Auburn University at Montgomery

Institutional Review Board

Policies & Procedures Manual

March 2020

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1 AUM IRB Guidelines

Comprehensive guidelines for human subjects research by faculty, staff and students.

The University policy on activities involving human subjects serves to comply fully with the regulations of the Office for Human Research Protections (OHRP) and the U.S. Food and Drug Administration (FDA), and to implement the principles outlined in the Belmont Report.

Auburn University at Montgomery (AUM) has a signed compliance agreement (Federal Wide Assurance - FWA) with the Office for Human Research Protections (OHRP), a subdivision of the Department of Health and Human Services. The assurance document provides written assurance that all federally-funded research conducted at this institution which involves human subjects will be in compliance with the Code of Federal Regulations (CFR) Title 45, Part 46. These regulations have been adopted by AUM to cover all research activities involving human subjects. The institution also abides by the regulations of the U.S. Food and Drug Administration Code of Federal Regulations, Title 21, Part 50 and Part 56.

At AUM, all human subjects research activities come under the purview and oversight of the Institutional Review Board, irrespective of whether the research is funded or non-funded, regardless of the risk. The human subjects policies apply to all AUM-affiliated faculty (adjunct, visiting professors, joint programs, etc), staff, and students conducting human subjects research on or off campus (domestic or international sites) as well as to visitors conducting research at AUM.

The IRB is charged with the responsibility of protecting the rights and welfare of human subjects involved in research. The composition of the IRB and the number of members on the committee are in accordance with federal regulations (CFR 45 part 46). IRB members are appointed by an executive committee of the IRB and on the recommendation of the Chairperson of the IRB. Members are appointed for renewable, three-year terms and include faculty with expertise in the various disciplines engaged in human subject research on campus, as well as community members. All members, whether regular or alternate, have full voting rights. There is no remuneration for individuals serving as IRB members, and no IRB members can participate in the review of any study on which they are a Principal researcher or Co-researcher or in any way have conflict of interest with the research under immediate review.

The Chairperson and Administrator of the IRB conduct an orientation for new members that includes the review of relevant materials provided (Belmont Report, Federal Regulations, University Policy, and IRB Guidelines), details concerning committee functions and procedures, and the *IRB Member Handbook,* (The *Handbook* will be returned at the end of the term.) CITI (Collaborative Institutional Training Initiative) web-based program includes a training course for IRB members that is also required. Each new member attends at least one IRB meeting for the purpose of observation before participating in the actual review of studies.

The IRB may, at its discretion, invite individuals with competence in special areas (ad hoc members) to assist in the review of complex issues that require expertise beyond, or in addition to, that available

on the committee. This person provides information but does not take part in voting. Similarly, researchers may request, or be invited, to attend IRB meetings to clarify issues concerning their proposed research activity. These researchers do not take part in committee deliberations or voting.

While the IRB is an independent body, the IRB reports to the Office of the Provost (Specifically the Associate Provost for Graduate Studies and Faculty Services).
The **Administrator of the IRB** serves as the liaison between the researchers and the IRB. The Administrator maintains all IRB files and records. The IRB Administrator provides administrative support for the IRB and assists researchers through the application and approval process. The Administrator acts on behalf of the IRB and the University when providing assurance of human subjects approval to sponsoring agencies, or when dealing with regulatory agencies. This staff is also responsible for regularly monitoring IRB compliance and updating IRB procedures with current and/or new relevant federal or state regulations. The IRB Administrator has voting responsibilities.

Direct all IRB correspondence (including application materials) to:

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IRB Administrator/Research Compliance Manager
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2 Historical Background of IRB Compliance

Historical Background

For many years, state and federal laws were silent on the issue of human research and experimentation. The situation changed, however, in 1971 with the first of a series of federal regulations. The then US Department of Health, Education and Welfare (DHEW) issued **The Institutional Guide to DHEW Policy on Protection of Human Subjects.** These guidelines set the initial review criteria into motion. Three years later, on July 12, 1974, Public Law 93-348 (known as the "National Research Act of 1974") was signed into law, creating the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, and set the definitive standards of the Institutional Review Board. Section 212 of the law specified, in part, that: "The Secretary of DHEW shall by regulation require that each entity which applies for a grant or contract under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application assurances satisfactory to the Secretary that it has established a board (to be known as an "Institutional Review Board") to review biomedical and behavioral research involving human subjects...in order to protect the rights of the human subjects of such research."

The **Belmont Report** was published on April 18, 1979, by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The report was an outgrowth of intensive discussions held in February 1976 at the Smithsonian Institution's Belmont Conference Center that were supplemented by the monthly deliberations of the Commission that were held over a period of three years. **The Belmont Report** is a statement of basic ethical principles and guidelines meant to assist individuals in resolving ethical problems that surround the conduct of research with human subjects. Two years later, on January 27, 1981, the Food and Drug Administration (FDA) and the National Institutes of Health set the regulatory standards in place for the Protection of Human Subjects and for the Operating Standards of the Institutional Review Boards.

On March 8, 1983, the US Department of Health and Human Services (DHHS), in response to the Belmont Report and the FDA's standards, extensively revised its 1974 basic policy and added new regulations governing additional protection for special classes of human subjects -- fetuses, pregnant women, in vitro fertilization, prisoners, children, mental and physical disabled or institutionalized individuals, and the elderly. In 2019 the revised Common Rule removed pregnant women from the special class of human subjects (vulnerable population.)

In April 1989, the White House Office of Science and Technology ordered all governmental agencies to adopt the DHHS policy as their own, with the Office for Human Research Protections (OHRP) of the National Institutes of Health as the coordinating agency. On June 18, 1991, OHRP issued its revised policies for the Protection of Human Subjects and two months later, on August 19, 1991, the regulations became effective, with OHRP becoming the coordinating agency for 19 US governmental agencies to ensure that institutions comply with the federal regulations which protect

human subjects in research. The regulations are known as the **Model Federal Policy of 1991** or simply by its legal citation, **45 CFR 46.,**

REVISED COMMON RULE - January 2019.

On January 19, 2017, the Department of Health and Human Services (HHS), along with 15 other federal agencies, published a final rule revising the Federal Policy for the Protection of Human Subjects, also known as the "Common Rule."[1] This regulation governs clinical research involving human subjects conducted or sponsored by the Federal departments and agencies that have adopted the regulations (16 Common Rule departments and agencies).

The revised Common Rule has an interim effective date of January 2019.

Below is a summary of several key provisions and changes Institutions and Researchers should prepare to comply with by July 19, 2018. The new regulations do not impact studies approved prior to July 19, 2019.

Provisions and changes include:

- New and Revised Definitions
- New Exemption Categories Regarding Secondary Research
- Elimination of Continuing Review
- Revised Informed Consent Requirements
- Harmonization with Other Agency Guidance
- Guidance on Application to Clinical Data Registries
- Cooperative Research Studies (single IRB)

New and Revised Definitions

The final rule provides new and revised definitions, including: "clinical trial," "human subject," "intervention," "private information," "identifiable private information," "identifiable biospecimen," "minimal risk," "research," and "written or in writing" (to include electronic formats). See definitions section.

- **Activities deemed not to be research.** The final rule amended the definition of "research" to include four new activities that are deemed to not be "research":

    - Scholarly and journalistic activities (e.g. oral history, journalism, biography, literary criticism, legal research, and historical scholarship);
    - Public health surveillance activities;
    - Collection and analysis of information, biospecimens, or records for criminal justice or criminal investigative purposes; and
    - Certain activities in support of intelligence, homeland, security, defense, or other national security missions.

New Exemption Categories Regarding Secondary Research

The final rule introduced new exemption categories from certain aspects of the Common Rule that relate to secondary research, if certain conditions are met.

- Secondary research for which consent is not required under the Common Rule:
    - Research using protected health information ("PHI") conducted by "covered entities" for "health care operations," "public health activities," or "research," as those terms are defined under the Health Insurance Portability and Accountability Act ("HIPAA") Rules. (This change is intended to eliminate duplication between the Common Rule and HIPAA, so HIPAA requirements will apply in these circumstances).
    - Storage or maintenance for secondary research use of identifiable private information or identifiable biospecimens when broad consent is obtained and if an IRB conducts a limited IRB review.
    - Other exemption categories include educational, benign behavioral interventions, and surveys/interviews.

Elimination of Continuing Review

- The final rule eliminated continuing review for many minimal risk studies (non-clinical research; benign behavioral interventions, consumer preference surveys and research)
- Unless an IRB determines otherwise, continuing review of research is not required if the research:

    - Is eligible for expedited review;

- Is reviewed by the IRB in accordance with the limited IRB review (new IRB regulatory category) procedure; or
- Only involves data analysis (including analysis of identifiable information or identifiable biospecimens) or access to follow-up clinical data from procedures that subjects would undergo as part of clinical care.

- The IRB must document the rationale for conducting continuing review if any of the above conditions are met. FDA still requires annual continuing review for FDA-regulated studies.

Revised Informed Consent Requirements

- Informed consent must begin with "a concise and focused presentation of the key information that is most likely to assist a prospective subject, or legally authorized representative, in understanding the reasons why one might or might not want to participate in the research. Institutions should update template informed consent forms to meet this requirement.
- The consent "must be organized and presented in a way that facilitates comprehension." The rule does not preclude the use of electronic formats for obtaining consent.
- Elements of new informed consent include:
  - Statement explaining the purpose, procedures, and reasonably foreseeable risks and discomforts of the research;
  - Statement that biospecimens may be used for commercial profit (when applicable), and whether or not the subject will share in that profit;
  - Statement regarding whether clinically relevant research results will be returned to subjects, and under what conditions; and
  - Statement specifically for research involving biospecimens about whether the research will or might include whole genome sequencing.
- Broad consent (*e.g.* prospective consent to unspecified future research) may be obtained in lieu of informed consent for secondary research use, storage, and maintenance of identifiable private information and identifiable biospecimens. Recommendations for a Broad Consent Template: **https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-d-august-2-2017/index.html**
- IRBs do not need to obtain informed consent in instances of obtaining information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects, under certain circumstances.
- For research involving collection of identifiable private information or identifiable biospecimens, subjects should be provided with:
  - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens; and
  - The information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent, where applicable; *OR*
  - A statement that the subject'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.

