## THE UNIVERSITY OF ALABAMA IN HUNTSVILLE

**FORM 1: INSTITUTIONAL REVIEW BOARD APPLICATION**

**Instructions:** In MS Word, highlight the shaded underlined box and replace with your text. Double-click checkboxes to check/uncheck. Provide signatures by typing in your name where appropriate. See submission instructions at the end of this form.

**If this application is to extend IRB approval of a study already reviewed and accepted by IRB then please fill out the entire form including the “Revision” sections and submit this application.**

**If this application is for a new protocol that has not been previously approved**

**by IRB then please disregard the “Revision” sections.**

**Is this application to extend IRB approval of a previously reviewed and accepted protocol?**

Yes No

**If yes, what is the Previous IRB Application Number: Principal Investigator/Study Director Name**: XXXXXXX

**Status**: Faculty  Staff Student

**Department**: **College/Research Center**: **Telephone**: **Email**: **Supervising Faculty Information** (if student)

**Name**:

**Campus Address**:

**Telephone**: **Email** :

**Funding:** External Internal Unfunded 

**Funding source** (if applicable): N/A

**Title of Study**: Exploring Undergraduate XXXX Students’ Experiences of Moral Distress and

Ethical Dilemmas through Reflective Journaling

**Purpose of Study**: To gain a deeper understanding of the lived experiences of undergraduate xxxxx students regarding moral distress and ethical dilemmas in the xxxx setting. (Summarize the purpose/objectives of this study in nontechnical, lay language).

## State the Hypotheses, Research Question, or Practice Question:

1.) What are the physiological, psychological, and emotional responses to ethical dilemmas and moral distress among undergraduate xxxxx students in the xxxx setting?

2.) What actions do undergraduate xxxxx students take when they encounter an ethical dilemma or a morally distressing situation?

3.) What resources do undergraduate xxx students suggest or recommend for academic settings to provide when an ethical dilemma or morally distressing situation is encountered in the xxxx setting?

**Description of Subjects**: Subjects will be undergraduate xxxxx students aged 18 or older enrolled in XXX (name of course) for the Fall Semester of 2024 at The University of Alabama in Huntsville College of xxxx. The anticipated sample size is 30 subjects. Subjects 18 years or older and of any race, ethnicity, sex, gender, and health status will be included.

(Please identify the anticipated sample size and where these subjects will be recruited from. Summarize the subject’s characteristics such as age, sex, race/ethnicity, and health status. If a special population (e.g. children or prisoner) will be included, provide a brief justification, and include form 6 if subjects are under 18 years of age or form 7 if a prisoner. *Please note when completing the IRB*

*application forms the use of the term “subjects” is required by federal regulation. However, guidelines provided by other organizations may prefer the term “participant”, you may use the term participant in supportive materials needed for your study*.

## FOR REVISIONS TO APPROVED STUDIES ONLY:

Complete the section below **ONLY** if there are revisions **since the last IRB approval** or exemption. Describe any changes/revisions to Descriptions of Subjects here:

(Identify any changes in the anticipated sample size or if there will be a change in where these subjects will be recruited from. If the addition of any special population (e.g. children or prisoner) will be included in this study, provide a brief justification

below, and include these changes in form 6 if subjects are under 18 years of age or form 7 if a prisoner. Please disregard if this is a first-time application.)

**How Subjects Will Be Selected and Recruited**: A letter of support from the Dean of the college/department has been provided (**Appendix A**). Subjects will be recruited by convenience sampling. The research personnel (Dr. XXX, Dr. XXX, and Ms. XXX) are instructors in the XXX course and the XXX sections at The University of Alabama in Huntsville College XXX and will not participate in study introduction to (course number) students. To mitigate coercion, a PhD in XXX Student, (name of student) , will introduce the study to the (course number) course at the beginning of the Fall Semester. Ms. XXX will follow a recruitment script (**Appendix B**) which will detail the study and note the voluntary nature of the study. Additionally, subjects will be informed by Ms. XXX that their participation or non- participation will have no impact on their course or grades and their responses will go directly to her for anonymization and will not be released to the instructors until the end of the semester.

