MEREDITH COLLEGE MANUAL FOR INSTITUTIONAL REVIEW BOARD (IRB) REVIEW

The Meredith College IRB has created this manual to assist you in preparing materials for IRB review by providing a reference guide to the ethical principles, federal regulations, and institutional review processes for research involving human participants at Meredith. All research involving human participants carried out by Meredith College faculty, staff or students must be reviewed by the IRB. Research may not involve human participants prior to IRB review and approval. All those involved in conducting any aspect of research are encouraged to familiarize themselves with the content of this manual, especially when determining how to appropriately use the services of the IRB. A few key things to know before getting started:

1. Before applying for IRB approval, you need to know that anyone at Meredith College who will come in contact with human participants or human participants' data must receive appropriate Human Subjects Research Training via CITI (www.citiprogram.org) prior to contact with participants or access to data. Renewal training is required every 3 years. As part of the IRB application process, you will be asked to provide the names of all individuals who will have contact with participants or access to identifiable data from participants. If you have questions about accessing CITI training, please contact the IRB.
2. The IRB approval process is an ongoing one. After you receive approval of your initial IRB application, you will continue to interact with the IRB by:
    - Applying for a modification approval prior to implementing any planned changes to IRB-approved research protocols (such as recruitment materials, consent forms, or measures/surveys);
    - Applying for an annual renewal of your IRB-approved project if involvement with human participants will continue beyond the initial approval date.
    - Reporting promptly to the IRB any unanticipated problems involving risks to human participants or noncompliance with the IRB-approved protocol.
    - Applying for closure of the IRB-approved project once the involvement with human participants is completed and only data analysis will continue.

Meredith College has an agreement with the federal government (a "Federal Wide Assurance") covering all human participant research conducted by Meredith faculty, staff, and students. In the Federal Wide Assurance (FWA00030732), Meredith pledges that all of its research with human participants will be performed in accord with the ethical principles of the *Belmont Report* as well as the requirements of federal regulations governing human subjects research, 45 CFR 46, which prescribe the IRB procedures.

The "*Belmont Report*" is the short title of the report, "*Ethical Principles and Guidelines for the Protection of Human Subjects Research*" issued in 1979 by the U.S. Department of Health, Education, and Welfare from The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This statement of ethical principles for research with humans is the conceptual and ethical foundation for related federal regulations. The *Belmont Report* explains three key ethical principles in research with human subjects:

- **Respect for persons** (applied by obtaining informed consent, consideration of privacy, confidentiality, and additional protections for vulnerable populations);

- **Beneficence** (applied by weighing risks and benefits, i.e., ensuring that benefits to either society, in the form of knowledge, and/or to individual participants, outweigh the risks to participants); and
- **Justice** (applied by equitable selection of participants). This is relevant primarily when there is significant risk to participants, and/or significant benefit to participants; it is less of an issue for minimal risk, and minimal to moderate benefit to participants.

The full text of the report is available at https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/.

Title 45 Code of Federal Regulations Part 46: Protection of Human Subjects (45 CFR 46), published by the U.S. Department of Health and Human Services, standardizes basic human participant protection measures. It applies to all research with human participants at Meredith College. *Subpart A, Basic HHS Policy for Protection of Human Research Subjects*, of 45 CFR 46 is often called "**The Common Rule**" because it has been adopted by the majority of federal agencies that sponsor research with human participants. This document includes additional subparts outlining protections for vulnerable populations such as pregnant women, prisoners, and children. The full text is available at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html.

PROJECTS REQUIRING IRB REVIEW

There are two main factors you must consider in determining whether your project is a study that requires IRB review according to federal regulations. If you answer yes to both of the following questions, your project requires IRB review.