- Each clinical trial conducted or supported by a Federal department or agency must have an approved consent form, and this form must be posted online on a publicly available federal Web site that will be established as a repository for such forms.

Harmonization with Other Agency Guidance

- The Common Rule previously did not require that agencies harmonize their guidance on application of the Common Rule. The final rule states that guidance can only be issued after consultation with the other sixteen Federal departments and agencies that adopted the Common Rule, unless the consultation is not feasible.
- The final rule requires the Secretary of HHS to issue guidance to assist IRBs in assessing privacy and confidentiality protections.

Guidance on Application to Clinical Data Registries

- Section 511 of the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA") requires HHS to provide guidance on how the Common Rule applies to clinical data registries. In an effort to provide such guidance, the preamble to the final rule states that the final rule does not apply to clinical data registry activities in the following circumstances:
    - Activities not conducted or supported by a Common Rule department or agency;
    - Activities that do not meet the definition of research, such as many quality improvement activities (for example, the creation of a registry designed to provide information about the performance quality of providers, and whose design is not influenced or altered to facilitate research, is not covered by the final rule even if it is known that the registry will be used for research studies);
    - Research studies that only involve obtaining and analyzing nonidentified information because it would not involve a "human subject";
    - Activities that qualify for an exemption; or
    - Institutions that release identifiable private information obtained in the course of patient clinical care to a clinical data registry for research because it is not engaged in "human subjects" research.

Cooperative Research Studies (Single IRB) – effective January 19, 2020

- A single IRB must approve cooperative studies for research (projects that involve more than one institution) conducted in the United States, except where:
    - More than a single IRB review is required by law (including tribal law); or
    - Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate.
- The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of such Federal department or agency.
- Documentation specifying the responsibilities of each entity, when research takes place at an institution in which IRB oversight is outsourced.

- Common Rule agencies and departments will be given authority to enforce compliance against IRBs that are not operated by an Federalwide Assurance (FWA)-holding institution.

3 Functions of the AUM IRB

The AUM IRB (Institutional Review Board) functions to protect the rights and welfare of human research participants. Thus, the IRB reviews all research activities, regardless of funding, that involve human subjects for compliance with applicable federal, state, local, and institutional regulations, guidelines, and ethical research principles. All funded research involving human subjects must be reviewed and approved under IRB procedures prior to receiving funding. The IRB has the authority to approve, require modifications (to secure approval of), and disapprove research proposals and to suspend or terminate research that is not conducted in accordance with the IRB's requirements or that has been associated with any possible harm to subjects. Standards for review of research protocols are based on the Belmont Report (Common Rule), Nuremberg Code, and World Medical Association for which federal regulations have been written.

AUM's Federalwide Assurances
FWA#: 00012889
IORG#: 0005227
IRB#: 0006286

To certify that AUM complies with these federal regulations, AUM filed **Institutional Assurance of Compliance with DHHS Regulations** with OHRP in 2018. Renewals take place every three years. The assurance includes a statement of ethical principles and institutional policy, a detailed identification of AUM's responsibilities, general procedures, the Institutional Review Board's policies and procedures, and the general responsibilities of the research investigator. As part of its assurance, AUM's IRB reviews all research involving human subjects regardless of sponsorship.

Registering an institutional review board (IRB) and obtaining a Federalwide Assurance (FWA) are related but separate processes.

- An institution must have an FWA in order to receive Federal support for research involving human subjects. Each FWA must designate at least one IRB registered with OHRP.

- Before obtaining an FWA, an institution must either register its own IRB, (an "internal" IRB), or designate an already registered IRB operated by another organization, (an "external" IRB), after establishing a written agreement with that other organization.

- AUM's IRB is registered with OHRP. The IRB Assurance number assigned to AUM is IRB 00006286.

- Additional requirements for obtaining and maintaining FWA and IRB Assurances with OHRP is a standing Institutional Review Board comprised of specific membership:
    - at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
    - at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
    - The IRB must make every nondiscriminatory effort to ensure that it does not consist entirely of men or entirely of women. Selections must not, however, be made on the basis of gender.
    - An IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote.
    - No IRB member may participate in the review of any project in which the member has a **conflicting interest**, except to provide information requested by the IRB.
    - An IRB must consist of at least 5 members. An IRB can have as many members as necessary to perform its duties effectively.

- An FWA approved IRB must have at least one dedicated staff person.

- An FWA approved IRB must have dedicated office space.

- An FWA must have a comprehensive education program in place to assure researchers are trained in research protections for human subjects.

- Other federal departments and agencies that conduct or support human subjects research permit use of the FWA as the assurance required by their regulations.

4 Membership and Job Responsibilities of Institutional Review Board Members (at AUM)

Federal Policy Requirements.

Institutional Review Boards (IRB) must have at least five members, with various backgrounds to promote and adequately review research activities commonly conducted by the institution. The IRB must be sufficiently qualified through the experience and expertise of its members and the diversity of their backgrounds, including considerations of their racial and cultural heritage and their sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

In addition to possessing the professional competence necessary to review specific research activities, the IRB must be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB must therefore include persons knowledgeable in these areas. No IRB, however, may consist entirely of members of one profession.

Specific requirements:

- If an IRB regularly reviews research that involves a **vulnerable category of subjects**, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, the IRB must consider the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects. Department of Education (ED) regulations require, in addition, that when an IRB reviews research for one of its programs that purposefully requires inclusion of handicapped children or mentally disabled persons as research subjects, the IRB must include at least one person primarily concerned with the welfare of these subjects 45 CFR 46.401-409 .
- The IRB must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- It must also include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- The IRB must make every nondiscriminatory effort to ensure that it does not consist entirely of men or entirely of women. Selections must not, however, be made on the basis of gender.
- An IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote.
- No IRB member may participate in the review of any project in which the member has a **conflicting interest**, except to provide information requested by the IRB.
- An IRB must consist of at least 5 members. An IRB can have as many members as necessary to perform its duties effectively.
- Special IRB committees may be formed to review specific protocols.
- In order to reach a consensus on full board reviews, a quorum must be present and in agreement.

A list of current IRB members must be submitted to the OHRP (Office of Human Research Protections) and also kept with the IRB's records. The list must identify members by name, earned degrees, representative capacity, indications of experience (such as board certifications and licenses) sufficient to describe each member's chief anticipated contributions to IRB deliberations, and any employment or other relationship between each member and the institution (e.g., full-time employee, stockholder, unpaid consultant, or board member). Any changes in IRB membership must be reported to the head of the department or agency supporting or conducting the research, unless the department or agency has accepted the existence of a DHHS-approved Assurance. In the latter case, changes in membership are to be reported to the OPRR.
[Federal Policy §§46.107(a)-(f) and 108(a)-(b)]

IRB Considerations.

The **nonaffiliated member of the IRB** should be drawn from the local community-at-large. Ministers, parents, teachers, attorneys, businesspersons, or homemakers are possible candidates. The person selected should be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration should be given to the type of community from which the institution will draw its research subjects. If the community is rural and agricultural, perhaps a farmer would be appropriate, in addition to a minister and/or attorney. If the community consists predominately of African-American, Hispanics, or another minority, then it would be advisable to have a member of that particular minority (or those minorities, if there is more than one significant minority population) on the IRB. The nonaffiliated member(s) should not be vulnerable to intimidation by the professionals on the IRB, and their services should be fully utilized by the IRB.

An **investigator** (PI) can be a member of the IRB; however, there is a stipulation that must be adhered to without exception: The investigator-as-member cannot participate in the review and approval process for any project in which he or she has a present or potential conflict of interest. When the investigator-member has a conflicting interest, he or she should be present only to provide information requested by the IRB. He or she should be absent from the meeting room during the discussion and voting phases of the review and approval process; IRB minutes should reflect whether or not these requirements have been met.

One of the most important actions to be taken in establishing an IRB is selecting the individual who will function as chair. The **IRB chairperson** should be a highly respected individual from within or outside the institution, fully capable of managing the IRB and the matters brought before it with fairness and impartiality. The task of making the IRB a respected part of the institutional community will fall primarily on the shoulders of this individual. The IRB must be, and must be perceived to be fair and impartial, immune from pressure by the institution's administration, the investigators whose protocols are brought before it, and other professional and nonprofessional sources.

There are specific responsibilities and authority placed on the IRB.
To carry out this mandate, the **IRB is given the authority** to perform the following tasks:

- Approve, modify, or disapprove research protocols
- Conduct continuation reviews on already-approved research protocols

- Observe & verify changes in research procedures
- Suspend or terminate approval of research protocols
- Handle allegations of noncompliance and assist in developing review policies.

Nine Basic Duties of IRB Membership:

1. Attend meetings
2. Avoid conflict of interest
3. Complete mandatory education policy requirements
4. Maintain confidentiality
5. Determine whether Federal Reports are required
6. Develop IRB Policy
7. Conduct protocol review
8. Apply discipline & regulatory knowledge
9. Handle allegations of reports of noncompliance

AUM IRB members are asked to serve a minimum of two years. Upon agreement by the Chair and other IRB members, terms may be extended. With the exception of the external member, IRB members should have a sound background in research, especially involving human subjects. Members may be self-nominated or nominated by AUM administrators, deans, department heads or other IRB members. Membership selection is made internally. The IRB membership decisions are guided primarily by OHRP mandates to maintain balance. A secondary priority is to have each academic college represented, as well as demographic representation.

