MANDATORY CONSENT FORM TEMPLATE

 – ADULT –

(Non-Treatment Studies)

**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:** *Color Memory, Word Skill, Math Skill* [Title can differ from your application in order to make your study more clear and/or less technical to subjects]

**Investigator Faculty Sponsor**

Brinkley E. Student, M.S. David Faculty, Ph.D.

Department of Psychology Department of Psychology

300 Peabody Hall 300 Peabody Hall

University of Mississippi University of Mississippi

University, MS 38677 University, MS 38677

(662) 915-5555 (662) 915-5555

BrinStud@go.olemiss.edu Dfacult@olemiss.edu

|  |
| --- |
| **Key Information for You to Consider** |
| * **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
* **Purpose**. The purpose of this research is [provide a brief description of why the research is being conducted, no more than 2-3 sentences].
* **Duration.** It is expected that your participation will last [expected duration].
* **Procedures and Activities.** You will be asked to [briefly highlight the key research activities/procedures].
* **Risks.** 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].
* **Benefits**. 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].
* **Alternatives.** As an alternative to participation, you could [note appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject. If there are no alternatives, state that, “Participation is voluntary and the only alternative is to not participate.”].
 |

 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.

**What you will do for this study**

1. Explain in simple, non-scientific language, everything that subjects will experience and be asked to do – so they know what to expect and don’t drop out because they were ‘blindsided’ with a procedure or stressful stimulus that wasn’t in the consent form.
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.

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.

*GOOD EXAMPLE:*

*You will come to the Peabody Hall Memory Laboratory on the 3rd floor on 2 days within the same week. The first day you will take Memory Tests. The second day you will take Surveys.*

1. *Tests (first day)*

*You will take three short tests:*

* *One is a color memory test. We will show you several cards that are different colors. After you look at the cards, we will mix the cards up and you will have to put them back in the order that they were in when we showed them to you.*
* *The second is a vocabu­lary test. We will ask you the meaning of some words.*
* *The last is a math test. You will work some math problems in your head.*

*2. Surveys (second day)*

 *You will fill out two surveys:*

* *The ‘demographics’ survey asks about your age, education, and income.*
* *The ‘stress’ survey asks about current ‘pressures’ you feel and the results of those, and includes 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 (or stressful stimuli in the case of non-survey studies) – 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 otherwise negatively affect your statistical analyses]

*BAD EXAMPLE:*

*Cognitive assessments and surveys will be done to test our hypothesis. You will take the Stroop test, which measures selective attention, cognitive flexibility, and processing speed, and the Peabody Picture Vocabulary Test (PPVT), which measures receptive vocabulary, and fill out some surveys.*

**Videotaping / Audiotaping**

*You will be videotaped while you perform the tests during the ‘Tests day’ so that we can score the test / quote your interview answers / take better notes – more accurately.*

**Time required for this study**

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

*This study will take about 1 hour for the 1st day and 30 minutes for the 2nd day – for a total of 1.5 hours.*

**Possible risks from your participation**

*Example 1: IF STRESSFUL/UNCOMFORTABLE SITUATION:*

*You may feel performance-related stress from taking the first day tests. Also, answering survey questions on your drug and alcohol use and on your sexual behaviors may be stressful. Please see the Confidentiality section for information on how we minimize the risk of a breach of confidentiality.*

*Example 2: IF ANONYMOUS AND 100% NON-SENSITIVE DATA:*

*There are no anticipated risks to you from participating in the study.*

*Example 3: IF NOT ANONYMOUS WITH SENSITIVE DATA:*

*Please see the Confidentiality section for information on how we minimize the risk of a breach of confidentiality, which is the only risk anticipated with this study.*

**Benefits from your participation**

List incentives in the next section, not here.

*You should not expect benefits from participating in this study. However, you might experience satisfaction from contributing to scientific knowledge. Also, answering the survey questions might make you more aware of habits you’d like to change – sometimes this can help lead to improved habits.*

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 test results, and physical and cognitive performance comparisons, etc.

**Incentives**

*You will get 1 hour of research credit toward your Psychology class if you complete the first day’s tests and another ½ hour if you complete the second day’s surveys, for a total of 1.5 hours credit.*

*Your name will also be entered into a drawing for $20 Wal-Mart gift cards. We estimate that your chance of getting one of the cards is about 1 out of 1000.* [*[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 from you anonymously: it will not be possible for anyone, even the researchers, to associate you 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: R*esearch team members will have access to your records. We will protect confidentiality by coding and then physically separating information that identifies you from your responses (which is even safer than how medical records are stored today).*
	2. *Members of the Institutional Review Board (IRB) – the committee responsible for reviewing the ethics of, approving, and monitoring all research with humans – have authority to access all records. However, the IRB will request identifiers only when necessary. We will not release identifiable results of the study to anyone else without your written consent unless required by law*.
	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].*

Confidentiality and Use of Video/Audio Tapes

* If audio and/or video recording, briefly explain the need for recordings [e.g., *This will allow two experimenters to score your test responses to check reliability*].
* 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 X months after your participation / after the end of the study – which is expected to be spring semester, 2019*)
3. how tapes 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.

**Right to Withdraw *(Adapt language to your study)***
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 / close your web browser*. 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 will be prorated based on … specify [e.g., the amount of time you spent in the study.*

*The researchers may stop your participation in the study without your consent and for any reason, such as protecting your safety or 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 ARE COLLECTING 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 MEDICAL OR 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 (Any identifiable information)**

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 or concerns regarding your rights as a research participant, please contact the IRB at (662) 915-7482 or irb@olemiss.edu.

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, then decide if you want to be in the study or not.

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

|  |
| --- |
| Choose one of the following two options, A or B: |

|  |
| --- |
| A. FOR IN-PERSON STUDIES, INCLUDE THE FOLLOWING: |

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.

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

Printed name of Participant

|  |
| --- |
| B. FOR ONLINE STUDIES, INCLUDE THE FOLLOWING: |

 “CLICK HERE IF YOU AGREE TO PARTICIPATE” [OR SIMILAR LANGUAGE]

**For Deception Studies: Suggested Format for Mandatory**

**Post-Data-Collection Re-consent**

|  |
| --- |
| **Put this on a separate page and give to the subject after you debrief on all aspects of the study that you withheld** |

Because I did not fully tell you in the consent form about some of the procedures in this study, the IRB requires that I get your consent in order to use the information I collected from you.

* If you do not give your consent, there will be no penalty from me, your instructor, the department, or the School – this is completely your choice.
* If you do consent to the use of the information collected, please sign below and date it.

“Following debriefing, I approve that the information collected from me in the *[Title]* study can be used by Mr. Student & Dr. Faculty.”

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

Printed Name of Participant