George Mason University
IRB Application

Project Title: [1974781-1]: Mental Health Help-Seeking Preferences in College Students [Request for Reliance Agreement]

PI: Natasha Tonge, PhD

Last edited by: Gracie Kelly

Last edited on: November 9, 2022

- [x] **Initial IRB Application**
- [ ] **Amendment/Modification**
- [ ] **Continuing Review/Closure**

1. Continuing Review Status Report / Closure N/A [x]

Summary of Research Progress:

Please provide a brief summary of the research progress (Include interim findings and any additional information that may affect how the study is conducted or risks to participants).

Have you completed data collection?	[ ] Yes	[ ] No
Have you completed data analysis?	[ ] Yes	[ ] No
Changes to Protocol/Informed Consent since last IRB Approval?	[ ] Yes	[ ] No
Has sponsor/funding source changed since the last review?	[ ] Yes	[ ] No

Subjects Enrolled Since Last Approval:

Total Number of Subjects Enrolled:

Risk/Benefit Change: [ ] Yes [ ] No

If yes, **Risk/Benefit Change Explanation:**

Have any adverse events occurred during the course of this study? [ ] Yes [ ] No

If yes, **Adverse Events Explanation:**

Have any unanticipated problems involving risks to subjects occurred? [ ] Yes [ ] No

If yes, **Unanticipated Problems Explanation:**

Have any subjects withdrawn from the research study? [ ] Yes [ ] No

If yes, **Withdrawn Subjects Explanation:**

Have you received any complaints about the research study? [ ] Yes [ ] No

If yes, **Research Complaints Explanation:**

2. Amendment Information N/A [x]

Complete this section for each type of amendment/modification.

Type of Amendment/Modification:

Description/Rationale for Change:

Changes marked with asterisks/italics when possible.

If a change in consent is being requested,

Re-Consent required based on proposed changes? ☐ N/A ☐ Yes ☐ No

If re-consent is not required, **Justification:**

If a change in investigators is being requested,

Type: **Name:**

If a change in enrollment is being requested,

Type: **By what amount?**

If a change in funding is being requested,

Type: ☐ Addition ☐ Deletion ☐ New OSP Proposal #

3. Principal Investigator Information

Name: Natasha Tonge, PhD **Department:** Psychology

Phone: 347-220-9758 **E-mail:** ntonge@gmu.edu

4. Co-Investigator/Student Researcher Information N/A ☐

Name: Gracie Kelly **Department:** Psychology

Phone: 601-955-3578 **E-mail:** akelly32@gmail.com

5. Additional Team Member Information N/A ☑

Complete this section for each "Team Member."

Name: **Department:**

Role: **E-mail:**

Role Experience:

Involved in the Consent Process? ☐ Yes ☐ No

6. Conflict of Interest Information N/A ☑

Complete this section for each "Conflict of Interest."

Name:

Is this a financial conflict of interest? ☐ Yes ☐ No

Explanation:

Management Plan for this Individual Reviewed by COI Committee? ☐ Yes ☐ No

7. Study Information

Type: Faculty/Staff Research

Type(s) of Data: ☐ Existing or Secondary Data Analysis ☑ Prospective

Requesting Reliance Agreement? ☐ Yes ☑ No

Research involves living individuals? ☑ Yes ☐ No

Research involves either obtaining data through intervention/ interaction with individual (including online surveys) or identifiable private information? ☑ Yes ☐ No

Does your project have a systematic design in advance, such as a scientific approach or protocol, for the definite purpose of contributing to generalizable knowledge? ☐ N/A ☑ Yes ☐ No

Not HSR Description:

If research is not HSR but you plan to submit a package to obtain an official letter, provide a brief summary of the research research including a description of the purpose of the research and the procedures involved.

8. Funding Information N/A ☑

Complete this section for each "Funding Source."

Type: *If external,* **OSP Proposal #:**

Agency:

☐ DHHS/NIH ☐ DOD ☐ DOJ

☐ NSF ☐ Dept. of Education ☐ Other:

9. MRI Information N/A ☑

Please describe in detail the use of MRI in your study:

I confirm that I will follow all of the MRI procedures outlined in this section of the application. ☐ Yes ☐ No

If no, **describe how MRI procedure will differ from the outlined MRI procedures above:**

10. Community Partner Information N/A ☑

Research Design:

Complete this section for each "Community Partner."