## You must provide the following:

* Summarize methods used to select subjects, selection process such as random sampling method, snowballing, convenience sampling etc. and how you will get access the population.
* Please identify the institution, clinic, or site from which subjects are to be recruited. Describe your procedures for identifying and recruiting subjects. Who will give you access to the population.
* How will subjects be identified and by whom?
* How will initial contact be made with prospective subjects and by whom (include a script if applicable)?
* Include a recruitment script that you will use to recruit subjects.
* Please describe all recruitment materials such as flyers, email invitations, student subject pool posting, social media postings, etc.
* Please include a copy of all recruitment materials in your IRB application, such as flyers, email invitations, student subject pool posting, social media postings, etc.
* ALL OF THESE MATERIALS MUST BE REVIEWED AND APPROVED BY THE IRB PRIOR TO USE.

## FOR REVISIONS TO APPROVED STUDIES ONLY:

Complete the section below **ONLY** if there are revisions **since the last IRB approval** or exemption. Describe any changes/revisions related to how subjects will be Selected or Recruited here:

* + (Summarize any changes made to how subjects will be selected and recruited. Carefully consider each of the bullet points listed above and if any changes have made from the previously approved protocol in relation to this section explain these changes in sufficient detail. Please disregard if this is a first-time application.)

**Background and qualifications of the principal investigator and additional personnel directly involved in the research:** The study personnel are listed below. Each member of the research team has completed CITI training in Human Subjects Research (HSR), Export Compliance (EC), Responsible Conduct of Research (RCR), and Conflicts of Interest (COI) (**Appendix C**).

* + **Name (PI)**: Dr.XXX is an Assistant Professor at The University of Alabama in Huntsville College of XXX and teaches in the XXXX course. Dr. XX obtained his PhD in in 2023 from The University of Alabama. Dr. XXX has been involved in several IRB approved studies and has published research in the area of moral distress.
  + **Name** : Dr. XXXis a XXX Assistant Professor at The University of Alabama College of XXX and teaches in the XXXX course and clinical. Dr. XX completed her EdD in 2022 from the University of Alabama.
  + **Name** : Ms. XXX teaches in the XXX course and clinical. Ms. XXX is currently completing her XXX degree at The University of Alabama in Huntsville.
  + **Name,** is a PhD student at The University of Alabama in Huntsville and the University of Alabama. Ms. XX is a novice researcher who is interested in the well-being of XXXX students. Ms. XX does not teach or guest lecture in XX or any other course in which XXXX students are enrolled in.
  + **Name** : Dr. XX is an Assistant Professor at the University of Alabama in Huntsville. She teaches in the undergraduate XXXX program, specifically with fifth semester XXXX students. Dr. XXX obtained her PhD in XXXXX through the University of Northern Colorado in 2021. Dr. XXXX is involved in several current research studies and her dissertation research was qualitative.

(Please briefly provide background information on the principal investigator (research background, human subject testing certification, CITI training, etc.) as well as all other researchers involved in the study in any capacity. This information may be attached as separate sheet as needed. Also, include information pertaining to the connection between the principal investigator and recruitment sites.)

## FOR REVISIONS TO APPROVED STUDIES ONLY:

Complete the section below **ONLY** if there are **revisions since the last IRB approval** or exemption. Describe any changes/revisions to the qualifications of the principal investigator and additional personnel directly involved in the research here:

(Provide a brief summary in any changes in the qualifications of the principal investigator as well as all other researchers involved in the study in any capacity. If there have been any additions to the research staff (including undergraduate and graduate assistants) please include documentation of their qualifications

(research background, human subject testing certification, CITI training, etc.). If new recruitment or testing sites have been included in this new protocol include information pertaining to the connection between the principal investigator and recruitment sites. Please disregard if this is a first-time application.)

