



MEREDITH COLLEGE INSTITUTIONAL REVIEW BOARD
GUIDELINES FOR THE PROTECTION OF HUMAN PARTICIPANTS IN RESEARCH

I. Introduction

Recognizing its responsibility to provide measures to reasonably protect individuals whenever research is conducted under its auspices, Meredith College requires all research projects involving human participants to be reviewed by the Institutional Review Board (IRB). The primary ethical objective of the Meredith IRB is to provide these core twin protections for research participants: independent review of risks and assurance of informed consent. Consequently, an IRB review is required prior to the initiation of the research so that these protections may be guaranteed.

The college assumes its responsibility for protecting human participants in accordance with the Code of Federal Regulations, Title 45 Part 46, and with requirements of other Federal agencies with appropriate jurisdiction. Furthermore, the college adopts the ethical principles and guidelines set forth in The Belmont Report, issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In assuming this responsibility, the college intends to encourage the conduct of research that will benefit the human condition and, at the same time, protect the rights and welfare of humans participating in the research, the investigators doing the research, and the college.

II. Administration

Executive functions to be performed by the college include the development of policy; the continuing education of faculty, staff and students with respect to policy; the modification of this policy to maintain its conformity with laws and regulations; and provision of appropriate administrative support and legal assistance for the Institutional Review Board. The college official responsible for carrying out or delegating these functions is the Vice President for Academic Affairs.

III. Definitions of Terms and Phrases

1. "Human Participant": means a living individual about whom an investigator (whether an employee of the college or a student) conducting research obtains: data, either through intervention or interaction with the individual or identifiable private information.

1.1 Intervention includes both physical procedures by which data are gathered and manipulations of the participant or the participant's environment that are performed for research purposes.

1.2 Interaction includes communication or interpersonal contact between investigator and participant.

1.3 Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that an individual has provided for specific purposes which one would reasonably expect not to be made public. Private information must be individually identifiable to an Investigator through name or code in order for obtaining that information to constitute research involving human participants.

2. "Legally Authorized Representative": means an individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective human participant to the individual's participation in the procedures involved in the research.

3. “Minimal Risk”: means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Evaluations of risk must consider how those who are intrinsically vulnerable (i.e., children, the mentally ill, people with retardation) and those who are situationally vulnerable (i.e., the impoverished, the unemployed, the incarcerated) may require special protection. Likewise, awareness of how records on participants might contribute to employment or insurance discrimination, criminal prosecution, social stigma, or other social, psychological, economic or legal harms must inform the determination of risk level.

4. “Research”: means a systematic investigation designed to develop or contribute to general knowledge. Excluded from this definition are the ordinary data gathering tasks typical of educational institutions for purposes of organizational management and assessment.

5. “Research Involving Human Participants Conducted under the Auspices of the College”: means for purposes of this policy when:

5.1 The research is funded externally by way of grant, contract, or similar agreement between the sponsor (public or private) and the College;

5.2. The research is funded internally by the college by way of grant, contract, or similar agreement;

5.3. The research is conducted upon assignment by the college; or

5.4. The research is actively assisted by the use of college facilities, resources, supplies, equipment, or personnel.

6. “Consent to Participate in Research”:

6.1 General Requirement:

Except as otherwise permitted by the Exempt Review (see Section IV – 4.3), no investigator may involve a human participant in research covered by this policy unless the investigator has obtained the informed consent of the participant or their legally authorized representative. The prospective participant or representative must have sufficient opportunity to consider whether or not to participate and there must be a minimal possibility of coercion or undue influence. The information that is given to the participant or representative shall be in language understandable to the participant or representative. No consent, whether oral or written, may include any exculpatory language through which the participant or representative is made to waive or to appear to waive any of the participant’s legal rights, or to release the investigator; the sponsor, the College, or its agents from liability for negligence.