1. **Is it research**? Research is a systematic investigation (including research development, testing, and evaluation) designed to test a hypothesis, permit conclusions to be drawn, and develop or contribute to generalizable knowledge. All research conducted for the purpose of developing or contributing to generalizable knowledge requires IRB review, regardless of intent to publish or present results.
2. **Does it involve human participants**? A human participant is a living individual about whom an investigator (faculty, staff, or student) conducting research:
    a. Obtains information for study or analysis through intervention (physical procedures by which information is gathered; manipulations of the participant or participant's environment for research purposes) or interaction (communication or interpersonal contact between investigator and participant via telephone, email, online, or in person)

    OR

    b. Obtains, uses, studies, analyzes, or generates information that is identifiable (contains one or more data elements that can be combined with other reasonably available information to identify an individual) **AND** private (occurs in a context in which an individual can reasonably expect no observation or recording is taking place, such as a public restroom; or provided for a specific purpose by an individual who can reasonably expect it will not be made public, such as a health care record). The terms "identifiable" and "private" are separate, and **only when both are true does the research become research with human participants**. If secondary data are identifiable but publicly available, or private but not identifiable, then the research with those data is **not** considered to be human participants research.

If your project does require IRB review, your next step is to determine the level of review that is needed.

LEVEL OF REQUIRED IRB REVIEW

When submitting your *Application for IRB Approval of Human Participants Research*, the Principal Investigator (PI) makes an initial recommendation regarding whether the proposal qualifies for:

1) Exempted from continuing IRB review,
2) Expedited IRB review, or
3) Full Board IRB review.

The recommendation is based on the federally specified criteria described in the **Level of Review** section below. When making the recommendation, the PI should indicate the relevant supporting paragraph from this section (see "PI recommendations" on Page 1 of the IRB Application). It is possible the IRB Chair or IRB members, as a group, may decide to recommend a different category for approval.

The IRB documents all research with human participants for audit by the Office of Human Research Protections of the US Department of Health and Human Services. Therefore, all proposals for research involving human participants are to be sent to the IRB regardless of the review status recommended by the PI and regardless of funding status.

Exempted from Continuing IRB Review (Unless Protocol Changes): Research can be exempted from further IRB review or even from the federal regulations on research with human participants entirely if it (a) entails no more than minimal risk **AND** (b) falls in one or more of the categories described below. When completing the IRB application, PIs should reference the appropriate category number when making the recommendation of 'exempt from continuing review'.

Exemption categories (1), (4), (5), (6), (7), and (8) may be applied to research participants that are children (under age 18) if the conditions of the exemption are met. Exemptions 2(a) and 2(b) may only be applied to research participants that are children if involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Exemptions 2(c) and 3 may not be applied to research involving children. These exemptions do not apply to research participants who are prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

Category 1: Research conducted in established or commonly accepted educational settings that specifically involve normal educational practices that are 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 instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 2: Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if **AT LEAST ONE** of the following criteria is met:

a) The information obtained is recorded in such a manner that the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participants;

b) Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation;

c) The information obtained is recorded in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination that there are adequate provisions to protect participant privacy and maintain confidentiality of data.

Category 3: Research involving benign behavioral interventions (brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the participants, **AND** the investigator has no reason to think participants will find the interventions offensive or embarrassing) in conjunction with the collection of information from an adult participant through verbal or written responses (including data entry) or audiovisual recording if the participant prospectively agrees to the intervention and information collection and **AT LEAST ONE** of the following criteria is met:

a) The information obtained is recorded in such a manner that the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participants;

b) Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation;

c) The information obtained is recorded by the investigator in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review to make the determination there are adequate provisions to protect participant privacy and maintain confidentiality of data.

If the research involves deceiving the participants regarding the nature or purposes of the research, this exemption is not applicable unless the participant authorizes the deception through a prospective agreement to participate in research in circumstances in which the participant is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Category 4: Secondary research for which consent is not required. Secondary research uses of identifiable private information or identifiable biospecimens, if **AT LEAST ONE** of the following criteria is met:

a) The identifiable private information or identifiable biospecimens are publicly available;

b) Information, which may include information about biospecimens, is recorded in such a manner that the identity of the human participants cannot readily be ascertained directly or through identifiers linked to the participants, the investigator does not contact the participants, **AND** the investigator will not re-identify participants;

c) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under the HIPAA Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule; 45 CFR parts 160 and 164, subparts A and E) for the purposes of "health care operations" or "research" as those terms are

defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b);

d) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501.

