APPLICATION FOR THE USE OF HUMAN RESEARCH PARTICIPANTS

IRB APPLICATION #: 2794 (To be assigned by the IRB)

I. APPLICATION INSTRUCTIONS

1. Complete each section of this form, using the gray form fields (use the tab key).
2. If you have questions, hover over the blue (?), or refer to the IRB Application Instructions for additional clarification.
4. Email the completed application, with the following supporting documents (as separate word documents) to irb@liberty.edu:
   a. Consent Forms, Permission Letters, Recruitment Materials
   b. Surveys, Questionnaires, Interview Questions, Focus Group Questions
5. If you plan on using a specific Liberty University department or population for your study, you will need to obtain permission from the appropriate department chair/dean. Submit documentation of permission (email or letter) to the IRB along with this application and check the indicated box below verifying that you have done so.
6. Submit one signed copy of the signature page (available on the IRB website) to any of the following:
   a. Email: As a scanned document to irb@liberty.edu
   b. Fax: 434-522-0506
   c. Mail: IRB 1971 University Blvd. Lynchburg, VA 24515
   d. In Person: Green Hall, Suite 1887
7. Once received, applications are processed on a first-come, first-served basis.
8. Preliminary review may take up to 3 weeks.
9. Most applications will require 3 sets of revisions.
10. The entire process may take between 1 and 2 months.
11. We cannot accept applications in formats other than Microsoft Word. Please do not send us One Drive files, Pdfs, Google Docs, or Html applications.

Note: Applications and supporting documents with the following problems will be returned immediately for revisions:

1. Grammar, spelling, or punctuation errors
2. Lack of professionalism
3. Lack of consistency or clarity
4. Incomplete applications

**Failure to minimize these errors will cause delays in your processing time**
## II. BASIC PROTOCOL INFORMATION

### 1. STUDY/THESIS/DISSERTATION TITLE (?)

**Title:** Creative Therapy For Anxiety: A Group Counseling Experience

### 2. PRINCIPAL INVESTIGATOR & PROTOCOL INFORMATION (?)

**Principal Investigator (person conducting the research):** Dr. Lisa Sosin, PhD, LPC, LLP, BASC

<table>
<thead>
<tr>
<th>Professional Title (student, professor, etc.):</th>
<th>Director PhD CES Program; Associate Professor</th>
</tr>
</thead>
<tbody>
<tr>
<td>School/Department (School of Education, LUCOM, etc.):</td>
<td>Department of Counselor Education and Family Studies, School of Behavioral Sciences</td>
</tr>
<tr>
<td>Personal Mailing Address:</td>
<td>701 Old Thomas Road Carter Building, Lynchburg, VA 24515</td>
</tr>
<tr>
<td>Phone:</td>
<td>(434) 592-4042</td>
</tr>
<tr>
<td>LU Email:</td>
<td><a href="mailto:lssosin@liberty.edu">lssosin@liberty.edu</a></td>
</tr>
</tbody>
</table>

**Check all that apply:**

- [ ] Faculty
- [ ] Staff
- [ ] Residential Graduate Student
- [x] Online Undergraduate Student

**This research is for:**

- [x] Faculty Research
- [ ] Master’s Thesis
- [ ] Doctoral Dissertation
- [ ] Other:

If applicable, indicate whether you have defended and passed your dissertation proposal:

- [ ] No (Provide your defense date):  
- [x] Yes (Proceed to Associated Personnel Information)

### 3. ASSOCIATED PERSONNEL INFORMATION (?)

**Co-Researcher(s):** John Harrichand; Tim Sosin; Michael Trexler

<table>
<thead>
<tr>
<th>School/Department:</th>
<th>Department of Counselor Education and Family Studies</th>
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</thead>
<tbody>
<tr>
<td>Phone:</td>
<td>(434) 592-4049</td>
</tr>
<tr>
<td>LU/Other Email:</td>
<td><a href="mailto:jharrichand@liberty.edu">jharrichand@liberty.edu</a>; <a href="mailto:tsosin@liberty.edu">tsosin@liberty.edu</a>; <a href="mailto:mtrexler@liberty.edu">mtrexler@liberty.edu</a></td>
</tr>
</tbody>
</table>

**Faculty Advisor/Chair/Mentor(s):** Dr. Lisa Sosin

<table>
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<td><a href="mailto:lssosin@liberty.edu">lssosin@liberty.edu</a></td>
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**Non-Key Personnel (Reader, Assistant, etc.):** N/A

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<tr>
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<td>LU/Other Email:</td>
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**Consultant(s) (required for Ed.D Candidates):** N/A

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<td>LU/Other Email:</td>
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</table>

### 4. USE OF LIBERTY UNIVERSITY PARTICIPANTS (?)

Do you intend to use LU students, staff, or faculty as participants OR LU students, staff, or faculty data in your study?

