**The University of Mississippi**

**Office of Research and Sponsored Programs**

***Division of Research Integrity and Compliance – Institutional Review Board***

**100 Barr Hall – University, MS 38677**

**irb@ olemiss.edu**

### APPLICATION TO CONDUCT RESEARCH WITH HUMAN SUBJECTS~ Instructions ~

* Always download the ***most recent*** version of this form ([research.olemiss.edu/irb/protocol](http://www.research.olemiss.edu/irb/protocol)).
* Prepare and send this form electronically in Word. [Note: this is a protected form, Spell Check will not work. Prepare your text in a separate document first, Spell Check, then cut and paste.]
* Answer **all** questions on this form completely. (If you have questions about this form, please contact the DRIC office at 662-915-7482 or irb@olemiss.edu.)
* Find examples of materials at <http://www.research.olemiss.edu/irb-forms>
* Complete and attach **all** supporting documentation and all appropriate appendices.
* *Incomplete submissions will not be reviewed.*

List all personnel involved with this research who will have contact with human subjects or with their identifiable data.

All personnel listed here must complete [CITI training](http://www.research.olemiss.edu/irb/education) before this application will be processed.

If more space is needed to list project personnel, please submit [Appendix A](http://www.research.olemiss.edu/irb-forms).

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| UM Personnel |
| PERSONNEL NAME  | PERSONNEL EMAIL (REQUIRED) \* | FACULTYOR STAFF | GRADUATESTUDENT | UNDERGRADSTUDENT | ROLE ON PROJECT |
| PI Name |  Email | Click to select | [ ]  | [ ]  | Primary Investigator (PI) |
| Name |  Email | Click to select | [ ]  | [ ]  | Click to enter text |
| Name |  Email | Click to select | [ ]  | [ ]  | Click to enter text |
| Name |  Email | Click to select | [ ]  | [ ]  | Click to enter text |
| Name |  Email | Click to select | [ ]  | [ ]  | Click to enter text |
| Name |  Email | Click to select | [ ]  | [ ]  | Click to enter text |
| Name |  Email | Click to select | [ ]  | [ ]  | Click to enter text |
| Name |  Email | Click to select | [ ]  | [ ]  | Click to enter text |

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| Non-UM Personnel (including UMMC) |
| NAME  | PERSONNEL EMAIL (REQUIRED) | Institution | ROLE ON PROJECT | Human Subjects Research Training Completed (List and attach description or certificate)\* |
| Name |  Email | Click to enter text | Click to enter text | Click to enter text |
| Name |  Email | Click to enter text | Click to enter text | Click to enter text |
| Name |  Email | Click to enter text | Click to enter text | Click to enter text |
| Name |  Email | Click to enter text | Click to enter text | Click to enter text |
| Name |  Email | Click to enter text | Click to enter text | Click to enter text |
| \*Only needed if ‘key’ personnel, (i.e., research staff responsible for the design of the study and all those who come in contact with human participants and/or identifiable data) |

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| APPLICATION TO CONDUCT RESEARCH WITH HUMAN SUBJECTS |
| **ABSTRACT:** **Briefly summarize your project using non-technical, jargon-free language that can be understood by non-scientists.** Include: (1) a statement of the research question and related theory supporting the reasons for, and importance of, the research; (2) the ages and characteristics of your proposed subjects and how you will recruit them; (3) the research design; and (4) a description of the procedure(s) subjects will undergo. Limit to the space below. [For examples, click here to visit the ORSP website.](http://www.research.olemiss.edu/irb-forms) |
| **TYPE YOUR ABSTRACT HERE** |
| 1. **Project Title:**
 |
|  |  |
| 1. **Principal Investigator:** **[ ]** Dr**.** **[ ]** Ms.**[ ]** Mr.
 |
| Department: | Work Phone: |
| E-Mail Address: | Home or Cell Phone: |
|  **If Principal Investigator is a student:** |
| **Graduate student:****[ ]** Dissertation **[ ]** Master’s thesis  **[ ]** Other graduate project | **Undergraduate student:****[ ]** Senior thesis: **[ ]** SMBHC  **[ ]** Croft Institute **[ ]** Other**[ ]** Other undergraduate project |
| **Research Advisor:** (required for student researchers) | **[ ]  Not applicable** (applies to staff & faculty only) |
| Department: | Work Phone: |
|  E-Mail Address: | Home or Cell Phone: |
|  |