**Description of Procedure**: Subjects who agree to the informed consent on the first day of the course after being introduced to the study by Ms. XXX will be prompted to complete demographic information (**Appendix D**). Thereafter, subjects will be provided with a Qualtrics link during their clinical debrief sessions for their 9 XXXX days throughout the semester to complete the journaling questionnaire (**Appendix E**). Subjects will have the opportunity to complete the questionnaire after their clinical on their own time. Subjects will be asked to acknowledge the informed consent prior to completing each questionnaire. XXX days will be spent on various units within (name location), Otherwise, subjects will complete their responses in an environment they feel comfortable. Responses will be housed within the Qualtrics Software provided by the University of Alabama in Huntsville. Ms. XXX will export the results into an excel spreadsheet to assign participant names to participant IDs as a means to keep participant responses together while also anonymizing them prior to releasing the anonymized data to the research team at the end of the semester (December 2024). Subjects will provide their names when completing the demographics questionnaire; however, these responses will not be linked to participant IDs of the journaling responses as a means to promote the anonymity of the respondents when the instructors receive access to the data at the end of the semester. The names will also be needed to ensure those who complete the journaling questionnaire also have demographic data. When final results are reported, the demographic responses will only be reported as a means to describe the sample and not tied directly to participant responses. Ms. XXXX will delete all names from the data once cross-checking responses and the assignment of participant IDs is complete.

The anonymized excel file will be uploaded to a shared UAH provided Google Drive by Ms. XXXX.

* + Summarize the process you will ask subjects to follow.
  + Describe in detail what will subjects be asked to do.
  + Provide a copy of the research script if applicable.
  + Briefly describe the setting in which the research will be conducted.

## FOR REVISIONS TO APPROVED STUDIES ONLY:

Complete the section below **ONLY** if there are revisions **since the last IRB approval** or exemption. Describe any changes/revisions to Procedures here:

(Summarize any changes to the process you will ask subjects to follow. Are there any changes to what subjects will be asked to do? Provide a copy of the research script with any edits if applicable. Briefly describe any changes in the setting in which the research will be conducted. Please disregard if this is a first-time application.)

**Instrumentation** (if applicable):

**1.) Informed Consent and Demographics Questionnaire (Appendix D):** This questionnaire will serve as the initial introduction to the study. Those who acknowledge the consent and agree to the terms will be prompted to complete basic demographic information (age, gender, sex, race, ethnicity) and other characteristics (second degree student, prior/current healthcare experience). Subjects will also input their names as a means to ensure those who complete the journaling portion of the study have demographic data. To promote anonymity, the names of those who complete the demographics questionnaire will not be linked to the journal responses. Demographic data is only being collected as a means to describe the overall sample.

**2.) Informed Consent and Reflective Journaling Questionnaire (E):** This questionnaire will be provided to subjects 9 times throughout the semester during the debrief sessions. This questionnaire will contain the informed consent and a prompt for subjects to re-acknowledge their understanding. The informed consent will be followed by

definitions of moral distress and ethical dilemmas and then questions related to the experience of ethical dilemmas and/or moral distress during their clinical day. The final section of the questionnaire will link to resources for subjects to consider utilizing if warranted. Subject responses will be voluntary and they may choose to respond or not respond during any of the 9 xxxxxx days throughout the semester.

* + Describe all materials such as questionnaires, surveys, cognitive tests, any and all designed materials or measures, equipment, etc. to be used in the study,
  + Provide a brief explanation for their use.
  + Attach a copy of these materials with your application

## FOR REVISIONS TO APPROVED STUDIES ONLY:

Complete the section below **ONLY** if there are revisions **since the last IRB approval** or exemption. Describe any changes/revisions to Instruments here:

(Describe all materials such as questionnaires, surveys, cognitive tests, any and all designed materials or measures, equipment, etc. that has been added that is to be used in the study, and provide a brief explanation for their use. Attach a copy of these materials with your application. Please disregard if this is a first- time application.)