The principles, authority, etc, of the IRB are based on the Belmont Report, Nuremberg Code, and Helsinki Declaration; all based on the ethical protection of human subjects during research.
The **Auburn University at Montgomery IRB** is independent of other institutional IRBs. The AUM IRB has dedicated professional staff (IRB Administrator/Research Compliance Manager). The staff positions and contact information are listed on the website.

5 Criteria for IRB Approval for Research

In order to consider approval of applications for human subjects research, the IRB must determine that all of the following requirements are satisfied:

A. Risks to subjects must be minimized by:

- Using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.
- Using procedures already being performed on the subjects for other purposes, whenever this opportunity exists.

B. Risks to subjects must be reasonable in relation to potential benefits to subjects and to the importance of the knowledge that may reasonably be required. In this regard, evaluation will include only those risks and benefits, that may result from the research itself, and not to risks and benefits that subjects would receive even if not participating in the research.

C. Selection of subjects must be equitable and take into account the purposes of the research, the setting in which it will be conducted, and the population from which subjects will be recruited.

D. Appropriate measures must be taken to obtain and document the informed prior consent of the subject, or the subject's legally authorized representative, to participate in the research.

E. Adequate provisions must be made for monitoring data collection to ensure the safety of subjects and to protect their privacy by maintaining anonymity or confidentiality of the data.

In all research involving human subjects, the confidentiality of identifiable information is presumed and must be maintained unless the researcher obtains the express permission of the subject to do otherwise. All instruments and procedures must be carefully designed to limit personal information to only that which is essential for the research. Data that could reveal a subject's identity should be stored in files which are accessible only to the project researcher and authorized staff.
The data on subjects should be coded to remove all personal identifying information.
When research protocols use audio and video taping of research subjects, subjects should always be told that taping will occur. Explicit consent must be obtained for any public use of the tapes such as use in the classroom or as part of a public presentation of the research results, for this use constitutes a waiver of the normal confidentiality of research data.
There have been instances in which the identities of subjects or research data have been sought by law enforcement agencies. This includes some studies, that involve collection of data on sensitive matters such as sexual behavior or criminal activities. Under federal law, researchers can obtain a Certificate of Confidentiality that will provide some protection against subpoenas of research data.

F. At Institutions where subjects are potentially vulnerable to coercion or undue influence, appropriate additional safeguards must be included in the study to protect the rights and welfare of these subjects. Such subjects include persons with acute or severe physical or mental illness, and

persons who are economically or educationally disadvantaged. Examples of settings where coercion may occur include classrooms, large participant payments/compensation that could influence participation or outcomes, and participants with impaired judgement.

Research that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution.

Materials Required for Submission to the IRB

Applications (IRB Protocol Form) to conduct research activities, involving human subjects must be filed with the AUM IRB (in the Office of Sponsored Programs) and must be approved prior to commencement of the activity. Materials required for submission include:

A. An IRB Protocol, complete with the following signatures:

1. Signature of the researcher (PI), who ensures accuracy of the information contained within the submitted materials and, upon approval, assures compliance with all aspects of IRB Protocol, entitled "Principal Investigator's Assurance".
2. Signature of the faculty sponsor if the researcher is a student. The faculty sponsor assumes responsibility for the student's research including:
    - Ensuring the accuracy of the information contained within the submitted materials.
    - Assuring the compliance with all aspects of Section B (page 2 of the IRB Protocol, entitled "Faculty Sponsor's Assurance").
3. Signature of Department Head who ensures accuracy of the information and that the research appropriately represents the academic endeavors of the department.

B. Responses to the application questions. Use complete sentences. Answer EVERY question. Clearly discuss, in lay language, the research procedures. Do not cut and paste from a grant proposal. The following must be included:

1. Complete answers to **all** questions.
2. All advertisements (i.e., newspaper, radio, flyers, etc.) to be used.
3. Inclusion/exclusion criteria for subject entry including notification to the IRB if a researcher proposes to include him/herself or members of their family as subjects in the proposed research.
4. If research is being conducted at sites other than AUM or in cooperation with other entities, a letter from the site/program director must be included indicating their cooperation or involvement in the project. NOTE: if the proposed research is a multi-site project, involving investigators or participants at other academic institutions, hospitals or private research organizations, a letter of IRB approval from each entity is required prior to initiating the project.

5. The last page of the protocol is a CHECK LIST for the use of the researcher to assure they have remembered to include all necessary documents/attachments.

C. When funding is being sought from an external agency (NIH, NSF, foundations, etc.), the number assigned by the IRB, or the proposal number assigned by the funding agency, should be inserted on the cover page of the application.

D. Consent and assent form(s) or consent scripts/letters. Examples of consent forms, information letters, and assent forms are provided on our website: www.aum.edu/research_compliance

E. If a proposed project involves a component of research that falls under the jurisdiction of the Institutional Animal Care and Use Committee, approval must be obtained from the AUM IACUC Office (in the Office of Sponsored Programs) prior to review by the IRB.

F. Supplemental Materials:

1. If access to research subjects is gained through other institutions, those institutions must be identified on the IRB form and an authorization letter or IRB approval must be provided prior to review (submission) by the AUM IRB.
2. All advertisements related to recruitment (i.e., newspaper, radio, flyers, emails, social media posts, etc.) to be used.
3. All the instruments to be used for the research, e.g. questionnaires, interview or focus group protocols, scales, medical history forms, demographic forms, phone screens, etc.

G. Participants must be informed of their role in the research through either an **informed consent or information letter.** The consent document must include the following information:

1) A statement that the study involves research.
2) The name(s) of the funding/research agency(ies).
3) Names of researchers and their qualifications.
4) An explanation of the purposes of the research.
5) The expected duration of the subject's participation.
6) A description of the procedures to be followed and what the subjects will be required to do in the study.
7) Identification of any procedures which are experimental.
8) A description of any reasonably foreseeable risks or discomforts to the subject. Risks are not limited to physical injury, but also include psychological, social, financial, legal, and others.
9) A description of any benefits to the subject or to others that may reasonably be expected from the research; there may be none other than a sense of helping the public at large when balanced by the appropriate level of risk.
10) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. In most NIJ studies the alternative will be to not participate in the study.
11) A statement describing the extent to which confidentiality of records identifying the subject will be maintained. For studies sponsored by NIJ the subject should be informed that private,

identifiable information will be kept confidential and will only be used for research and statistical purposes. If, due to sample size or some unique feature, the identity of the individual cannot be maintained, the subjects need to be explicitly notified. If the investigator intends to disclose any information, the subject needs to be explicitly informed what information would be disclosed, under what circumstances, and to whom. The subject must be informed of any potential risks which may result from this disclosure and must explicitly provide prior written consent.

12) For research involving more than minimal risk [1], an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
13) An explanation of whom to contact for answers to questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject. This should include name and telephone number or other appropriate methods.

A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. **This document must be written in language that is easy for the participant to understand. Technical terminology is discouraged. If used, must be explained in layman's terms. CFR 46.116.** The consent form should be written on an 8th grade level. Consideration that the participant may have limited comprehension, skills, physical impairment such as limited vision, or consideration that the participant may speak/read English as a second language.

6 IRB Protocol Submission Instructions

- All members of the research team and faculty/department personnel signing the protocol must complete CITI training prior to submission and completion reports attached to protocol.
- The IRB Protocol Review Form must be typed (not handwritten).
- Forms must have the appropriate signatures.
- We will not accept any electronic versions if the signatures are not included.
- Determination for type of review (exempt, expedited, full board) will be made by the IRB.

Include the appropriate informed consent document and/or assent document. The informed consent form is a crucial element in conforming to the Department of Health and Human Services' regulations on human subjects research. (Those regulations can be found in the Code of Federal Regulations, 45 CFR 46.) These guidelines are important both legally and ethically, so researchers should make every effort to stay in compliance. IRB groups like the one at AUM advocate ethical, responsible human subjects research and endeavor to assist researchers in their attempts to develop and conduct HHS-compliant studies of human populations.

- Include **all** instruments that will be used for data collection (surveys, interview questions, health history questionnaires, etc.)
- Complete the Protocol Review Checklist at the end of the IRB Protocol Review Form
- Remember to review your document carefully prior to submission for clerical and grammatical errors.

Fill in all required areas and send as an email attachment to:

AUM IRB
Attn: Debra Tomblin
Office of the Provost
dtomblin@aum.edu

7 Time Considerations for Initial Review

The IRB recommends that the researcher consult with the IRB early in the planning stages of research in order to facilitate the coordination of the various grant and committee deadlines to which the research may be subject for review. There are separate campus committees that are also mandated to review research for compliance with a variety of other regulations, including the use of animals (IACUC), HIPAA, and hazardous chemicals, etc.

A. The length of time required for the IRB to review an application is largely dependent on the review category into which a given application falls:

1. Exempt Review category applications are reviewed, and researcher is generally notified by the IRB Office within 7 to 15 days of the receipt date. The researcher receives a letter of determination.
2. Projects qualifying for expedited review are sent to the IRB office on a regular basis. The researcher receives a revision memo or approval letter within 7 to 15 days of the receipt date.
3. Rather than a set schedule, the AUM IRB reviews protocols as they are submitted.

8 Education and Training for Researchers (CITI)

Required Educational Training for the Protection of Human Research Subjects

- **AUM faculty/staff/students:** to assure compliance with regulations and assure protection of human subjects AUM requires training for researchers. All researchers, staff, students, and others who interact with human subjects (all research team members) must complete a required educational program on the protection of human subjects before the IRB can review a proposal. AUM is provides this training through CITI (Collaborative Institutional Training Initiative) **http://www.citiprogram.org**. This certification process must be completed and documented with the IRB office (and renewed every three years). Beginning January 1, 2010, a new protocol will not be accepted by the IRB until all members of the research team have completed the CITI training and the training documented in AUM's IRB office.

