MANDATORY CONSENT FORM TEMPLATE

 – ADULT –

(Treatment Studies ONLY)

>>>USE ONLY IF YOUR SUBJECTS HAVE A **DISORDER** WHICH YOU AIM TO TREAT<<<

**Key and Instructions**

Required Content is highlighted in yellow (remove highlighting before submission) and includes:

-Consent to Participate in Research

-Study Title

-Investigator(s) and contact info

-Key Information

-The purpose of the study

-What you will do for this study

-Time required for this study

-Possible risks from your participation

-Benefits from your participation

-Confidentiality

-Right to withdraw

-IRB Approval

-Statement of Consent

-Note to Participants

Content that is required when applicable to your study is highlighted in green (remove highlighting before submission, or if not applicable to your study, delete the section before submission) and includes:

-Minimum age verification

-Videotaping/Audiotaping

-Incentives

-Confidentiality and Use of Audio/Video Tapes

-Student Participants in Investigators’ Classes

-Protected Health Information

-Compensation for Illness or Injury

-Post-Data Collection Re-Consent

-Collection of identifiable private information or identifiable biospecimens

-Genome sequencing of biospecimens

-Clinical Feedback

*Optional / Suggested Language & Examples* are italicized and can be modified to fit your study. If used, unitalicize the wording before submission. If not used, delete the wording before submission.

INSTRUCTIONS are in boxes and should be deleted before submission.

[Guidance] is in brackets with blue text and should be deleted before submission.

**Consent to Participate in Research**
**Study Title:** *Examination of post-narrative writing processing on PTSD* [Title can differ from your application in order to make your study more clear and/or less technical to subjects]

**Investigator Faculty Sponsor**

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 By checking this box I certify that I am 18 years of age or older.

Use unless it’s impossible for a minor to volunteer. Use for all student samples.

|  |
| --- |
| **Key Information for You to Consider** |
| * **Purpose**. The purpose of this research is [provide a brief description of why the research is being conducted, no more than 1 sentence].
* **Duration.** It is expected that your participation will last [expected duration].
* **Activities.** You will be asked to [briefly highlight the key research activities/procedures].
* **Why you might not want to participate.** Some of the foreseeable risks or discomforts of your participation include [describe the most important risks. Consider those most probable and/or highest magnitude of harm].
* **Why you might want to participate.** Some of the benefits that may be expected include [insert direct benefits, or if no direct benefit to subject state no direct benefit but the researchers hope to learn/gain xyz].
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**What you will do for this study**

1. Explain in simple, non-scientific language, everything that subjects will experience and be asked to do.
2. All procedures listed in the IRB application should be described here. Inform subjects on pre-laboratory requirements here, as well: e.g., “You cannot smoke, consume caffeine, or eat 4 hours before coming to the lab;” “You must wear shorts and tennis shoes.”
3. Describe questionnaires, surveys, and interviews, and describe or provide examples of the most personal and sensitive questions you will ask or stimuli you will show (e.g., distressing photos, descriptions, audio/videotapes).
4. State if you will take photographs or audio or video recordings.
5. If procedures and timelines are complicated, add a visual aid: study flow chart (best), bulleted lists, or table.
6. Most treatment study procedures and timelines are complicated, so provide a visual aid for subjects: add a study flow chart (best), bulleted list or table.
7. You MUST disclose all experimental conditions (e.g., treatment & placebo control groups) and HOW subjects will be assigned to groups (e.g., random assignment)

Many studies are simply an evaluation of an intervention or program or services that all subjects will receive regardless of whether they consent to the research, e.g., applying standard medical / psychological / counseling practices, delivering new classroom content to students. Make that distinction clear to subjects: ask consent only for the evaluation component, i.e., the intervention etc. should not be mentioned as something subjects will be asked to do.

**Use the Adult Template consent form (Non-Treatment Study) in these cases**.

*GOOD:*

*There are 4 parts to this study: Interview and surveys, writing sessions, email surveys, and follow-up interview and surveys. You will come to the Peabody Hall 3rd floor PTSD Laboratory for all but the email surveys. The first day you will do the interview & surveys. Writing sessions will be done on 3 days within a one-week period in the laboratory. Brief weekly surveys will be emailed to you for the next 4 weeks. One month after the last writing session, you will complete another interview and surveys in the laboratory.*

1. *Interviews & surveys (first day)*
* *You will be interviewed by a clinical psychology doctoral student researcher about your stressful life events and related symptoms. The interview asks specific questions about PTSD symptoms, such as flashbacks, nightmares, and avoidance of thoughts and trauma-related cues.*
* *The surveys are on how much you talked about the event before today, your physical health, your thoughts about the event, and how much time you spend in leisure activities. The surveys include some sensitive questions, such as, “Do you use drugs or alcohol to reduce your stress?” and “Does your stress affect your sex life?”* [List some of your most sensitive questions – so the subject can decide if he or she really wants to do your study – this helps prevent subject drop outs or omitted answers, which will negatively affect your statistical analyses]