- [x] Yes (Complete the section below)
- [ ] No (Proceed to Funding Source)

**# of Participants/Data Sets:** 10  
**Department:** Student Counseling Services
I obtained permission from the Department Chair, and attached proof to this application.

Note: You must submit the original Chair signature or emailed documentation to the IRB for verification.

### 5. FUNDING SOURCE (?)

**Is your research funded?**
- [x] No ([Proceed to Study Dates])
- [ ] Yes (Complete the section below)

**Grant Name/Funding Source:**

**Funding Period (Month & Year):**

**Grant Number:**

### 6. STUDY DATES (?)

When will you perform your study? *(Approximate dates for collection/analysis):*
- **Start:** March, 2017, if possible
- **Finish:** May 2017

### 7. COMPLETION OF REQUIRED CITI RESEARCH ETHICS TRAINING (?)

**List Course Name(s) (School of Education, Psychology/Counseling, etc.):**

Lisa Sosin Completed requirements: CITI ID: 3678936
- CITI Health Info. Privacy and Security for Students and Instructors
- Social and Behavioral REsponsible Conduct of Research
- CITI Conflicts of Interests
- Psychology/Counseling

John Harrichand:
- Belmont Report and CITI Course Introduction (ID:1127)
- History and Ethical Principles - SBE (ID:490)
- Assessing Risk - SBE (ID:503)
- Informed Consent - SBE (ID:504)
- Privacy and Confidentiality - SBE (ID:505)
- Liberty University (ID:15111)
- Students in Research (ID:1321)
- Collaborative Research (RCR-Basic) (ID:16598)
- Research Involving Human Subjects (RCR-Basic) (ID:13566)
- Responsible Conduct of Research (RCR) Course Conclusion (ID:1043)

Michael Trexler:
- Belmont Report and CITI Course Introduction (ID: 1127)
- History and Ethical Principles - SBE (ID: 490)
- Assessing Risk - SBE (ID: 503)
- Informed Consent - SBE (ID: 504)
- Privacy and Confidentiality - SBE (ID: 505)
- Liberty University (ID: 15111)
- Defining Research with Human Subjects - SBE (ID: 491)

Tim Sosin:
Liberty University (ID: 15111) 07-Feb-2017 No Quiz
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680) 07-Feb-2017 5/5 (100%)
Belmont Report and CITI Course Introduction (ID: 1127) 07-Feb-2017 3/3 (100%)
History and Ethical Principles - SBE (ID: 490) 07-Feb-2017 4/5 (80%)
Defining Research with Human Subjects - SBE (ID: 491) 07-Feb-2017 4/5 (80%)
The Federal Regulations - SBE (ID: 502) 07-Feb-2017 4/5 (80%)
Assessing Risk - SBE (ID: 503) 07-Feb-2017 5/5 (100%)
Informed Consent - SBE (ID: 504) 07-Feb-2017 5/5 (100%)
Privacy and Confidentiality - SBE (ID: 505) 07-Feb-2017 5/5 (100%)
Unanticipated Problems and Reporting Requirements in Social and Behavioral Research (ID: 14928) 07-Feb-2017 5/5 (100%)
Research with Prisoners - SBE (ID: 506) 07-Feb-2017 3/5 (60%)

Date(s) of Completion: Harrichand, (04/12/15; 04/13/15); L. Sosin (4/12/15); Trexler, (12/18/2015), T. Sosin

III. OTHER STUDY MATERIALS AND CONSIDERATIONS

8. STUDY MATERIALS LIST (?)
Please indicate whether your proposed study will include any of the following:

<table>
<thead>
<tr>
<th>Study Material</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recording/photography of participants (voice, video, or images)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participant compensation (gift cards, meals, extra credit, etc.)?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Advertising for participants (flyers, TV/Radio advertisements)?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>More than minimal psychological stress?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Confidential material (questionnaires, surveys, interviews, test scores, etc.)?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Extra costs to the participants (tests, hospitalization, etc.)?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>The inclusion of pregnant women (for medical studies)?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>More than minimal risk?*</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Alcohol consumption?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Waiver of the informed consent document?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Protected Health Information (from health practitioners/institutions)?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>VO₂ Max Exercise?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Please indicate whether your proposed study will include the use of blood:

<table>
<thead>
<tr>
<th>Use of blood?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total amount of blood:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood draws over time period (days):</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please indicate whether your proposed study will include any of the following materials:

<table>
<thead>
<tr>
<th>Material</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>The use of rDNA or biohazardous material?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>The use of human tissue or cell lines?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Fluids that could mask the presence of blood (including urine/feces)?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Use of radiation or radioisotopes?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

*Minimal risk is defined 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 everyday life or during the performance of routine physical or physiological examinations or tests. [45 CFR 46.102(i)]. If you are unsure if your study qualifies as minimal risk, contact the IRB.

9. INVESTIGATIONAL METHODS (?)
Please indicate whether your proposed study will include any of the following:

<table>
<thead>
<tr>
<th>The use of an Investigational New Drug (IND) or an Approved Drug for an Unapproved Use?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ No</td>
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<tr>
<td>☐ Yes (Provide the drug name, IND number, and company):</td>
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</table>

<table>
<thead>
<tr>
<th>The use of an Investigational Medical Device or an Approved Medical Device for an Unapproved Use?</th>
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<tbody>
<tr>
<td>☐ No</td>
</tr>
<tr>
<td>☐ Yes (Provide the device name, IDE number, and company):</td>
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</tbody>
</table>

IV. PURPOSE

10. PURPOSE OF RESEARCH (?)

Write an original, brief, non-technical description of the purpose of your research.

Include in your description your research hypothesis/question, a narrative that explains the major constructs of your study, and how the data will advance your research hypothesis or question. This section should be easy to read for someone not familiar with your academic discipline:

Many college students suffer with anxiety at levels that can hinder personal and academic success. The Creative Exposure Intervention was recently developed and used with positive results with individuals suffering with anxiety in a clinical setting (Sosin & Rockinson-Szapkiw, 2016). The intervention combines cognitive-behavioral therapy (CBT), mindfulness training, and art therapy techniques for the treatment of anxiety; interventions which are well supported in the counseling literature (Barlow, 2014; Bazargan & Pakdaman, 2016; Bernstein, Tanay, & Vujanovic, 2011). This study will introduce and utilize the intervention in a group format with a small sample of people (6-10) who report mild-moderate anxiety and then explore the intervention's effectiveness. The purpose of the research is to help alleviate anxiety symptoms in the participants and to explore their experiences in the group.

V. PARTICIPANT INCLUSION/EXCLUSION CRITERIA

11. STUDY POPULATION (?)

Provide the inclusion criteria for the participant population (gender, age range, ethnic background, health status, occupation, employer, etc.): To explore the counseling group experience, participants will be a purposeful sample of male and female students, age 18 and over, who report experiencing mild to moderate levels of anxiety symptoms.

Provide a rationale for selecting the above population: According to statistics from Student Counseling Services, many students at Liberty University are suffering with anxiety. These symptoms impact student's ability to function and flourish in their personal and academic lives. Additionally, the volume of students in need of counseling for anxiety is large, more than can be served in individual counseling at times. An effective group may be a way of providing services at Student Counseling Services to more than one student suffering with anxiety at a time. Finally, findings from the study may be disseminated to the field and therefore help others provide effective services in academic and clinical settings.

Are you related to any of your participants?

☐ No
☐ Yes (Explain):
If applicable, indicate who will be excluded from your study population (e.g., persons under 18 years of age): Persons under 18 years old who do not meet inclusion criteria.

If applicable, provide rationale for involving any special populations (e.g., children, ethnic groups, mentally disabled, low socio-economic status, prisoners): N/A

Provide the maximum number of participants you plan to enroll for each participant population and justify the sample size (You will not be approved to enroll a number greater than the number listed. If at a later time it becomes apparent that you need to increase your sample size, submit a Change in Protocol Form and wait for approval to proceed): 6-10 individuals

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ANSWER THE FOLLOWING QUESTION ONLY IF YOU ARE CONDUCTING A PROTOCOL WITH NIH, FEDERAL, OR STATE FUNDING:

Researchers sometimes believe their particular project is not appropriate for certain types of participants. These may include, for example, women, minorities, and children. If you believe your project should not include one or more of these groups, please provide your justification for their exclusion. Your justification will be reviewed according to the applicable NIH, federal, or state guidelines: N/A

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12. TYPES OF PARTICIPANTS (?)
Who will be the focus of your study? (Check all that apply)

- ☑ Normal Participants (Age 18-65)
- ☐ Minors (Under Age 18)
- ☐ Over Age 65
- ☑ University Students
- ☐ Active-Duty Military Personnel
- ☐ Discharged/Retired Military Personnel
- ☐ Inpatients
- ☐ Outpatients
- ☐ Patient Controls
- ☐ Pregnant Women
- ☐ Fetuses
- ☐ Cognitively Disabled
- ☐ Physically Disabled
- ☐ Participants Incapable of Giving Consent
- ☐ Prisoners or Institutional Individuals
- ☐ Specific Ethnic/Racial Group(s)
- ☐ Other potentially elevated risk populations
- ☐ Participant(s) related to the researcher

*Note: Only check the boxes if the participants will be the focus (for example, ONLY military or ONLY students). If they just happen to be a part of the broad group you are studying, you only need to check “Normal Participants.”*

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VI. RECRUITMENT OF PARTICIPANTS

13. CONTACTING PARTICIPANTS (?)
Describe in detail how you will contact participants regarding this study: After receiving IRB approval, participants will be recruited through advertising via posters, splash page, convocation slides, Student Counseling Services’ social media (Facebook and Twitter), and word of mouth with Student Counseling Services. We will request that candidates read the
informed consent and contact the researcher at Student Counseling Services (Mike Trexler) if interested in participating in the group. Mike Trexler will contact the potential participant to review the consent forms and to obtain the signed consent forms from each candidate. Each candidate will be screened by Mike Trexler to determine if he/she meets inclusion criteria. The screening follows the normal procedure of students who receive counseling services at Student Counseling Services. If the candidate meets inclusion criteria he/she will be added to the group until 6-10 group members are obtained. Students who do not meet inclusion criteria will be offered individual services at Student Counseling Services.

*Note:* Please submit all letters, emails, flyers, advertisements, or social media posts you plan to use to recruit participants for your study. If you will contact participants verbally, please provide a script that outlines what you plan to say to potential participants. Submit these items as separate Word documents to irb@liberty.edu.

### 14. LOCATION OF RECRUITMENT (?)

**Describe the location, setting, and timing of recruitment:** Student Counseling Services, Green Hall 1830, Group Room. Recruitment will begin in March and continue until 6-10 individuals are ascertained.

### 15. SCREENING PROCEDURES (?)

**Describe any screening procedures you will use when recruiting your participants (i.e., screening survey, database query, etc.):** Selected candidates will be scheduled to complete the customary triage assessment with Student Counseling Services. This process consists of completing informed consent, L24, L30, and a semi-structured interview. Participants will also complete the DSM-5 Anxiety Survey during the triage assessment. Selected participants will complete a battery of assessments currently implemented for each student receiving services at Student Counseling Services. These assessments include Mental Health Survey (brief), Current Experiences Survey (brief), Satisfactiion with Life Survey, Theistic Spiritual Outcomes Survey, DSM-5 Self-Rated Cross-Cutting Symptom Measures, Personality Inventory for DSM-5, and Rosenberg Self-Esteem Scale. Participants who endorse mild to severe on the DSM-5 measure will also complete such assessments as Depression Survey, Anxiety Survey, Anger Survey, Mania Survey, and Repetitive Thoughts and Behavior Survey. Participants who endorse symptoms on the Current Experiences Survey will also complete Cyber-Pornography Use Inventory (CPU9-9) and Eating Attitudes Test (EAT-26). Candidates who experience mild to moderate anxiety and who do not have depression, mania, or substance use disorders will be invited to participate. These assessments will not be used for the research project, however they are required for all students treated at Student Counseling Services.

Only respondents who are willing to participate and meet the study criteria of experiencing mild to moderate anxiety will be eligible to participate in the counseling group.

### 16. RELATIONSHIPS (?)

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Rev 1/2017
Does the researcher have a position of grading or professional authority over the participants (e.g., is the researcher the participants’ teacher or principal)?