6.2 Elements of Consent:

6.2.1 Except as provided in Section III—6.4 of this policy, involving Waiver or Alteration of Consent, the following basic elements of information shall be provided to the participant:6.2.1.1 A statement that the study involves research, a fair explanation of the purposes of the research and the expected duration of the participant’s involvement, a description of the procedures to be followed and identification of any procedures which are experimental.6.2.1.2 A description of any reasonably foreseeable discomforts and risks to the participant;6.2.1.3 A description of any benefits to the participant or to others which reasonably may be expected as a result of doing the study; 6.2.1.4 If applicable, a disclosure of any appropriate alternative procedures or course of treatment, which might be advantageous for the participant;

6.2.1.5 A statement describing the extent and methods employed by which confidentiality of records identifying the participant will be maintained;

6.2.1.6 For research involving more than minimal risk, an explanation as to whether any compensation and/or any medical treatments are available if injury occurs, and if so, what they consist of, or where further information may be obtained. This information must be in the exact wording approved in

advance by the Vice President for Academic Affairs.6.2.1.7 An explanation of whom to contact for answers to pertinent questions about the research, procedures and research participant's rights, and whom to contact in the event of a research-related injury; and6.2.1.8 A statement that participation is voluntary and that the participant is free to withdraw his or her consent and to discontinue participation in the project at any time without penalty or loss of benefits.

6.2.2 When determined to be appropriate by the investigator or the Institutional Review Board, one or more of the following optional elements of information shall also be provided to the participant:

6.2.2.1 A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus), if the participant is or may become pregnant which are currently unforeseeable;

6.2.2.2 Anticipated circumstances under which the participant's involvement may be terminated by the investigator without regard to the participant's consent;

6.2.2.3 Any additional costs to the participant that may result from participation in the research;

6.2.2.4 The consequences of a participant's decision to withdraw from the research, and procedures for orderly termination of involvement by the participant;

6.2.2.5 A statement that the researcher will communicate to the participant significant new findings developed during the course of research, which may affect the participant's willingness to continue participation;

6.2.2.6 The approximate number of participants involved in the study; and

6.2.2.7 Information in addition to that specifically mentioned that the IRB or the investigator believes would meaningfully add to the protection of the rights and welfare of the participants.

6.3 Documentation of Informed Consent:

Consent shall be documented by use of a written consent form that embodies the elements of informed consent as set forth in Section III.– 6, and that is approved by the Institutional Review Board. The consent form shall be signed by the participant or the participant's legally authorized representative and a copy shall be given to the person signing the form. The principal investigator must be properly identified with a signature and the consent form must include the investigator's name and affiliation with a department or unit of Meredith College.

Since the original consent document is a college record, it must be kept in a secure department or unit file. Copies of the proposed consent form shall accompany the protocol submitted by the investigator to the Institutional Review Board.

6.4 Waiver or Alteration of Consent:

The Institutional Review Board may approve a consent procedure which waives or alters some or all of the above elements of consent provided the Institutional Review Board finds and documents any of the following:

6.4.1 The research is to be conducted for the purpose of demonstrating or evaluating:

6.4.1.1 federal, state, or local benefit or service programs which are not themselves research programs; or

6.4.1.2 procedures for obtaining benefits or services under these programs; or

6.4.1.3 possible changes in or alternatives to these programs or procedures; and the research could not practicably be carried out without the waiver or alteration;

6.4.2 The only record linking the participant and the research would be the consent document and the principal risk would be the potential harm resulting from a breach of confidentiality. Each participant shall be asked whether he or she wants documentation linking himself or herself with the research and the participant's wishes will govern; or

6.4.3 The research involves no more than minimal risk to the participants; involves no procedures for which written consent is normally required outside the research context; the waiver or alteration will not adversely affect the rights and welfare of the participants; the research could not practicably be carried out without waiver or alteration and, wherever appropriate, the participants will be provided with additional pertinent information after participation.

