Table of Contents

Introduction

Auburn University ("University") is committed to the protection of human subjects participating in research activities. The Auburn University Institutional Review Board (IRB) was established in 1981 to evaluate all research activities involving human subjects to ensure the protection of the subjects and compliance with federal guidelines and regulations. The Auburn University IRB is charged with:

1) Protecting all human research subjects;
2) Educating and informing university faculty, staff, and students about human subjects issues;
3) Assisting investigators with the research protocol submission, review and approval process;
4) Reviewing and approving research protocols;
5) Providing continuing oversight of research activities involving human subjects;
6) Ensuring that Auburn University complies with applicable federal, state, and local regulations and guidelines.

While all federal agencies are concerned with the protection of human research subjects, two agencies, the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA) have assumed leadership roles in ensuring such

protection. Regulations for DHHS and FDA are codified at 45 CFR 46[1] and 21 CFR 50, respectively. (See Appendices A and B.) Guidelines for the University review and approval process meet the basic requirements of 45 CFR 46 and other federal departments and agencies (see Appendix C for references to codification) and adhere to the principles of *The Belmont Report* (1979) and the *Nuremberg Code* (1948). (See Appendices D and E.)

Office of Human Subjects (OHS) Administrative Organization

The Office of Human Subjects (OHS), a unit under the direction of the Associate Provost and Vice President for Research, provides administrative support for the IRB and assists investigators with protocol submission, revisions, monitoring, and reporting. OHS maintains all official records for human subjects research activities. The chief administrative official of OHS is the Coordinator. The mission of OHS is to create, promote, and maintain an environment, an infrastructure and the resources to encourage and support research endeavors of the University while ensuring full

---

[1] 45 CFR 46 Subpart A is known as *The Common Rule*. Until 1991, federal departments and agencies that conduct, support, or regulate research used a variety of policies and procedures to protect human research subjects. To eliminate confusion and promote uniformity, each of these departments and agencies adopted as regulation a common federal policy for the protection of human research subjects. The FDA has concurred in the common policy, but has not adopted the policy in its entirety. Instead, the FDA has made selected changes to its IRB and informed consent regulations that correspond to the common policy.

compliance with all federal, state, and university regulations and policies applicable to human subjects research.

Responsible Parties

IRB Chairperson

The responsibilities of the Chair include the following:

1) Coordinate and oversee all functions and activities of the IRB.
2) Classify protocols and protocol revisions as exempt or non-exempt. This responsibility may be delegated to the Coordinator or an experienced IRB member.
3) Determine the appropriate method of review, expedited or full, for non-exempt protocols. This responsibility may be delegated to the Coordinator or an experienced IRB member.
4) Assign primary and secondary reviewers for protocols and protocol revisions to be reviewed by the IRB. This responsibility may be delegated to the Coordinator or an experienced IRB member.
5) Convene and conduct the monthly IRB meetings. In the event that the Chair is unable to convene a meeting, the Chair shall appoint an Interim Chair to do so.
6) Respond on behalf of the IRB to faculty questions or inquiries concerning protocol approvals, monitoring, disapprovals, suspensions and/or terminations;

7) In collaboration with the Coordinator of OHS, recommend to the Vice President for Research individuals who may serve as a Community or Alternate Member of the IRB.
8) In collaboration with the Coordinator of OHS, assure that all research that utilizes human subjects complies with University and sponsor policies and relevant state, local, and federal guidelines and regulations.

Coordinator (OHS)

The Coordinator provides campus-wide leadership in developing University policies and assuring that research activities involving human subjects are in compliance with federal, state, and local laws and regulations. Responsibilities of the Coordinator include:

1) Providing leadership for and oversight of the submission, review, and approval of protocols and protocol revision requests;
2) Ensuring that OHS provides appropriate and adequate support to the IRB;
3) Developing educational programs and materials on human subjects research issues and ensuring meaningful delivery of such programs to faculty, staff, and students;
4) Performing quality assurance reviews for compliance with regulations, policies, and operating procedures;
5) Serving as a non-voting member of the IRB;

6) Providing current information regarding regulatory and policy changes to the IRB and investigators;
7) In collaboration with the IRB Chair, recommending to the Vice President for Research individuals who may serve as a Community or Alternate Member of the IRB;
8) Working with investigators to prepare protocols for submission to the IRB;
9) Supervising the OHS staff to ensure appropriate services for and effective communications with faculty, staff, and students interacting with OHS;
10) Serving as the liaison between the University and outside regulatory agencies;
11) Assuring that Auburn University meets all reporting and/or application deadlines with regard to the University's compliance with regulations and sponsor/agency policies.

Program Administrator (OHS)

Under direction of the Coordinator, the Program Administrator provides administrative support and assistance to the IRB and the Coordinator. Duties include, but are not limited to, those outlined below.

1) Minutes and Meetings
    a) Schedule, attend, and take minutes for all IRB meetings;
    b) Prepare and distribute meeting agenda for each scheduled meeting of the IRB.
2) Protocols

a) Receive, log, and review (preliminary) for obvious errors and omissions, all protocols and protocol revision requests;

b) Distribute packets (protocols, protocol revisions, agenda and meeting minutes) to members of the IRB prior to the next scheduled meeting;

c) Provide advice and assistance to investigators in the preparation of protocols and protocol revision requests.

3) Correspondence

a) Protocol approval, denial, suspension and termination;

b) Requests for protocol clarifications and/or modifications;

c) Protocol expiration notices;

d) Protocol reports;

e) Letters of confirmation to project sponsors.