Category 5: Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human participants.

Category 6: Taste and food quality evaluation and consumer acceptance studies:

a) If wholesome foods without additives are consumed, or

b) 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.

Category 7: Storage or maintenance of secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations that 1) broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained as required, 2) broad consent is appropriately documented or a waiver of documentation is appropriate, and 3) if there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of participants and maintain confidentiality of data.

Category 8: Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, **if ALL of the following criteria are met**:

a) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with the requirements for informed consent (outlined in the Basic HHS Policy for Protection of Human Subjects 45 CFR 46.116(a)(1) through (4), (a)(6), and (d));

b) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with the requirements for documentation of informed consent (outlined in the Basic HHS Policy for Protection of Human Subjects 45 CFR 46.117):

c) An IRB conducts a limited IRB review and makes the determination that adequate provisions have been made to protect the privacy of participants and maintain confidentiality of data and that the research to be conducted is within the scope of the broad consent; AND

d) The investigator does not include returning individual research results to participants as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

Expedited IRB Review: Research activities that (1) present no more than minimal risk to human participants, **AND** (2) involve only procedures listed in one or more of the categories below may be reviewed by the IRB through the expedited review procedure. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human participants. The categories in this list apply regardless of the age of participants, except as noted.

The expedited review procedure may not be used in instances for which identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. The expedited review procedure may not be used for classified research involving human participants. PIs should reference the appropriate paragraph number (i.e., category) below when making the recommendation of expedited review.

Category 1: Clinical studies of drugs and medical devices **ONLY** when condition (1) or (2) is met:

1) Research on drugs for which an investigational new drug application 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 (a) an investigational device exemption application is not required; or (b) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

1) From healthy, non-pregnant 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, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, 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.

Category 3: Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of

exfoliation or if routine patient care indicates a need for extraction; or (c) excreta and external secretions (including sweat).

Category 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. 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 participants or an invasion of the participant's privacy; (b) weighing or testing sensory acuity; or (c) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes.

Category 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.

Category 8: Continuing review of research previously approved by the convened (full board) IRB as follows:

1) Where (a) the research is permanently closed to the enrollment of new participants; (b) all participants have completed all research-related interventions; and (c) the research remains active only for long-term follow-up of participants; or
2) Where no participants have been enrolled and no additional risks have been identified.

Category 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 (full board) meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Full Board IRB Review: Research projects that are not exempted from continuing review (unless protocol changes) or eligible for expedited review by the IRB Chair must be reviewed and approved by the convened IRB, at a face-to-face meeting.

FACTORS IN IRB REVIEW

Risk: Minimal risk (for human participants other than prisoners) means that the probability and magnitude of harm and 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. Risk should be considered in terms of both severity and probability, and should not be understood to apply to only physical risk, though such risks are important to consider. In reviewing a study, the IRB evaluates emotional and psychological risks, potential insurability risks, as well as risks to professional or community standing. For example, in conducting a drug use survey, respondents could face severe penalties in the workplace or in their

community if their answers were revealed, though the survey itself does not represent a physical or psychological risk.

Risks to participants must be minimized by using procedures that are consistent with sound research design and do not unnecessarily expose participants to risk, and whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes. Risks to participants must be reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may be reasonably expected to result.

Benefit: In assessing the potential benefits of a study, researchers should consider the direct benefit to potential participants in the study (as may be the case in a study providing access to a valuable intervention) as well as the long-term societal benefits that the study may make possible through generalizable knowledge. Participant incentives for participation are not considered a benefit.

Selection of Participants: In accordance with Belmont principles, both the burdens and benefits of research should be distributed equitably. Equitable distribution of research burdens and benefits is an important factor in the selection of subject populations for a study when the study involves appreciable risk or appreciable benefit that is not otherwise obtainable.