- **Non-AUM affiliated personnel:** That engage in human subjects research at AUM through a collaboration must also obtain training in human subjects protections. CITI serves almost 900 institutions worldwide so it is very possible that the researcher can obtain CITI training at their institution of primary affiliation.

CITI certification process must be renewed and documented with the IRB every five years.

- A new protocol will not be accepted by the IRB until all members of the research team have completed the CITI training and the completion of the training is documented in AUM's IRB Office.

Instructions for CITI training:

- For registration into the program, you must create your own unique username and password. http://www.citiprogram.org/
- **To prevent non-AUM researchers from utilizing AUM's program there are several screening requirements: 1) institutional ID # is required. This is your student or faculty/staff ID. 2) also, required is registration with your aum.edu e-mail address. Failure to register using these identifiers will result in being rejected from the system. Periodic screening takes place and non-affiliated users are removed. Contact dtomblin@aum.edu with questions.**
- Select "New Users Register Here"
- Select "Participating Institutions" and find "Auburn University at Montgomery" in the drop down menu
- Create your username and password
- Enter your name and email address (aum.edu)
- Click on "Submit"
- Complete the Course Registration Information

Click on "Submit"

Once you have created your username and password, and completed the Course Registration information, you are ready to select the "Curriculum appropriate to your research activities."

Group 1: Biomedical Research

Group 2: Social/Behavioral Research (most of our researchers are in this category)

Group 3: IRB Members

There are several required modules; therefore, you may exit and enter the site periodically in order to complete the modules. The time required to complete each module is largely dependent upon one's knowledge base concerning the protection of human subjects.

After completing all required modules, please go to the **Institutional Home Page** (Auburn University at Montgomery). From here, you will be able to download a **Course Completion Report.** This report will provide a detailed record of your accomplishments. A copy of this file will (automatically) also be sent to the AUM IRB Office.

Regarding CITI course selection:
The AUM IRB makes the following recommendations if you have questions contact dtomblin@aum.edu :

- **Researchers in social sciences** (faculty, staff, and students) such as: psychology, sociology, public administration, political science, ethics, business, communication, education, etc.: **Social & Behavioral Research-Basic/Refresher.** Social/behavioral research (SBR) is typically characterized by data collection methods such as questionnaires, interviews, focus groups, direct observation, and non-invasive physical measurements
- **Researchers in clinical areas** such as med-technology, laboratory science, etc: **Biomedical Research – Basic/Refresher.**
- **IRB members**: IRB Members – Basic Refresher.
- Researchers conducting **animal research**: select the course specific to the specimen you are conducting research (amphibians, cats, gerbils, guinea pigs, dogs, rats, etc).

Passing Requirement:
All researchers, staff, students, must complete the Modules with a mastery score of at least **80%.**

Failure to Complete the Training Modules:
Failure to complete the training could result in revocation of your protocol approval for research or other action(s) deemed appropriate by the IRB.

If you have any questions regarding this requirement, you can contact the IRB Research Compliance Manager at dtomblin@aum.edu

Upon completion of any module the report is automatically sent to the IRB Administrator. The researcher should also attach a copy to his/her IRB protocol.

9 Categories of IRB Review

Categories or Types of IRB Review

According to Federal Regulations that govern research [45 CFR 46.102 (f)], **Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains:
(**1**) data through *intervention* or *interaction* with the individual, or
(**2**) identifiable *private information*.
Intervention [45 CFR 46.102 (f)] includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between the investigator and subject. **Research** is defined as: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Within the IRB review there are three general categories of review: A. *exempt*, B. *expedited,* and C. *full board review*.

A. Exempt) Review

Auburn University at Montgomery requires that all research involving human subjects receive review and approval before the research begins. The federal regulations, however, allow specific categories of research to be **exempt** from continuing IRB review. It does not mean that the proposed research is exempt from being reviewed. Research activities in which the only involvement of human subjects will be in one or more of the following categories may be considered for administrative (exempt) review. The exempt categories do not apply to research involving **prisoners or children under the age of 18**.

1. 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.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, and achievement), survey procedures, interview procedures or observation of public behavior, unless:
   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.
   Note: Exemption category (2) does not apply to research with minors, except for research involving observations of public behavior when the investigator(s) does not participate in the activities being observed.

3. 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 paragraph **(b)(2)** of this section, if:

a. 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.

4. 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.

5. Research and demonstration projects that 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.

6. 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 an 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.
If it is determined that a research project falls into the Exempt Review Category, the primary reviewer for that application will notify the PI via memo or email of any modifications and/or additional information needed in order to complete the review. Once the project is approved, the IRB office will notify the PI via email or memo with a determination of the review category and approval.

B. Expedited Review

Research activities that (1) present no more than minimal risk to human subjects and (2) involve only procedures listed in one or more of the following categories 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 subjects. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Note: The categories in this list apply regardless of the age of subjects, except as noted. The expedited review procedure may not be used when the identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability, damage the subjects'

financial standing, employability, insurability, reputation, or be stigmatize them unless reasonable and appropriate protections are implemented so that risks related to the invasion of privacy and breach of confidentiality are minimal.

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   (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 increase the risks or decrease the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   (b) 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:

   (a) 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
   (b) from other adults and children, 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.
   (c) All safety practices must be followed regarding blood borne pathegens.

3. Prospective collection of biological specimens for research purposes by non-invasive means.

   (a) **Examples:** (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at the 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 sub-gingival 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 non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. When medical devices are employed, they must be cleared/approved for

marketing. (Studies intended to evaluate the safety and effectiveness of the medical device including studies of cleared medical devices for new indications are not generally eligible for expedited review,)

(a) **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 when appropriate given the age, weight, and health of the individual.

(b) **Research that involves DEXA (Dual Energy x-**ray absorptiometry) - A **DEXA scan** is a non-invasive test that measures bone mineral density to assess if a person is at risk of osteoporosis or fracture. **DEXA** stands for dual energy x-ray absorptiometry. If using DEXA scans in your research contact AUM Kinesiology Department, Dr. Angela Russell. Approval from the State of Alabama Radiation Committee.

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). (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).** 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) 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:
   (a) when (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
   (b) when no subjects have been enrolled and no additional risks have been identified; or
   (c) when 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 when 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.

An expedited review procedure consists of a review by the IRB Chairperson and/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.

C. <u>Full Board Review</u>

All other applications will be reviewed by the IRB at a convened meeting. A quorum of members, including at least one member whose primary concerns are in nonscientific areas, must be present for voting purposes. Full copies of all applications to be reviewed at the meeting are distributed to the members approximately ten days in advance. After the meeting, the PI is notified regarding the review status of the application. The IRB may approve, require clarifications/modifications (in order to secure approval), table (i.e., response from researcher must be brought back to full convened meeting or an expert in the research field consulted), or disapprove the research project.

10 Violations of AUM IRB Human Subjects Protections Policy

The AUM IRB works cooperatively with researchers to protect the rights and welfare of research participants, as well as to protect the scientific integrity of the data of human research participants. In order for research activities to be conducted ethically, they should produce complete, accurate, and reliable scientific data in return for the contributions of the people who volunteer to participate in them.

The IRB is bound by FWA (Federalwide Assurance) and the Code of Federal Regulations (45CFR46.101 through 409). As specific to 45CFR46.114 "The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB requirements or that has been associated with unexpected serious harm to subjects."

Non-compliance refers to: acts of commission or omission which result in the conduct of human subjects research that is inconsistent with the requirements established in the federal regulations relating to human subject protections, with Alabama state law, the policies and procedures of the AUM IRB, or the specific requirements of the AUM IRB or another IRB with the authority and responsibility for overseeing the research.

Non-compliance can take several forms. Examples include, but are not limited to:

- Protocol Exception – the enrollment of a research subject in a protocol that fails to meet the protocol inclusion criteria or did meet the protocol exclusion criteria.
- Protocol Deviation – a departure from the protocol for a research subject once that subject has been enrolled.
- Conducting research activities prior to obtaining IRB approval, or after IRB approval has expired.
- Making changes to the research protocol without submitting a Request for Modification form to the IRB.

All incidents of non-compliance must be reported to the IRB. Incidents can be reported by anyone, including the Principal Investigators, members of a research team, or research participants.

AUM IRB has aligned our policy with the Auburn University policy. Upon notification to the IRB office of noncompliance the following steps will be taken:

1) When non-compliance is discovered, the IRB chair will speak with the investigator and ask for more information.
2) Then, if it appears there is indeed non-compliance, the PI fills out the non-compliance report and submits it to the IRB Administrator.
3) A sub-committee (Chair, Co-Chair and 1-2 more IRB members and the IRB Administrator) meet to discuss the issue with the PI.

4) The sub-committee proposes a plan of action.
5) The full board will meet and discuss the noncompliance report filed by the PI and the plan of action from the subcommittee. A final decision is made on how to resolve the issue. One aspect of that decision includes a determination of the event as being serious or on-going. Most cases involve neglect rather than willful noncompliance but when these cases continue, the PI is warned about ongoing noncompliance that would affect their ability to continue research at AUM.

Appendix

Policy: #1

AUM IRB

Adoption Date: June 2009

AUM IRB Policy on International Research

I. To What Does This Policy Apply:

This policy defines the standards and parameters for the conduct of biomedical, behavioral and social science conducted outside the United States.