4) Records

The Program Administrator shall be responsible for keeping all records in accordance with federal, state and local requirements. Examples of these records include:

a) Copies of all research protocols reviewed, approved sample consent documents, progress reports submitted by investigators, statements of significant new findings provided to subjects, and reports of injuries to subjects;

b) Minutes of IRB meetings in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for

requiring changes in or disapproving research; and a written summary of the discussion of issues and their resolution;

c) Records of continuing review activities;

d) Copies of all correspondence between the IRB and the investigators;

e) A list of IRB members with detail sufficient to meet the requirements of federal, state, and local regulations;

f) Written procedures for the IRB;

g) Statements of significant new findings provided to subjects.

5) Support for the Coordinator of OHS.

The Coordinator of OHS works directly with the IRB on all matters involving the protection of human research subjects. The Administrator will maintain records of all official correspondence and other materials generated by the Coordinator in the execution of Coordinator's duties.

Investigator

The Investigator has primary responsibility for the following:

1) Submitting accurate and complete protocol review forms and appropriate supporting documentation and materials for approval by the IRB prior to initiating the research activity;

2) Ensuring that all projects are carried out in accordance with the approved protocol;

3) Promptly advising the IRB of any changes necessary to conduct the research and receiving approval from the IRB prior to implementing such changes;

4) Ensuring that all individuals interacting with study participants have received appropriate instruction/training in conduct of the project;
5) Securing and documenting the legally informed consent of the participant or the participant's legally authorized representative, and, where appropriate, the assent of any participants who have not attained the legal age of consent;
6) Monitoring data collected to ensure the safety of participants;
7) Appropriately protecting the privacy of participants and maintaining confidentiality of the data;
8) Promptly providing participants with statements of any new findings that may affect their health or well-being.

Any individual who holds one of the following positions may be identified as a Principal Investigator ("Investigator") for a human subjects research activity:

- Tenure track faculty (full, associate, and assistant professors)
- Nontenure-track research faculty (full, associate, and assistant research professors)
- Research Fellow IV
- Director of a formal university Institute or Center
- Librarians holding faculty status equivalent to or greater than Assistant Professor

Any individual who holds one of the following positions may be identified as a Principal Investigator for sponsored activities if one of the individuals listed above is also named as a Co-Principal Investigator on the project:

- Instructors
- Adjunct/Affiliate faculty
- Emeritus faculty
- Curators
- Resident
- Research Fellow III
- Post Doctoral Fellow

9) When a graduate student will have primary responsibility for carrying out the research to complete the requirements for a degree, the student should be named as the Lead Graduate Student (LGS).

Department Heads/Chairpersons

The chief administrator of each Department, Research Institute, Center or Unit:

1) Is responsible for overseeing faculty, staff, and students working with human subjects in his/her overall area of jurisdiction;
2) Must ensure that prior to initiation of work, each investigator wishing to engage in research involving human subjects files the appropriate protocol review form(s) and receives IRB approval;
3) Is mutually responsible, with the Investigator, for informing the IRB of deviations from the approved protocol and reporting accidents or incidents encountered in the performance of the project;

4) Should ensure that all faculty, staff, and students have received appropriate instruction regarding the performance of research activities involving human subjects;
5) Must determine that appropriate facilities and equipment are available for the approved research activity.

Dean

The Dean of each unit involved in human subjects research is responsible for ensuring that all departments have access to the resources necessary to conduct the research in accordance with the approved protocol and in a manner designed to protect the research subjects from unnecessary risk/harm while participating.

Institutional Official (IO)

The IO is responsible for ensuring that Auburn University complies with applicable human subjects research policies, guidelines, and regulations. The IO is the individual who signs, and has the authority to sign, all commitments on behalf of Auburn University to ensure that the requirements of the Office of Human Research Protections (OHRP) will be met in accordance with the University's FederalWide Assurance (FWA). The IO is further responsible for signing all institutional reports required by federal regulatory agencies and sponsors. The Associate Provost and Vice President for Research is Auburn University's designated IO.

Auburn University Institutional Review Board Procedures and Guidelines

IRB Membership

Regular Members

The IRB shall be composed of at least five (5) regular members with sufficiently varied backgrounds to promote complete and adequate review of research activities commonly conducted by the University. The composition shall include, at a minimum, the following individuals:

1) At least one member whose primary concerns are in scientific areas,
2) At least one member whose primary concerns are in nonscientific areas,
3) At least one member (Community Member) who is not otherwise affiliated with the institution and who has no immediate family member affiliated with the institution.

Every effort will be made to ensure that:

1) The IRB consists of both men and women, although no selection shall depend upon gender, and
2) The IRB is not composed of members of a single profession/discipline.

Members shall serve three (3) year, rotating appointments. The Chair of the IRB shall be a faculty member in his/her second or third year of appointment. Rotating

membership vacancies, regular and alternate, shall be filled for compliance with University policy and applicable regulations. The President of Auburn University appoints IRB members and the IRB chair from a list of faculty candidates recommended by the Rules Committee of the University Senate and a list of community candidates from the IO. The President also approves alternate and community IRB members from a list of prepared by the IO. Faculty members appointed to the IRB shall not serve more than one consecutive term without the concurrence of the Senate Rules Committee and the President. The Coordinator, OHS, shall be a standing, non-voting member of the IRB.

Alternate Members

In order to comply federal regulations regarding the minimum number of members and composition of the IRB, it may be necessary to use Alternate Members. An Alternate Member is one who serves in place of, or in addition to, a regular member for the purpose of reviewing and approving protocols.