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| 1. **Funding Source:**

Is there funding for this project? [ ]  Yes ⇨ [ ]  No | If Yes, is the funding:Internal: [ ]  Source: External: [ ]  Agency:  [ ]  Pending [ ]  AwardedPI on external funding:  |
| 1. **Anticipated Beginning and Ending Dates of Human Subjects Contact:**
 | Beginning Date:**mm /** **dd /** **yy**Ending Date: **mm / dd / yy**Not Applicable:**[ ]**  |
| Research Methodology/Procedures |
| 1. **Check all procedures below that apply to your study:**
 |
|  **[ ]** Pre-existing data  | Source of data: Do data have identifiers?**[ ]** Yes\* **[ ]** No\*if health information, you may need to fill out [Appendix F](http://www.research.olemiss.edu/irb-forms) |
|  [ ]  Observation [ ]  Oral history [ ]  Interview [ ]  Focus group |
|  **[ ]** Questionnaire or Survey \*Anonymous? **[ ]** Yes  **[ ]** NoDistribution: [ ]  Internet [ ]  Mail [ ]  E-mail [ ]  In person [ ]  Other: . |
| **\*Anonymous** or **Confidential?** Anonymous means (1) the investigator cannot associate a subject with his/her data and (2) the data cannot identify a subject. Examples: Surveys with no names handed to an investigator are not anony­mous; surveys placed by the subject in a group data envelope can be anonymous; surveys with no names and with demo­graphic data that can identify a subject (e.g., the only African-American in a class) are not anonymous, interviews, by definition, are NOT anonymous |
|  [ ]  Experiment/manipulation [ ]  Treatment study (for a disorder) [ ]  Other:  |  **[ ]** Exercise\*  **\***Exercise Intensity  **[ ]**  Moderate **[ ]**  More than moderate  |
|  [ ]  Collection of college student grades, ACT scores, etc. from colleague’s class or from Registrar  See [FERPA-covered records release policy](https://secure4.olemiss.edu/umpolicyopen/ShowDetails.jsp?istatPara=1&policyObjidPara=11774093) for more information |
|  [ ]  Videotaping\*  [ ]  Audio recording \* \*You **must** use and attach a [release form](http://www.research.olemiss.edu/irb-forms) if you plan to disseminate **quoted** comments or taped content (This covers you and UM legally – Not for IRB purposes) |
|  [ ]  X-ray (E.g. DEXA ~ contact [Health & Safety](http://www.olemiss.edu/safety/) for training requirements). |
|  **[ ]** Collection/use of blood, urine, other bodily fluids, or tissues **\*\***  | Has IBC application been submitted? [ ]  Yes [ ]  NoIf Yes, has IBC application been approved? [ ]  Yes [ ]  No |
|  **\*\*** May require IBC approval; see [research.olemiss.edu/health-safety/ibc](http://www.research.olemiss.edu/health-safety/ibc) for more information. Contact [Health and Safety](http://www.olemiss.edu/safety/) for training requirements. |
|  [ ]  Use of drugs, biological products, or medical devices |
| 1. **Deception or Omission of Elements of Consent:**

 Do any of the following apply to your study? [ ]  **No**[ ]  The study uses surreptitious videotaping.[ ]  The study gives subjects deceptive feedback, whether positive or negative.[ ]  The study uses a research confederate.[ ]  The study has misleading or deceptive: (1) study descriptions; (2) procedure explanations; and/or (3) survey instructions/rationales.  If you checked any of the above, please complete [**Appendix D**](http://www.research.olemiss.edu/irb-forms). |
| Participant Information |
| 1. **Subject Characteristics:** Number: Age Range:
 | If under 18, parental consent is required. |
| **For adult subjects only, state how you will ensure they are 18+** | [ ]  **Checkbox on Consent Form**[ ]  **Other:**[ ]  **Not applicable** |
| 1. **Briefly describe subject population:**
 | E.g. 2nd grade students, college students, etc. Justify exclusion of any racial or gender group. |
| 1. **Potentially Vulnerable Subjects Targeted:** Check all applicable groups