- No (Proceed to Procedures)
- Yes (Explain what safeguards are in place to reduce the likelihood of compromising the integrity of the research, e.g., addressing the conflicts in the consent process and/or emphasizing the pre-existing relationship will not be impacted by participation in the research):

VII. RESEARCH PROCEDURES

17. PROCEDURES (?)

Write an original, non-technical, step by step, description of what your participants will be asked to do during your study and data collection process. If you have multiple participant groups, (ex: parents, teachers, and students) please specify which group you are asking to complete which task(s). You do not need to list signing/reading consent as a step.

<table>
<thead>
<tr>
<th>Step/Task/Procedure</th>
<th>Time (Approx.)</th>
<th>Participant Group(s) (All, Group A, Group B, etc.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Student Counseling Services Triage Assessment</td>
<td>60</td>
<td>All</td>
</tr>
<tr>
<td>2. Student Counseling Services Battery of Assessments</td>
<td>30</td>
<td>All</td>
</tr>
<tr>
<td>3. Counseling Group (including DSM V Level II Anxiety Survey: pre-group) at Student Counseling Services (See document entitled Research Step by Step process)</td>
<td>Six 90 min. Sessions</td>
<td>All</td>
</tr>
<tr>
<td>4. DSM V Level II Anxiety Survey: post group and individual debriefing interview (see interview questions)</td>
<td>60</td>
<td>All</td>
</tr>
</tbody>
</table>

Note: Please submit all instruments, surveys, interview questions or outlines, observation checklists, etc. that you plan to use for your study. Submit these items as separate Word documents to irb@liberty.edu.

18. STUDY LOCATION (?)

Please describe the location(s) in which the study will be conducted. Be specific (include city, state, school/district, clinic, etc.): Student Counseling Services, Green Hall 1830, Group Room

VIII. DATA ANALYSIS

19. NUMBER OF PARTICIPANTS/DATA SETS (?)

Estimate the number of participants to be enrolled or data sets to be collected: 6-10
20. ANALYSIS METHODS

Describe how the data will be analyzed and what will be done with the data and the resulting analysis, including any plans for future publication or presentation:

After the debriefing interviews have been transcribed by the researchers, participants will be emailed a copy of the transcript and will have the opportunity to review and approve for accuracy. Data will then be analyzed in accordance with the procedures described below. When the researchers have finished analyzing the data and have written the results, they will send an e-mail each participant to thank them for participating in the study and to provide them a summary of the findings and, as a member checking procedure standard in qualitative studies (Creswell, 2013), invite them to confirm or clarify description and interpretation of findings.

Exit survey and debriefing interview data will be qualitatively analyzed to examine participant's experience of the group. Moustakas’ (1994) phenomenological approach will be employed for data analysis. After we first set aside (i.e., “bracket”) our own experiences with the phenomenon, we will reduce data into significant statements, recording them in an excel spread sheet, in order to describe the general experience of the participants. These statements will then be grouped thematically. We will then organize themes into a coherent textual description focusing on what participants experienced. Our next step will be to develop structural descriptions focusing on the contexts that influenced participants' experiences. We will seek to answer the question, “How did participation in the Creative Exposure Group impact group members? The textual and structural descriptions will then be synthesized in order to develop a description of the participants experience in the group.

IX. PARENTAL/GUARDIAN CONSENT

21. PARENTAL/GUARDIAN CONSENT REQUIREMENTS

Does your study require parental/guardian consent? (If your participants are under 18, parental/guardian consent is required in most cases.)
- [x] No (Proceed to Child Assent)
- [ ] Yes (Answer the following question)

Does your study entail greater than minimal risk without the potential for benefits to the participant?
- [x] No
- [ ] Yes (Consent of both parents is required)

X. ASSENT FROM CHILDREN

22. CHILD ASSENT

Is assent required for your study? (Assent is required unless the child is not capable due to age, psychological state, or sedation OR the research holds out the prospect of a direct benefit that is only available within the context of the research.)
- [x] No (Proceed to Consent Procedures)
- [ ] Yes
XI. PROCESS OF OBTAINING INFORMED CONSENT

23. CONSENT PROCEDURES (?)

Describe in detail how and when you will provide consent information (If applicable, include how you will obtain consent from participants and/or parents/guardians and/or child assent.): Participants will be given an informed consent for participating in the Creative Counseling Group and the research study. Detailed description of the study on the informed consent will be followed by the statement "I have read and understand the description of the study and contents of this document. I have had an opportunity to ask questions and have all my questions answered. I hereby acknowledge the above and give my voluntary consent for participation in this study. I understand that I must be 18 years or older to sign this informed consent and participate in this study. I understand that should I have any questions about this research and its conduct, I should contact one of the researchers listed above. If I have any questions about rights or this form, I should call the current IRB chair for Liberty University, Liberty University, IRB Review, 1971 University Blvd., Carter 134, Lynchburg, VA 24502. By clicking yes I agree to participate in this study".

