**INSTRUCTIONS**

Mississippi College established the Institutional Review Board (IRB) to protect the rights of human participants and to promote professional research. The Mississippi College IRB and application to the IRB are based on federal guidelines and requirements. Details of these are provided at National Institutes of Health (NIH) and US Department of Health and Human Services (HHS) websites and by the training provided by these agencies.

There are three types of review and approval status you may receive from the IRB: Exempt Review, Expedited Review, or Full Board Review. While most studies at MC qualify for Exempt status, the majority of faculty require their students to go through the process of obtaining Expedited status to give students the opportunity to learn about conducting more advanced research. Expedited status requires Human Subjects Research training (obtained without cost online – see the IRB website) and usually an informed consent document.

Please check one of the following to indicate the level of review you would like your student to seek:

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| **EXEMPT REVIEW** |  | Go to page 3. |
| **EXPEDITED REVIEW** |  | Go to page 8. |
| **FULL IRB REVIEW** |  | If you answered “yes” to any questions in Section 7 while completing the Expedited Review Section, check the Full Board Review box on page 16. |

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| **Application Submission Checklist** |
| Complete this electronic application and checklist and submit via email to the Institutional Review Board at irb@mc.edu. Please include your name and date in the file name when saving this file for sending as an email attachment. **Handwritten applications will not be accepted.**  **For student researchers, this application must be sent**  **from your faculty advisor’s email account.**  **AGREEMENT: I understand that electronic submission of this applications from my Mississippi College email account constitutes my signature.**  **Required items for submission:**  Informed Consent Form (unless Waiver of Informed Consent is requested (see page 8 of this application) (For research with minors, both parental permission and child assessment are required).  IRB Training certificates for you and ALL co-investigators, faculty advisor, research assistances, etc.  Methodology section fully describing study procedures and methods.  For student researchers, faculty advisor approval and submission of IRB application and protocol.  **Additional items to submit, if applicable:**  Surveys/Questionnaires (paper or online) in **final** version.  Psychometric testing instruments and assessments.  Interview and focus group questions.  Recruitment scripts (email, telephone, verbal announcement, postcard, brochure, flyer, etc.).  Request for Waiver of Informed Consent document, if applicable  Letter(s) of permission/cooperation to recruit participants and/or conduct the research project from school(s), organization(s), or any off-campus location.  **Involvement of co-investigators from other institutions:**  Documentation of IRB approval from the co-investigator’s institution/organization. |
| Submit your application to the IRB at [irb@mc.edu](mailto:irb@mc.edu)  **Incomplete applications may result in delay of your application approval.**  **Please review all sections carefully before submitting.** |

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| **EXEMPT REVIEW** |  |

Exempt Review may be offered to research that does not require initial or continuing review by the IRB. If you feel your research meets the following criteria, complete the following sections and submit your application via email to [irb@mc.edu](mailto:irb@mc.edu). Otherwise, continue to the Expedited Review section.