Organization Name: **Zip Code or Country:**

Which of these statements best describe the role of the community partner in the study?

- ☐ Community partners only provide access to study subjects or project sites. They are not involved with study design, subject recruitment, data collection, or data analysis.
- ☐ Community partners do not make decisions about the study design or conduct, but provide guidance to the research about the study design, subject recruitment, data collection, or data analysis.
- ☐ Community partners make decisions with the researcher(s) about the study's research activities and/or help conduct those studies (i.e., study design, subject recruitment, data collection, and/or data analysis).

11. Data Information

Identifiable Data/Protected Health Information (PHI):

Indicate all PHI/Identifiable Data either collected as part of study data or reviewed as part of existing data.

- ☑ Name
- ☐ Elements of dates including birth date, admission date, date of death, and all ages 89 years of age or older
- ☐ Fax numbers
- ☐ Social Security number
- ☐ Health plan beneficiary numbers
- ☐ Certificate or license numbers
- ☐ Device identifiers and serial numbers
- ☐ Internet Protocol (IP) address numbers
- ☐ Full face photographic images and comparable images
- ☐ None of the above will be collected
- ☐ Geographic information smaller than state
- ☐ Telephone numbers
- ☑ Electronic mail address
- ☐ Medical record numbers
- ☐ Account numbers
- ☐ Vehicle identifiers and serial numbers including license plate numbers
- ☐ Web Universal Resource Locators (URLs)
- ☐ Biometric identifiers, including finger and voice prints
- ☐ Any other unique identifying number, characteristic, or code

If Other, **Description:**

Personally Identifiable Data: ☑ Yes ☐ No

Protected Health Information: ☐ Yes ☑ No

Who has access to PHI?

PHI Shared Outside Research Team: ☐ Yes ☐ No

If yes, **Explanation:**

12. Existing Data/Documents/Specimens Information N/A ☑

Do all the data/specimens exist at the time of this application? ☐ Yes ☐ No

If no, **Existing Data Explanation:**

Specific Aims and Purpose:

Describe the aims and purpose of the study including which variables will be extracted from the data:

Data/Specimens Description:

Include information about the source of original data/specimens.

Are the data/specimens publicly available? ☐ Yes ☐ No

Will you be obtaining the data by accessing an Electronic Health Record (EHR) or other medical record? ☐ Yes ☐ No

If yes, **Record Access Description:**

Will the data you receive be coded by the data owner? ☐ Yes ☐ No

If yes, **Describe the key and whether you will have access to the key:**

Is indirect identification of the data possible? ☐ Yes ☐ No

Demographic Data:

Describe any demographic data in the data set:

Demographic Data Justification for Identifiers:

If the data set contains identifiers, please provide a justification as to why a de-identified data set could not be used instead.

Original Subject Population:

Describe the original subject population (age, gender, etc.) if possible:

13. Privacy and Confidentiality of Existing Data N/A ☑

Confidentiality of Identifiable Existing Data

Describe how confidentiality of identifiable existing data will be maintained (if applicable):

Data Originally Consented

Did the consent form for the original prospective study allow for use of data by other researchers at a later date?

☐ Yes ☐ No ☐ Unknown ☐ N/A

Plan to obtain consent for use of existing data? ☐ Yes ☐ No

Consent Process:

If you plan to obtain consent, describe the consent process. Otherwise, please explain why obtaining retroactive consent is not possible.

Will there be a Data Use Agreement in place? ☐ Yes ☐ No

14. Study Information and Location *(Prospective Data Studies Only)* N/A ☐

Will the research be conducted outside of the United States? ☐ Yes ☑ No

Research Locations:

The study will be available as an online survey. George Mason University is the only study site.

Have other IRB or site approvals been sought or will they be sought prior to study initiation? ☐ Yes ☑ No

If yes, **Other Approvals Description:**

Describe these other approvals (facility authorizations, biosafety review, IRB approval from collaborating institutions, approval from public school system IRBs, etc.).

Registration on ClinicalTrials.gov required? ☑ No ☐ Yes: **NCT #:**

15. International Study Sites *(Prospective Data Studies Only)* N/A ☑

Complete this section for each "International Site."