Dismissal of an IRB Member

Excessive absenteeism or consistent failure to adequately and appropriately assist with the review of protocols may lead to the dismissal of an IRB member. Prior to dismissing any duly appointed member, the IRB chair shall obtain the concurrence of IRB, such concurrence indicated by a majority vote of the IRB members in good standing. Every effort will be made to replace the dismissed member with a person having similar experience and qualifications.

Consultants

Where the Coordinator and Chair determine that the composition of the IRB is not sufficiently diverse or does not have the necessary expertise to adequately and appropriately review a research protocol, paid or un-paid consultants may be used to assist with the review of protocol (or revision to a protocol) and make recommendations to the IRB regarding its dispensation.

Meetings

The IRB shall meet monthly. To facilitate the timely review of research protocols and protocol revision requests, the IRB chair may, from time to time, convene additional meetings. Research will be approved only at a meeting at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. No protocol shall be approved unless it receives the approval of a majority of those members present at the meeting.

All meetings of the IRB shall be open to the public unless proprietary and/or confidential information (e.g., trade secrets, methods and materials under transfer agreement, participant information, etc.) is under discussion. In such instances, the Chair may ask public attendees to leave the meeting for the duration of such discussions.

Activities to Which These Policies and Procedures Apply

In accordance with the University's FWA, this policy applies to all research involving human subjects conducted 1) by the faculty, staff, and/or students of Auburn University

regardless of source of support and/or 2) on AU premises or in AU facilities by a third party.

Review and Approval of Human Subjects Research Activities

Project Classification

In general, research activities involving human subjects may be divided into two distinct categories – "exempt" and "non-exempt." An exempt activity is one that does not require review by a member of the IRB or by the full IRB. In accordance with federal regulations, and subject to any additional restrictions placed upon specific activities by a federal agency or sponsor, the following activities are classified as exempt:

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, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

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: (i) 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 which are conducted by or subject to the approval of federal 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 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.

Exempt Protocols

If a protocol meets the requirements for exempt classification as outlined above, the Investigator must submit the original and one (1) completed copy of the Protocol Submission Form (PSF) to OHS. If the Investigator plans to use recruiting materials, survey questionnaires, etc., these instruments also must be attached to the PSF prior to submission. This includes any scripts or dialogue that will be read to participants or used for the recruiting of subjects via radio or television advertisements.

Non-exempt Protocols

Human research projects that do not fit any of the categories above are classified as non-exempt. Only the Chair or his/her designee is authorized to determine that a protocol is exempt.

Two methods, "expedited" and "full board," are used to review non-exempt protocols and protocol revisions. Investigators are strongly encouraged to contact the OHS for guidance in protocol preparation and determination of the appropriate method for reviewing their projects. The IRB Chair or designee will make this determination and appropriately advise the Investigator regarding the requirements for protocol submission and approval of his/her project.

Criteria for Approval of Research

The minimum criteria for approval of research are:

1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. The IRB will consider only those risks and benefits that may result from the research. The IRB cannot consider possible long-range effects of applying knowledge gained in the research.
3) Selection of subjects is equitable. Criteria for making this determination will include, for example, the purposes of the research and the setting in which the research will be conducted and special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disable persons, or economically or educationally disadvantaged persons.
4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with the applicable federal, state, and local regulations.
5) Informed consent will be appropriately documented in accordance with the applicable federal, state, and local regulations.

6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
8) The research proposal, if any, is in agreement with the protocol submitted to the IRB for review and approval.

Additional Considerations for Approval – Protected Populations

Pregnant Women, Human Fetuses and Neonates

The following conditions must be met in addition to those criteria listed above. (See *Criteria for Approval of Research.*) Pregnant women or fetuses may be involved in research if all of the following conditions are met:

1) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
2) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;
3) Any risk is the least possible for achieving the objectives of the research;

4) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, and legally informed consent of the woman is obtained;

5) If the research holds out the prospect of direct benefit solely to the fetus then the legally informed consent of the pregnant woman and the father is obtained. The father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

6) Each individual providing consent under paragraph 4) or 5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

7) For children who are pregnant, appropriate assent and permission are obtained. (See *Children.*)

8) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

9) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

10) Individuals engaged in the research will have no part in determining the viability of a neonate.

Prisoners

Prior to approving research involving prisoners, the IRB must find that the following conditions, in addition to those criteria listed above (*Criteria for Approval of Research.*), are met.

1) Any possible advantages accruing to the prisoner through his or her participation in the research cannot be so great that the participant will be unduly influenced to participate;
2) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
3) Procedures for the selection of subjects are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. The principal investigator must provide written justification for selecting control subjects in any manner other than random selection from the group of available prisoners who meet the characteristics needed for the research project;
4) All information must be presented in language which is understandable to the subject population;
5) There must be adequate assurance that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner must be clearly informed in advance that participation in the research will have no effect on his or her parole; and
6) Where the IRB finds there may be a need for follow-up examination or care of participants after of their participation, adequate provision must be made for

such examination or care taking into account the varying lengths of individual prisoners' sentences. Participants must be informed of such potential needs and the arrangements made to satisfy them prior to participation.

DHHS Supported Projects

Research involving prisoners that is funded by the US Department of Health and Human Services (DHHS) requires not only the approval of the IRB but also of the Secretary of DHHS. The Secretary has delegated this responsibility to OHRP. Approved projects may not be initiated until OHRP has approved the project. OHRP approval can take from several weeks to several months so the Investigator should anticipate a lengthy delay between protocol submission and project initiation.