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| **Application for Exempt Review**  Please complete this form to request an Exempt Review. An Exempt research project may qualify for a Waiver of Informed Consent. **Note: Only the IRB may determine which activities qualify for Exempt Review.**  Tab to or click on each block and type in your information. The box will expand as you type. Email completed application to irb@mc.edu. | | | | | |
| **Application Date** |  | | | | |
| **Project Title** |  | | | | |
| **Principal Investigator Information** | Name |  | | E-mail |  |
| School and Department |  | | Status:  Select one | Faculty/Staff Student Other  (If student, provide information for responsible faculty below.) |
| Campus or Mailing Address |  | | Phone |  |
| **Faculty Advisor, if PI is a student** | Name |  | | E-mail |  |
| School and Department |  | | Phone |  |
| List additional co-investigators below, including those from other institutions. Please attach contact information for additional researchers. Use an additional page to list co-investigators if needed. | | | | | |
| **Name and Credentials**  **(PhD, MS, etc.)** | | | **Department and School (provide address if off-campus)** | | **Contact Information** |
|  | | |  | | Phone: |
| E-mail: |
|  | | |  | | Phone: |
| E-mail: |
|  | | |  | | Phone: |
| E-mail: |
| **Purpose of the Project** | | | | | |
| In the box below, provide a brief summary (250 words) of the purpose of the project in layman’s terms including  (a) background information as necessary, (b) research question(s), and (c) explanation of why the study is needed. | | | | | |
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| **Participant Information** |
| Explain exactly what the participants will be asked to do. Include the amount of time that each participant will need to devote to the study. Include copies of any questions or surveys that will be given to the participants with your application. You should not collect any data, especially personally identifiable information (PII) (e.g. name, date of birth, address, phone number, e-mail address, social security number), unless doing so is necessary and you have specific plans to analyze or otherwise make use of the data. If PII is collected, there must be a plan for the protection of each individual’s information, to maintain confidentiality. Explain how each variable measured supports the purpose of your study. If methodology involves interviewing participants, include a list of interview questions, and attach them as an appendix to this application. If this is part of a thesis or dissertation insert your entire Methodology section below. Use as much space as necessary. If there is not enough room below please attach an additional document addressing this information. |
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| Please check all descriptors that best apply to this proposed research project.  Note: To be eligible for Exempt Review, ONLY the characteristics listed in the left column may exist. If your study meets any of the characteristics in the RIGHT column, an Expedited Review may be necessary. | |
| **Data Collection Method** | |
| Surveys/Questions | Private records/ files |
| Educational tests (cognitive, diagnostic, aptitude) | Interview/Observation |
| Public archival data | Audio or video recording |
|  | Physical procedure (body measurements, venipuncture, etc. |
| **Participant Information** | |
| Individuals 18 years and older | Individuals younger than 18 |
| General population | Vulnerable population (mentally, or physically impaired; prisoners; elderly; pregnant women; fetuses; non-English speakers |
| **Factors of Participation** | |
| Voluntary | Involuntary |
| Confidential | Social, physical, or psychological risk |
| Anonymous | Potential for more than minimal risk\* |
| \***Minimal Risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. | |

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| **Categories for Exempt Review** | | |
| **IF NO CHECKS WERE PLACED IN THE RIGHT-SIDE COLUMN ON THE PREVIOUS PAGE:** Your study may qualify for Exempt Review. Only the IRB may determine which activities qualify for Exempt Review. From the six categories presented below, check “Yes” for the categories that you believe describe your proposed research and “No” for all others. If none of the categories apply, your research may not qualify for Exempt review and you may need to have a signed Informed Consent form from participants.  **INFORMED CONSENT:** If your research project **will not** qualify for Exempt Review based on one or more of the following categories, please move on to the Expedited Review section. You will need to develop an Informed Consent form and attach it as a separate file with your completed application. Contact the IRB Chair if you have questions at [irb@mc.edu](mailto:irb@mc.edu).  **Check “Yes” or “No” for each item below.** | | |
| **Categories of Exemption** | **Yes** | **No** |
| **Evaluation/Comparison of Instructional Strategies** – Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. This exemption category cannot be used for FDA regulated research.  **If “Yes,”** in the box below describe the educational setting in which the research will be conducted and the type of normal educational practices involved. |  |  |
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| **Educational Tests, Surveys, Interviews, or Observations** – Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation. This exemptions category cannot be used for FDSA regulated research. |  |  |
| **Public Officials or Candidates for Public Office** – Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under the previous paragraph if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. This exemption category cannot be used for FDA regulated research.  **If “Yes,”** in the box below describe how subjects may be identified or are at risk, or state the Federal statute that allows the confidentiality of the subject to be maintained throughout the research and thereafter. |  |  |
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| **Collection or Study of Existing Data** – Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. This exemption category cannot be used for FDA regulated research.  Note: To qualify for this exemption, the data, documents, records, or specimens must be in existence before the project begins. Additionally, under this exemption, an Investigator (with proper authorization) may inspect identifiable records, but may only record information in a non-identifiable manner. |  |  |
| **Research and Demonstration Projects** – Research and demonstration projects which are conducted by or subject to approval of Federal Departmental or Agency heads (such as the Secretary of HHS), and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; (iv) possible changes in methods or levels of payment for benefits or services under those programs. This exemption category cannot be used for FDA regulated research. If “Yes,” proof of approval by Department/Agency Head should be attached.  Note: This exemption applies to Federally funded projects only and requires authorization or concurrence from the funding agency. Additionally, specific criteria must be satisfied to invoke this exemption. Also, this exemption category does not apply if there is a statutory requirement that this project be reviewed by an IRB or if the research involves physical invasions or intrusion upon the privacy of subjects. |  |  |
| **Food Quality Evaluation and Consumer Acceptance Studies** – Taste and food quality evaluation and consumer acceptance studies (i) if wholesome food, 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 contaminate at or below the level found to be safe by the FDA or approved by the EPA or the Food Safety and Inspection Service or the U.S. Department of Agriculture. |  |  |