II. Policy Statement:

- This organization is committed to upholding the standards for ethical research and informed consent expectations articulated in the Belmont Report for all research conducted outside the United States. Research conducted outside the United States will conform to the same ethical and regulatory standards to which domestic research is held and will be conducted in accordance with US Federal regulations for the protection of human research subjects (45 CFR 46, et seq.) regardless of the funding source. Refer to **International Compilation of Human Research Protections Guide.**

- Research conducted outside the United States will comply with the relevant laws of the host country. Researchers will collaborate whenever possible with a research or educational institution familiar with the local culture and research-related issues. It will be incumbent upon all researchers to ensure that the cultural caveats of the host country are respected and that the participants will not be subjected to retaliation from local authorities or the local community. No research involving humans shall be initiated prior to obtaining appropriate IRB approval.

- An IRB must review and approve all international research involving human subjects. An international institution or site considered engaged in research must obtain IRB approval from an institution that holds a Federalwide Assurance in the country where the research is taking place (if the research is supported by federal funding). Review by a local IRB or local Ethics Board will be sought whenever possible even for research not supported by federal funding. The IRB or Ethics Board must be knowledgeable about and sensitive to, local community composition, mores and standards of conduct. In the event that no such local IRB or Ethics Board exists in the immediate local where the research is to take place, steps will be taken either to identify such a review board within the general region or to identify a local institution that could serve in a comparable capacity (i.e., a tribal council, school board, town committee, hospital board, etc.). Copies of the local IRB approval will be maintained by the IRB Administrator as research documentation.

- The informed consent discussion, as well as all consent documents, will be in the subjects' native language. A translator/interpreter may be employed to help with the consent process. Family members will not be asked to provide such translation because they may not be able to fully explain the study's risks and benefits to the potential subjects. If subjects are likely to be unable to provide written consent, the researchers will provide justification in the protocol submitted to the IRB for a waiver of written consent as well as an acceptable alternative method of obtaining oral consent that is appropriate to both the subjects and their culture.

AUM IRB Policy: #2
Adoption Date: May 2011

AUM IRB Policy of Review of Joint Research with AU/AUM projects requiring IRB Review

I. To What Does This Policy Apply:

This policy defines the standards and parameters for the human subjects research that involve resources and/or academic programs involving Auburn University and Auburn University at Montgomery.

II. Policy Statement:

- Human subjects research that is a result of the AU/AUM joint academic programs (Public Administration and Nursing) will generally not require complete IRB submission and review by both the AU and AUM IRB's. The PI's primary university's (or where student's Thesis/Dissertation director is located) IRB will take the responsibility of review, determination, approval, maintenance, compliance, and closure, etc. At the time of initial approval, it is the responsibility of the primary university's IRB to send the letter of approval to the secondary university for their review and file. The secondary university reserves the right to require changes to the initial IRB protocol submitted by the primary university.

- In the case of unanticipated problems involving risks to subjects or others; serious or continuing noncompliance, and researcher misconduct the secondary institution's IRB will be notified immediately.

- AU research that utilizes AUM resources such as: students (as subjects), researchers, facilities, or supplies will require the submission and approval from both university's IRB's.

- AUM research that utilizes AU resources such as: students (as subjects), researchers, facilities, or supplies will require the submission and approval from both university's IRB's.

AUM IRB Policy: #3
Adoption Date: May 2011

AUM IRB Policy of Review of Oral History Projects

I. To What Does This Policy Apply:

This policy provides guidance for the review of oral history research projects by the IRB.

II. Policy Statement:

In general, the IRB agrees that oral history interviews are not designed to contribute to generalizable knowledge and are therefore not subject to IRB review. However, at the present time, the Office for Human Research Protections has not issued formal guidance regarding oral history and the federal regulations. Therefore, determination will be made, on a case-by-case basis, as to whether the research meets the definition of research specified in the federal regulations. Until formal federal guidance is issued, the IRB would like to provide researchers with the following research scenarios [1] as examples of research that would or would not require IRB review.

Scenario 1

Oral history activities, such as open ended interviews, that ONLY document a specific historical event or the experiences of individuals without an intent to draw conclusions or generalize findings would NOT constitute "research" as defined by HHS regulations 45 CFR part 46.

Example: An oral history video recording of interviews with holocaust survivors is created for viewing in the Holocaust Museum. The creation of the video tape does NOT intend to draw conclusions, inform policy, or generalize findings. The sole purpose is to create a historical record of specific personal events and experiences related to the Holocaust and provide a venue for Holocaust survivors to tell their stories.

Scenario 2

Systematic investigations involving open ended interviews that are designed to develop or contribute to generalizable knowledge (e.g., designed to draw conclusions, inform policy, or generalize findings) WOULD constitute "research" as defined by HHS regulations at 45 CFR part 46.

Example: An open ended interview of Gulf War veterans to document their experiences and to draw conclusions about their experiences to help the VA evaluate VA health benefit policy for these veterans.

Scenario 3

Oral historians and qualitative investigators may want to create archives for the purpose of providing a resource for others to do research. Since the intent of the archive is to create a repository of information for other investigators to conduct research as defined by 45 CFR part 46, the creation of such an archive WOULD constitute research under 45 CFR part 46.

Example: Open ended interviews are conducted with surviving Negro League Baseball players in order to create an archive for future research. The creation of such an archive would constitute research under 45 CFR part 46 since the intent is to collect data for future research.

Oral history research that does meet the definition of research is likely to qualify for review by the expedited mechanism (rather than meet the criteria for exemption because the interviews are generally audio or videotaped). Therefore, such research must be submitted to the IRB using the IRB protocol application. The IRB will determine whether a study involving oral history receives exempt, expedited or full board review as defined by the federal regulations.

Researchers are encouraged to contact the Office of Sponsored Programs/IRB with questions pertaining to oral history research and IRB review prior to completing a protocol application.

Source:

[1]The scenarios were taken from a workshop presented by Tracy Arwood, Clemson University and Helen McGough, University of Washington held at the 2007 Social, Behavioral, Educational Research Conference. The scenarios were taken from a December 2003 e-mail exchange with Michael Carome, Associate Director Regulatory Affairs, OHRP and Lori Bross, Assistant to the Vice President for Research – Research Compliance, The Graduate School, Office of Research Compliance, Northern Illinois University, DeKalb, IL. Source: http://www.nyu.edu/research/resources-and-support-offices/getting-started-withyourresearch/human-subjects-research/forms-guidance.html

AUM IRB Policy: #4
Adoption Date: n/a

AUM IRB Explanation of Age of Majority

I. To What Does This Policy Apply:

This policy provides explanation for the age of majority for "youth" as defined in the State of Alabama.

II. Policy Statement:

Age of majority is frequently confused with a similar concept, the **age of license,** which also pertains to the threshold of adulthood but in a much broader and more abstract way. As a legal term of art, "license" means "permission," and it can implicate a legally enforceable right or privilege. Thus, an age of license is an age at which one has legal permission from the government to do something. The age of maturity, on the other hand, is legal *recognition* that one has grown into an adult.

For example, in any jurisdiction, the ages at which an individual is allowed to exercise the franchise (vote), leave school without taking a diploma, enter into legally binding contracts (other than for necessaries, to which no age of license applies), operate a motor vehicle, purchase and consume alcoholic beverages, and so on, are all ages of license, at which the law permits an individual to perform certain acts and exercise certain rights, with or without any restrictions.

Age of majority pertains solely to the acquisition of control over one's person, decisions and actions, and the correlative termination of the legal authority and responsibility of the parents (or guardian(s), in lieu of parents) over the child's person(s) and affairs generally.

Many ages of license are correlated to the age of majority, but they are nonetheless legally distinct concepts. One need not have attained the age of majority to have permission to exercise certain rights and responsibilities. Some ages of license are actually higher than the age of majority. For example, the age of license to purchase alcoholic beverages is 21 in all U.S. states. For most other purposes, the age of majority in the U.S. is 18. The age of majority in Mississippi is 21 (Mississippi). Two territories (American Samoa and Puerto Rico) retain 14 as the age of majority.[1].

Source: Law Encyclopedia. West's Encyclopedia of American Law. Copyright © 1998 by The Gale Group, Inc.

Policy #5
AUM IRB
Adoption Date: August 2013

AUM IRB Policy for handling non-compliance issues in human subject research

I. To What does this Policy Apply:

When referring to human subjects research, non-compliance refers to acts of commission or omission which result in the conduct of human subjects research that is inconsistent with the requirements established in the federal regulations relating to human subject protections, with Alabama state law, the policies and procedures of the AUM IRB, or the specific requirements of the AUM IRB or another IRB with the authority and responsibility for overseeing the research.

Non-compliance can take several forms. Examples include, but are not limited to:

- Protocol Exception – the enrollment of a research subject in a protocol that fails to meet the protocol inclusion criteria or did meet the protocol exclusion criteria.
- Protocol Deviation – a departure from the protocol for a research subject once that subject has been enrolled.
- Conducting research activities prior to obtaining IRB approval, or after IRB approval has expired.
- Making changes to the research protocol without submitting a modification form to the IRB.

All incidents of non-compliance must be reported to the IRB. Incidents can be reported by anyone, including the Principal Investigators, members of a research team, or research participants.

II. Policy Statement:

In alignment with the AU IRB policy, we propose the following process for non-compliance:

1) When non-compliance is discovered, the IRB chair will speak with the investigator and ask for more information.
2) Then, if it appears there is indeed non-compliance, the PI fills out the non-compliance report (attached) and submits it to the IRB Administrator.
3) A sub-committee (Chair and 1-2 more IRB members and the IRB Administrator) meet to discuss the issue with the PI.
4) The sub-committee proposes a plan of action.

5) The full board will meet and discuss the noncompliance report filed by the PI and the plan of action from the subcommittee. A final decision is made on how to resolve the issue. One aspect of that decision includes a determination of the event as being serious or on-going. Most cases involve neglect rather than willful noncompliance but when these cases continue, the PI is warned about ongoing noncompliance that would affect their ability to continue research at AUM.