## Duration of Study

1. **Total amount of time with each subject**: Up to 5 Hours (5 Min introduction, 30 Min for each journal session (9 sessions total).
2. **Time to complete study**: 5 Months (August – December)

## FOR REVISIONS TO APPROVED STUDIES ONLY:

Complete the section below **ONLY** if there are revisions **since the last IRB approval** or exemption. Describe any changes/revisions here:

## Revision to the Total amount of time with each subject:

* 1. **Time to complete study**:

**Benefit(s) of the Study**: Benefits of this study include fostering subject moral agency through reflective journaling and contributing to the knowledge of the experiences of ethical dilemmas and moral distress among undergraduate nursing students.

(Summarize *any* potential benefits to include physical, psychological, social, economic, and/or legal. These benefits are to be included in consent form as well. Describe potential benefits/significance of the study to science or society. ) Benefits do not include incentives and compensation for participation in the study, see below.

## FOR REVISIONS TO APPROVED STUDIES ONLY:

Complete the section below **ONLY** if there are revisions **since the last IRB approval** or exemption. Describe any changes/revisions to Benefits here: Please disregard if this is a first-time application.

**Compensation and Incentives with Monetary Value:** Subjects will receive no compensation for participating in or completing this study.

* Summarize the incentives for participation in the research for example gaining an insight into research, etc.
* Summarize the compensation that will be received for participating in the research (for example research credit hours for students, monetary incentives for non- students, etc.).

## \*Financial Compensation options include:

* + 1. A PI may choose to offer an incentive to all subjects equally, but, if so, the compensation must be reasonable and not so high as to be coercive.
    2. A PI may choose to not offer any incentives for participating in the study.
    3. If the PI does want to offer an incentive but cannot offer an incentive to subject, this option may be more suitable:
       - A PI will require subjects to answer a qualifying question to be eligible to be entered into a drawing, and if the subjects answers the question correctly, their names would be entered into a drawing for an incentive. (*Please note the subjects may select not to enter into the drawing and would not be penalized for opting out of this opportunity for an incentive. Also note, the qualifying question can be any question of the PI's choosing)*

## FOR REVISIONS TO APPROVED STUDIES ONLY:

Complete the section below **ONLY** if there are revisions **since the last IRB approval** or exemption. Describe any changes/revisions to Incentives and Compensation here:

(Summarize any changes in the incentives for participation in the research. If there are any changes in compensation please summarize this below. Please disregard if this is a first-time application.)

**Possible Risks to Subject(s) and Precautions Taken to Avoid Risks**: The primary potential risk to participants may be re-traumatization when recalling ethical dilemmas or morally distressing events. All potential subjects will be provided a link to The University of Alabama in Huntsville Student Counseling Services and moral distress resources from the XXXXX on the final section of each questionnaire. A secondary risk is associated with data privacy and confidentiality. All data will be stored on encrypted devices and software.

## UAH Counseling Center: [UAH - Counseling Center](https://www.uah.edu/counseling-center)

Summarize *any* potential risks to include physical, psychological, social, economic, and/or legal.

* These risks are to be included in consent form as well.

For Biological studies only: the study must be submitted and approved by the Biosafety Officer at The University Environmental Health and Safety Committee before submission to the IRB. Call 256-824-6053 or Email: <https://www.uah.edu/oehs/contact>

## FOR REVISIONS TO APPROVED STUDIES ONLY:

Complete the section below **ONLY** if there are revisions **since the last IRB approval** or exemption. Describe any changes/revisions to possible risks and precautions here:

(summarize any additional potential risks including physical, psychological, social, economic, and/or legal. These additional risks are to be included in a revised consent form. Please disregard if this is a first-time application.)

