**The University of Mississippi**

**Office of Research and Sponsored Programs**

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

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

[**irb@olemiss.edu**](mailto:irb@olemiss.edu)

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| **APPLICATION FOR EXEMPTION** |
| Purpose: Many studies qualify for an abbreviated review, according to the federal regulations and university policy. |
| * **Part I of this form screens for a brief review.** |
| * **Part II of this form completes the abbreviated IRB application.** |
| * **Part III of this form gives instructions for obtaining the required assurances.** |
| * **The IRB makes the final determination on whether you must fill out a full application.** |
| **Always** download the most recent version of this form: <http://www.research.olemiss.edu/irb/protocol/forms>. |
| Prepare and send application form as a **Word** document. **Upload the completed form and attachments (and pdf of email assurance if PI is a student)** at <https://research.olemiss.edu/irb/submit>. |
| **Note: Some class project studies may qualify for a classroom waiver of IRB Application. Instructors: see form** [**here.**](http://www.research.olemiss.edu/irb-forms) |
| **PART I — Screening** |
| 1. **Do any of the following apply to your study?** |
| **Research Methods:**  Clinical Treatment study  Yes  No  Exercise  Yes  No  X-rays  Yes  No  Collection of blood, urine, other bodily fluids, or tissues  Yes  No  Use of blood, urine, other bodily fluids, or tissues with identifiers  Yes  No  Use of drugs, biological products, or medical devices  Yes  No  Use of drugs, biological products, or medical devices  Yes  No  Use of data collected in the European Economic Area (EEA)\*  Yes  No  **Targeted Subjects:**  Prisoners  Yes  No  **Elements of Deception:**  The study uses surreptitious videotaping  Yes  No  The study gives subjects deceptive feedback, whether positive or negative  Yes  No  The study uses a research confederate (i.e., an actor playing the part of subject)  YesNo |
| **If you checked Yes to any of the above, STOP HERE and fill out the** [**FULL IRB APPLICATION FORM**](http://www.research.olemiss.edu/irb/protocol/forms)**.** |
| 1. **Questionnaire or Survey?** (include questionnaire or survey as an attachment)  Yes  No   If Yes, answer 2a and 2b.  If No, proceed to 3.  **a. Anonymous?\***  Yes  No  **b. Sensitive Information?\***  Yes  No  **If you answered No to 2a AND Yes to 2b, STOP HERE and fill out the FULL IRB APPLICATION FORM.** |
| **\*Anonymous or Confidential?** Anonymous means (1) the recorded data cannot associate a subject with his/her data, and (2) the data cannot identify a subject. *Examples:* surveys with no names but with demographic data that can identify a subject (e.g., the only African-American in a class) are not anonymous.  **\*Sensitive Information?** Sensitive information includes but is not limited to (1) information that risks damage to a subject’s reputation; (2) information that involves criminal or civil liability; (3) information that can affect a subject’s employability; and (4) information involving a person’s financial standing. *Examples:* Surveys that ask about porn use, illegal drug or alcohol use, religion, use of alcohol while driving, AIDS, cancer, etc. contain sensitive information.  **\*European Economic Area** - Collection of data in the European Economic Area (the 28 states of the European Union and Iceland, Liechtenstein, Norway, and Switzerland). Special considerations apply -if data are not 100% anonymous. See [GDRP Guidance](file:///C:\Users\nabby\Downloads\Guidance\GDPR%20-%20General%20Data%20Protection%20Regulation.docx) for more information |

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| **CATEGORIES FOR EXEMPT REVIEW** |

1. **The ONLY involvement of human subjects will be in the following categories** (check all that apply)

**PLEASE READ CAREFULLY: MUCH CHANGED WITH NEW REGULATIONS, JANUARY 2019**

**1)** **Educational Research:** Research conducted in established or commonly accepted educational settings, involving normal educational practices. Research is not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

**2****)** **Surveys, Interviews, Educational Tests (cognitive, diagnostic, aptitude, achievement), or Observation of Public Behavior (including video or auditory recording).**

**At least one of the following MUST be checked.**

(i) Information recorded by the investigator cannot readily identify the subject (either directly or indirectly)

(ii) Disclosure of subjects’ responses outside the research could **NOT** reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, educational advancement, employability, or reputation

(iii) Information recorded by the investigator includes identifiers and the investigator specifies strong security measures to protect the data (e.g., encryption for electronic data; multiple locks for paper data). Minors are **NOT** permitted under this sub-category

Public observation involving minors with no investigator interaction. Minors are **ONLY** permitted under these conditions.

**3)** **Benign Behavioral Interventions (BBI):** Research involving interventions in conjunction with collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection.

* BBI is limited to communication or interpersonal contact; cognitive, intellectual, educational, or behavioral tasks; manipulation of the physical, sensory, social or emotional environment
* Intervention Requirements:
  + brief duration (maximum intervention = 3 hours within one day; data collection may extend more hours & over days)
  + painless/harmless (transient performance task-related stress, anxiety, or boredom are acceptable)
  + not physically invasive (no activity tracker, blood pressure, pulse, etc.)
  + unlikely to have a significant adverse lasting impact on subjects
  + unlikely that subjects will find interventions offensive or embarrassing
  + no deception / omission of information, such as study purpose, unless subject prospectively agrees.