Definitions of Terms Used in Research

1. **Adverse effect:** An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (e.g., headache following spinal tap or intestinal bleeding associated with aspirin therapy). IRBs should establish policies and procedures for monitoring such effects in approved studies.

2. **Age of Majority:** Pertains to the acquisition of control over one's person, decisions, and actions, and the correlative termination of the legal authority and responsibility of the parents or guardian(s) over the child's persons and affairs generally. In the State of Alabama and Nebraska, the age of majority is 19, in Mississippi, 21. In other states the age of majority is 18. At the age of majority a subject can sign consent to participate in research. If the subject is under the age of majority, a parent or guardian must sign a parental consent form.

3. **Assent:** Agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research.

4. **Assurance:** A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved [Federal Policy 46.103].

5. **Authorized Institutional Official:** An officer of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research.

6. **Autonomy:** Personal capacity to consider alternatives makes choices, and act without undue influence or interference of others.
7. Belmont Report: A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.

8. **Beneficence**: An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

9. **Benefit:** A valued or desired outcome; an advantage.

10. **Biologic:** Any therapeutic serum, toxin, anti-toxin, or analogous microbial product applicable to the prevention, treatment, or cure of diseases or injuries.

11. **Blind Study Designs**: See: Masked Study Designs; Double-Masked Design; and Single-Masked Design.

12. **Broad Consent:** The Final Rule presents a new concept of "broad consent" in 46.116(a) and (d), which addresses elements of consent for the storage, maintenance, and secondary research use of private information or identifiable biospecimens. The preamble defines broad consent as "seeking prospective consent to unspecified future research." Waivers and refusals of broad

consent are addressed in 46.116(e). Broad consent may be obtained only for the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens.

13. **Case-Control Study**: A study comparing persons with a given condition or disease (the cases) and persons without the condition or disease (the controls) with respect to antecedent factors. (See: Retrospective Studies.)

14. **Case-Control Study**: A study comparing persons with a given condition or disease (the cases) and persons without the condition or disease (the controls) with respect to antecedent factors. (*See: Retrospective Studies*.)

15. **Certification:** The official notification by the University that a research project or activity involving human subjects has been approved by the IRB.

16. **Children (minors):** 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.

17. ***Clinical Trial -** The final rule added the definition of "clinical trial," which was not defined in the previous version of the Common Rule. A clinical trial is "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes." *revised Common Rule definition.

18. **Coercion:** persuading an otherwise unwilling person to do something by using force or threats
19. **Cohort**: A group of subjects, initially identified as having one or more characteristics in common, who are followed over time. In social science research, this term may refer to any group of persons who are born at about the same time and share common historical or cultural experiences.
20. **Cognitively impaired**: Having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

21. **Compensation:** Payment or medical care provided to subjects injured in research; does not refer to payment (remuneration) for participation in research.

22. **Competency:** Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. (*See also: Incompetence, Incapacity*.)

23. **Confidentiality:** Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others, in ways that are inconsistent with the understanding of the original disclosure, without permission.

24. **Cooperative research projects:** Those projects normally supported through grants, contracts, or similar arrangements, which involve institutions in addition to the grantee or prime contractor (such as a contractor with the grantee, or a subcontractor with the prime contractor).

25. **Control(s)**: Subject(s) used for comparison who are not given a treatment under study or do not have a given condition, background, or risk factor that is the object of study. Control conditions may be concurrent (occurring more or less simultaneously with the condition under study) or historical (preceding the condition under study). When the present condition of subjects is compared with their own condition on a prior regimen or treatment, the study is considered historically controlled.

26. **Contraindicated**: Disadvantageous, perhaps dangerous; a treatment that should not be used in certain individuals or conditions due to risks (*e.g.*, a drug may be contraindicated for pregnant women and persons with high blood pressure).

27. **Correlation Coefficient**: A statistical index of the degree of relationship between two variables. Values of correlation coefficients range from -1.00 through zero to +1.00. A correlation coefficient of 0.00 indicates no relationship between the variables. Correlations approaching -1.00 or +1.00 indicate strong relationships between the variables. However, causal inferences about the relationship between two variables can never be made on the basis of correlation coefficients, no matter how strong a relationship is indicated.

28. **Cross-Over Design**: A type of clinical trial in which each subject experiences, at different times, both the experimental and control therapy. For example, half of the subjects might be randomly assigned first to the control group and then to the experimental intervention, while the other half would have the sequence reversed.

29. **Data and Safety Monitoring Board:** A committee of scientists, physicians, statisticians, and others that collects and analyzes accumulating data during the course of a clinical trial to monitor for adverse effects and other trends (such as an indication that one treatment is significantly better than another, particularly when one arm of the trial involves a placebo control) that would warrant modification or termination of the trial, or notification of subjects about new information that might affect their willingness to continue in the trial.

30. **Debriefing:** Giving subjects previously undisclosed information about the research project following completion of their participation in research. (Note that this usage, which occurs within the behavioral sciences, departs from Standard English, in which debriefing is obtaining rather than imparting information.)

31. **Deception:** giving the appearance or perception different from the true one.

32. **Declaration of Helsinki:** A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associations in various countries. It was revised in 1975 and 1989.

33. **Dependent Variables**: The outcomes that are measured in an experiment. Dependent variables are expected to change as a result of an experimental manipulation of the independent variable(s).

34. **Descriptive Study**: Any study that is not truly experimental (e.g., quasi-experimental studies, correlational studies, record reviews, case histories, and observational studies).

35. **Device (medical):** Therapeutic, diagnostic, or prosthetic articles which do not interact chemically with the body (e.g., pacemakers, intrauterine contraceptive devices, diagnostic test kits, crutches, artificial joints).

36. **DHEW** A federal agency: U.S. Department of Health, Education and Welfare; reorganized in 1980 as the Department of Health and Human Services (DHHS) and the Department of Education.

37. **DHHS** A federal agency: U.S. Department of Health and Human Services; formerly the Department of Health, Education and Welfare (DHEW).

38. **Double-Masked Design**: A study design in which neither the investigators nor the subjects know the treatment group assignments of individual subjects. Sometimes referred to as "double-blind." marriage, parenthood, financial independence, or other means, depending on state law.

39. **Emancipated Minor:** A legal status conferred upon persons who have not yet attained the age of legal competency as defined by state law (for such purposes as consenting to medical care), but who are entitled to treatment as if they had by virtue of assuming adult responsibilities such as being self-supporting and not living at home, marriage, or procreation. (*See also: Mature Minor*.)

40. **Emergency use:** The use of a test article on a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval.

41. **Ethnographic Research**: The study of people and their culture. Ethnographic research, also called fieldwork, involves observation of and interaction with the persons or group being studied in the group's own environment, often for long periods of time. (*See also: Fieldwork*.)

42. **Experimental:** Term often used to denote a therapy (drug, device, procedure) that is unproven or not yet scientifically validated with respect to safety and efficacy. A procedure may be considered "experimental" without necessarily being part of a formal study (research) to evaluate its usefulness. (*See also: Research*.)

43. **Experimental Study**: A study in which subjects are randomly assigned to groups that experience carefully controlled interventions manipulated by the experimenter according to a strict logic allowing causal inference about the effects of the interventions under investigation. (*See also: Quasi-Experimental Study*).

44. **FDA** Food and Drug Administration; an agency of the federal government established by Congress in 1912 and presently part of the Department of Health and Human Services.

45. **Federal Policy (The)** the federal policy that provides regulations for the involvement of human subjects in research. The Policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency that takes appropriate administrative action to make the Policy applicable to such research. Currently, sixteen federal agencies have adopted the Federal Policy. (Also known as the "Common Rule."

46. **FWA**: Federal Wide Assurance. Contract entered between AUM and the OHRP (Office of Human Research Protection/HHS Health and Human Services) to guarantee protections to human subjects in research. FWA approval qualifies an entity to apply for NIH, NSF, etc. funding opportunities.

47. **Fieldwork**: Behavioral, social, or anthropological research involving the study of persons or groups in their own environment and without manipulation for research purposes (distinguished from laboratory or controlled settings). (*See also: Ethnographic Research.*)

48. **Full Board Review:** Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting [Federal Policy 46.108].

49. **Generalizable Knowledge:** Typically, this involves some variation of the thought that the results are intended / expected to be applied to a larger population beyond the site of data collection or the population studied.

50. **Grant:** Financial support provided for research study designed and proposed by the principal investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant. (*Compare: Contract.*)

51. **Guardian:** An individual who is authorized under applicable state or local law to consent on behalf of another person (i.e., children) to general medical care.

52. **Helsinki Declaration:** *See: Declaration of Helsinki*

53. **Historical Controls**: Control subjects (followed at some time in the past or for whom data are available through records) who are used for comparison with subjects being treated concurrently. The study is considered historically controlled when the present condition of subjects is compared with their own condition on a prior regimen or treatment.

54. ***Human Subject -** The final rule expanded the definition of "human subject" to cover the collection of biospecimens (this does not include non-identified biospecimens). The new definition includes "a living individual about whom an investigator, whether professional or student conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens." *Revised Common Rule definition.

55. **Incapacity:** Refers to a person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Often used as a synonym for incompetence. (*See also: Incompetence.*)

56. **Incapacity:** Technically, a legal term meaning inability to manage one's own affairs. Often used as a synonym for incapacity. (*See also: Incapacity.*)

57. **Independent Variables**: The conditions of an experiment that are systematically manipulated by the investigator.

58. ***Identifiable Private Information:** Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. *Common Rule revision.

59. **Informed consent:** The knowing, legally effective consent of any individual or the individual's legally authorized representative. Such consent can be obtained only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

60. **Interaction:** The communication or interpersonal contact between investigator and subject.

