Personnel - Review

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Department Sponsored Research

Principal Investigator	Start Date	End Date	Role
☑	04-Jan-2024		PI

WCU Status:
Staff

UNAFFILIATED PERSONNEL

Use this section to add research personnel who are not affiliated with WCU. Additionally, if a research team member is unaffiliated with WCU and their institution does not have an IRB, please fill out and include the Individual Investigator Agreement. This form may be found here.

PROJECT SUMMARY

Protocol Number
2024-01-04-02

Submission Number
2024-01-04-02-01

*1. Project Title:
Journeying through anxiety with journaling.

*Principal Investigator
Ball, Mallory

*Submission Type
IRB Request for Initial Review of Research

Protocol Type

2. Funding Source, if applicable. For internal grants and/or awards please select, Western Carolina University.

*3. Project Description: provide a concise (3-5 sentences) summary of the purpose and rationale of the activity using lay language.
The purpose of this project is to assess the effect of journaling on middle school student anxiety. Students will be completing questionnaires before and after journaling. This will be done 2-3 times a week.

*4. Does data collection involve the use of a survey?
☑ Yes ☐ No

*a. Is the intended population any member of the WCU Community?
☐ Yes ☑ No

*5. Does your research **only** involve using an existing data set where no recruitment is necessary?
☐ Yes ☑ No

*6. Is your study an Applicable Clinical Trial?
☐ Yes ☑ No

*7. Intended use(s) of data collected: *check all that apply*
☑ Thesis or Dissertation
☑ Grant Proposal
☐ Classroom Project
☑ Publication
☐ Off-Campus Presentation
☐ Other

*8. Will you be accessing health medical records, psychotherapy notes and/or substance abuse records?
☐ Yes ☑ No

CONFLICT OF INTEREST/DUAL RELATIONSHIPS

*1. Are there any known or potential conflicts of interests (financial or other personal considerations that may compromise or potentially appear to compromise an investigator's objectivity, see University Policy 54) between the researchers and the participants or other entities related to this research?
☐ Yes ☑ No

*2. Do any of the research team members have an authority relationship (ex. Instructor/student, supervisor/employee, physician/patient, or other) with the potential participants?
☑ Yes ☐ No

PARTICIPANT POPULATION AND RECRUITMENT

1. Enrollment Information

*a. Expected maximum number of participants:
20

*b. What are the inclusion criteria for the study? (What characteristics of the study population make them eligible to participate?):
8th graders at Swain County middle school

*c. What are the exclusion criteria for participation in the study? (For example, age or physical restrictions. “Not meeting inclusion criteria” is insufficient.):
middle schoolers not in 8th grade and not at Swain County middle school

d. Does the study include any of the following vulnerable populations, either as the target population or incidentally? If the following populations will be excluded from your study, please select "Excluded". Please note, pregnant women may be incidental to a research project if a control does not exist to check for this vulnerability.
Vulnerable Populations:

Minors	Target
Prisoners	Excluded
Pregnant Women	Incidental
Non-English Speaking	Excluded
Mentally or Decisionally Impaired	Excluded
Educationally or Economically Disadvantaged	Incidental
WCU Students/Employees	Excluded
Native Americans	Incidental

e. Describe your plans to provide additional protections for any targeted vulnerable populations (ex. for minors, parental permission and child assent will be obtained prior to participation):
Parental permission will be obtained prior to approaching students for participation. Students will be informed that participation is voluntary and students will be given an alternative option if they do not with to participate in the study.

2. Recruitment Procedures
Please submit recruitment materials. (e.g. flyers, emails, scripts). If you are recruiting in person or via phone call, please include the script to be used during recruitment.

*a. Select all methods that will be used to recruit individuals.

*Method	Other
Name of Document	Letter Home to Parents
File Upload	

*b. Explain the details of the recruitment process (when will recruitment occur, where will recruitment take place, how will recruitment material be distributed, etc):
Students will be approached during break time for their participation with a verbal script and minor assent form.