OHRP will approve biomedical or behavioral research, which involves prisoners as subjects only if the research involves solely the following:

1) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior (must present no more than minimal risk and no more than inconvenience to the subjects);
2) Study of prisons as institutional structures or of prisoners as incarcerated persons (must present no more than minimal risk and no more than inconvenience to the subjects);
3) Study of conditions affecting prisoners as a class (e.g., vaccine trials and other research on illnesses which are much more prevalent in prisons than

elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults); or

4) Study of practices, both innovative and accepted, which can reasonably be expected to improve the health or well-being of the subject.

Children

The following criteria and determinations must be met in addition to all other criteria and determinations required for IRB approval of a research protocol:

1) Research not involving greater than minimal risk may be approved if, in addition to all other conditions outlined in the document, adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.
2) Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects may be approved if an intervention or procedure, or the monitoring of a procedure, is likely to contribute to the subject's well-being, and
   a) The risk is justified by the anticipated benefit to the subjects;
   b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
   c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

3) Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition may be approved if:

   a) The risk represents a minor increase over minimal risk;

   b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

   c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

   d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

4) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children requires the approval of both OHRP and the IRB. Such research may be approved if:

   a) The applicable of the conditions outlined in 1), 2), and 3) of this section are met, or

   b) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

c) The research will be conducted in accordance with sound ethical principles; and

d) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

OHRP approval can take from several weeks to several months so the Investigator should anticipate a lengthy delay between protocol submission and project initiation.

Duration of Approval

A protocol will be approved for up to one year. As a courtesy, notifications of impending expiration will be sent to investigators and the relevant unit head approximately forty-five (45) days in advance of the expiration date. Continuation of the project beyond a year requires submission of an Annual Report and Protocol Renewal Form (PRF). Failure to submit the PRF in a timely fashion may lead to closure or suspension of the protocol. (See Delinquent *Final Report/Request for Renewal.*) Once a protocol has expired, the protocol will be closed and a notification of expiration sent to the Investigator and Department Head/Chair. The expired protocol, and all relevant documentation/ information, will be retained by OHS for a minimum of three years past the project end date or a longer time if required by a sponsor or a state or federal statute or regulation.

Protocol Review

Expedited Review

The IRB will use an Expedited Review procedure for protocols that meet the requirements in Appendix F, *Expedited Review Procedure*, and either or both of the following apply:

1) Some or all of the research appears on the list and is found by the reviewer(s) to involve no more than minimal risk,
2) Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Where a federal or state Department or Agency restricts, suspends, terminates, or chooses not to authorize AU's use of the expedited review procedure, the protocol will be reviewed by the full IRB.

After determining that a protocol or protocol revision meets the requirements for expedited review, the IRB Chair will assign the protocol to a second or third year, voting IRB member to review and make recommendations for a) approval, b) approval with modifications/clarifications, or c) referral to full IRB review. The reviewer of an expedited protocol may not disapprove a research protocol. If a protocol is referred for full IRB review, it can only be disapproved by failure to obtain a majority vote of approval from a properly convened IRB meeting.

Full IRB Review

Protocols that do not meet the requirements for exempt or expedited review will be reviewed by at a properly convened meeting of the IRB, i.e., a meeting at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. A member, regular or alternate, who represents the prison population must always be present for the review and approval of a protocol for studies involving prisoners. In order for the research to be approved, the protocol must receive the approval of a majority of those members present at the meeting.

Review Outcomes

Full IRB reviews have four possible outcomes:

1) Approved – After appropriate review, it is determined that the project meets all of the requirements for approval and the project can go forward as described in the protocol. A letter of approval, signed by the Coordinator, will be sent to the Investigator. The investigator may begin working on the project after receiving notice that the protocol has been approved.
2) Approved with Modifications/Clarifications – The protocol meets all of the criteria for approval if minor clarifications are provided or changes are made by the Investigator. A letter stating the outcome of the initial review and outlining the areas for which information (or modification) is required will be sent to the Investigator. The investigator must submit all information and materials requested to the OHS. Once the information and materials have

been received, the Chair or designee will determine whether the information and/or changes are sufficient to approve the protocol. A letter stating the outcome of the final review will be sent to the Investigator. The Investigator may begin working on the project only after receiving a notice from the Coordinator that the protocol has been approved.

3) Tabled – The protocol, as presented, has such serious defects or omissions that it is impossible to make a decision. A letter detailing the defects or omissions will be sent to the Investigator with a request to contact the Coordinator for assistance. After making the appropriate corrections or additions, the Investigator must resubmit the protocol for full IRB review.
4) Disapproved – The protocol fails to meet, and cannot be made to meet, one or more of the criteria for approval. The Coordinator will send a letter to the Investigator stating the outcome and the reasons for disapproval. An appeal process (see *Appeal of IRB Decisions*) is available for investigators who believe that the determination has been made in error.

Protocol Revisions

Revisions to all protocols, exempt and non-exempt, must be approved prior to implementation. Protocol revisions may be exempt, require full IRB review or be eligible for expedited review (even though the original protocol required full IRB review). To request a revision of an approved protocol, the Investigator should complete and submit a Protocol Revision Form (PRF) to the OHS. The classification and type of review

required will be determined using the same guidelines used for a new or renewed protocol.

Final Reporting

Within thirty (30) days of project completion, the Investigator must submit a final report to OHS using the approved Final Report Form (FRF).

Actions and Sanctions for Noncompliance

Failure to Follow an Approved Protocol

Additional Oversight

Where there has been demonstrated non-compliance with the approved protocol, the IRB may impose additional requirements and/or require additional oversight of the project. The IRB shall notify the investigator of its findings/concerns and the additional measures to be taken as a result of non-compliance.