**At least one of the following MUST be checked.**

(i) Recorded information cannot readily identify the subject (either directly or indirectly)

(ii) Any disclosure of subjects’ responses outside the research could NOT reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation

(iii) Information is recorded with identifiers and the investigator specifies strong security measures to protect the data (e.g., encryption for electronic data, multiple locks for paper data)

**4)** **Secondary Research**: Secondary Research for which consent is not required: use of identifiable information or identifiable biospecimens that have been or will be collected for some other ‘primary’ or ‘initial’ activity if at least one of the following criteria is met.

**At least one of the following MUST be checked.**

(i) identifiable information or biospecimen is **publicly available**

(ii) information recorded by the investigator **cannot readily, directly or indirectly identify the subject**, and the investigator **does not contact** the subject or **re-identify** the subject;

(iii) research **involves only** collection and analysis involving investigator’s use of identifiable health information when use is regulated by HIPAA (this will be reviewed and approved as expedited)

(iv) research information collected by or on behalf of the federal government using government-generated or -collected information obtained for non-research activities

**5)** **Research and Demonstration Projects on Federal Programs**: The study is conducted pursuant to specific federal statutory authority and examines certain federal programs that deliver a public benefit [call IRB for details if you think your study may fit].

**6)** **Food Tasting/Evaluation**: Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

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| **PART II — Abbreviated Application** | | | |
| 1. Project Title: Click to enter text. | | | |
| 1. Principal Investigator:  Dr.  Ms.  Mr. Enter PI Name | | | |
| Department: Click to enter text. | Dept Chair’s email (for cc of approval): Click to enter text. | | |
| Work Phone: Click to enter text. | Home or Mobile Phone: Click to enter text. | | |
| E-Mail Address: Click to enter text. | | | |
| **If Principal Investigator is a student:** | | | |
| Graduate student:  Dissertation  Master’s thesis  Other graduate project | | Undergraduate student:  Senior thesis:  SMBHC  Croft Institute  Other undergraduate project | |
| Research Advisor: Advisor Name (required for student researchers) | | | |
| Department: Click to enter | | | Work Phone: Click to enter |
| E-Mail Address: Click to enter | | | Home or Cell Phone: Click to enter |
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| 1. **Funding Source:**   Is this project funded?  Yes No  If Yes, is the funding:  Internal : Source: Click to enter  External : Pending/Agency: Click to enter  Awarded/Agency: Click to enter  PI(s) on external funding: Click to enter | | | |
| 1. **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 OR the Alternative to CITI/ Abbreviated CITI (ACITI) training**](http://www.research.olemiss.edu/irb/education) **before this application will be processed\*.**  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | PERSONNEL NAME | **PERSONNEL EMAIL (REQUIRED) \*** | FACULTY  **OR STAFF** | GRADUATE  **STUDENT** | UNDERGRAD  **STUDENT** | 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 | | 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 |   **If space is needed to list additional project personnel or non-UM personnel, submit** [**Appendix A**](http://www.research.olemiss.edu/irb-forms).  **\*See** [**Exempt Human Research Policy**](https://secure4.olemiss.edu/umpolicyopen/ShowDetails.jsp?istatPara=1&policyObjidPara=11082360) **for training exceptions** | | | |