**How You Will Ensure Confidentiality/Anonymity**: To promote confidentiality and anonymity of the subjects, only one member of the research team (name) will have access to the Qualtrics responses with the subject names. Ms. (Name) will ensure all respondents who completed journaling responses also completed the demographics questionnaire. The demographics data will not be linked to the responses. Once the data is anonymized and participant IDs are assigned to the journaling responses, Ms. (Name) will remove the names from the data entirely and release the data to the rest of the research team at the end of the Fall 2024 semester. Data will be stored within Qualtrics and Google Drive both of which are encrypted services maintained by the University of Alabama in Huntsville. Additionally, data will be stored on password-protected devices only accessible to the research team.

* Summarize provisions to protect privacy interests and the method for securely collecting, storing the data.
* Summarize the disposal of research data.
* Describe how confidentiality will be assured?

## FOR REVISIONS TO APPROVED STUDIES ONLY:

Complete the section below **ONLY** if there are revisions **since the last IRB approval** or exemption. Describe any changes/revisions to Confidentiality and Anonymity here:

(Summarize any changes in the provisions to protect privacy interests or the method for securely collecting, storing, and possible disposal of research data. Are there any changes in how confidentiality will be assured? Please disregard if this is a first-time application.)

**Procedures for Attaining Informed Consent or Assent**: The initial consent will be acknowledged by all potential subjects at the start of the XXX Course for the Fall 2024 Semester and will be followed by the demographics questionnaire for those who wish to participate. To mitigate coercion, the study will initially be introduced by Ms. (name) who is not a faculty member or instructor for the XXX Course or any other course XXX students may be enrolled in. Subjects will be given a form containing a link/QR code to the informed consent and reflective journaling questionnaire by their

instructors (List instructors) during the clinical debrief sessions throughout the semester. Subjects will be asked within the questionnaire to re- acknowledge their consent and will then be prompted to complete the reflective journaling responses. Both the initial consent and consent re-acknowledgements will be imbedded in the Qualtrics questionnaires; therefore, a completed waiver of written consent form is provided in this application. Consent acknowledgements will be maintained for 3 years within the original Qualtrics response data. After 3 years, the consent documents will be destroyed.

Describe the procedures to be used to obtain consent, the circumstances under which consent will be sought and obtained, the timing of obtainment:

* Will there be a delay between obtaining consent and actual participation in the research?
* Which research personnel will obtain consent (please provide personnel qualifications as requested above)?
* What steps will be taken to minimize the possibility of coercion and/or undue influence?
* If the study involves minors (under the age of 18) describe the procedure to obtain assent and how it will be documented. Also include how parental permission for the participation of minors will be obtained and documented. See **Form 10** Youth Assent Form and Youth/Guardian Consent Form.
* Describe any and all procedures for reobtaining informed consent/assent (for example, in studies involving multiple sessions and how it will be documented.)

## FOR REVISIONS TO APPROVED STUDIES ONLY:

Complete the section below **ONLY** if there are revisions **since the last IRB approval** or exemption. Describe any changes/revisions to Obtaining Informed Consent of Assent here:

* (Summarize any changes made to the procedure for attaining informed consent or assent. Carefully consider each of the bullet points listed above and if any changes have

made from the previously approved protocol in relation to this section explain these changes in sufficient detail. Please disregard if this is a first-time application.)

## Documentation of Informed Consent by Subject(s) Attached? Yes No

(Attach consent form. Any waiver of consent justification needs to follow U.S. Health and Human Service justification see links below for details.)

## Documentation of all study personnel qualification(s) as stated above attached?

Yes  No

**Are copies of all materials as stated above attached?** Yes  No [**http://www.hhs.gov/ohrp/policy/consentckls.html**](http://www.hhs.gov/ohrp/policy/consentckls.html)**,** [**http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c11**](http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c11)**, or** [**http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c10**](http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c10)**.)**

**INVESTIGATOR ASSURANCE STATEMENT & SIGNATURE**

By my signature as Principal Investigator, I acknowledge my responsibilities for this Human Subjects Study and affirm that:

* I have reviewed and will comply with the Belmont Report: <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>,
* I have reviewed and will comply with informed consent regulations: <http://www.hhs.gov/ohrp/policy/consent/index.html>
* I will report (and will instruct other key personnel to report) adverse or unanticipated problems to chair of the IRB, 256-824-6100 or [irb@uah.edu](mailto:irb@uah.edu) :<http://www.hhs.gov/ohrp/policy/advevntguid.html>
* I have reviewed and acknowledge the Investigator Responsibilities: <http://answers.hhs.gov/ohrp/categories/1567>.
* I will not modify the protocol unless (a) the IRB has approved changes prior to implementation or (b) it is necessary to eliminate an apparent, immediate hazard to a subject(s);
* I will verify that all personnel are licensed/credentialed for the procedures they will be performing, if applicable;
* I will apply for continuing review of the protocol at least annually unless directed by the IRB to apply more frequently;
* I understand I may be audited;
* I will conduct the protocol as represented here and in compliance with IRB determinations and all applicable local, state, and federal law and

regulations; and will provide the IRB with all information necessary to review the protocol; and will refrain from protocol activities until receipt of formal IRB approval.

## CONFLICT OF INTEREST ACKNOWLEDGMENT

Federal Guidelines require assurances that there are no conflicts of interest in research projects that could affect the welfare of human subjects. If this study presents a potential conflict of interest, additional information will need to be provided to the IRB. Examples of potential conflicts of interest in research involving human subjects may include, but are not limited to:

* A researcher or family member participates in research on a technology, process or product owned by a business in which the faculty member holds a financial interest.
* A researcher or family member participates in research on a technology,

process or product developed by that researcher.

* A researcher or family member has a financial or other business interest in an entity which is supplying funding, materials, products, or equipment for the current research project.
* A research or family member serves on the Board of Directors of a business which is supplying funding, materials, products, or equipment for the current research project.
* A researcher receives consulting income from an entity that is funding the

current research project.

Do any members of the study team, or any of their family members, have a financial or other business interest in the source(s) of funding, materials, or equipment

related to this research study? Yes No

If you answered yes, contact the IRB Chair.

“Family Members” is defined to include spouse or any dependent. “Dependent” is any person, regardless of his or her legal residence or domicile, who receives 50 percent or more of his or her support from the Investigator or his or her spouse or who resided with the Investigator for more than 180 days during the reporting period.

# Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: 08/04/2024

**Supervising Faculty Signature** (if student): **Date:**

This signature acknowledges I am the Principal Investigator and/or Supervising Faculty.

## Submission Instructions:

Save file as a pdf file with the extension form 1 (investigator’s last name first initial) (year month date). Example: form1smithj20200401. This will be J. Smith submitting a proposal on April 1, 2020 as a first submission. If multiple submissions are provided in a single day, append a letter a-z at end of file name. Submit electronically to [irb@uah.edu.](mailto:irb@uah.edu)

**THE UNIVERSITY OF ALABAMA in HUNTSVILLE**

**FORM 11: Request for Waiver of Written Documentation of Informed Consent**

***Directions: Address the criteria listed below and attach this form to your application. Also, state in your application that you are requesting a waiver of written documentation of informed consent and describe what you will do to obtain consent in the procedure section of your application. The IRB often requires investigators to provide participants with a written information statement about the research when written documentation is waived; you may wish to include one in your initial application.***

***NOTE that the UAH IRB does not allow passive consent .***

1. **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; subjects must be asked whether they want documentation**

**linking themselves to the project or not (and the participants’ wishes will prevail); OR**

1. **The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.**

**NOTE: The first criterion is not included in FDA. The second is in both FDA and HHS regulations, 21 CFR 56.109 (c). In cases where documentation is waived, the IRB may require PIs to provide subjects with a written statement about the research.**

## Appendix A: Dean of College of XXXX Letter of Support

**Appendix B: Study Introduction and Recruitment Script**

Good **[Morning, Afternoon, Evening]**,

My name is **[state name]** and I am here today to introduce a research study that myself and your nursing faculty members are conducting. The aim of this study is to explore undergraduate xxx students’ experiences of ethical dilemmas and/or morally distressing situations in the xxx setting. To accomplish this aim, we are asking for your voluntary participation in completing a reflective journaling activity after each of your 9 xxxxx days.