Suspension and Termination

At its discretion, the IRB may suspend or terminate any project which is not being conducted in accordance with the approved protocol or which has been associated with unexpected, serious harm to participants. A suspension or termination, including a statement of the reasons for the IRB's action, shall be reported promptly to the Investigator, the appropriate Dean and Department Head/Chair, and the Vice President for Research. When the project is a sponsored activity, the Director of the Office of Sponsored Programs will also be notified.

The IRB Chair, with the concurrence of the Coordinator or, in the absence of the Coordinator, one voting member of the IRB, may suspend a project immediately if it appears that there has been, or the potential is great for, serious harm to participants. Following suspension, the Chair shall convene a meeting of the IRB to examine the circumstances of the suspension and determine the requirements for rectification of the problem or terminate of the protocol. Termination of a protocol requires a majority vote at a properly convened meeting of the IRB. An investigator who disagrees with the IRB's decision to suspend or terminate a project may appeal the decision in accordance with the section of this policy entitled *Appeal of IRB Decisions*.

Use of Collected Data

The IRB shall decide whether or not data collected inappropriately (either without an approved protocol or through unapproved methods) may be used for any further research purpose, including publication and dissemination of the results of the research. The primary consideration in making this decision shall be the risk imposed on the participants through further use of the data.

Delinquent Final Reports

Within thirty days (30) of project completion the Investigator must submit a final project report to OHS. Both the Investigator and the Department Head/Chair will be notified in writing of delinquent final reports. No new protocols will be approved by the IRB until all delinquent reports have been filed.

Delinquent Annual Report/Request for Renewal

Investigators should leave sufficient time, usually 30 days, for review and approval of all annual reports and requests for renewal prior to the expiration date of an approved protocol, including requests for protocol renewal. If the annual report and request have not been reviewed and approved prior to the original expiration date, the Investigator must suspend all work on the project until the request is approved. If the Investigator fails to file an annual report and request for renewal prior to the expiration date, the protocol will be closed. For a period of thirty (30) days following the protocol expiration date, the Investigator may file an annual report and request that the protocol be re-opened and renewed subject to favorable review. Requests to re-open and renew a closed protocol will not be honored if more than thirty (30) days have elapsed since the protocol expired. In this case, a new protocol submission will be required.

Disciplinary Actions

As with any policy of Auburn University, sanctions may apply for non-compliance with this human subjects research policy. The appropriate Dean (or designated Associate Dean), Director, or Vice President shall utilize the standard disciplinary procedures set forth as a condition of each person's employment with Auburn University. Other sanctions may be imposed in accordance with sponsor requirements and obligations or other applicable AU policies.

Appeal of IRB Decisions

If an investigator disagrees with requirements or findings of the IRB, or a designated reviewer, the Investigator may, with the concurrence of the appropriate Dean/Department Head or Chair, submit a written appeal to the IRB stating the reasons for objecting to the required changes and/or proposing an alternative resolution. The investigator may also request a meeting with the IRB to discuss the differences of opinion and resolve them.

If no satisfactory resolution is reached, the Investigator may submit a written appeal to the Associate Provost and Vice President for Research requesting assistance. The Vice President will attempt to mediate a solution to the situation. However, neither the Vice President nor any other administrative official can override a suspension, termination, or disapproval by IRB.

The University's Authority Regarding IRB Decisions

Research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by other University officials. In accordance with federal regulation, these officials may not approve the research if it has not been approved by an IRB. However, they may decide that it is not in the best interests of the University to allow a research project which has been approved by the IRB to go forward.

Informed Consent

The investigator must 1) obtain legally effective informed consent from each participant or the participant's legally authorized representative, 2) give the prospective participant sufficient opportunity to consider whether or not to participate in the research, and 3) minimize the possibility of coercion or undue influence in gaining the participant's consent prior to involving the participant in the research. The information that is given to the subject or the representative must be in language understandable to the subject or the representative. Informed consent, whether oral or written, cannot include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the Investigator, the sponsor (if any), or the university or its agents from liability for negligence.

The investigator must include the following basic elements of informed consent:

1) A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2) A description of any reasonably foreseeable risks or discomforts to the subject;
3) A description of any benefits to the participant or to others which may reasonably be expected from the research;

4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5) A statement describing the extent, if any, to which records which identify the participant will be kept confidential;
6) For research involving more than minimal risk, an explanation of any compensation the participant will receive and an explanation of any medical treatments available to the if injury occurs and, if so, what these treatments consist of, and/or where further information may be obtained;
7) An explanation of whom to contact for answers to questions about the research and the participants' rights, and whom to contact in the event of a research-related injury; and
8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled. (If participant data will be anonymous so that his/her data cannot be withdrawn upon his/her withdrawal from the project, the participant should be so informed.)

When appropriate, one or more of the following elements of information must also be provided to each subject:

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

2) Anticipated circumstances under which the Investigator may discontinue the participant's involvement without participant's consent;
3) Additional costs to the participant that may result from participation in the research;
4) Consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation;
5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
6) The approximate number of subjects involved in the study.

If the Investigator wishes the IRB to waive or alter some of these elements of informed consent, he/she must provide documentation that:

1) The research or demonstration project is to be conducted for or subject to the approval of state or local government officials and is 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; and
2) The research cannot not practicably be carried out without the waiver or alteration.