Site Contact:

Name: **Credentials:**

Experience: *(with study location and total time spent working on site)*

Potential physical, psychological, social or economic risks? ☐ Yes ☐ No

If yes, **Potential Risk Explanation:**

Individuals in jeopardy for providing investigators with opinions on this topic? ☐ Yes ☐ No

If yes, **Individual Harm Explanation:**

Specific regulations for the conduct of research in this area of the world? ☐ Yes ☐ No

If yes, **Specific Regulations Explanation:**

16. Study Procedures *(Prospective Data Studies Only)* N/A ☐

Study Purpose:

Describe the aims and specific purposes of the study (include information about any relevant background research/citations if applicable).

Although it is typical for medical providers to ask brief questions screening for mental health symptoms, patients may not always feel comfortable self-disclosing these symptoms. Further, many people rely on other sources (such as family, friends, and religious leaders) for emotional support. Peoples' willingness to seek help for mental health symptoms and which sources they tend to self-disclose to vary across demographic, clinical, and personality variables (Picco et al., 2018; Liddon et al., 2018; Bhui & Bugra, 2002; Reynolds et al., 2022; Samuel & Kamenetsky, 2022; Steel, 1991). The aims of this study are to 1) identify which providers or other sources individuals are most likely to self-disclose mental health symptoms to, and 2) determine whether demographic, clinical, or personality traits best predict willingness to self-disclose mental health symptoms to specific provider types.

Study Procedures:

Provide a COMPLETE description of the study procedures in the sequence they will occur including the amount of time each procedure will take (attach all surveys, questionnaires, standardized assessment tools, interview questions, focus group questions/prompts or other instruments of data collection). Indicate if any of these procedures will take place regardless of whether or not subjects participate in the research.

Recruitment. Participants will be recruited for the study via GMU's Sona Systems (Psychology Department Participant Pool). The proposed study description for Sona Systems is uploaded in the study package.When participants sign up via Sona, they will be provided a direct link to the Qualtrics survey.

Consent. The Qualtrics survey will begin with a consent form (uploaded in the study package). Participants will not be able to proceed with the rest of the study until they have indicated their consent in Qualtrics. Participants will be asked if they would like study personnel to retain their contact information to be invited to participate in future research but will be able to opt out.

Surveys. After indicating consent, participants will then complete all study surveys on Qualtrics. Broadly, they will complete measures of demographics, culture and identity, help-seeking, trust, self-disclosure, self-stigma, shame, and physical and psychological health. All survey measures are uploaded in the study package. In total, it is expected that the surveys will take 1.5 hours to complete.

Credit Granting. When participants consent to participate in the survey, Qualtrics will record a unique StudyID provided by Sona. Participant names, email addresses, and StudyIDs will be downloaded from Sona and stored in a password-protected file on a folder within Mason's OneDrive network that is accessible only by IRB-approved research team members. Participant data in Qualtrics will only contain the StudyID and not names, email addresses, or any other identifying information. We will maintain a list of participants who complete or partially complete this study. The list includes participant names, email addresses and StudyIDs. We will temporarily use this list to determine if participants completed the study so that we can award appropriate credit in Sona. We keep this list separate from the rest of participant data.

Will false or misleading information be presented to subjects? ☐ Yes ☑ No

Deception Description:

Describe the deception that will be employed and the need for deception in this study.

Debriefing Information:

Describe debriefing procedures and attach debriefing script/information sheet if applicable. If there is a compelling reason not to fully debrief participants after the project, please describe why you do not intend to fully debrief participants.

Waiver of Normal Informed Consent:

Provide information and assurances of the following:

☐ *The research project involves no more than minimal risk to the subjects.*

☐ *The deception employed in this research project will not adversely affect the rights and welfare of the participants.*

☐ *The research could not be carried out without the approval of the deception practices described above.*

Will participants be audio or videotaped? ☐ Yes ☑ No

Recording Type: ☐ Audio ☐ Video

Description:

Describe the use of audio or videotape (including purpose).

A/V Consent:

If the audio/video tape consent is separate from the informed consent for the main study, discuss the method of audio/video consent and attach the A/V consent form.

Storage During Study:

What are your plans for storage of the audio/video taped material during the course of the data collection?

Storage After Study:

What are the plans for ultimate disposition or storage of the audio/video taped material?