*2. Random assignment to treatments and writing sessions (3 days in one week)*

* *You will be randomly assigned to one of three different writing groups. Random assignment means you have an equal chance of being placed into any one of the three groups, and it’s done similar to flipping a coin.*
* *If you are placed into one of the two ‘experimental’ groups, you will write about your most traumatic life experience. If you are in the third group (control group), you will write about how you use your time. At the end of the study, if you are in the control group, you will be offered the treatment that appeared most helpful.*
* *Writing sessions will be done on each of 3 days within a week for 20 minutes. You will select from two sets of mood figures to gauge your mood immediately after writing.*

*3. Weekly email surveys*

* *We will send you a link to a 2-minute online survey once a week for 4 weeks.*

*4. Interviews & surveys (last day)*

* *This will be a repeat of the first day’s interview and surveys and will be done one month after your last writing session.*

**Videotaping / Audiotaping**

*You will be videotaped during the interviews so that we can be sure the interviewer accurately rated your answers.*

**Time required for this study**

List estimated time for each day or session along with total time.

*This interview & survey days (first and last days) of the study each take about 1 hour. Writing days are about 30 minutes each (times 3 days). Weekly emails take only a few minutes. Total time for the study is about 5hours.*

**Possible risks from your participation**

*Many people feel uncomfortable remembering a traumatic life event and feel strong emotions. Participation in the trauma writing sessions may lead to less distress associated with your traumatic experience. Also, answering survey questions on your drug and alcohol use and on your sexual behaviors may be stressful. There are no other anticipated risks to you, except for a breach of confidentiality which we are minimizing with the steps described below.*

**Benefits from your participation**

List incentives in the next section, not here.

*Previous participants of writing studies have rated the experience as important and meaningful and stated that they would participate in the study again. Although the trauma writing sessions may lead to less distress associated with your traumatic experience, there will likely be large individual differences among participants in this study: you may see big improvements or you may see no change. If you are assigned to the control group, you will receive no direct benefit from writing – unless you opt for the writing treatment that will be offered to you immediately after the study. Finally, some people who’ve had traumatic experiences get some benefit simply from having a better understanding of PTSD symptoms through the interviews on PTSD.*

Take the opportunity to ‘sell’ your study here, because the IRB knows that better motivated subjects can yield better data, and that improves the cost/benefit ratio that IRB weighs for each study. For example, subjects appreciate and can use feedback from some measurements, such as medical values, performance comparisons, etc.

**Incentives**

*You will receive 5 hours of experimental course credit for being part of this project.*

*Your name will also be entered into a drawing for $20 Wal-Mart gift cards. Your chance of getting one of the cards is about 1 out of 10.* [*[Go here to see PROCUREMENT REQUIREMENTS for payments & gift cards for subjects]*](http://www.research.olemiss.edu/irb/guidance/incentives)

**Confidentiality**

1. If data are recorded so that subjects cannot be associated with their data [no names or email addresses, except on the consent form or on research credit certificates, etc.], state: *All information in the study will be collected anonymously: it will not be possible to associate your name with your responses.*
2. If #1 doesn’t apply, state:
	1. how you will maintain confidentiality. Describe how you will store identifiable data and who will have access to it. Example: *Members of the research team will have access to your records. We will protect confidentiality by physically separating information that identifies you from your responses – which is more secure than the way medical records must be stored.*
	2. *Members of the Institutional Review Board (IRB) – the committee responsible for reviewing the ethics of, approving, and monitoring all research with humans – has authority to access all records. However, the IRB will request identifiers only in special cases.*
	3. If applicable to your study, state: *The project’s research records also may be reviewed by [Food and Drug Administration (if FDA regulated), Office for Human Research Protections (if funded by DHHS), other external funding agency].*
	4. If applicable to your study, describe the conditions where State of Mississippi law requires you to break confidentiality [e.g., admission in an interview (not on a survey) of child or elder abuse].
	5. If *d* doesn’t apply, state: *We will not release identifiable results of the study to anyone else without your written consent unless required by law*.

Confidentiality and Use of Video/Audio Tapes

* If audio and/or video recording, briefly explain the need for recordings (e.g., *Taping will allow two experimenters to score your test responses for accuracy purposes*).
* State:
1. who will have access to the recordings (e.g., *Only experimenters on the research team will have access*.)
2. what will be done with recordings – with a specific time frame (e.g., *Tapes will be kept indefinitely / kept after transcription / destroyed after X months after your participation / after the end of the study – which is expected to be spring semester, 2019*)
3. how these will be stored (e.g., *Tapes will be locked in a file cabinet in a locked office*).

If you plan to take photographs or make audio, video, or other types of recordings – to use beyond research analysis, specify the use here (e.g., in publications, presentations, your dissertation manuscript, or promotional purposes). Then have the subjects sign a standard release (under examples and templates here: <http://www.research.olemiss.edu/irb-forms> ) after they sign the consent form. This protects you and UM legally.

