The Mississippi College Institutional Review Board (IRB) was established to protect the rights and welfare of research subjects. It is modeled following standards established by the U.S. Department of Health and Human Services (HHS). Specifically, the regulations 45 CFR 46, also known as the Common Rule, are employed.

IRB members use the ethical principals of the Belmont Report, issued in 1978 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The principals are:

- Respect for persons
  - Treat individuals as autonomous agents
  - Protect persons with diminished authority
- Beneficence
  - Do unto others as you would have them do unto you
- Justice
  - Distribute the risks and potential benefits of research equally among those who may benefit from the research

The MC IRB patterns decisions for approval of IRB application submissions after the HHS’ Decision Charts (http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html).
Mississippi College IRB Application Process

Please make certain your Request for External Review application is complete using the Submission Checklist on page 2. Especially important is your proof of certification for the required HHS Human Subject Research Training.

You must make certain you have completed the online HHS Human Subject Research Training (http://www.hhs.gov/ohrp/education/training).

If your IRB application is not complete, it will be returned to you and no further action will be taken until it is resubmitted.
If your IRB application is complete, the Board Chair will determine in which category your submission belongs. The length of time required for review and decision is as follows:

- **Exempt**: 1-2 weeks
- **Expedited**: 2-4 weeks
- **Full Board Review**: 4-8 weeks
Your IRB submission will be deemed Exempt if your research represents no more than minimal risks to participants and does not involve special populations (such as the mentally retarded, some types of studies with children, prisoners, etc.). The purpose of this review is to determine if research is in keeping with the exempt categories as defined by regulation and thus exempt from Expedited or Full Review. Research that falls into one of the categories below may deemed Exempt:

- 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.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), 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.
- 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.
- Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, 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; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- 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.

It should be noted that only members of the IRB may determine that a study is exempt from Expedited or Full Review. If the category is determined to be Exempt, no further review is needed and you will receive an Exemption Letter in the form of an email. You may begin your research upon receiving the Exemption Letter, but you must notify us of any changes in your study.
Mississippi College IRB Application Process

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/humansubjects/guidance/45cfr46.html).

Your IRB submission will be deemed appropriate for Expedited Review if your activities present no more than minimal risk to human subjects, and involve only procedures listed in one or more of the following categories fully described at the HHS website (http://www.hhs.gov/ohrp/policy/expedited98.html). The categories involve (1) clinical studies of drugs and medical devices, (2) collection of blood samples, (3) collection of biological specimens by noninvasive means, (4) collection of data through noninvasive procedures, (5) research involving materials that have been collected, or will be collected solely for nonresearch purposes, (6) collection of data from voice, video, digital, or image recordings,

(7) research on individual or group characteristics or behavior, (8) continuing review of research previously approved by the convened IRB, and (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.

When approved, you will receive an Approval Letter. At this point, you may begin your research! If the Board recommends revisions to your IRB submission and/or imposes contingencies, you will need to make the necessary changes and resubmit your application.
Your IRB submission will be deemed appropriate for Full Board Review if your research has potential risk to human subjects. This may include but is not limited to:

- Research that involves the administration of drugs or other substances to subjects where an IND/IDE are required,
- Research that materially affects the pregnancy of a woman or the health/well-being of fetuses in utero,
- Research involving subjects with life-threatening physical conditions,
- Research involving physically intrusive procedures,
- Research which previous experience (by the particular investigator or other investigators) has been shown to create a potential of risk to subjects,
- Research that may result in a significant level of psychological or physical stress,
- Research which potentially could put the subject at risk for legal or civil liability or invade a subject’s privacy in regard to sensitive aspects of his/her behavior (e.g., illegal conduct, drug use, sexual behavior, alcohol use) when there is a possibility that the subject could be identified,
- Research involving prisoners,
- Research that places protected populations (such as children, mentally retarded individuals, mentally ill individuals, patients with medical disorders) at more than minimal risk,
- Research involving waivers of any HIPAA regulations.

When approved, you will receive an Approval Letter. At this point, you may begin your research! If the Board recommends revisions to your IRB submission and/or imposes contingencies, you will need to make the necessary changes and resubmit your application.