17. Study Population *(Prospective Data Studies Only)* N/A ☐

Estimated Number of Subjects: 200 - 1000

Estimated Participation Time / Subject: 1.5 hours

Target Population:

Describe the target population (age, sex, ethnic background, health status, etc.)

The target population is adults 18 and older.

Non-English Speaking Participants? ☐ Yes ☑ No

Inclusion/Exclusion

Summarize the inclusion/exclusion criteria for participation in the study:

Inclusion criteria include minimum English language fluency sufficient to complete the consent and survey, must have regular access to the internet, and have access to a SONA systems account.
Participants cannot participate in this study more than once.

How will researchers determine that the criteria are met?

Participants will be notified that the consent form and study procedures are only available in English. Participants will be asked to verify that they are 18 or older. Adverstising will only occur in SONA systems and thus all participants will need to have an account in order to register for the study.

Enrollment restrictions based on gender, pregnancy, race or ethnic origins? ☐ Yes ☑ No

If yes, **Describe the process and reasons for restriction(s):**

Do any researchers listed on the application have a relationship to any of the participants that could unduly influence them to participate? ☐ Yes ☑ No

If yes, **Describe the relationship and how any possibility of undue influence will be managed:**

18. Minors *(Prospective Data Studies Only)* N/A ☑

Does this study pose greater than minimal risks to the minors? ☐ Yes ☐ No

Does the research involve children who are wards? ☐ Yes ☐ No

Advocate Appointment Description:

If the study involves wards and poses greater than minimal risk to minors, describe the appointment of an advocate. Additionally, fully describe guardianship and anticipated interactions with the guardian.

Recruitment Process:

Describe the order of the recruitment process (parental and child) and how the study will be presented to minors.

Assent Process:

Describe the assent process including how you will obtain active assent from minors (this process should be appropriate to the age/maturity of the child) and permission from parents. If requesting a waiver of active assent or permission, describe the specific reasons for this request.

19. Prisoners *(Prospective Data Studies Only)* N/A ☑

Inclusion Rationale:

In order to utilize prisoners as subjects one of the following must be true, check the appropriate box.

- ☐ Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects
- ☐ Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects
- ☐ Research on conditions particularly affecting prisoners as a class
- ☐ Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

Rationale Explanation:

Potential Benefits:

What, if any, advantages accrue to the prisoner participants? How do these advantages compare with the general living conditions in the prison?

Does this study include follow-up care or interactions? ☐ Yes ☐ No

Follow-Up Description:

If yes, describe how the investigators will ensure availability of contact information for the subjects

20. Pregnant Women, Fetuses, and Neonates *(Prospective Data Studies Only)* N/A ☑

Potential Risks:

Describe data on risks from any preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women.

Potential Benefit

Describe the potential for direct benefit to the pregnant woman, fetus, or neonate.

Fetus of Neonate Viability:

If applicable, describe how the viability of the fetus or neonate will be determined.

Fetus Identity Protection:

If applicable, describe how the identity of dead fetuses or fetal material will be protected.

21. Other Vulnerable Populations *(Prospective Data Studies Only)* N/A ☑

Special Consent Practices:

Describe any special consent practices to ensure understanding by the potentially vulnerable individuals and any additional signatures from legally authorized representatives.

Special Practices for Ongoing Assessment:

Describe any special practices for ongoing assessment of fitness to participate in study (if applicable).

Practice in Case of Incarceration:

Describe practices if individuals in study become incarcerated during the course of the study (if applicable).

22. Recruitment Process *(Prospective Data Studies Only)* N/A ☐

Recruitment Materials: *(Attach all recruitment materials)*

- ☐ Flyers
- ☑ SONA posting
- ☐ Social media
- ☐ Other
- ☐ Emails
- ☐ Phone/Verbal Recruitment Scripts
- ☐ Mechanical Turk

If Other, **Description:**

Recruitment Process:

Describe the processes used for selecting subjects and the methods of recruitment including when, how, and by whom the subjects will be recruited.

Students will be recruited from GMU Sona systems through an online posting (proposed Sona posting uploaded in study package).

23. Consent Process *(Prospective Data Studies Only)* N/A ☐

Process Description:

Describe the consent process including how consent will be obtained, how information will be discussed with and distributed to subjects, and how participants will indicate consent even if a waiver of signature is being requested below.