If you answered “Yes” to any of the above categories, you may STOP here and submit your application to the IRB at [irb@mc.edu](mailto:irb@mc.edu). If you wish a Waiver of Informed Consent, please answer the following question:

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| **Waiver of Informed Consent** | | |
|  | **Yes** | **No** |
| The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants if certain conditions are met and if sufficient justification is provided. The research should involve no more than minimal risk to the subjects; the waiver will not adversely affect the rights and welfare of the subjects, the research could not practicably be carried out without the waiver; and, whenever appropriate, the subjects will be provided with additional pertinent information after participation.  A waiver may be granted if the only record linking the subject and the research would be the consent document and the principal risk would be potential harm from a breach of confidentiality. Each subject should be asked if he or she wants documentation linking himself or herself with the research, and his or her wishes should govern.  Check box to the right indicating waiver request. If waiver is not being requested, provide a copy of the Informed Consent form to be used for this study. |  |  |

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| **EXPEDITED REVIEW** |  |

Research that meets criteria for Expedited Review is reviewed by the IRB Chair or IRB Member and must present only minimal risk to human subjects and only involve procedures in one or more of the categories described in Section 7. Most MC research studies will fall in to this category.

The following categories of research may qualify for Expedited Review according to the US Department of Health and Human Services:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   1. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   2. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   1. (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   2. from other adults and children [[2]](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html" \l "footnote2), considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means.  
   Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)  
   Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101(b)(4)](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101(b)(2)](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html) and (b)(3). This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB as follows:
   1. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   2. where no subjects have been enrolled and no additional risks have been identified; or
   3. where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

[[1]](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html" \l "backfootnote1) An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in [45 CFR 46.110](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html).

[[2]](http://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html" \l "backfootnote2) Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." [45 CFR 46.402(a)](http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html).

Source: [63 FR 60364-60367](http://www.hhs.gov/ohrp/news/federal-register-notices/federal-register-11-09-1998-vol-63-no-216/index.html), November 9, 1998.

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| **Application For Expedited Review**  Tab to or click on each block and type in your information. The box will expand as you type.  Email completed application to irb@mc.edu. | | | | | |
| **Application Date** |  | | | | |
| **Project Title** |  | | | | |
| **Principal Investigator Information** | Name |  | | E-mail |  |
| School and Department |  | | Status:  Select one | Faculty/Staff  Student  Other  (If student, provide information for responsible faculty below.) |
| Campus or Mailing Address |  | | Phone |  |
| **Faculty Advisor, if PI is a student** | Name |  | | E-mail |  |
| School and Department |  | | Phone |  |
| List additional co-investigators below, including those from other institutions. Please attach contact information for additional researchers. Use an additional page to list co-investigators if needed. | | | | | |
| **Name and Credentials**  **(PhD, MS, etc.)** | | | **Department and School (provide address if off-campus)** | | **Contact Information** |
|  | | |  | | Phone: |
| E-mail: |
|  | | |  | | Phone: |
| E-mail: |
|  | | |  | | Phone: |
| E-mail: |