61. **Intervention:** Includes both physical procedures by which data are gathered (i.e., venipuncture) and manipulation of the subject or the subject's environment that are performed for research purposes.

62. **Investigational (new drug or device):** A drug or device permitted by the FDA to be tested on humans but not yet determined to be safe and effective for a particular use in the general population and not yet licensed for marketing.

63. **Institution** (1): Any public or private entity or agency (including federal, state, and local agencies) [Federal Policy 46.102(b)].

64. **Institution** (2): A residential facility that provides food, shelter, and professional services (including treatment, skilled nursing, intermediate or long-term care, and custodial or residential care). Examples include general, mental, or chronic disease hospitals; inpatient community mental health centers; halfway houses and nursing homes; alcohol and drug addiction treatment centers; homes for the aged or dependent, residential schools for the mentally or physically handicapped; and homes for dependent and neglected children.

65. **Institutional Review Board:** A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research [Federal Policy 46.102(g), 46.108, 46.109].

66. **Institutionalized:** Confined, either voluntarily or involuntarily (e.g., a hospital, prison, or nursing home).

67. **Internally Funded:** Funding for the research project is provided by the institution. Examples: department funding, Research Council, etc.

68. **investigator:** In clinical trials, an individual who actually conducts an investigation [21 CFR 312.3]. Any interventions (e.g., drugs) involved in the study are administered to subjects under the immediate direction of the investigator. (*See also: Principal Investigator*.)

69. **IRB** *See: Institutional Review Board.*

70. **Justice:** An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.

71. **Legally Authorized Representative:** An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the research procedure(s).

72. **Longitudinal Study**: A study designed to follow subjects forward through time.

73. **Masked Study Designs**: Study designs comparing two or more interventions in which either the investigators, the subjects, or some combination thereof do not know the treatment group assignments of the individual subjects. Sometimes called "blind" study designs. (*See also: Double-Masked Design; Single-Masked Design.*)
74. **Mature Minor:** Someone who has not reached adulthood (as defined by state law) but who may be treated as an adult for certain purposes (e.g., consenting to medical care). Note that a mature minor is not necessarily an emancipated minor. (*See also: Emancipated Minor*.)

75. **Medical Device:** A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body. Such devices include diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic pins or other orthopedic equipment.

76. **Mentally Disabled:** *See: Cognitively Impaired.*

77. ***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. *Revised Common Rule definition.

78. Monitoring: The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design and subject protections.

79. **Non-therapeutic Research:** Research that has no likelihood or intent of producing a diagnostic, preventive, or therapeutic benefit to the current subjects, although it may benefit subjects with a similar condition in the future.

80. **Normal Volunteers:** Volunteer subjects used to study normal physiology and behavior or who do not have the condition under study in a particular protocol, used as comparisons with subjects who do have the condition. "Normal" may not mean normal in all respects. For example, patients with broken legs (if not on medication that will affect the results) may serve as normal volunteers in studies of metabolism, cognitive development, and the like. Similarly, patients with heart disease but without diabetes may be the "normals" in a study of diabetes complicated by heart disease.

81. **Null Hypothesis**: The proposition, to be tested statistically, that the experimental intervention has "no effect," meaning that the treatment and control groups will not differ as a result of the intervention. Investigators usually hope that the data will demonstrate some effect from the intervention, thereby allowing the investigator to reject the null hypothesis.

82. **Nuremberg Code:** A code of research ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting human subjects.

83. **Office of Human Research Protections** The office within the National Institutes of Health, an agency of the Public Health Service, Department of Health and Human Services, responsible for implementing DHHS regulations (45 CFR Part 46) governing research involving human subjects.

84. **Open Design**: An experimental design in which both the investigator(s) and the subjects know the treatment group(s) to which the subjects are assigned.

85. **Parent:** A child's biological or adoptive parent.

86. **Paternalism:** Making decisions for others against or apart from their wishes with the intent of doing them good.

87. **Permission:** The agreement of the parents or guardians to the participation of their child or ward in research.

88. **Pharmacology:** The scientific discipline that studies the action of drugs on living systems (animals or human beings).

89. **Phase 1, 2, 3, 4 Drug Trails:** Different stages of testing drugs in humans, from first application in humans (Phase 1) through limited and broad clinical tests (Phase 3), to post marketing studies (Phase 4).
    a. **PHASE 1 DRUG TRIAL** Phase 1 trials include the initial introduction of an investigational new drug into humans. These studies are typically conducted with healthy volunteers; sometimes, where the drug is intended for use in patients with a particular disease, however, such patients may participate as subjects. Phase 1 trials are designed to determine the metabolic and pharmacological actions of the drug in humans, the side effects associated with increasing doses (to establish a safe dose range), and, if possible, to gain early evidence of effectiveness; they are typically closely monitored. The ultimate goal of Phase 1 trials is to obtain sufficient information about the drug's pharmacokinetics

and pharmacological effects to permit the design of well-controlled, sufficiently valid Phase 2 studies. Other examples of Phase 1 studies include studies of drug metabolism, structure-activity relationships, and mechanisms of actions in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes. The total number of subjects involved in Phase 1 investigations is generally in the range of 20-80.

b. **PHASE 2 DRUG TRIAL** Phase 2 trials include controlled clinical studies conducted to evaluate the drug's effectiveness for a particular indication in patients with the disease or condition under study, and to determine the common short-term side effects and risks associated with the drug. These studies are typically well-controlled, closely monitored, and conducted with a relatively small number of patients, usually involving no more than several hundred subjects.
c. **PHASE 3 DRUG TRIAL** Phase 3 trials involve the administration of a new drug to a larger number of patients in different clinical settings to determine its safety, efficacy, and appropriate dosage. They are performed after preliminary evidence of effectiveness has been obtained, and are intended to gather necessary additional information about effectiveness and safety for evaluating the overall benefit-risk relationship of the drug, and to provide adequate basis for physician labeling. In Phase 3 studies, the drug is used the way it would be administered when marketed. When these studies are completed and the sponsor believes that the drug is safe and effective under specific conditions, the sponsor applies to the FDA for approval to market the drug. Phase 3 trials usually involve several hundred to several thousand patient-subjects.
d. **PHASE 4 DRUG TRIAL** Concurrent with marketing approval, FDA may seek agreement from the sponsor to conduct certain postmarketing (Phase 4) studies to delineate additional information about the drug's risks, benefits, and optimal use. These studies could include, but would not be limited to, studying different doses or schedules of administration than were used in Phase 2 studies, use of the drug in other patient populations or other stages of the disease, or use of the drug over a longer period of time [21 CFR 312.85].

90. **PHS** Public Health Service. Part of the U.S. Department of Health and Human Services, it includes FDA, NIH, CDC, SAMHSA, and HRSA.

91. **Placebo**: A chemically inert substance given in the guise of medicine for its psychologically suggestive effect: used in controlled clinical trials to determine whether improvement and side effects may reflect imagination or anticipation rather than the actual power of a drug.

92. **Principal Investigator:** The scientist or scholar with primary responsibility for the design and conduct of a research project.

93. **Prisoner:** An individual involuntarily confined in a penal institution, including persons: (1) sentenced under a criminal or civil statue; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities (e.g., for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution [45 CFR 46.303(c)].

94. **Privacy:** Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

95. **Private Information:** Behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information, provided for specific purposes by an individual, which that individual can reasonably expect will not be made public, (i.e., a medical record.)

96. **Prophylactic:** Preventive or protective; a drug, vaccine, regimen, or device designed to prevent, or provide protection against, a given disease or disorder.

97. **Prospective Studies**: Studies designed to observe outcomes or events that occur subsequent to the identification of the group of subjects to be studied. Prospective studies need not involve manipulation or intervention but may be purely observational or involve only the collection of data. IRBs should note that prospective studies do *not* qualify for exemption under Federal Policy §45 CFR 46.101(b)(4) because the data or specimens in prospective studies are not extant at the time the study begins.

98. **Protocol**: The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

99. **Purity:** The relative absence of extraneous matter in a drug or vaccine that may or may not be harmful to the recipient or deleterious to the product.

100. **Quasi-Experimental Study**: A study that is similar to a true experimental study except that it lacks random assignment of subjects to treatment groups. (*See also: Experimental Study*.)

101. **Random, Random Assignment, Randomization, Randomized Conditions, and Randomized Trials**: Assignment of subjects to different treatments, interventions, or conditions according to chance rather than systematic (e.g., as dictated by the standard or usual response to their condition, history, or prognosis, or according to demographic characteristics). Random assignment of subjects to conditions is an essential element of experimental research because it increases the probability that differences observed between subject groups are the result of the experimental intervention.

102. **Remuneration:** Payment for participation in research. (NOTE: The use of the term "compensation" is confined to payment or provision of care for research-related injuries.)

103. **Research:** Systematic investigation designed to develop or contribute to general knowledge. Under this definition some demonstration, service, and training projects may be considered to include research activities.

104. **Respect for Persons:** An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

105. **Retrospective Studies:** Research conducted by reviewing records from the past (e.g., birth and death certificates, medical records, school records, or employment records) or by obtaining information about past events elicited through interviews or surveys. Case control studies are an example of this type of research.

106. **Review (of research):** The concurrent oversight of research on a periodic basis by an IRB. In addition to the at least annual reviews mandated by the federal regulations, reviews may, if deemed appropriate, also be conducted on a continuous or periodic basis [Federal Policy 46.108(e)].

107. **Risk:** The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." (*See also: Minimal Risk*.)

108. **SAMHSA** Substance Abuse and Mental Health Services Administration; includes the Center for Substance Abuse Prevention, the Center for Substance Abuse Treatment and the Center on Mental Health Services. Previously the Alcohol, Drug Abuse, and Mental Health Administration.