Consent will be obtained via Qualtrics. Participants will read Informed Consent document (attached), which provides all essential information. Participants will then indicate their consent by clicking "I agree." Participants will not be able to proceed with the survey if they have not indicated their consent to participate in the study.

Consent Setting:

Consent will take place online via Qualtrics.

Who will obtain consent:

Consent will take place online via Qualtrics.

Is a waiver of signature on the Informed Consent being requested? ☑ Yes ☐ No

Waiver Justification:

- ☐ The only record linking the subject and the research would be the consent document AND the principal risk would be potential harm resulting from a breach of confidentiality.
- ☑ The research presents no more than minimal risk of harm to subjects AND involves no procedure for which written consent is normally required outside of the research context.
- ☐ The subjects are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk to subjects, and there is an appropriate alternative mechanism for documenting informed consent

Waiver Explanation:

Participation will be exclusively online in order to facilitate easier participation and minimize burden on participants. By waiving the requirement for a signature, we also better protect participant confidentiality because it prevents personal information from being stored in Qualtrics. Electronic

documentation via Qualtrics survey (in which participants will be asked to click a button indicating their consent) will allow for documentation of consent without these added barriers.

24. Privacy and Confidentiality of Prospective Data

N/A ☐

Privacy and Confidentiality Protection:

How will the researchers protect the privacy of the participants and the confidentiality of the data obtained? Please specify whether the data will be collected in a public or private setting.

Privacy. Privacy will be protected by informing participants of the nature of the study prior to their signing up or indicating interests, which will give them the opportunity to control whether they show interest. A description of the study will be included in the SONA listing so that potential participants can understand what all the study entails before signing up to participate.

Confidentiality. Records of consent will be in Qualtrics. Qualtrics maintains the highest security standards, including encrypted data transfer (preventing hacker interception), password-required access to data, and a secure survey environment (writing responses directly to their computer server, leaving no trace on participants' computers). See Qualtrics.com for more details on confidentiality and security.

Consent form data will be downloaded from Qualtrics and stored along with participant identifying information in a password-protected file, on a folder within Mason's OneDrive network that is accessible only by IRB-approved research team members. Participant ID numbers will be stored in this same file.

Will results of the research be shared with the participants? ☐ Yes ☑ No

If yes, **Dissemination Process:**

Participant Disclosure of intent to harm or potential child abuse or neglect? ☐ Yes ☑ No

If yes, **Participant Disclosure Explanation:**

Include this information in the consent form.

25. Data Storage Information *(Prospective Data Studies Only)*

N/A ☐

Will copies of data be stored on Mason property? ☑ Yes ☐ No

If not, **Explain why copies of the data can't be stored on Mason property:**

Location: Data will be served on the Mason-owned OneDrive server in a password-protected document.

Duration: *Must be stored at least 5 years.*

☐ At least 5 years after the study ends ☑ Indefinitely

☐ Other:

When will identifiable information/the identification key be destroyed? *(if applicable)*

If participants agree to be recontacted for future studies, their contact information (name and email address) will be kept in a password-protected file on Mason OneDrive for up to 5 years or if the participant asks to withdraw this information.

Final Data Destruction:

Please indicate if you plan to store the data indefinitely or describe your data destruction plans for once the data storage period has ended.

The data will be stored indefinitely for future research, as additional research questions that could be answered with this data could arise.

26. Risk/Benefit Analysis *(Prospective Data Studies Only)* N/A ☐

Probability of Harm:

- ☐ Very Likely
- ☐ Likely
- ☑ Not Likely
- ☐ None

Risk Summary:

Summarize the nature & amount of risk if any (include side effects, stress, discomfort, physical risks, psychological and social risks).

The primary risk is the experience of psychological distress for participants in answering questions about mental health struggles. This distress is not likely to be greater than that experienced when thinking or talking about these issues with friends or families. There is also a risk that participants could experience boredom or fatigue from completing the surveys.

Risk Minimization:

What procedure(s) will be utilized to prevent/minimize any potential risks?

In case any participants experience psychological distress related to the study, within the consent form and at the end of the survey we will provide the number for Mason's Center for Psychological Services Emotional Support Line, a free call-in line that is staffed from 8:30am – 8:30pm every day for general stress. Further, at the beginning of the survey we will inform participants they can take breaks at any time for risk of fatigue or boredom.