**Principal Investigator Agreement**

I certify that I, as well as all co-investigators, have completed the required Mississippi College IRB online training and that certificates for each investigator are included with this application. I agree to not begin data collection/analysis until I receive IRB approval. I agree to obtain approval before making any changes or additions to the project. I will provide progress reports at least annually or as requested. I agree to report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects. A copy of the informed consent will be given to each subject, if applicable, and, if applicable, a signed original will be retained in my files.

Principal Investigator Initials: \_\_\_\_\_\_\_\_\_\_

**Faculty Advisor Agreement** (If the Principal Investigator is a student)

I certify that, as the student’s faculty advisor, I have read and approved the materials submitted and completed the required Mississippi College IRB online training.

Faculty Advisor Initials: \_\_\_\_\_\_\_\_\_\_\_

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| 1. **Completion of required Human Subjects Training for all investigators. NOTE:** Investigators from institutions or organizations not affiliated with Mississippi College must either complete Mississippi College’s required online IRB Training or provide documentation that similar training has been completed elsewhere. Use an additional page to list co-investigators if needed. | | | |
| Investigator Name | IRB Training Institution | Certificate Number | Date of Certification |
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| 1. **Current or Planned Funding Source (Internal or External)** | |
| Has project received approval for grant funding?  Yes  No | |
| Grant/Contract No. (if available): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Funding Source: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| 1. **Conflict of Interest** |
| Will members of the research team have financial interest in, receive personal compensation from, or hold a position in an industry sponsoring this study or otherwise have a potential conflict of interest regarding the conduct of this study?  Yes  No If yes, please provide explanation in the box below. |
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| 1. **Student Investigators** |
| Check box(es) below:  Undergraduate  Masters  Education Specialist  Doctoral  None |

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| 1. **Purpose of the Project** |
| In the box below, provide a brief summary (250 words) of the purpose of the project in layman’s terms including  (a) background information as necessary, (b) research question(s), and (c) explanation of why the study is needed. |
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| 1. **Enrollment Information** | |
| Expected Number of Participants | \_\_\_\_\_\_ |
| Expected Gender Representation | Males: \_\_\_\_\_\_ Females: \_\_\_\_\_\_ |
| Expected Age Range of Participants | \_\_\_\_\_\_ to \_\_\_\_\_\_ |

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| 1. **Vulnerable Populations** | | |
| A “Yes” response to any one of items A through E will necessitate Full Review and Written Informed Consent from the participants and/or the participant’s parent or guardian. Complete the rest of this application, including the Full Board Review section below. | | |
| **Type of Population:** | **Yes** | **No** |
| 1. Children: minors under 18 years of age. |  |  |
| 1. Non-English speaking. |  |  |
| 1. Decisionally impaired or mentally incompetent. |  |  |
| 1. Prisoners, parolees, and/or other convicted offenders. |  |  |
| 1. Pregnant women. (Check “Yes” if study is about pregnancy, pregnant women, and/or the fetus or neonate.) |  |  |