*c. Does this research study include any compensation, course extra credit, monetary inducements, or reimbursement for participation?
☐ Yes ☑ No

INFORMED CONSENT/ASSENT

INFORM

Consent is obtained from adult individuals participating in a study.

Assent is given by minors agreeing to participate in the study. Additionally, parents must give consent allowing their children to participate in research.

Consent and assent templates may be found here

*1. Explain how informed consent and assent (if applicable) will be obtained. Include information about: the setting, whether participants will have an opportunity to ask questions, and the roles of any non-research personnel involved:
Parental consent forms will be sent home to parents and returned with signatures. Once signed parental consent forms are obtained, students will be approached for their participation with a verbal script and minor assent form.

*2. Are you requesting a waiver or modification to the required elements for informed consent for participants, or legally authorized representatives? Please note, obtaining verbal or implied consent requires you to request a waiver of consent.
☐ Yes ☑ No

*Please upload a copy of your informed consent/informed assent materials with your protocol.

File Upload	

*3. Will any procedures involve the use of deception? Research utilizing deception must qualify for a waiver of consent. Please ensure you checked 'Yes' to Question 2, above. Participants must be debriefed about the deception after participation. Please review the Guidance on the Use of Deception in Research Projects.

☐ Yes ☑ No

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3. Documentation of consent

a. Please select all that apply all that apply

☑ Signed consent will be obtained from participants, legally authorized representatives, and/or parents

☐ Electronic consent will be obtained from participants via the web or email

☐ Verbal / implied consent will be obtained using an information sheet or script

☐ Other

STUDY PROCEDURES

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1. Projected recruitment, data collection, and data analysis dates:
From: date of IRB approval

*To:

31-Dec-2026

*2. List and describe the data that will be collected from participants. Upload a copy of each data collection instrument. If you are using an existing data set, please describe the data points already collected; you are not required to upload the existing data set.

Describe type of Data	
Name of Data Collection Instrument	Journal prompts
File Upload	

Describe type of Data	
Name of Data Collection Instrument	SCARED questionnaire
File Upload	

*3. Provide a sequential description of the activities in which participants will engage, including length of participation (if there are multiple sessions include frequency and length of each session), nature of intervention (if applicable), and indicate the timepoints of each data collection type listed above. If you are using an existing data set, please explain how you will be using the data in your research.
Students will be completing questionnaires before and after journaling. This will be done 2-3 times a week for 6 weeks. Questionnaires should take about 20 minutes and participants will be given 1 hour to journal each time. The journaling will be the intervention and the (SCARED) pre and post questionnaires will assess the impact of journaling on levels of anxiety of the participants. The parent portion of the questionnaire will be completed by parents at the beginning and end of the intervention period (sent home with child for parent to complete), while the child portion of the questionnaire will be completed each time before and after journaling for the participants.

RISK AND BENEFITS SECTION

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1. Provide a description of the anticipated benefits from this study
The benefits listed in this section should also be included in the Benefits section of the informed consent.

☐ Participants of the study may directly benefit. Please note, compensation for participation is not considered to be a benefit.

☑ Society may benefit from the study:

Explain
Society may benefit as this intervention could be identified as a successful method of assessment and improvement of anxiety in middle schoolers. This provides a benefit to teaching methods, mental wellness of middle schoolers, and additional support for this type of intervention in the scientific/psychological community.

2. Give a full description of potential risks to study participants.

The risks listed in this section should also be included in the Risk section of the informed consent. Please also consider whether the disclosure of participants' responses outside the research team would place the subject at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, educational advancement or reputation.

Minimal risk: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

a. Indicate the appropriate level of risk for each category below.

Social	*	No foreseeable risk
Economic	*	No foreseeable risk
Physical	*	No foreseeable risk

*b. Explain the nature of the risk, its likelihood of occurring, and its potential impact on participants:
There is a risk that the questions about mental state may be triggering for participants.

*c. Explain what steps have been taken to minimize these risks, including trained personnel, emergency contacts and appropriate facilities:
Mental health resources will be included in the consent and survey documents. The recruitment script will clearly state that questions may ask about anxiety and may potentially trigger emotions.