Subject Benefits:

Describe any probable benefits (if any) of the research for the subject(s) (Do not address compensation in this section).

We anticipate no direct benefits to participation. However, student participants recruited via Sona Systems are expected to obtain "first-hand knowledge of the basic processes by which psychology… operates" via their direct participation in psychological studies. All student participants will be thoroughly debriefed according to GMU IRB and GMU Psychology Department guidelines, which specify that these participants should be provided with information regarding the study methods, design, and potential significance of results after their participation is completed. This is expected to be of pedagogical benefit to student participants.

Public Benefits:

Describe the benefits to society and general knowledge the study is likely to yield.

This study will likely yield valuable information about who people self-disclose mental health symptoms to and what factors make someone more or less likely to self-disclose. This information will be useful to clinicians and could lead to improved care for patients who are not comfortable self-disclosing mental health symptoms in all settings.

27. Subject Costs and Compensation *(Prospective Data Studies Only)* N/A ☐

Are there financial costs to the subjects? ☐ Yes ☑ No

Explain any financial costs to the subjects and provide an estimate of the cost:

Subjects paid or otherwise compensated for participation? ☑ Yes ☐ No

Amount: 1 credit/hr

Describe the nature of any compensation to subjects *(Cash, gifts, etc.)*:

Participants who participate through Sona Systems will receive credits in Sona Systems that count toward requirements/extra credit in Psychology courses

Partial *(if subject does not complete study)***:**

Participants will be compensated 1.5 credit for an 1.5 hours of participation in the study. Participants who do not complete the study will receive credits in proportion to total items completed, with the minimum compensation of half a credit.

When and How Provided:

Sona credits will be entered within 72 hours of study completion.

Research Credit Alternative:

Participants can typically complete summaries of research studies as an alternative to participating in research studies. In the consent form, we direct participants to consult with their course instructors for alternatives specific to their course.

28. Drugs *(Prospective Data Studies Only)* N/A ☑

IND Requirement:

☐ Valid IND

IND #:

IND Information:

- ☐ Sponsor protocol imprinted with IND number
- ☐ Written communication from the sponsor documenting the IND number
- ☐ Written communication from the FDA documenting the IND number

☐ Exempt from the IND Requirements

IND Exemption:

- ☐ Approved Drugs
- ☐ Serological Tests
- ☐ A clinical investigation involving the use of a placebo when the investigation does not otherwise require submission of an IND.
- ☐ Bioavailability/Bioequivalence Studies
- ☐ The drug has been approved by Radioactive Drug Research Committee as a radioactive drug for certain research use under the criteria in 21 CFR 361.1(b)
- ☐ Cold Isotopes for Research Use

IND Oversight:

☐ N/A - the study is exempt from IND requirements

- ☐ N/A - The investigator does NOT hold the IND.
- ☐ The FDA requirements of a sponsor (including GMP when applicable) have been assumed by a contract research organization.
- ☐ An audit has documented that the investigator is compliant with FDA sponsor requirements (including GMP when applicable).

Plan for Storage, Control and Dispensation:

29. Devices *(Prospective Data Studies Only)* N/A ☑

Device Type:

- ☐ This project evaluates the safety or effectiveness of a device in subjects, controls, or their specimens.
- ☐ This project involves a humanitarian use device.

IDE/HDE Requirements:

- ☐ The device has an IDE or HDE

  IDE/HDE #:

  IDE Information:

  - ☐ Sponsor protocol imprinted with IDE/HDE number
  - ☐ Written communication from the sponsor documenting the IDE/HDE number
  - ☐ Written communication from the FDA documenting the IDE/HDE number

- ☐ The device qualifies for an abbreviated IDE

  Abbreviated IDE Criteria Met? ☐ Yes ☐ No

  Significant Risk vs. Non-Significant Risk Device Determination for Abbreviated IDE:

Device is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject.	☐ Yes	☐ No
Device is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject.	☐ Yes	☐ No
Device is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject.	☐ Yes	☐ No
Device otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.	☐ Yes	☐ No

  Other Risks Explanation:

  Serious Risk to Health and Safety Explanation:

- ☐ The device is exempt from IDE requirements

  IDE Exemption Information:

  - ☐ Category 1
  - ☐ Category 3

☐ Category 2 ☐ Category 4

Plan for Storage and Control:

If the device has an IDE or HDE or qualifies for an abbreviated IDE, describe the plan for storage and control of the device to ensure that only authorized investigators will have access.