XII. USE OF DECEPTION

24. DECEPTION (?)

Are there any aspects of the study kept secret from the participants (e.g., the full purpose of the study)?
☒ No
☐ Yes (describe the deception involved and the debriefing procedures):

Is deception used in the study procedures?
☒ No
☐ Yes (describe the deception involved and the debriefing procedures):

Note: Submit a post-experiment debriefing statement and consent form offering participants the option of having their data destroyed. A debriefing template is available on our website.

XIII. WAIVER OR MODIFICATION FOR REQUIRED ELEMENTS IN THE INFORMED CONSENT PROCESS

25. WAIVER OF INFORMED CONSENT ELEMENTS (?) ☒ N/A

Does the research pose no more than minimal risk to participants (i.e., no more risk than that of everyday activities)?
☐ No, the study is greater than minimal risk.
☒ Yes, the study is minimal risk.

Will the waiver have no adverse effects on participant rights and welfare?
☐ No, the waiver will have adverse effects on participant rights and welfare.
☒ Yes, the waiver will not adversely affect participant rights and welfare.

Would the research be impracticable without the waiver?
☐ No, there are other ways of performing the research without the waiver.
☒ Yes, not having a waiver would make the study unrealistic. (Explain):
Will participant debriefing occur (i.e., will the true purpose and/or deceptive procedures used in the study be reported to participants at a later date)?

- No, participants will not be debriefed.
- Yes, participants will be debriefed.

*Note: A waiver or modification of some or all of the required elements of informed consent is sometimes used in research involving deception, archival data, or minimal risk procedures.*

### XIV. WAIVER OF SIGNED INFORMED CONSENT DOCUMENT

#### 26. WAIVER OF SIGNED CONSENT (?)

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Would a signed consent form be the only record linking the participant to the research?</td>
<td>☐ No, there are other records/study questions linking the participants to the study.</td>
</tr>
<tr>
<td></td>
<td>☑ Yes, only the signed form would link the participant to the study.</td>
</tr>
<tr>
<td>Does a breach of confidentiality constitute the principal risk to participants?</td>
<td>☐ No, there are other risks involved greater than a breach of confidentiality.</td>
</tr>
<tr>
<td></td>
<td>☑ Yes, the main risk is a breach of confidentiality.</td>
</tr>
<tr>
<td>Does the research pose no more than minimal risk to participants (i.e., no more risk than that of everyday activities)?</td>
<td>☐ No, the study is greater than minimal risk.</td>
</tr>
<tr>
<td></td>
<td>☑ Yes, the study is minimal risk.</td>
</tr>
<tr>
<td>Does the research include any activities that would require signed consent in a non-research context (e.g., liability waivers)?</td>
<td>☐ No, there are not any study related activities that would normally require signed consent</td>
</tr>
<tr>
<td></td>
<td>☑ Yes, there are study related activities that would normally require signed consent</td>
</tr>
<tr>
<td>Will you provide the participants with a written statement about the research (i.e., an information sheet that contains all of the elements of an informed consent form but without the signature lines)?</td>
<td>☐ No, participants will not receive written information about the research.</td>
</tr>
<tr>
<td></td>
<td>☑ Yes, participants will receive written information about the research.</td>
</tr>
</tbody>
</table>

*Note: A waiver of signed consent is sometimes used in anonymous surveys or research involving secondary data. This does not eliminate the need for a consent document, but it eliminates the need to obtain participant signatures.*

### XV. CHECKLIST OF INFORMED CONSENT/ASSENT

#### 27. STATEMENT (?)

Submit a copy of all informed consent/assent documents as separate Word documents with your application. [Informed consent/assent templates](#) are available on our website. Additional information regarding consent is also available on our website.

### XVI. PARTICIPANT PRIVACY AND CONFIDENTIALITY

#### 28. PRIVACY (?)

Describe what steps you will take to protect the privacy of your participants (e.g., If you plan to interview participants, will you conduct your interviews in a setting where others cannot easily overhear?): All assessment and group sessions will be conducted in a confidential space within Student Counseling Services.