IV. Institutional Review Board

1. General Duties

The Institutional Review Board is responsible for the review and approval, or suggestions of modifications for approval, or disapproval of all research subject to this policy. In applying for approval, investigators must present written protocols to the Institutional Review Board and it is the Board's responsibility to supply the format and to be a source of advice. To qualify for these general duties, members of the Institutional Review Board are expected to complete the "Training Module for Assurances" offered as an online tutorial by the Department of Health and Human Services Office for Human Research Protections (<http://ohrp.osophs.dhhs.gov/educmat.htm>), or an equivalent tutorial or workshop. The IRB Chair is required to complete this tutorial and/or any other training mandated by agencies with which the college enters research contracts.

2. Membership

The Institutional Review Board shall be composed of seven individuals. The board will consist of two faculty members with expertise in the natural and applied sciences; two faculty members with expertise in the social and behavioral sciences; one member of the faculty whose areas of expertise are non-scientific; one member unaffiliated with Meredith College and who is not part of the immediate family of a person affiliated with the college; and one member to Chair the Board and serve as Meredith's designated "Human Protections Administrator". Consistent with the requirements of Federalwide Assurance (FWA) status, the Human Protections Administrator must be a College employee capable of operationally supervising the program for protecting human participants and remaining fully informed of the institutional protections in place. Ordinarily, the IRB Chair will be the Director of the Undergraduate Research Program, with exceptions as deemed necessary by the VPAA. To the extent that faculty strengths allow, one of the members should have formal training in ethics. In addition, at least three alternate members, one scientist, one non-scientist, and one who is non-affiliated will be named to serve on reviews about which one of the regular members may have a conflict of interest or may be unavailable. No member who has a conflicting interest in particular research may participate in the Institutional Review Board's initial or continuing review of that research except to provide information requested by the Institutional Review Board.

Because conflicts of interest would be hard to avoid, institutional grants and contract officials should not serve as IRB members. The composition of the Institutional Review Board should include members who can represent the perspectives of participants, who are unaffiliated with the institution, and whose primary concerns are in nonscientific areas. An individual can fulfill one, two, or all three of these categories. All of these categories should be represented each time the Board meets.

Members shall have varying backgrounds to promote complete and adequate review of research activities commonly conducted under the auspices of the college. The Institutional Review Board shall be sufficiently qualified through the experience and expertise of its members and the diversity of the members' backgrounds (including consideration of their sex, race, culture, and sensitivity to such issues as community attitudes) to promote respect for its advice and counsel in safeguarding the rights and welfare of human participants. In addition to possessing the professional competence necessary to review specific research activities, the Institutional Review Board shall be able to ascertain the acceptability of proposed research in terms of college commitments and regulations, applicable law, and ethical standards of professional conduct and practice. The Institutional Review Board shall, therefore,

include persons knowledgeable in these areas and willing to avail themselves of opportunities to remain current in these important matters.

All members will be appointed for terms of no more than three years. The procedures for the selection and appointment of members shall be consistent with general practice as detailed in the Meredith College Faculty Handbook. Membership of the Institutional Review Board shall be staggered so that the terms of no more than two members will expire in any given year. Except for the IRB Chair & Human Protections Administrator, members may serve for no more than one additional consecutive term.

The Institutional Review Board, at its discretion, may invite individuals with competence in special areas to assist in the review of complex issues that require expertise beyond, or in addition to that available on the Institutional Review Board, These individuals may not vote with the Institutional Review Board. If the individual is not an employee of the college, such an invitation may be extended only with the approval of the Vice President for Academic Affairs.

3. Responsibilities and Functions of the Institutional Review Board

3.1 The Institutional Review Board develops and documents its procedures for:

3.11 Conducting initial and continuing reviews of research and for reporting its findings and actions to the investigator(s).

3.12 Determining which projects require review more often than annually.

3.13 Screening reports of changes in proposed research activity, especially in situations involving unanticipated risks to participants or others.

3.14 Establishing compliance with then current protections for vulnerable categories of participants (e.g., children, prisoners, etc., see 45 CFR 46.111 (b)).