IDE Oversight:

- ☐ N/A - study is either exempt from IDE requirements or qualifies for an abbreviated IDE.
- ☐ Investigator does NOT hold the IDE.
- ☐ The FDA regulatory requirements of a sponsor (including GMP where applicable) have been assumed by a contract research organization.

  Contract Research Organization:
- ☐ An audit has been performed which documents that the investigator is compliant with FDA sponsor requirements (including GMP when applicable).

  FDA Sponsor Requirement Audit Description:

30. Form Complete

Thank you for completing the **George Mason University IRB Application.**

Investigator Certification:
By signing this package in IRBNet, I certify that the information provided in this project is correct and that no other procedures will be used in this protocol. I agree to conduct this research as described in the attached supporting documents. I will request and receive approval from the IRB for changes prior to implementing these changes. I will comply with all IRB policies and procedures in the conduct of this research. I confirm that copies of the study data will be stored on Mason property. I will be responsible for ensuring that the work of my co-investigator(s)/student researcher(s) complies with this protocol. I understand that I am ultimately responsible for the entire conduct of this research.

If you have any questions or concerns about this application or any other IRB issue, please feel free to contact the IRB Office.

Based on your responses, the following additional documentation must be included with this package before submission. Upload additional documentation in the Designer.

Additional required documentation:

- Attach all surveys, questionnaires, standardized assessment tools, interview questions, focus group questions/prompts or other instruments of data collection.
- Attach SONA posting.
- Attach all consent documents.

Please click Preview to review the information you have provided in this form. Refer to the end of the document for this checklist as you continue to prepare this submission. Please use this checklist to ensure that you have attached all the necessary documentation for complete IRB review.

George Mason University
Request for Reliance Agreement

Project Title: [1974781-1]: Mental Health Help-Seeking Preferences in College Students [IRB Application]

PI: Natasha Tonge, PhD

Last edited by: Gracie Kelly

Last edited on: November 9, 2022

1. External Collaborator Contact Information N/A ☑

Complete this section for each "External Collaborator."

Name: **Position:**

E-mail: **Phone:**

Institution: **Department:**

School:

Mailing Address:

2. IRB of Record Request N/A ☑

IRB of Record: **External FWA #:**

Contact Information:

Is the other institution's IRB a member of SMART IRB? ☐ Yes ☐ No

Project Summary:

GMU Investigator Roles/Responsibilities/COI:

External Investigator Roles/Responsibilities:

External Research Team Training:

If GMU will be designated the IRB of Record, explain how the GMU PI will train and supervise the research team members at the other institution.

IRB Authorization Agreement Justification:

Provide information about why GMU should enter into an IRB Authorization Agreement (IAA).

Does this project require secure storage of data at GMU? ☐ Yes ☐ No

If yes, **Where/How Data Will Be Stored:**

3. Local Context Information for Other Research Site N/A ☑

Age of Majority:

Institutional FWA Extended to Non-Federally Funded Research? ☐ Yes ☐ No

Local, Community, Cultural Issues:

Are there any local, community or cultural issues that may be different for the other site's population of subjects that require consideration?

Local or State Laws:

Are there any state or local laws that need to be considered that would impact this research protocol or informed consent document (e.g. wards of state, emancipated minors, mandatory reporting)?

Other Relevant Information:

Site Specific Informed Consent Requirements:

- ☐ Site IRB office has approved the local consent form(s) being submitted by the site PI
- ☐ A consent form is not needed for this site's involvement in the study.
- ☐ Site prefers to provide required consent language here

Compensation Statement:

Site approved statement regarding compensation in the event of a research related injury.

Additional Information:

Any additional required information that must be included in an informed consent form based on site policy or state law.

Is the other site a HIPAA covered entity for the intended research? ☐ Yes ☐ No

If yes, **Site Specific HIPAA Requirements**

Confirm that the HIPAA covered site will be responsible for its own HIPAA requirements and add any relevant information.