Review and Documentation of Informed Consent: Any person invited to participate in a research study should be given a description of the study that is clear and complete enough for the individual to judge whether she or he wants to participate. Consent forms and informational letters should be written in simple language so as to be easily understood by persons with no technical background in the field. The standard consent process and documentation of that process is that all participants will sign a document containing all the elements of informed consent, as specified in the federal regulations. Some or all of the elements of the consent, or the documentation of consent, meaning signatures, may be waived under certain circumstances. Unless waived by the IRB, participants must sign and date the consent form prior to participation in the study. The signed consent form should be retained in the researcher's files and a copy of the consent form should be provided to the person giving consent. In the case that research participants are under the age of 18, both a parent/guardian permission to participate form and youth assent form must be signed and dated. A copy of each form must also be provided to the parent/guardian and youth, respectively. In the case of children too young to sign their name, the IRB may approve child verbal assent with parent/guardian signed and dated permission form. Unless the IRB approves exceptions, the following information must be provided to the participant when seeking informed consent:

- A statement that the study involves "research", an explanation of the purposes of the research and the expected duration of participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
- A description of any reasonably foreseeable risks or discomforts to the participant;
- A description of any benefits to the participant or to others that may be reasonably expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
- A statement describing the extent, if any, to which confidentiality of the records identifying the participant will be maintained;

- An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights. Questions concerning a research project should be referred to the Principal Investigator, whereas questions concerning the rights of human participants should be referred to the IRB Chair.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participants is otherwise entitled.
- One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
    - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant; or
    - A statement that the participant's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
- The approximate number of participants involved in the study; and
- The amount and schedule of incentive payments, if any.

Safety Monitoring: When appropriate, the research plan should make adequate provision for monitoring the data collected to ensure the safety of participants, i.e., the Data Safety Monitoring Plan (DSMP).

Privacy of Participants and Confidentiality of Data: There should be adequate administrative, procedural, and technical provisions to protect the privacy of participants and to maintain the confidentiality of data.

Additional Safeguards for Vulnerable Participants: When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, decisionally-impaired individuals, economically/educationally disadvantaged individuals, or those who have other vulnerabilities, such as women who are pregnant, additional safeguards must be included to protect the rights and welfare of these participants.

Recruitment and Payment of Participants: Researchers must use appropriate methods for identifying and recruiting potential research participants and compensating participants for their time. Participation must not be subject to undue influence.

THE PROCESS OF IRB REVIEW

In order to determine the type of review (exempt, expedited, full board) necessary, the IRB Chair screens the entire application and decides as to the type of review required. It is the responsibility of the IRB Chair to make the ultimate determination of whether or not a human participants study is exempt from continuing review as well as the type of review for studies not deemed exempt. PIs should anticipate that questions or concerns would emerge in the process of review by the IRB. Submission typically begins a dialogue between the IRB and the PI who seeks to resolve these

questions or concerns. Every effort is made in this process to proceed expeditiously so that the research may begin at the earliest possible time.

Exempt from continuing review: If the IRB Chair determines a project is exempt from the need for approval and continuing review, the researcher does not need to notify the IRB unless he/she wishes to amend the study. **However, research that has been declared to be "exempt" from continuing review must still be closed/terminated with the IRB when the research is completed**.

Expedited IRB review: Projects eligible for expedited review are reviewed and approved by the IRB Chair, acting on behalf of the convened IRB. The IRB Chair may suggest or require revisions, and finally, approve the study.

Full board IRB review: All applications determined to require full board review are assigned to review at a convened meeting. IRB members receive a complete packet of study materials to review individually prior to the meeting and then meet to ask questions, discuss their concerns, and make suggestions as a group. The PI of the research project is asked to provide a brief oral overview of the study at the start of the meeting and to remain available for possible questions in a separate room from the IRB members to ensure privacy of the discussion and deliberations. A quorum of IRB members must be present for the discussion and vote. Depending on the nature of the study, IRB members with specific expertise may also need to be present, such as for research involving children, to satisfy the IRB's preference for expertise in this research (this is not formally required by the federal regulations, but relevant expertise is expected). The convened IRB votes; a simple majority is required for approval. Research that is initially reviewed by the full board may be able to be reviewed on an expedited basis at renewal if there have been no problems.