**[ ]** Children/adolescents - Complete [Appendix B](http://www.research.olemiss.edu/irb-forms) if applicable.[ ] Mentally ill – outpatients[ ]  Mentally ill – inpatients[ ]  Cognitively impaired[ ]  Elderly, if institutionalized[ ]  Pregnant females[ ]  Prisoners - Complete [Appendix C](http://www.research.olemiss.edu/irb-forms).[ ]  HIV+[ ]  Other: **[ ]  Not applicable** |
| 1. **Recruitment Procedures**:**a.** How will you recruit subjects? Check all that apply:

[ ]  Sona System[ ]  UM bulletin boards, where: [ ]  Class announcements[ ]  Letters to parents/guardians[ ]  E-mail – specify groups: [ ]  Radio/TV/newspaper ads[ ]  Other: [List all recruitment sites.] | **b.** Are subjects in a subservient power relationship to investigators or to parties with an interest in the research, such as students in an instructor/investigator’s class or employees of the investigator?[ ]  Yes [ ]  NoIf Yes, how will you ensure that their participation is truly voluntary? |
| Recruitment ad/e-mail/oral announcement is attached: [Recruitment materials must state “This study has been approved by UM’s Institutional Review Board (IRB). Ensure subject inclusion/exclusion criteria matches what will be used for the study.] | [ ]  Yes [ ]  No [ ]  **Not applicable** |
| **c.** Describe incentives for subjects, if any (money, drawing, class points\*, etc.).\*If class points, there must also be alternative assignments for earning points, involving comparable time and effort. | [ ]  No incentives |
| **d.** List pro-rating rate for incentives for any study drop-outs**.** | [ ]  Not applicable |
| 1. **CONSENT PROCEDURES\*: Check all that apply.**

**[ ]** Oral (attach script)[ ]  Information letter – used in survey research (attach)[ ]  Informed consent form (attach)[ ]  Assent form for children or subjects with intellectual disabilities (attach) [ ]  Not applicable – Explain: [ ]  Request waiver of ***written*** consent – justify: [ ]  Request waiver of consent – justify: **\***[**See examples and templates here**](http://www.research.olemiss.edu/irb-forms) | If you plan to enroll non-English speaking participants, the consent form and assent document(s) must be translated into the appropriate language(s) and included with this submission.For subject populations where competence to consent is highly questionable (e.g. some psychiatric populations), explain how competency will be determined and by whom.  |
| 1. **a. Where will the study be conducted?** **Check all that apply.**

**[ ]** UM campus – specify:  (if clinical trial facility, must be approved by SOP)[ ]  Local community: elementary/secondary school(s) or child care facility. Complete [Appendix B](http://www.research.olemiss.edu/irb-forms).[ ]  Local community: other – specify:  [ ] Another U.S. location– specify:  [ ]  Another country – specify: Complete [Appendix E](http://www.research.olemiss.edu/irb-forms). See [GDPR](file:///C%3A%5CUsers%5Cmlcore%5CBox%20Sync%5CORIC%5CWebsite%20Forms%5CIRB%5CGuidance%5CGDPR%20-%20General%20Data%20Protection%20Regulation.docx) Guidance**B. HAVE YOU OBTAINED PERMISSION?**[ ]  Approval letter attached[ ]  Not applicable – Explain: -if giving a survey, whether on or off campus, please ensure the person giving permission (e.g., the teacher of a class) has an explicit opportunity to see the survey before they give their permission for its distribution |
| 1. **Describe ALL possible risks to subjects.**
 | **List steps to minimize risks, including experimenter and research assistant training/expertise.** For example, an emergency plan to handle potential adverse events for traumatic experience surveys or psychology research with children. |
| **a.** Physical:  |  | [ ]  n/a |
| **b.** Emotional:  |  | [ ]  n/a |
| **c.** Social/interpersonal:  |  | [ ]  n/a |
| **d.** Occupational:  |  | [ ]  n/a |
| **e.** Financial:  |  | [ ]  n/a |
| **f.** Legal:  |  | [ ]  n/a |
| **g.** Other:  |  | [ ]  n/a |
| 1. **What are the potential benefits, if any, to subjects** (e.g. recognition of health risks, reduced stress, increased physical fitness, etc.) **Potential benefits do not include incentives offered for participation.**