Waiver or alteration may also be requested by providing documentation of the following:

1) The research involves no more than minimal risk to the subjects;
2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3) The research could not practicably be carried out without the waiver or alteration; and
4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

DHHS Funded Collaborative Projects

The University is automatically considered to be "engaged" in human subject research whenever it receives a direct DHHS award to support such research, even where all activities involving human subjects are carried out by a subcontractor or collaborator. In such cases, the University bears ultimate responsibility for protecting human subjects under the award. The University is also responsible for ensuring that all collaborating institutions engaged in the research hold an OHRP approved FWA (or Multiple Project Assurance (MPA) until such time as OHRP no longer recognizes MPAs) prior to their initiation of the research. *Even if all of the activities involving human subjects are carried out by the collaborator or a subcontractor*, investigators who engage in collaborative research activities must have University IRB approval prior to project initiation. Approval will not be given until the Investigator 1) submits for review a research protocol for human subject activities taking place in Auburn facilities or involving Auburn personnel or students, 2) the institutional Assurance approval number

and expiration date of the collaborating institution, and 3) documentation of the IRB review and approval of the research project by the collaborating institution.

Unaffiliated Investigators

Investigators who are not acting as employees or agents of an institution or other entity which holds a current FWA (or MPA) are subject to all of the human protection requirements and policies of the University. Such investigators must enter into an arrangement with the University under which they agree to be bound by the human protection policies of the University. A copy of the University's Unaffiliated Investigator Agreement (UIA) is available from the OHS. The Investigator may pursue execution of the UIA or may request that OHS do so. Protocol approval will be withheld until a fully executed UIA has been obtained.

Physicians in Private Practice

When collaborating with individual physicians operating in private practice settings that are not covered under an Assurance, the Investigator should follow the procedure for *Unaffiliated Investigators*. When collaborating with a group of physicians operating within their own private practice under an Assurance, the Investigator should follow the procedure for *Collaborative Projects*.

Education/Training

Investigators and Key Personnel

All Investigators, including the Lead Graduate Student, must complete the University core educational modules available on the OHS website (http://www.auburn.edu/research/vpr/ohs/training.htm) or in hard copy from OHS prior to engaging in humans subjects research. Annually thereafter, the Investigator must complete at least one approved continuing education activity of the Investigator's choice. A list of approved materials and activities is available from OHS. Investigators may request approval from the IRB to substitute continuing education activities, particularly those pertaining specifically to their own research project, on a case by case basis.

It is the responsibility of the Investigator to ensure that all key personnel involved in the project have appropriate training in human subjects research, including completion of the University core educational modules prior to engaging in such activities.

IRB Members

All IRB Members, regular and alternate, must complete University core training for IRB members.

Conflict of Interest

IRB members, Investigator(s), Co-Investigators, and others having a vested interest in or who are in a position to affect the outcome of human subjects research have the obligation to avoid ethical, legal, financial, or other conflicts of interest and to ensure that their activities and interests do not conflict with their obligations to either the University or the research participants.

Financial Conflicts of Interest

In response to federal regulation and the requirements of the National Science Foundation (NSF) and the DHHS, the University has an approved Conflict of Interest Policy for investigators engaging in activities sponsored by NSF and DHHS. This approved policy was adopted (see Appendix G.) in its entirety for all investigators and key personnel who engage in human subjects research regardless of the source of funding. Forms are available on the web at http://www.auburn.edu/research/vpr/ohs/Forms/ index.htm or from the OHS or OSP.

IRB members who have any significant financial interest in the protocol being considered must recuse themselves from discussion and voting of the protocol.

Other Conflicts

An IRB member who is designated as the Investigator or Co-Investigator cannot offer a motion or vote 1) on their own protocols, or 2) to accept (with or without modifications) or reject any protocol in which the Investigator is a member of his/her department.

IRB members who have a professional role in the protocol being considered must recuse themselves from discussion and voting of the protocol.

Reporting Concerns Regarding Human Subjects Research Activities

The IRB and Office of Human Subjects will investigate all reported concerns regarding human subjects research activities. A formal complaint should be made to either the IRB Chair or the OHS Coordinator. The complaint should include:

- The complainant's name,
- The nature of the complaint or event,
- The individual or unit against whom the complaint is lodged,
- A description of the events or charges including applicable dates of observations and any substantiating documentation,
- The signature of the complainant.

A formal complaint will be kept confidential to the extent possible to protect all concerned. However, the complainant should be aware that it may be necessary to disclose his/her name.

Within three (3) days of receiving the formal complaint, the IRB Chair shall appoint a three (3) member subcommittee to investigate the complaint. The individual or unit about whom the complaint is lodged will be informed of the complaint and asked for pertinent information and documentation of the events/actions in question. The subcommittee may also seek additional information including, but not limited to, interviewing involved parties and reviewing project related documents and documentation. If, after reviewing all of the documentation and evidence gathered, the subcommittee finds that there is sufficient evidence, a formal investigation will be initiated. The subcommittee shall prepare a report of its findings for the IRB. At a properly convened meeting, the IRB shall, as expeditiously as possible, review the concern and determine what action should be taken. In accordance with the process described in this policy (*Suspension and Termination)*, the IRB Chair, may suspend a project immediately pending the outcome of a formal investigation.

No employee or student shall be discriminated against or be subject to any reprisal for reporting perceived noncompliance with any of the regulations or policies pertaining to human subjects research.