Today, you are being provided with a QR code and link to access the informed consent and, if you choose to participate, a brief demographics questionnaire. My role in this project is to match the name you provide to any of your future responses to the journaling activities. Your name will not be linked to your responses, instead I will be assigning a participant ID. This promotes the anonymity of your responses when the data is released to your instructors when the course is completed in December. Additionally, your demographic details are only being used to describe the overall sample and will not be linked to individual responses. Your instructors will not know which participant IDs are associated with which demographics. This step is being taken to promote anonymity and the confidentiality of your responses. Your responses to the reflective journaling activity will be analyzed for overarching themes and subthemes.

Again, your instructors will not know who participated and who did not participate in this research study. There are no incentives for your participation and there will be no benefits or penalties to your grade in this course or any of your other courses if you choose to or not participate.

The demographics questionnaire you complete today consists of 10 questions and should take about 5 minutes to complete. The reflective journaling activities you will complete after your 9

hospital clinical days on your own, consists of the informed consent, definitions of moral distress and ethical dilemmas, and 8 questions, 5 of which are reflective journaling prompts. Each reflective journaling activity should take about 30 minutes to complete. Overall, expect to spend up to 5 hours of your time throughout the semester participating in this study.

Your participation is strictly voluntary. If you choose to participate in the study, you will be free to drop out at any point. Please access the following link/QR code for the informed consent.

Please complete this questionnaire whether you choose to participate or not. You will only

complete the demographics portion if you select “yes” to the informed consent

acknowledgement question. Regardless of whether you select “yes” or “no,” each of you will be provided with links to various resources which may be beneficial should you ever experience an ethical dilemma or morally distressing situation.

Should you have questions about this project, please direct them to Dr. xxxxxxxx

We thank you for your consideration in participating in this study!

## Appendix C: CITI Training

**Attached the 4 required CITI certificates for each team member**

## Appendix D: Informed Consent and Demographics Questionnaire

**Exploring UG xxxxxxx Students’ Experiences of MD and Ethical Dilemmas (Intro and Demographics)**

**Start of Block: Informed Consent**

Q1 **Consent Form:** Exploring Undergraduate xxx Students’ Experiences of Moral Distress and Ethical Dilemmas through Reflective Journaling

You are invited to participate in a research study examining the experience of ethical dilemmas and moral distress by undergraduate xxxx students completing xxxx rotations. This study is designed to help us better understand the experience of undergraduate xxx students regarding ethical dilemmas and moral distress in the xxx setting.

**KEY INFORMATION:** Consent is being sought for research purposes and participation is voluntary. The purpose of this study is to explore experiences of ethical dilemmas and/or moral distress by undergraduate xxxxstudents in the xxxx setting. You should expect to spend 5 minutes completing this demographic questionnaire should you choose to participate in this study. If you choose to participate in this study, you will be provided a link to the journal questions at the end of your xxx day to complete on your own time once the xxx day ends. It may take up to 30 minutes to complete your response to the journaling questions. Expect to spend up to 5 hours total over the course of the semester. Your responses will be anonymized by Ms. xxxx and will not be released to your instructors until after the semester is over. The primary potential risk to participants may be re-traumatization when recalling ethical dilemmas or morally distressing events. You will be provided with resources to mitigate these risks and address any discomfort or distress experienced as a result of this study. Benefits of this study include fostering your own moral agency through reflective journaling and contributing to the knowledge of the experiences of ethical dilemmas and moral distress among undergraduate xxx students. The primary investigator is Dr. xxxxx from The University of Alabama in Huntsville.