3.2 Functions of the Institutional Review Board:

3.21 Be responsible for the Full, Expedited, or Exempt Review (see Section IV—4) of proposed research protocols involving human participants. For research to proceed from a Full Review the protocol must be approved by no less than four members of the IRB; in an Expedited or Exempt Review approval must be unanimous.

3.22 Exercise authority to approve, require modifications in, or disapprove all research covered by this policy.

3.23 Require that information given to participants as part of consent is in accordance with this policy and applicable law.

3.24 Require documentation of informed consent or waive documentation in accordance with this policy.

3.25 Provide written notice to investigators of its decision to approve or disapprove the proposed research, or of modifications required to secure Institutional Review Board approval. If the Institutional Review Board decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

3.26 Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and exercise elective authority as appropriate to observe or have a third party observe the consent process and the research. Research that involves minimal risk, the use of existing data, or only the analysis of data when no additional contact with participants is involved, does not require continuing review.

3.27 Be responsible for reporting to the Vice President for Academic Affairs and to any appropriate government agency, any adverse events or continuing non-compliance by investigators with the requirements and determinations of the Institutional Review Board.

3.3 The Institutional Review Board maintains the following documents as the official record of its activities:

3.3.1 Copies of all research protocols reviewed, scientific evaluations, if any, that accompany the protocols, approved sample consent documents, progress reports submitted by investigators, reports of injuries to participants, and any statements of significant new findings provided to participants as Section III-6.2.2.5 anticipates;

3.3.2 Minutes of Institutional Review Board meetings in sufficient detail to show attendance at the meetings; actions taken by the Board; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution;

3.3.3 Records of continuing review activities;

3.3.4 Copies of all correspondence between the Institutional Review Board and the investigators;

3.3.5 Written procedures for the Institutional Review Board (see Section IV – 3.1);

3.3.6 A list of Institutional Review Board members as required by the United States Department of Health and Human Services;

These official documents shall be retained for at least six years prior to disposal, and documents with applicability to active research projects shall be retained until at least six years after completion of the research.

4. Types of Research Reviews Conducted by the Institutional Review Board

There are three types of review for proposed research protocols submitted to the Institutional Review Board. A Full Review requires examination of the protocol by the Institutional Review Board at a convened meeting. An Expedited or Exempt Review is conducted by an IRB Subcommittee.

4.1 Full Review

The review must be conducted with a majority of the members present at a convened meeting. Approval of no less than four members of the Board is required for a Full Review approval to be official. Any member of the Institutional Review Board may request a Full Review of a research protocol about which s/he has concerns. Research protocols or activities may be disapproved only after a Full Review. The status of protocols for Full Review will be officially documented through the minutes of the Board meetings.

4.2 Expedited Review

The Institutional Review Board may permit Expedited Review by a Subcommittee consisting of the IRB Chair and a rotating regular member. The Subcommittee may exercise all of the authorities of the Institutional Review Board except they may not disapprove the research. This type of review is preferred for the categories of research identified by the Department of Health and Human Services in the Federal Register as eligible for an expedited review. Eligibility depends upon recognition of the research as belonging to a category involving no more than minimal risk. Expedited Review may also be conducted for consideration of minor changes in research that was previously approved, during the time period for which approval was granted. Lastly, an Expedited Review may determine whether research involving human participants is exempt from the requirement of IRB approval. The Institutional Review Board shall adopt a method for documenting all research protocols which are pending, have been approved, or determined to be exempt under this expedited procedure.

4.3 Exempt Review

An investigator may submit a research protocol to the Institutional Review Board for Exempt Review if the research involving human participants will be in one or more of the following exempt categories:

4.3.1 Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

4.3.1.1 research on regular and special education instructional strategies; or

4.3.1.2 research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

4.3.2 research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) if information taken from these sources is recorded in such a manner that participants cannot be identified.