 |
| 1. **How will you maintain data confidentiality?**

**[ ]** All data are anonymous (go to next section).[ ]  Data are confidential.[ ]  \*Data kept in locked file cabinets.[ ]  \*Data kept in locked room.List building/room number for data storage: \*For identifiable data that will be physically stored (locked drawer, file cabinet etc.) posted restricted access signage is required. See our Restricted Access signage template [here](https://www.research.olemiss.edu/irb-forms).When will data be de-identified?  [ ]  n/a | **Anonymous** or **Confidential?**Anonymous means (1) the investi­gator cannot associate a subject with his/her data and (2) the data cannot identify a subject. **The IRB encourages permanent retention of data** **for potential future use because** **this improves the cost/benefit ratio.** |
| **IRB recommends that investigators physically separate sensitive data from identifiers. Here is a method that separates data from identifiers across 2 devices and greatly reduces breach of confidentiality risks:****1. Record data on one storage device****2. Add a code number to each subject****3. Copy the code and move the identifying data to a separate device** |
| Project Description |
| 1. **Describe your project in the spaces below.** Spaces will expand as you enter text.
 |
| **a.** Problem statement (including specific aims of your project): |
| **b.** Brief literature review that points to a need for this research (including references): |
| **c.** Description of procedures: |
| **d.** Measures: (attach all measures – with labels that correspond to your list below) |
| **Survey / Test / Questionnaire (e.g. WAIS)** |
| **Name and Acronym** | **Is there published psychometric support?** |
| **1**  | [ ]  Yes [ ]  No |
| **2**  | [ ]  Yes [ ]  No |
| **3**  | [ ]  Yes [ ]  No |
| **4**  | [ ]  Yes [ ]  No |
| **5**  | [ ]  Yes [ ]  No |
| **Other Measures** (e.g. heart rate) |
| **Name** |
| **1**  |
| **2**  |
| **3**  |
| **4**  |
| **5**  |
| **e.** Provide a numbered step-by-step list of all procedures from the point of view of the subjects, starting with recruitment. Include when consent will be obtained and from whom. Elaborate on more complex items. Attach scripts of procedural instructions to subjects. [For examples, click here to visit the ORSP website.](http://www.research.olemiss.edu/irb-forms) |
| **1** |
| **2**  |
| **3**  |
| **4**  |
| **5**  |
| **f.** Data analysis methods: |
| **g.** Debriefing and/or feedback on test results (procedures, forms, scripts, and statements):**[ ]  Not applicable** |

1. **Appendix Checklist:**

 **A. Additional Personnel not listed on first page of application?**

 [ ]  **No** [ ]  **Yes** – **complete** [**Appendix A**](http://www.research.olemiss.edu/irb-forms)

 **B. Will the research be conducted in schools or child care facilities?**

 [ ]  **No**  [ ]  **Yes** – **complete** [**Appendix B**](http://www.research.olemiss.edu/irb-forms)

 **C. Will any of your subjects be prisoners?**

 **[ ]  No [ ]  Yes – complete** [**Appendix C**](http://www.research.olemiss.edu/irb-forms)

 **D. Does your research involve deception or omission of elements of consent?**

 [ ]  **No**  [ ]  **Yes** – **complete** [**Appendix D**](http://www.research.olemiss.edu/irb-forms)

 **E. Will your research be conducted outside of the United States?**

 [ ]  **No** [ ]  **Yes** – **complete** [**Appendix E**](http://www.research.olemiss.edu/irb-forms)

 **F. Will your research involve protected health information?**

 [ ]  **No** [ ]  **Yes** – **complete** [**Appendix F**](http://www.research.olemiss.edu/irb-forms)