Appendix A. 45 CFR 46

Appendix B. 21 CFR 50

Appendix C. AGENCY CODIFICATIONS OF COMMON RULE (REFERENCES)

Code of Federal Regulations Reference	Department/Agency
7 CFR 1c	Department of Agriculture
10 CFR 745	Department of Energy
14 CFR 1230	National Aeronautics and Space Administration
15 CFR 27	Department of Commerce
16 CFR 1028	Consumer Product Safety Commission
22 CFR 225	International Development Cooperation Agency, Agency for International Development
24 CFR 60	Department of Housing and Urban Development
28 CFR 46	Department of Justice
32 CFR 219	Department of Defense
34 CFR 97	Department of Education
38 CFR 16	Department of Veterans Affairs
40 CFR 26	Environmental Protection Agency
45 CFR 690	National Science Foundation
49 CFR 11	Department of Transportation

Appendix D. THE BELMONT REPORT

Appendix E. THE NUREMBERG CODE

Appendix F. RESEARCH THAT QUALIFIES FOR EXPEDITED REVIEW

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure

The source for these guidelines is 63 FR 60364-60367, November 9, 1998. The guidelines may be amended from time to time. The Auburn University IRB will comply fully with guidelines applicable at the time a protocol is reviewed and will make every effort to inform investigators when changes in the guidelines occur. The investigator may review these categories for changes via the web at http://ohrp.osophs.dhhs.gov/index.html.

A) 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. 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.

B) The categories in this list apply regardless of the age of subjects, except as noted.

C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability,

insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

D) The expedited review procedure may not be used for classified research involving human subjects.

E) Standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

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 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   b) Research on medical devices for which (i) an investigational device exemption application (21 CFR 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, nonpregnant 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[2], 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.

3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples — hair and nail clippings in a nondisfiguring manner; deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; permanent teeth if routine patient care indicates a need for extraction; excreta and external secretions (including sweat); uncannulated saliva collected either in an unstimulated fashion or

---

[2] Children is defined as 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. If research is to be conducted in Alabama, the legal age for consent is 19 years. For research conducted in other states ask OHS for assistance in determining the legal age.

stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; placenta removed at delivery; amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; supra- and subgingival 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; mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; sputum collected after saline mist nebulization.

4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications. Examples— 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; weighing or testing sensory acuity; magnetic resonance imaging; electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; moderate exercise, muscular strength testing, body composition assessment, and

flexibility testing where appropriate given the age, weight, and health of the individual.

5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes.
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.
8) Continuing review of research previously approved by the convened IRB as follows:
   a) where (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) where no subjects have been enrolled and no additional risks have been identified; or
   c) where 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 where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Definitions

Assent — a child's affirmative agreement to participate in research. Failure of a child to object should not, absent affirmative agreement, be construed as assent.

Children — 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.

Dead fetus — a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscle

Delivery — complete separation of the fetus from the woman by expulsion or extraction or any other means.

FederalWide Assurance — A FederalWide Assurance formalizes an institution's commitment to DHHS to protect human subjects and is required prior to receiving federal funding. Auburn University's Assurance approval number and expiration date are available from the Office of Human Subjects.

Fetus — the product of conception from implantation until delivery.

Guardian— an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

Human subject — 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 — 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 investigator and subject.

Key personnel — individuals who contribute in a substantive way to the scientific development or execution of a project, whether or not they receive compensation from the award supporting that project. The principal investigator and collaborators are included in this category.

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 procedure(s) involved in the research.

Minimal risk — 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.

Neonate — means a newborn.

Nonviable neonate — a neonate after delivery that, although living, is not viable.

Parent — a child's biological or adoptive parent.

Permission — the agreement of parent(s) or guardian to the participation of their child or ward in research.

Pregnancy — the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

Prisoner — any individual involuntarily confined or detained in a penal institution, including individuals sentenced to such an institution under a criminal or civil statute,

individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Private information — individually identifiable information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Research — a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Viable — a neonate which is able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

Appendix G. PROCEDURES FOR AUBURN UNIVERSITY CONFLICT OF INTEREST POLICY (HUMAN SUBJECTS RESEARCH ACTIVITIES)

SCOPE

These procedures apply to all research activities, which involve the use of human subjects. NOTE: They also apply to all proposals submitted to the National Science Foundation (NSF) and the Public Health Service (PHS). *It is not necessary to complete two separate sets of forms.*

DEFINITIONS

Investigator - means the principal investigator, co-principal investigators, and any other person at the university who is responsible for the design, conduct, or reporting of 1) research or educational activities funded or proposed for funding by the National Science Foundation or the Public Health Service or 2) research activities involving the use of human subjects.

Significant Financial Interest - means anything of monetary value, including, but not limited to, salary or other payments for services (e.g. consulting fees or honoraria); equity interests (e.g. stocks, stock options or other ownership interests); and intellectual property rights (e.g. patents, copyrights and royalties from such rights). The term does not include:

- Salary, royalties or other remuneration from Auburn University;
- Any ownership interests in the university, if the university is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program;
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- Income from service on advisory committees or review panels for public or nonprofit entities;
- An equity interest that, when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests:
    a. Does not exceed $10,000 in value determined through reference to public prices or other reasonable measures of fair market value; and
    b. Does not represent more that a 5% ownership interest in any single entity;
- Salary, royalties or other payments that, when aggregated for the Investigator and the Investigator's spouse and dependent children are not expected to exceed $10,000 during the next twelve month period

Investigator's immediate family - means the Investigator's spouse and any dependent children. Throughout these procedures, Significant Financial Interest of the Investigator also shall include the interests of the Investigator's immediate family.

Business Enterprise - means any corporation, partnership, proprietorship, firm, enterprise, franchise, trust, or other entity.

Disclosure Form - is initially submitted at the time a proposal is submitted to the Sponsor and is updated during the period of an award either on an annual basis or as new reportable Significant Financial Interests are obtained. The Auburn University disclosure form is available from OHS or from the OHS Web Pages.