*Note: Privacy refers to persons and their interest in controlling access to their information.*
29. CONFIDENTIALITY (?)

**How will you keep your data secure (i.e., password-locked computer, locked desk, locked filing cabinet, etc.)?:** Assessments done by Student Counseling Services to determine appropriateness for the group will not be used in the study. However, all documentation collected at SCS is stored on a secure server within SCS and is firewall protected by Liberty University. The DSM V Level II pre and post group surveys, the debriefing interview survey, and the transcript of the debriefing interview will be stored with all identifying information removed in a locked filing case in Dr. Sosin's office (DSM V Level II and debriefing surveys) or on her password protected computer (transcriptions of debriefing interview) for up to three years. The audio tapes will be destroyed after the recorded debriefing interviews are transcribed. At the start of the project, participants will be given numbers that correspond with each piece of data to protect their identity. Additionally, information may be shared among researchers via the web on a university secure site (i.e. https) or private Dropbox account, however, information will not be shared until participants have been given numbers to replace their names.

**Who will have access to the data (i.e., the researcher and faculty advisor, only the researcher, etc.)?:** All four researchers will have access to the data.

**Will you destroy the data once the three-year retention period required by federal regulations expires?**

- [x] Yes (Explain how the data will be destroyed): deleted files and emptied trash, or shredding of paper files

*Note: All research-related data must be stored for a minimum of three years after the end date of the study, as required by federal regulations.*

30. ARCHIVAL DATA (?)

**Is all or part of the data archival (i.e., previously collected for another purpose)?**

- [x] No (Proceed to Non-Archival Data)
- [ ] Yes (Answer the questions below)

**Is the archival data publicly accessible?**

- [ ] No (Explain how you will obtain access to this data): 
- [x] Yes (Indicate where the data is accessible from, i.e., a website, etc.):

**Will you receive the data stripped of identifying information (e.g., names, addresses, phone numbers, email addresses, social security numbers, medical records, birth dates, etc.)?:**

- [x] No (Describe what data will remain identifiable and why this information will not be removed): As each piece of data comes to Dr. Sosin (first the pre and post group DSM V Level II surveys, next the debriefing survey, and finally the audio recording of the debriefing interview and subsequent transcripts), she will replace the names of participants with numbers. Nothing will remain stored without the identifying information removed. No data analysis will occur without all identifiable information removed. No record will be kept with any identifiable information retained.

- [ ] Yes (Describe who will link and/or strip the data—this person should have regular access to the data and should be a neutral party not involved in the study):
Can the names or identities of the participants be deduced from the data set?

- □ No (Place your initials in the box: I will not attempt to deduce the identity of the participants in this study):
- □ Yes (Describe):

<table>
<thead>
<tr>
<th>Please provide the list of data fields you intend to use for your analysis and/or provide the original instruments used in the study:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. DSM Level II Survey</td>
</tr>
<tr>
<td>2. Post Group Debriefing Survey</td>
</tr>
<tr>
<td>3. Post Group Debriefing Interview Recording, which will be destroyed after the transcript is ascertained.</td>
</tr>
<tr>
<td>Copies of these documents are included with this application.</td>
</tr>
<tr>
<td>Note: If the archival data is not publicly available, submit proof of permission to access the data (i.e., school district letter or email). If you will receive data stripped of identifiers, this should be stated in the proof of permission.</td>
</tr>
</tbody>
</table>

31. NON-ARCHIVAL DATA (?)

If you are using non-archival data, will the data be anonymous (i.e., data does not contain identifying information and cannot be linked to identifying information by use of pseudonyms, codes, or other means—for studies involving audio/video recording or photography, select “No”)?

- □ N/A: I will not use non-archival data (data was previously collected, skip to Media)
- □ No (Complete the “No” section below)
- □ Yes (Complete the “Yes” section below)

**COMPLETE THIS SECTION IF YOU ANSWERED “NO”**

Can participant names or identities be deduced from the data?

- □ No
- □ Yes (Describe):

Will a person be able to identify a subject based on other information in the data (i.e., title, position, sex, etc.)?

