The Informed Consent Form must include these required elements:

- Title of the study, exactly as it appears on the human participant’s application
- Affiliation with Florida A&M University (clearly identify who you are and your role in this project)
- Investigator contact information (and advisor contact information, if investigator is a student)
- Purpose of the study
- Procedures to be followed
- Discomforts or risks (if none are known, state as such)
- Benefits of the study to participants and society
- Duration/timeframe of participation
- Compensation (if applicable)
- Statement that participation is voluntary
- Statement that participants may withdraw their participation at any time (if data collection is not anonymous)
- Statement that participants can decline to answer specific questions, if applicable
- Confidentiality assurances, procedures (How the data will be kept secure and confidential, please remember that Georgia is an “Open Records” state and you cannot guarantee confidentiality).
- Statement that participants must be 18 years of age or older to participate. If subjects are minors, parental consent and minor’s consent is required.
- Signature and date lines (for participants and investigators), unless using passive consent
- Connecting page numbers if more than one page (e.g. Page 1 of 2, Page 2 of 2)
- To contact the Office of Animal Welfare and Research Integrity for Answers to questions about the rights of research participants please email IRB@famu.edu or call 850-412-5246.

*A parental informed consent form used when minors are involved must also contain the above elements, but will need to be reworded to reflect that the parents are consenting for their children to participate.

Additional Considerations of Informed Consent:

1. All wording must be an 8th grade reading level or below. A layperson or someone unfamiliar with your research should easily understand it. Avoid highly technical terms, jargon, etc.

2. Injury clause should be included if any risk of injury exists (physical or psychological).
The Review Process

Types of Review and Review Timeframe

* Full Board Review – Research protocols which required full board approval are forwarded to all members of the committee at least two weeks in advance of the scheduled meeting dates to allow time for each member to individually review each application. The applications are then discussed at the scheduled meeting by the full committee. A quorum, defined as a majority of the committee’s membership, must be present for the meeting.

Researchers need to allow sufficient time for this review process to occur, including the possibility that the committee might request additional information and/or changes in the protocol, thus requiring a second board review. While most proposals are reviewed under the “expedited” process, it is possible that a full board review may be necessary. The need to be aware of meeting dates and submission deadlines is imperative.

* Expedited Review – Researchers need to understand that requesting an “expedited review” has a particular meaning under federal regulations, and that this type of review (described in the next paragraph) may actually require a longer amount of time than expectations about the word “expedited”. For this reason, please allow ample time for the review of an expedited application, which may take up to three weeks to complete.

When an expedited review seems appropriate, the protocol will be forwarded to at least two committee members for their independent review. If committee members agree that the research falls within the categories for which an expedited review is permitted and involves no more than minimal risk, and agree that the research can be approved, or conditionally approved with only minor modifications, the IRB will so inform the researcher and notify the committee at its next meeting. If the reviewers do not agree on an action, or if any of them so requests, the protocol will be considered ineligible for expedited review and will be placed on the agenda for the next meeting to receive a full board review. Applicants are notified of this action and advised that they may elect to attend the next IRB meeting, if they so desire.

*Exempt Approval – Exempt requests are reviewed by the Animal Welfare and Research Integrity according to the definition and regulatory standards for exempt activities. Researchers are reminded that the IRB must grant exemption; the researcher may not make that determination.

Length of IRB Approval

The IRB usually approves research for a period of one year, which is the maximum allowed [Federal Policy §46.109 (e)]. Investigators who need to continue their research beyond that time may request up to two one-year extensions. This request may be made by submitting a completed Continuation Request Form to the committee.