4.3.3 research involving survey or interview procedures, except where all of the following conditions exist:

4.3.3.1 Responses are recorded in such a manner that the human participants can be identified, directly or through identifiers linked to the participants;

4.3.3.2 Responses that, if they became known outside the research, could reasonably place the participant or respondent at risk of criminal or civil liability or be damaging to the participant's financial standing or employability; and

4.3.3.3 The research deals with sensitive aspects of the participant's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

All research involving survey or interview procedures is considered exempt when the respondents are elected or appointed public officials or candidates for public office.

4.3.4 research involving the observation (including observation by participants) of public behavior, except where all of the conditions listed under IV—4.3.3 above exist.

4.3.5 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 participants cannot be identified, directly or through identifiers linked to them.

Federal Guidelines notwithstanding, the Meredith IRB will not exempt research evaluating foods for any purpose. Such research may qualify for an expedited review if minimal risk of food allergic reactions is established.

Except as may be provided by law (e.g., research funded by the United States Department of Health and Human Services), the Institutional Review Board has final authority to determine whether particular research is subject to this policy or exempt under one of the categories stated above. An investigator who believes his or her research is exempt shall submit a written protocol to the Institutional Review Board together with a statement to justify the exemption; the format of the protocol will be supplied by the Institutional Review Board. The determination of exempt status shall be made by means of the Expedited Review (see Section IV-4.2 above).

5. Criteria for Approval of Research

In order to approve research covered by this policy, the Institutional Review Board shall determine that all of the following requirements are satisfied:

5.1 Risks to participants are minimized either by using procedures which have sound research design and which do not unnecessarily expose participants to risk, or by using procedures already being performed on the participants for diagnostic or treatment purposes;

5.2 Risks to participants are reasonable in relation to anticipated benefits (e.g., importance of the knowledge that may result). Anticipated benefits is not to include any consideration of financial or other incentives offered to participants.

5.3 Selection of participants is equitable. In making this assessment the Institutional Review Board should take into account the purposes of the research and the setting in which the research will be conducted;

5.4 Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with, and to the extent required by this policy;

5.5 Informed consent will be appropriately documented, in accordance with, and to the extent required by this policy;

5.6 Where appropriate, the protocol makes adequate provision for monitoring the research to insure the safety of participants;

5.7 Where appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data;

5.8 Where any participants are likely to belong to one or more of the vulnerable categories identified in 45 CFR 46.111 (b), or considered by the IRB to merit special care, additional safeguards have been included in the study to protect the rights and welfare of these participants;

6. Suspensions or Termination of Approval

The Institutional Review Board shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the Board's requirements or that has been associated with unexpected harm to participants. Any suspension or termination of approval shall include a statement of the reasons for the Institutional Review Board's action and shall be reported promptly to the investigator, to the Vice President for Academic Affairs and, if the research is externally funded, to the sponsor.

7. Role of College Officials

Institutional Review Board approvals, actions, and recommendations are subject to review and to disapproval or further restrictions by the Vice President for Academic Affairs, or his or her designee. In such situations, the written rationale for the disapproval or added restriction(s) should become a part of the official record of IRB deliberations (see Section IV-3.3). However, Institutional Review Board disapproval or restrictions or conditions cannot be rescinded or removed except by further action of the institutional Review Board or in the case of federally funded research, by appeal to the Department of Health and Human Services or other federal agency with appropriate jurisdiction.

V. Cooperative Research or Research Outside of the United States

In the event of research in which the College and another Institution(s) or party cooperate in the conduct of some or all of the research, the investigator shall comply with this policy. To avoid duplications of effort, the Institutional Review Board with the concurrence of the Vice President for Academic Affairs may use joint review, or reliance upon the review of another qualified Institutional Review Board.

In the event of research subject to this policy taking place in part or in whole in the jurisdiction of another nation, procedures normally followed in the other country may be adopted in lieu of the procedural requirements of this policy as long as they are deemed by the Institutional Review Board to afford at least equivalent protections to human participants.