- □ No
- □ Yes (Describe):

Describe the process you will use to collect the data and to ensure the confidentiality of the participants (i.e., you may know who participated, but participant identities will not be disclosed or pseudonyms will be used):

Each participant will be assigned a number by the researchers. All of their data, recorded and written, will be identified and organized using the number rather than name. No real names will be used in the reporting of the data for scholarly purposes. Only researchers will have access to the data and this data will already have all identifying information removed.
**Note:** If you plan to maintain a list or codebook linking pseudonyms or codes to participant identities, include this information and state that the list or codebook will be stored securely in a location that is separate from the data. Include this location along with who will have access to the data in your description.

**COMPLETE THIS SECTION IF YOU ANSWERED “YES”**

Describe the process you will use to collect the data to ensure that it is anonymous:

Place your initials in the box: I will not attempt to deduce the identity of the participants in this study:

**Note:** If you plan to use participant data (i.e., photos, recordings, videos, drawings) for presentations beyond data analysis for the research study (e.g., classroom presentations, library archive, or conference presentations) you will need to provide a materials release form to the participant.

**32. MEDIA USE (?)**

<table>
<thead>
<tr>
<th>Question</th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will your participants be audio recorded?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Will your participants be video recorded?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Will your participants be photographed?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If you answered “YES” to any of the above questions, include information regarding how participant data will be withdrawn if he or she chooses to leave the study*: The debriefing focus group will be audio recorded and transcribed verbatim. Once the transcript is ascertained the audio recording will be destroyed.

Will your participants be audio recorded, video recorded, or photographed without their knowledge??

*Note on Withdrawal: Add the heading “How to Withdraw from the Study” on the consent document and include a description of the procedures a participant must perform to be withdrawn.

**Note on Deception:** Attach a post-experiment debriefing statement and a post-deception consent form, offering the participants the option of having their recording/photograph destroyed and removed from the study.

**XVII. PARTICIPANT COMPENSATION**

**33. COMPENSATION (?)**

<table>
<thead>
<tr>
<th>Question</th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will participants be compensated (e.g., gift cards, raffle entry, reimbursement)?</td>
<td></td>
<td></td>
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</table>

Will compensation be pro-rated if the participant does not complete all aspects of the study?

*Proceed to Risks*
Note: Research compensation exceeding $600 per participant within a one-year period is considered income and will need to be filed on the participant’s income tax returns. If your study is grant funded, Liberty University’s Business Office policies might affect how you compensate participants. Contact the IRB for information on who to contact for guidance on this matter.

XVIII. PARTICIPANT RISKS AND BENEFITS

34. RISKS

Describe the risks to participants and any steps that will be taken to minimize those risks. (Risks can be physical, psychological, economic, social, or legal. If the only potential risk is a breach in confidentiality if the data is lost or stolen, state that here): Participants may experience emotional/psychological distress during group sessions. Ongoing assessment will be conducted through the study to minimize risks. In cases of significant psychological distress, participants will be exited from the group and enter into individual counseling services and/or more intense services at Student Counseling Services, where the Creative Counseling for Anxiety Group will take place. For medical or mental health emergencies, LUPD will be contacted.

Will alternative procedures or treatments that might be advantageous to the participants be made available?

☐ No
☒ Yes (Describe): In cases of significant emotional/psychological distress, participants will be exited from the group and enter into individual counseling services and/or more intense services. For medical or mental health emergencies, LUPD will be contacted.

If your study is greater than minimal risk, describe provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the participants (e.g., proximity of the research location to medical facilities, or your ability to provide counseling referrals in the event of emotional distress): In cases of significant emotional/psychological distress, participants will be exited from the group and enter into individual counseling services and/or more intense services. For medical or mental health emergencies, LUPD will be contacted.

35. BENEFITS

Describe the possible direct benefits to the participants. (If participants are not expected to receive direct benefits, please state “No direct benefits.” Completing a survey or participating in an interview will not typically result in direct benefits to the participant.): The potential benefit to the participants includes increased self-awareness and decreased anxiety. These outcomes can support them both personally and academically.

Describe the possible benefits to society: The potential presentation and publication of the findings of this study may prove beneficial to others suffering with anxiety and those who clinically treat them.

Evaluate the risk-benefit ratio. (Explain why you believe this study is worth doing, even with any identified risks.): The risks of this study are minimal; however, the results have potential benefits to students, future counseling clients, clinicians who treat them, and counselor educators. Studies indicate that individuals in this age group experience moderate levels of anxiety on a daily basis (Beiter et al., 2015; Gallagher, 2008). The proposed study seeks to
address this mental health need among college students and to measure its effect.