1. **Attachments Checklist:**

**Did you submit:**

1. **survey or questionnaires?**

 [ ] **Yes** [ ] **Not Applicable**

1. **interview questions?**

 [ ] **Yes** [ ] **Not Applicable**

1. **recruitment email, announcement, or script?**

 [ ] **Yes** [ ] **Not Applicable**

1. **Informed consent form?**

 [ ] **Yes** [ ] **Not Applicable**

1. **If using class points as incentives, are there alternative assignments available for earning points that involve comparable time and effort?**

 [ ] **Yes** [ ] **Not Applicable**

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| ASSURANCES ~ Conflict Of Interest And Fiscal Responsibility |
| Do you or any person responsible for the design, conduct, or reporting of this study have an economic interest in, or act as an officer or a director of any outside entity whose financial interests may reasonably appear to be affected by this research? |
| [ ]  YES [ ]  NO | If Yes, please explain any potential conflict of interest. |
| Do you or any person responsible for this study have existing financial holdings or relationships with the sponsor of this study? |
| [ ]  YES [ ]  NO[ ]  N/A | If Yes, please explain any potential conflict of interest. |
| ASSURANCES |
| Principal Investigator Assurance |
| **Principal Investigator’s Assurance**[ ]  I certify that the information provided in the application is complete and correct. As Principal Investigator, I have the ultimate responsibility for the protection of the rights and welfare of the human participants, conduct of the research, and the ethical performance of the project. I will comply with all UM policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of participants in human research, including, but not limited to the following:* The research will be performed by qualified personnel according to the approved research protocol;
* No changes will be made in the research protocol or informed consent document(s) until approved by the IRB;
* Informed consent will be obtained from the participants, if applicable and appropriate;
* Adverse events and/or unanticipated problems will be reported to the IRB as required.

[ ]  I certify that I, and all key personnel, have completed the required initial and/or refresher CITI courses in the ethical principles and regulatory requirements for the protection of human research participants.    **Typed Signature/Name of Principal Investigator Date** |
| Research Advisor’s Assurance Via Email |
| **Research Advisor’s\* Assurance (required for student projects)**Email your Advisor with the following:1. Email subject line: “IRB Advisor Approval Request from (your name)”2. Your IRB submission materials as attachments3. Copy and paste the statements below into the body of the email4. Save the reply email from your Advisor as a pdf and submit via the online portal along with your IRB submission materials. 5. The online submission portal can be found at: I <https://research.olemiss.edu/irb/submit> **\*The research advisor must be a UM faculty member. The faculty member is considered the responsible party for the ethical performance and regulatory compliance of the research project.**Please review my attached protocol submission. Your reply email to me will constitute your acknowledgement of the assurances below.Thank you,[type your name here]As the Research Advisor, I certify that the student investigator is knowledgeable about the regulations and policies governing research with human participants and has sufficient training and experience to conduct this particular research in accordance with the approved protocol.I agree to meet with the investigator on a regular basis to monitor research progress.Should problems arise during the course of research, I agree to be available, personally, to supervise the investigator in solving them.I will ensure that the investigator will promptly report incidents (including adverse events and unanticipated problems) to the IRB.If I will be unavailable, for example, on sabbatical leave or vacation, I will arrange for an alternate faculty member to assume responsibility during my absence, and I will advise the IRB by email of such arrangements.I have completed the required CITI course(s) in the ethical principles and regulatory requirements for the protection of human research participants. |

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| department chair’s assurance |
| **Department Chair’s Assurance**All PIs\*: Email your Department Chair with the following:1. Email subject line: “IRB Department Chair Approval Request from (your name)” 2. Your IRB submission materials as attachments3. Copy and paste the statement below into the body of the email4. Copy and paste your Abstract into the body of the email5. Save the reply email from your Chair as a pdf and submit via the online portal along with your IRB submission materials. 6. The online submission portal can be found at : <https://research.olemiss.edu/irb/submit> **\*If the PI is a Department Chair, submission of the protocol will constitute acknowledgement of the assurance.** Please review my attached protocol submission. Your reply email to me will constitute your acknowledgement of the assurances below.Thank you,[type your name here]As Department Chair, I acknowledge that the below described research is in keeping with the standards set by our Department and I certify that the Principal Investigator has met all departmental requirements for approval of this research.  |
|  |