DETERMINATIONS AND ACTIONS OF IRB REVIEW

The IRB sends written notification to the PI of determinations and actions taken. If revisions to new and continuing human participant applications are required, correspondence is sent to the PI detailing requests for revisions, clarification, or additional information as well as information regarding continuing review.

The IRB may provide the PI with any of the following determinations and actions:

1. Exemption from Continuing Review: If the IRB determines a project is exempt from the need for approval and continuing review, the researcher does not need to notify the IRB unless he/she wishes to amend the study. **However, research that has been declared to be "exempt" from continuing review must still be closed/terminated with the IRB when the research is completed**.
2. Approval of Research: In the case of an approval with no changes, the research may proceed once the PI receives written documentation of IRB approval. Unless otherwise specified, the approval period for research approved without changes is one year less one day from the date at which approval was granted. Prior to the end of that period, **the PI must either apply for continuing review (renewal) or closure/termination with the IRB if the research is completed**.
3. Stipulated Changes Required Prior to Approval: The IRB may determine that a study may be approved pending resolution of stipulated minor changes. Minor changes are those changes that do not involve potential for increased risk or decreased benefit to the human participants. Some examples of minor changes include changes to consent forms or measures that clarify language, correcting typographical errors, requesting that specific information be added to recruitment materials, and so forth. If the study is receiving expedited review, the IRB Chair

reviews the changes. More than one round of requested changes and responses might be required. If the study is receiving review by the convened IRB, but the nature of the changes is minor and the convened IRB members agree, the requested changes may also be reviewed by the Chair rather than requiring another meeting of the convened IRB.

4. Deferral: The term "deferral" is generally used to describe the situation in which an IRB determines that substantive changes must be made to the protocol prior to approval, and the convened IRB must review those changes. Subject to IRB discretion, a proposal may be withdrawn if the PI does not respond to a deferral within a reasonable amount of time.
5. Disapproval: If the IRB determines that the research cannot be conducted at Meredith College or by faculty/staff members or students of Meredith College, the project, as proposed, is disapproved and may not go forward. Disapproval usually indicates that a proposal requires major changes not likely to be feasible without a complete investigator reassessment of the protocol. Only the convened IRB may disapprove a study.
6. Suspension or Termination of Research Study by IRB: The Chair of the convened IRB may suspend a study at any time if the Chair or any other IRB member determines the study requires further review or evaluation. This determination may be made due to a serious adverse event, a serious unanticipated problem, noncompliance, or other danger to human participants. If a project is suspended, research (including all contact with participants not required to ensure their safety) must immediately cease. Changes to the protocol to address the reasons for the suspension must be approved by the convened IRB. Termination by the convened IRB however, is not subject to revision or reinstatement. To continue a terminated study in the future, a new proposal must be submitted, reviewed, and approved. The new proposal needs to address the concerns that precipitated the termination.

Researchers may appeal the IRB requirement for specific changes in the protocol and/or consent document(s). At the discretion of the Chair, the PI may make such an appeal in writing to the IRB. At the IRB's discretion, the PI may be invited to the IRB meeting at which her/his case will be discussed.

RECORD RETENTION AFTER IRB REVIEW

Research records are to be retained by Meredith College for a period of five (5) years after the submission of the Closure Form and final report on the research project are submitted and accepted by the IRB, unless a longer retention period is specified by the sponsor, funding source, or regulation.

The retention of the original research records shall be the responsibility of the Principal Investigator (or Faculty Sponsor if PI is a student) on behalf of Meredith College, but at all times shall remain the property of Meredith College, unless otherwise specified by law, regulation or agreement. The retention of IRB-related research records shall be the responsibility of the Meredith College IRB Administrator. However, the PI should include, with the original research records, copies of IRB-approved materials such as recruitment flyers/ads, consents, etc. used during the progression of the research.