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| **Research Methodology/Procedures** | |
| 1. **Check all procedures below that apply to your study:** | |
| Pre-existing data or biological samples  - Source of data: Click to enter text.  -Do data/samples have identifiers? Yes\* No  **\*** PHI be reviewed and approved as expedited and a HIPAA waiver authorization request (Appendix F) will be needed. | |
| **\*Describe how data will be secured** (e.g., encryption for electronic data; multiple locks for paper data).  Click to enter text.  Will physical copies of identifiable data be kept? Yes**\*** No  If yes, please list the data storage location (office/room number): Click to enter text.  \*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). | |
| Observation  Oral history- Use and attach the required [release form](http://www.research.olemiss.edu/irb-forms) if you plan to disseminate **quoted** comments or taped content from histories, interviews, and/or groups. (This covers you and UM legally – Not for IRB purposes)  Interview- Attach interview questions.  Focus group- Attach topic and questions. | |
| Questionnaire or survey\* - Attach questionnaire or survey  If online, list platform (e.g., Qualtrics): \*If using Qualtrics for anonymous surveys, [see guidance here.](http://www.research.olemiss.edu/irb/guidance/qualtrics)  Click to enter text. | |
| The study has misleading or deceptive\*  (1) study descriptions;  (2) procedure explanations; and/or  (3) survey instructions/rationales.  \*In the abstract, provide complete details and a rationale for employing misleading/deception information. Include [**Appendix D**](http://www.research.olemiss.edu/irb-forms) in your attachments. | |
| 1. **Consent Procedures:** | |
| Oral -Attach script\*  Information Sheet/Cover Letter - Attach\* **No subject signatures required**,  Not applicable, Explain Click to enter text.  \*For both oral consent and the information sheet see our ‘Sample Information Sheet’ [example here](http://www.research.olemiss.edu/irb-forms): under Templates. This template is for exempt protocols only and ensures that all elements of consent are addressed. | |
| **Project Summary** | |
| 1. **Briefly summarize your project using non-technical, jargon-free language that can be understood by non-scientists.**   **See** [**http://www.research.olemiss.edu/irb-forms**](http://www.research.olemiss.edu/irb-forms) **for abstract examples.** | |
| **Give a brief statement of the research question supporting the reasons for, and importance of, the research:** Click to enter text. | |
| **Describe the ages and characteristics of your proposed subjects.**  Click to enter text. | |
| For studies using only adult subjects, state how you will ensure they are 18+: Not applicable  First question on survey/interview  Other: Click to enter text. | |
| **Recruitment Procedures**: **a.** How will you recruit subjects? Check all that apply:  Sona System  Class announcements  Letters to parents/guardians  [Recruitment materials **must** state “This study has been reviewed and determined to be Exempt by UM’s Institutional Review Board (IRB). | E-mail – specify groups: Click to enter text.  Radio/TV/newspaper ads  UM bulletin boards, where: Click to enter text.  Other: Click to enter text.  [List all recruitment sites.] |
| ***Briefly* describe the research design AND carefully explain how your study will meet each of the requirements of the category criteria you checked on Page 2**: Click to enter text. | |
| Give a *detailed* description of the procedure(s) subjects will undergo (from their perspective):  Click to enter text. | |
| 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. Does your research involve deception or omission of elements of consent?**  No  Yes – complete [Appendix D](http://www.research.olemiss.edu/irb-forms)  **D. Will your research be conducted outside of the United States?**  No  Yes – complete [Appendix E](http://www.research.olemiss.edu/irb-forms)    **E. Will your research involve** [**protected health information (PHI)**](https://privacyruleandresearch.nih.gov/irbandprivacyrule.asp)**?**  No  Yes – complete [Appendix F](http://www.research.olemiss.edu/irb-forms) if applicable | |

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| 1. **Attachments Checklist:**   **Do you have:**   1. **Advisor assurance** – required for student research protocols   Yes  Not Applicable   1. S**urvey or questionnaires?**   Yes  Not Applicable   1. I**nterview questions?**   Yes  Not Applicable   1. F**ocus group questions?**   Yes  Not Applicable   1. **Recruitment email, announcement, or script?**   Yes  Not Applicable: No subject contact   1. **Information sheet or oral script?**   Yes  Not Applicable: No subject contact   1. **Debrief statement and re-consent**   Yes  Not Applicable   1. **Permissions for locations outside the University? \***   Yes  Not Applicable  **\*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. **If using class points as incentives, are there alternative assignments available for earning points that involve comparable time and effort?**   Yes  Not Applicable   1. **If using an anonymous survey through Qualtrics and giving incentives in a separate survey, have you read and conducted the testing of the surveys according to the** [**procedures here?**](http://www.research.olemiss.edu/irb/guidance/anonymous)   Yes  Not Applicable |

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| **Part III: 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 describe any potential conflict of interest. Click to enter text. |
| **Do you or any person responsible for this study have existing financial holdings or relationships with the sponsor of this study?** | |
| Yes  No  Not applicable | If Yes, please describe any potential conflict of interest. Click to enter text. |
| **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:   * Informed consent will be obtained from the participants, if applicable and appropriate; * Any proposed modifications to the research protocol that may affect its designation as an exempt (brief) protocol application will be reported to the IRB for approval prior to being implemented. * 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 or CITI Alternative courses in the ethical principles and regulatory requirements for the protection of human research participants.  Click to enter text. Click or tap to enter a date.  **Typed signature/name of Principal Investigator Date** | |
| **Research Advisor’s\* Assurance (required for student projects)**  **\*The research advisor must be a UM faculty member with current CITI training. The faculty member is considered the responsible party for the ethical performance and regulatory compliance of the research project.**  Email your Advisor with the following:  1. Email subject line: **“IRB Advisor Approval Request from (your name)”**  2. Your IRB submission materials as attachments  3. Copy and paste the statements below into the body of the email  4. Save the reply email from your Advisor as a pdf and submit via the online portal along with your IRB submission materials**. Protocol review cannot begin without an advisor assurance for student PIs.**  **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.** | |

**\*Please upload your materials to the online portal using the following file naming system:**

Lastname advisor assurance ex. Smith advisor assurance.pdf

Lastname IRB exempt application ex Smith IRB exempt application.doc

Lastname recruitment script

Lastname information sheet

Lastname appendix A-F

Lastname survey/interview/group materials

**\*** Please upload the application and information sheet as word documents.

The online submission portal can be found at : <https://research.olemiss.edu/irb/submit>