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| 1. **Participant Information** |
| Explain exactly what the participants will be asked to do. Include the amount of time that each participant will need to devote to the study. Include copies of any questions or surveys that will be given to the participants with your application. You should not collect any data, especially personally identifiable information (PII) (e.g. name, date of birth, address, phone number, e-mail address, social security number), unless doing so is necessary and you have specific plans to analyze or otherwise make use of the data. If PII is collected, there must be a plan for the protection of each individual’s information, to maintain confidentiality. Explain how each variable measured supports the purpose of your study. If methodology involves interviewing participants, include a list of interview questions, and attach them as an appendix to this application. If this is part of a thesis or dissertation insert your entire Methodology section below. Use as much space as necessary. If there is not enough room below please attach an additional document addressing this information. |
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| 1. **Summary Checklist** | | | |
| These items ARE NOT an all-inclusive list of methods or procedures but are intended to provide “triggers” or reminders for you to provide appropriate information in subsequent questions in the application or to provide supplemental materials necessary for the review process. | | | |
| **Checklist Item:** | | **Yes** | **No** |
| 1. Will research include use of existing data, research records, patient records, retroactive chart review, and/or human biological specimens (Submit data collection form with this application.)? | |  |  |
| 1. Will data collection include surveys, questionnaires, or psychometric testing (Submit copy of survey/questionnaire with this application.)? | |  |  |
| 1. Will data collection include interviews or focus groups (Provide interview/focus group questions with this application.)? | |  |  |
| 1. Will research include deception or less than full disclosure? | |  |  |
| 1. Will research include accessing student educational records? | |  |  |
| 1. Will data collection include: | Audio recording? |  |  |
| Video recording? |  |  |
| Photography? |  |  |

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| 1. **Full Description of the Study Procedures** | |
| What is the study design or the research method to be used? |  |
| What will you ask your participants to do or what will you do to your participants? |  |
| What data will you collect? |  |
| What are you attempting to learn or identify by conducting this study? |  |
| What will be the duration of the entire study? |  |
| What is the duration each participant will be involved in the study (i.e., the approximate length of time and number of sessions, surveys, or observations)? |  |
| What follow-up with participants will be required (if any)? |  |
| Where will participants be studied (if off Mississippi College’s campus, please indicated addresses of locations and include any letters indicating permission to conduct the research in off-campus locations)? |  |

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| 1. **Full Description of the Population (Sample)** | |
| How will you identify your population, and what is the sampling method? |  |
| How will participants be recruited (Explain how participants will be contacted and submit any recruitment script, letters, flyers, or advertising in its final print or electronic form)? |  |

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| 1. **Confidentiality (The IRB expects researchers to access the minimal amount of data to conduct the study and to comply with federal regulations pertaining to privacy and the management of protected information.)** | |
| How will participant’s identities be protected or eliminated from the data (including surveys, audio/video recordings, photographs, etc.)? |  |
| During the study, where will data be stored? What security measures will be applied? |  |
| Who will have access to the data? Provide explanation of why they need access. |  |
| If data is to be shared with entities not affiliated with Mississippi College, what are the procedures for ensuring confidentiality? |  |
| When and how will data be destroyed, or if it will not be destroyed, how will it be stored after the study is complete? |  |

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| 1. **Risks and Benefits to Society and Participants** | |
| What are the risks to participants associated with participating in the study (psychological, social, economic risks; known side effects; risk of pain/injury)? |  |
| What measures will be used to minimize risk? |  |
| What benefits to society may be achieved by conducting this study? |  |
| What benefits to participants may be experienced by participating in the study? |  |
| What incentives will be provided to participants (if any)? |  |
| What costs may be required of participants? |  |
| What happens if participants decline all or a portion of the procedure or choose to discontinue prior to completion of the study? |  |

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| 1. **Data Analysis** | |
| How will the data be analyzed? |  |
| Who will perform the data analysis? |  |

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| 1. **Informed Consent** | |
| Describe the process for obtaining informed consent (if applicable). |  |

If you provided a “Yes” response to any one of items A through E will” in section 7 above, you will need to check “Yes” below and undergo a Full Board Review.

If you did NOT provide a “Yes” response to any one of items A through E will” in section 7 above, you may proceed to the Application Submission Checklist on the next page.

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| **FULL BOARD REVIEW** |  |

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| **Full Board review** | **Yes** |
| My application will require Full Board Review |  |

We’ll use the information you provided in the Expedited Review application above to conduct a Full Board Review.

Please continue to the Application Submission Checklist on the next page.