistance, contact the Office for Research Protections.
- Handwritten applications will NOT be accepted.

Project Title: Counseling and Psychological Services (CAPS) Data Contribution to the Center for the Study of Collegiate Mental Health (CSCMH)

Principal Investigator: Dr. Ben Locke PSU User ID (e.g., abc123): bdl10

Email Address: bdl10@psu.edu

A. Waiver of *Documentation* of Informed Consent – Complete if "Implied consent" or "Verbal consent" is checked in Question 43 of the *Application for the Use of Human Participants*

NOTE: A waiver of *documentation* of informed consent occurs when you are obtaining informed consent but participants are not required to sign the consent form (e.g., implied consent, verbal consent). The act of their completing and submitting the survey/interview would be considered their implied consent to participate.

1. One of the following two conditions must be met to allow for a process other than signed informed consent to be utilized. Choose which condition is applicable:

☐ The only record linking the participant and the research would be the informed consent form. The principal risk to the participant is the potential harm resulting from a breach of confidentiality. Each participant will be asked whether he/she wants documentation linking the participant with the research and the participants wishes will govern. → Explain how your study fits into the category:

☐ The research presents no more than minimal risk of harm to participants & involves no procedures for which signed consent is normally required outside of the research context. → Explain how your study fits into the category:

B. Waiver of Informed Consent – Complete if "Passive/Opt out consent" is checked in Question 43 of the *Application for the Use of Human Participants*

NOTE: A waiver of informed consent means that the IRB is not requiring the principal investigator to obtain informed consent (i.e., the participants are sent a letter and are not required to act unless they do NOT wish to participate in the study OR the investigator is not required to obtain consent from participants) OR a consent procedure which does not include or which alters some or all of the required elements of consent.

1. Explain why a waiver of informed consent is being requested. We are seeking permission to waive the standard process of obtaining informed consent. We believe that having clients sign an informed consent form would compromise the anonymity of their data. Furthermore, given the high volume of intakes conducted at CAPS, the limited amount of time available at each computer station for clients to complete the routine intake paperwork, and the fact that a significant portion of clients are coming to CAPS in distress, we believe that many clients will not read the entire language of the standard implied consent form. Therefore, we believe that a brief opt out statement will more effectively communicate to a larger number of clients the purposes of data collection and allow clients to more effectively make decisions about participation.

2. Describe how this study meets all four of the following conditions:
- The research involves no more than minimal risk to the participants. → Explain how your study meets this criteria: Because SDS and CCAPS data are collected as part of routine clinical practice at CAPS, the only additional risk posed by this study is

the transmission of anonymous, de-identified data from CAPS to CSCMH and storage within CSCMH. The risk of data security becoming compromised is viewed as minimal for several reasons. First, no personally identifying information is included in the CCAPS or SDS. Second, all client data is assigned a strong, alpha-numeric ID when it is uploaded to CSCMH. Third, data will be encrypted during transmission, and fourth, it will not be possible to trace data back to a specific individual based once it has been uploaded. Fifth, the softwared developed by Titanium that is used to upload the data has been in use at CAPS and at more than 400 counseling centers nation wide for several years. CAPS has not experienced a single instance in which data security has been breached within the Titanium medical records system, nor are we aware of any compromises to data security in any other counseling center. Finally, in a pilot test of archival data conducted by CSCMH in the winter of 2009, data from 66 counseling centers across the country, including CAPS, were successfully and securely uploaded to and stored by CSCMH without incident.

- The waiver will not adversely affect the rights and welfare of participants. → Explain how your study meets this criteria: Clients will be given the right to opt out of having their anonymous data uploaded and contributed to CSCMH. By being given the option not to contribute their data, clients' welfare will not be adversely affected.

- The research could not practicably be carried out without the waiver. → Explain how your study meets this criteria: We believe that having clients sign an informed consent form would compromise the anonymity of their data. Confidentiality is of the utmost importance in the cousneling profession, and we consider it an unnecessary risk to ensuring the protection of clients' identity to require them to sign an informed consent form. Furthermore, because the standard language associated with a typical informed consent form is somewhat lengthy, and because clients have limited time in which to complete the intake process at CAPS (which includes filling out the CCAPS and SDS at a computer terminal and meeting with a staff counselor), we believe that many clients may not participate in the study simply due to perceived time constraints brought on by the lengthy standard consent form.. More importantly, we fear that many clients, who are in distress, would not take the time to read the entire form, thereby rendering implied or informed consent meaningless for these clients. We believe that a brief opt out statement that explicitly identifies the nature of the study will more effectively communicate to clients what their participation would entail, thereby increasing the number of clients who can meaningfully choose to participate or not participate.

- Will participants be provided with additional pertinent information after participation?
  ☒ Yes
  ☐ No → Explain why not:

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APPENDIX 11
USE OF COMPUTER AND/OR INTERNET IN RESEARCH

Form Instructions:
- To complete the form, press TAB or SHIFT TAB between boxes and enter an 'X' or text. For assistance, contact the Office for Research Protections.
- Handwritten applications will NOT be accepted.

Project Title: Counseling and Psychological Services (CAPS) Data Contribution to the Center for the Study of Collegiate Mental Health (CSCMH)

Principal Investigator: Ben Locke PSU User ID (e.g., abc123): bdl10

Email Address: bdl10@psu.edu

This appendix is largely not applicable. Secure computer kiosks are used in the course of routine clinical practice to gather information from clients seeking services at CAPS. The kiosks used are heavily secured and are data collection can only occur at the 4 on-site kiosks. The proposed research will pool data after it has been collected and stored for routine clinical service, not before. Therefore, the following 2 questions are not applicable.

A. Complete this Appendix if the response to Question 59 in the *Application for the Use of Human Participants* is YES.

1. Is there a method in place to authenticate the identity of participants (i.e., use of pin number, logging into a site)?
   _____ No → Explain why an authentication method is not in place: _____
   ___ __ Yes → Describe the authentication method:

2. Will data be sent in an encrypted format?
   _____ No → Explain why data will not be sent in an encrypted format: _____
   _____ Yes → Describe the level of encryption: _____

B. Complete this Appendix if the response to Question 60 in the *Application for the Use of Human Participants* is YES.

1. Identify the commercial service provider who will collect and/or store the data.
   _____ SurveyMonkey
   _____ Zoomerang
   _____ PsychData
   _____ Other → Identify the commercial service provider: _____

2. Describe the commercial service provider's confidentiality policies and procedures - include information about security audits of the server. If policies & procedures are attached, indicate such.

   _____