109. **Scientific Review Group:** A group of highly regarded experts in a given field, convened by NIH to advise NIH on the scientific merit of applications for research grants and contracts. Scientific review groups are also required to review the ethical aspects of proposed involvement of human subjects. Various kinds of scientific review groups exist, and are known by different names in different institutes of the NIH (e.g., Study Sections, Initial Review Groups, Contract Review Committees, or Technical Evaluation Committees).

110. **Secretary:** A U.S. Cabinet Officer. In the context of DHHS-conducted or -supported research, usually refers to the Secretary of Health and Human Services.

111. **Significant Risk Device:** An investigational medical device that presents a potential for serious risk to the health, safety, or welfare of the subject.

112. **Single-Masked Design**: Typically, a study design in which the investigator, but not the subject, knows the identity of the treatment assignment. Occasionally the subject, but not the investigator, knows the assignment. Sometimes called "single-blind design."

113. **Site Visit:** A visit by agency officials, representatives, or consultants to the location of a research activity to assess the adequacy of IRB protection of human subjects or the capability of personnel to conduct the research.

114. **Social Experimentation**: manipulation of, or experimentation in, social or economic systems; used in planning public policy.

115. **Sponsor** (of a drug trial): A person or entity that initiates a clinical investigation of a drug usually the drug manufacturer or research institution that developed the drug. The sponsor does not actually conduct the investigation, but rather distributes the new drug to investigators and

physicians for clinical trials. The drug is administered to subjects under the immediate direction of an investigator who is not also a sponsor. A clinical investigator may, however, serve as a sponsor-investigator. The sponsor assumes responsibility for investigating the new drug, including responsibility for compliance with applicable laws and regulations. The sponsor, for example, is responsible for obtaining FDA approval to conduct a trial and for reporting the results of the trial to the FDA.

116. **Sponsor-Investigator** An individual who both initiates and actually conducts, alone or with others, a clinical investigation. Corporations, agencies, or other institutions do not qualify as sponsor-investigators.

117. **Statistical Significance**: A determination of the probability of obtaining the particular distribution of the data on the assumption that the null hypothesis is true. Or, more simply put, the probability of coming to a false positive conclusion. [*See* McLarty (1987), p. 2.] If the probability is less than or equal to a predetermined value (e.g., 0.05 or 0.01), then the null hypothesis is rejected at that significance level (0.05 or 0.01).

118. **Surveys**: Studies designed to obtain information from a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.

119. **Test article:** Any drug/biological product/medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulations.

120. **Therapeutic Intent:** The research physician's intent to provide some benefit to improving a subject's condition (e.g., prolongation of life, shrinkage of tumor, or improved quality of life, even though cure or dramatic improvement cannot necessarily be effected.) This term is sometimes associated with Phase 1 drug studies in which potentially toxic drugs are given to an individual with the hope of inducing some improvement in the patient's condition as well as assessing the safety and pharmacology of a drug.

121. **Therapy**: Treatment intended and expected to alleviate a disease or disorder.

122. **Variable** (noun) An element or factor that the research is designed to study, either as an experimental intervention or a possible outcome (or factor affecting the outcome) of that intervention.

123. **Voluntary**: Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

124. **Vulnerable Population**: study populations that require special protections as required from OHPR. These include: pregnant women, prisoners, elderly, participants under the age of 19, physically or mentally challenged.

125. **Written or In Writing:** The new definition of ‘‘written or in writing’’ is included in the Final Rule to clarify that these terms include electronic formats, which aligns the Common Rule with U.S. Food and Drug Administration (FDA) and the International Council for Harmonisation (ICH)

initiatives to promote electronic consent. The Final Rule's preamble notes that the definition does not preclude the possibility that consent forms could be in media other than paper or electronic formats and still meet the requirements of the Common Rule.

(Template Participant Informed Consent)

Auburn University at Montgomery (*Department*)

INFORMED CONSENT

Concerning Participation in a Research Study

(*Title of Study*)

You are invited to participate in a study of *(state what is being studied*).

Research Purpose & Procedures:

We hope to learn (*state what the study is designed to investigate*). You were selected as a possible participant because (*state why the respondent was selected*). If you decide to participate, (*I/we*), (*name the investigators and associates, if any*), will (*describe procedures to be followed, including purposes, how long they will take, and their frequency*). What is this research about?

Risks or Discomforts/Potential Benefits:

- *Explain or describe any discomforts and inconveniences that reasonably can be expected and estimate the total time required of the subject.*
- *Describe risks identified in the protocol and precautions taken to reduce risks.*
- *If there is a possibility of additional cost to the subject because of participation, describe.*
- *If extra credit is involved, state amount.*
- *Describe benefits that reasonably can be expected.*
- *If any benefits are described, add:* We cannot promise you that you will receive any or all of these benefits.

Alternative Procedures:

(*Describe appropriate alternative procedures that might be advantageous to the respondent, if any. You must disclose the nature of any treatment that is being withheld*). If needed.

Provisions for Confidentiality:

Any information obtained in connection with this study that can be identified with you will remain confidential and will be disclosed only with your permission. If you give us your permission by signing this document, we plan to disclose (*state persons or agencies to whom the information will be furnished and the purposes of the disclosure*). (*If the subject will receive compensation, describe the amount or nature.*

Management of Research-related Injury:

If medical treatment for physical injuries is available, state the extent of treatment that will be provided and where it will be carried out. In the case of a social/behavioral research project include appropriate referrals (ex: for psychological counseling.)

Contacts for Additional Information:

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions about the study, you can contact the investigator, *(name, email, phone number)*. If you have any questions about your rights as a volunteer in this research, contact Debra Tomblin, Research Compliance Manager, AUM, 334-244-3250.

Voluntary Participation & the Right to Discontinue Participation without Penalty:

If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without penalty. If you decide later to withdraw from the study, you may also withdraw any information that has been collected about you. Your decision whether to participate will not prejudice your future relations with Auburn University at Montgomery (*and name of cooperating institution or agency, if any*). The researcher may discontinue the study at any point. The researcher may terminate your participation from the project at any point.

We will give you a copy of this consent form to take with you.

YOU ARE MAKING A DECISION WHETHER TO PARTICIPATE. YOUR SIGNATURE INDICATES THAT YOU HAVE DECIDED TOPARTICIPATE, HAVING READ THE INFORMATION PROVIDED ABOVE.

Participant's signature & Date

_____ _____

Investigator's signature

(Template Information Letter)

INFORMATION LETTER
Concerning Participation in a Research Study
Auburn University at Montgomery

(*Title of study, matching the title of the research protocol submitted to the IRB*)

Description of the research and your participation
You are invited to participate in a research study conducted by (*insert the Principal Investigator's name here, along with the student's name if the research is being performed by a student under the direction of the Principal Investigator*). The purpose of this research is (*explain the purpose of the study in easily understood language*).

Your participation will involve (*describe the procedures to be followed in easily understood language*).

The amount of time required for your participation will be (*provide an estimate of the expected duration of the participant's participation in the study*).

Risks and discomforts
There are no known risks associated with this research. OR There are certain risks or discomforts associated with this research. They include (*describe any reasonably foreseeable risks or discomforts to the participant. You may also describe the measures you will take to minimize these risks and discomforts.*)

Potential benefits
(*Describe any benefits to the participant and to others that may reasonably be expected from the research*.) OR There are no known benefits to you that would result from your participation in this research. If appropriate, add: This research may help us to understand (*limit to a brief statement*).

Protection of confidentiality
(Describe the extent to which the confidentiality of records identifying the participant will be maintained. If appropriate, precede this description with: We will do everything we can to protect your privacy. If appropriate, follow this description with: Your identity will not be revealed in any publication that might result from this study.)

Voluntary participation

Your participation in this research study is voluntary. You may choose not to participate and you may withdraw your consent to participate at any time. You will not be penalized in any way should you decide not to participate or to withdraw from this study.

Contact information
If you have any questions or concerns about this study or if any problems arise, please contact (*insert the Principal Investigator's name here*) at Auburn University at Montgomery at (*xxx)xxx.xxxx*. If you have any questions or concerns about your rights as a research participant, please contact the AUM Institutional Review Board (IRB) Administrator (in the Office of Sponsored Programs) at (334) 244-3250 or dtombin@aum.edu.

Sample **Child Assent**

ASSENT to Participate in a Study
Concerning Participation in a Research Study
Auburn University at Montgomery

Purpose of the Research

We are asking you to take part in a research study because we are trying to learn more about (*outline what the study is about in language that is both appropriate to the child's maturity and age.*)

Procedure/Intervention/Method

If you agree to be in this study, you will … (*Describe the procedures and the duration of participation. Describe what will take place from the child's point of view in a language that is both appropriate to the child's maturity and age.*).

Risks

(*Describe any risks to the child that may result from participation in the research.*)

Benefits

Being in this study will help us to understand…(*Describe any benefits to the child from participation in the research.*)

Alternative Procedures and Voluntary Participation

If you don't want to be in this study, you don't have to be in it. Remember, being in this study is up to you, and no one will be upset if you don't want to participate. You can change your mind later if you want to stop. Please talk this over with your parents before you decide whether or not to participate. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say "yes," you can still decide not to do this.

Confidentiality

All of your records about this research study will be kept locked up so no one else can see them. (*Explain how the records will be kept confidential.*)
You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call me (*insert your name and telephone number*) or ask me next time.

Signing my name at the bottom means that I agree to be in this study. My parents and I will be given a copy of this form after I have signed it.
Printed Name of Child _____

Signature of Child _____

Date _____

Researcher contact information (name and phone number):

If you have any questions or concerns about your rights as a participant, please contact the AUM Institutional Review Board (IRB) Administrator (in the Office of Sponsored Programs) at (334) 244-3250 or dtomblin@aum.edu