Reviewer - is the responsible representative of the university who reviews the disclosure form to determine if a conflict of interest exists and determines what conditions or restrictions, if any, should be imposed by the university to manage, reduce, or eliminate such conflict of interest. This individual is the appropriate Associate Dean closest to the Investigator in the university's reporting hierarchy.

Conflict of Interest - exists when the Reviewer reasonably determines that a Significant Financial Interest could directly and significantly affect the design conduct, or reporting of research or educational activities.

Authorized Institutional Representative - is, for the purposes of these procedures, the Associate Provost and Vice President for Research. The Authorized Institutional Representative is responsible for certifying that the institution has implemented a written conflict of interest policy that is consistently applied and enforced; that to the best of his/her knowledge, all financial disclosures required by that conflict of interest policy have been made; and that all identified conflicts of interest are or will be satisfactorily managed, reduced or eliminated prior to the institution's expenditure of any funds under an award, in accordance with the institution's conflict of interest policy. Conflicts that cannot be either eliminated or satisfactorily managed for projects dealing with human subjects will not be approved by the Institutional Review Board.

DISCLOSURE REQUIREMENTS

Each Investigator must disclose to the Reviewer all Significant Financial Interests of the Investigator and the Investigator's immediate family

- That would reasonably appear to be affected by the research or educational activities funded or proposed for funding; and
- In entities whose financial interests would reasonably appear to affected by such activities.

All financial disclosures must be on file at the time a proposal governed by these procedures is submitted. They also must be updated during the term of the award on an annual basis or as new, reportable Significant Financial Interests are obtained.

Upon receipt of a disclosure, the Reviewer must:

- Determine whether a conflict of interest exists;
- Determine what conditions or restrictions, if any, should be imposed by the institution to manage, reduce or eliminate such conflicts of interest;
- Certify that the Investigator's disclosure has been filed before a proposal will be approved by the university's Authorized Institutional Representative; and
- Certify that no actual or potential conflict of interest exists or that appropriate conditions or restrictions will be imposed to ensure protection of research activities before an award can be accepted by the university.

If AU carries out funded research through subgrantees, contractors or collaborators, AU will ensure that Investigators working for such entities comply with AU's conflict of interest policy by requiring a signed assurance of compliance from the subgrantees, contractors or collaborators.

SANCTIONS FOR NON-DISCLOSURE

As with any policy of Auburn University, sanctions shall apply for non-compliance with the implementation procedures of the Conflict of Interest policy. The appropriate Dean (or designated Associate Dean for Research), Institute Director, or Vice President shall utilize the standard disciplinary procedures set forth as a condition of each person's employment with Auburn University. Other sanctions which might be imposed include but are not limited to:

- Prompt notification to sponsor of the corrective action taken or to be taken
- Freezing expenditures from involved accounts
- Terminating sponsored agreements entered into in violation of this policy
- Invalidation of data acquired during the course of the project
- Penalties if conflict of interest is determined to be in violation of the Alabama Ethics Act
- Suspension or dismissal

MANAGEMENT OF ACTUAL OR POTENTIAL CONFLICT OF INTEREST

Within sixty (60) days after identification of a conflict of interest, the Reviewer may impose conditions or restrictions on an Investigator or a covered project to manage, reduce, or eliminate conflicts of interest. The following are examples of actions which might be taken:

- Public disclosure of Significant Financial Interests;

- Monitoring of the project by independent reviewers;
- Modification of the project plan;
- Disqualification from participation in the portion of the project that would be affected by the Significant Financial Interests;
- Divestiture of Significant Financial Interests; or
- Severance of relationships that create conflicts.

The Investigator shall have the right to appeal the decision of the Reviewer by submitting concerns, in writing, to the IRB.

If the Reviewer determines that imposing conditions or restrictions would be either ineffective or inequitable, and that the potential negative impacts that may arise from a Significant Financial Interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the Reviewer may allow the project to go forward without imposing such conditions or restrictions. Reviewer determination to the contrary, the Institutional Review Board shall not be overruled in matters dealing with human subjects research and may deny approval of the project.

MAINTENANCE OF RECORDS

A disclosure form must be filed with the Reviewer before submission of a proposal sponsor. The Reviewer will maintain such disclosures with due care for their confidential

nature. Updates shall be filed before a covered project award can be accepted by the university, but not less frequently than annually.

The Reviewer shall be responsible for maintenance of records relating to all decisions regarding whether or not a conflict exists. Additionally, the Reviewer shall maintain all documentation of university actions to manage, reduce or eliminate conflicts of interest.

These records shall be maintained until at least three (3) years after the later of the termination or completion of the award to which they relate, or the resolution of any Federal Government action involving those records. These records shall be available for audit by Auburn University and Government officials.

CERTIFICATIONS

The signature of the Reviewer will be required on the Protocol Submission Form to certify that the disclosure has been filed and that the proposal may be signed for submission to sponsor. To ensure compliance with the federal regulations, Auburn University will require such certification before approval for submission of the proposal is given by the Authorized Institutional Representative. The Investigator and the Reviewer will provide additional certifications that any conflict has been managed, reduced or eliminated before the Authorized Institutional Representative will accept a covered award on behalf of the university.

The Authorized Institutional Representative will certify to the sponsor that the university has implemented a written and enforced conflict of interest policy that is consistent with federal regulations; that to the best of his/her knowledge, all financial disclosures required by that conflict of interest policy have been made; and that all identified conflicts of interest will have been satisfactorily managed.