**PROCEDURE TO BE FOLLOWED IN THE STUDY:** Participation in this study is completely voluntary. Once your acknowledgement of consent is given; you will be asked to complete a demographic questionnaire. This session will take about 5 minutes. During your 9 xxx days, you will be provided with a form containing a QR code to a Qualtrics questionnaire containing another informed consent, definitions of moral distress and ethical dilemmas, and questions regarding your experience of ethical dilemmas and/or moral distress during your xxxx day. You will complete the questionnaire on your own time after xxxx if you choose to do so. The reflective journaling component may take up to 30 minutes to complete.

## DISCOMFORTS AND RISKS FROM PARTICIPATING IN THIS STUDY: The primary

potential risk to participants may be re-traumatization when recalling ethical dilemmas or morally distressing events. All potential subjects will be provided a link to The University of Alabama in Huntsville Student Counseling Services and moral distress resources from the xxxxx on the final section of each questionnaire. A secondary risk is associated with data privacy and confidentiality. You will be able to mark "prefer not to say" or respond with "N/A" on the demographic questions should you wish to not provide the requested information. All data will be stored on encrypted devices and software.

Your responses will be anonymized by Ms. x and provided to instructors at the end of the semester. **Dr. xxx, Dr. xxx, and Ms. xxxx will not be informed who or who did not participate, and your grades will not be impacted by your participation or non- participation.**

**EXPECTED BENEFITS:** Benefits of this study include fostering your own moral agency through reflective journaling and contributing to knowledge regarding the experience of moral distress and ethical dilemmas among undergraduate x students.

**INCENTIVES FOR PARTICIPATION:** There will be no incentives or monetary compensation offered for participation in this study.

**CONFIDENTIALITY OF RESULTS:** Participant numbers will be used to record your data, and these numbers will be made available only to those researchers directly involved with this study, thereby promoting strict confidentiality and anonymity. This consent form will be destroyed after 3 years. The data from your session will only be released to those individuals who are directly involved in the research and only using your participant number.

**FREEDOM TO WITHDRAW:** You are free to withdraw from the study at any time. You will not be penalized because of withdrawal in any form. Investigators reserve the right to remove any participant from the session without regard to the participant’s consent.

**CONTACT INFORMATION:** If you have any questions, please ask them now. If you have questions later on, you may contact the corresponding Principal Investigator, Dr. xxx, a[t xxxxxuah.edu.](mailto:phm0002@uah.edu) If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the Office of the IRB (IRB) at 256.824.6992 or email the IRB chair Dr. Ann Bianchi at [irb.@uah.edu.](mailto:irb.@uah.edu) This study was approved by the Institutional Review Board at UAH and will expire in one year from 00/00/0000.

Q2 Have you reviewed the informed consent?

By selecting “yes” I am acknowledging I have reviewed the Informed Consent and wish to voluntarily participate in this study. I understand that I am free to withdraw from this study at any time.

o Yes (1)

o No (2)

*Skip To: End of Survey If Have you reviewed the informed consent? By selecting “yes” I am acknowledging I have reviewed the... = No*

**End of Block: Informed Consent**

**Start of Block: Demographics**

Q3 Please enter your name.

Your name will not be linked to your journaling responses and will be removed from the data by Ms. xxxxx before being released to your instructors at the end of the Fall 2024 semester.

Q4 Please enter your age or type "prefer not to say." Type your response in the box below.

Q5 What is your sex? Please select your response from the choices below.

o Female (1)

o Intersex (2)

o Male (3)

o Prefer not to say (4)

Q6 What is your preferred gender? Please select your response from the choices below.

o Male (1)

o Female (2)

o Non-binary / third gender (3)

o Agender (4)

o Gender Fluid (5)

o Gender Queer (6)

o Gender Questioning (7)

o Transgender (8)

o Other (please specify) (9)

o Prefer not to say (10)

Q8 Which race/ethnicity best describes you? Please select your response from the choices below.

o American Indian or Alaskan Native (1)

o Asian or Pacific Islander (2)

o Black or African American (3)

o Hispanic (4)

o White or Caucasian (5)

o Multiple Ethnicities or Other (please specify) (6)

o Prefer not to say (7)

## Appendix E: Informed Consent and Reflective Journaling Activity