PROTECTION OF PARTICIPANT PRIVACY AND CONFIDENTIALITY

1. Confidentiality and Anonymity

a. Will the data from your study be:

☐ Confidential (The researcher can directly or indirectly match the data to the participant but participant identity is not disclosed.)

☑ Anonymous (Not even the researcher can match the data to the participant.)

☐ Neither (The researcher can match the data to the participant and participant identity will be disclosed.)

d. Describe any potential ethical or legal circumstances when it would be necessary to break confidentiality? For example, there are federal and state mandatory reporting laws for child and elder abuse.
Any circumstances described here must also be included on the consent form.

*e. Do the data to be collected relate to illegal activities?
☐ Yes ☑ No

2. Data Protection and Safeguards

*a. How will data be monitored to ensure the safety of subjects (For example, use of a Data and Safety Monitoring Board, having a data monitoring plan, or designating individuals on the research team to monitor the data for integrity and validity)?
The students will receive journals that include an assigned participant number that is randomized and not connected to any identifying information. They will use this number to include on their pre and posttest surveys.

b. Describe measures you are taking to store and safeguard study data. Please list the full physical address where data will be maintained, if applicable. For example, if data is being stored on campus please give sufficient detail as to where: WCU Camp Building Office 110J. Alternatively, if data is being stored off campus please provide the street address with sufficient detail.

☑ Data not linked to identifying information

☑ Maintain consent forms in a separate location from data.

List location:
Consent documents will be kept in the PI's office

☐ Using subject codes on all data collected and maintaining the key linking subject codes with identifiable information in a separate location from data.

☐ Locking cabinets/doors

☐ Data kept in area with limited public access

☐ Password protected computers

☐ Encryption

☐ iPads, tablets, digital storage devices and removable media will be kept in a secure location

☐ Other

*c. Do you plan to keep the data for more than three years?
Study records must be stored by the PI for a minimum of three years after a study has been closed such that they are accessible for inspection by the IRB, federal, and state agencies.
☐ Yes ☑ No

d. Data Sharing:

*Will identifiable data be shared outside of the research team?
No, only anonymous or de-identified data will be shared

Use this section to upload any additional documents. Please name the document accordingly.

*I certify that, to the best of my knowledge, the information provided on this form is true and accurate. By submitting this request, the Principal Investigator accepts responsibility for ensuring that all members of the research team follow the study procedures as described in the IRB approved application, comply with all IRB communication, and uphold the rights and welfare of all study participants. ☑

EXTERNAL SITES

*Are you recruiting participants, collecting data or obtaining records at any off-campus location?
☑ Yes ☐ No

*Sites may include K-12 schools, churches, business, public agencies, universities etc. List each site and briefly describe site involvement. **A dated permission letter on agency letterhead must be uploaded for each site. If the external site is requesting WCU IRB approval prior to providing permission, the PI must include dated correspondence showing the external site is aware of the research and will approve of it, once IRB approval is received.**

External Site Name	Swain Middle School
List activities conducted at site (recruitment, data collection, record source)	
Permission Letter	

FOR RESEARCH INVOLVING QUALTRICS SURVEYS

I understand that approval of the use of WCU's online survey software (Qualtrics) is limited to the survey(s) specifically described in this IRB proposal. Any further use of Qualtrics for research purposes will require me to submit and receive approval for an amendment to this proposal or a new IRB proposal before I can proceed. Use of Qualtrics is governed by WCU Policies on Conducting Surveys (Policy 51) and Ethics in Research (Policy 56), and to IRB policies. This checkbox indicates adherence to these policies.
☐

CERTIFICATION

****By submitting this request, the Principal Investigator accepts responsibility for ensuring that all members of the research team follow the study procedures as described in the IRB approved application, comply with all IRB communication, and uphold the rights and welfare of all study participants.***
☑

When your application is complete, click 'Lock Form' in the top right corner. Then click the 'Submit' button to submit your application to the Research Compliance office.