**Alternative Treatments**

Explain other avenues to get help for subjects’ disorder and tell where this is available.

*There are alternatives to writing treatments for PTSD symptoms. These generally consist of techniques that aim to get you to perceive the traumatic experience and symptoms in a different way (for example, Cognitive Processing Therapy) or to reduce the anxiety and distress associated with the traumatic experience (for example, imaginal exposure). Treatment outside of the experiment is available on campus at the Psychological Services Center (662-915-7385) or University Counseling Center (662-915-3784).*

**Right to Withdraw**
You do not have to volunteer for this study, and there is no penalty if you refuse. If you start the study and decide that you do not want to finish, just tell the experimenter. Whether or not you participate or withdraw will not affect your current or future relationship with the Department of Psychology, or with the University, and it will not cause you to lose any benefits to which you are entitled.

*Inducements, if any, will be prorated based on (the amount of time you spent in the study.)*

*The researchers may terminate your participation in the study without regard to your consent and for any reason, such as protecting your safety and protecting the integrity of the research data. If the researcher terminates your participation, any incentives will be prorated based on the amount of time you spent in the study.*

***INCLUDE THE FOLLOWING PARAGRAPH ONLY IF YOU ARECOLLECTING DATA FROM STUDENTS IN YOUR CLASS***

**Student Participants in Investigators’ Classes**

Special human research subject protections apply where there is any possibility of coercion – such as for students in classes of investigators. Investigators can recruit from their classes but only by providing information on availability of studies. They can encourage you to participate, but they cannot exert any coercive pressure for you to do so. Therefore, if you experience any coercion from your instructor, you should contact the IRB via phone (662-915-7482) or email (irb@olemiss.edu) and report the specific form of coercion. You will remain anonymous in an investigation.

***INCLUDE THE FOLLOWING PARAGRAPH ONLY IF YOU ARE COLLECTING DATA FROM A HIPAA COVERED ENTITY (e.g., hospitals, physicians, mental health centers)***

**Protected Health Information**
Protected health information is any personal health information which identifies you in some way. The data collected in this study includes: (describe here). A decision to participate in this research means that you agree to the use of your health information for the study described in this form. This information will not be released beyond the purposes of conducting this study. The information collected for this study will be kept (indefinitely) or (until the study is complete) or (insert an expiration date or describe an event upon which the authorization will expire). While this study is ongoing you may not have access to the research information, but you may request it after the research is completed.

***INCLUDE THE FOLLOWING PARAGRAPH ONLY IF YOU ARE CONDUCTING A DRUG/SUPPLEMENT STUDY OR OTHER STUDY THAT INVOLVES PHYSICAL RISKS***

**Compensation for Illness or Injury**

“I understand that I am not waiving any legal rights or releasing the institution or their agents from liability from negligence. I understand that in the event of physical injury resulting from the research procedures, The University of Mississippi does not have funds budgeted for compensation for 1) lost wages, 2) medical treatment, or 3) reimbursement for such injuries. The University will help, however, obtain medical attention which I may require while involved in the study by securing transportation to the nearest medical facility.”

***IF YOU ARE COLLECTING IDENTIFIABLE PRIVATE INFORMATION OR IDENTIFIABLE BIOSPECIMENS, INCLUDE THE APPROPRIATE CONTENT FROM THE APPLICABLE OPTION, AFTER YOU MODIFY IT TO SUIT YOUR STUDY***

**Collection of Identifiable Private Information or Identifiable Biospecimens**

A statement that identifiers might be removed from your identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you (or from the legally authorized representative), if this might be a possibility. **OR**

A statement that, even if identifiers are removed, your information or biospecimens collected as part of the research will not be used or distributed for future research studies.

***IF YOU ARE COLLECTING BIOSPECIMENS, MODIFY THE FOLLOWING TO SUIT YOUR STUDY***

**Genome Sequencing of Biospecimens**

State whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

**Clinical Feedback**

State whether clinically relevant research results will be disclosed to subjects, and if so, under what conditions.

**IRB Approval**
This study has been reviewed by The University of Mississippi’s Institutional Review Board (IRB). The IRB has determined that this study fulfills the human research subject protections obligations required by state and federal law and University policies. If you have any questions, concerns, or reports regarding your rights as a participant of research, please contact the IRB at (662) 915-7482.

Please ask the researcher if there is anything that is not clear or if you need more information. When all your questions have been answered, you can decide if you want to be in the study or not.

**Statement of Consent**
I have read the above information. I have been given a copy of this form. I have had an opportunity to ask questions, and I have received answers. I consent to participate in the study.

Furthermore, I also affirm that the experimenter explained the study to me and told me about the study’s risks as well as my right to refuse to participate and to withdraw.

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| --- | --- |
| Signature of Participant | Date |

Printed name of Participant