

# **INSTITUTIONAL REVIEW BOARD**

## **Policy and Implementing Guidelines**

### **PURPOSE**

The Institutional Review Board (IRB) at the University of South Alabama will be responsible for the review of all research projects involving human subjects and which are carried out on the campuses of the University of South Alabama, the medical center, the hospitals and clinics, or any of its affiliated institutions, **REGARDLESS OF SOURCE OF FUNDING**. This review will determine the following:

- A. Whether those subjects will be placed at risk; if so, whether the risk is outweighed by the benefit to the subject and the importance of the knowledge gained as to warrant a decision to allow the subject to accept those risks;
- B. If the rights and welfare of such subjects are adequately protected by the informed consent to be obtained by appropriate methods;
- C. If adequate steps are taken in conduct of research activity to avoid involvement of pregnant women so that such activity would not place the fetus at risk.

### **DEFINITIONS**

- A. Research - As defined by Code of Federal Regulations 45 CFR 46.102(d), research means a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge.
- B. Clinical investigation - As defined by Code of Federal Regulations 21 CFR 312.3(b), 'clinical investigation' means any experiment in which a drug is administered or dispensed to, or used, involving one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.
- C. Human subject - A living individual about whom an investigator (whether professional or student) conducting research obtains the following:
  - 1. Data through intervention or interaction with the individual. Intervention includes both physical procedures by which data is gathered (e.g., venipuncture, medical or other treatment) and manipulation of the subject or the subject's environment that are performed for research purposes. Interaction also includes communication or interpersonal contact between investigator and subject.
  - 2. Identifiable private information. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be individually identifiable (i.e., a medical record, questionnaire, etc.). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

- D. Risk - The exposure of an individual to the possibility of injury (physical, psychological, sociological or other) as a consequence of any activity which goes beyond the application of those established as accepted methods necessary to meet the person's needs or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service.
- E. Minimal risk - The risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- F. Investigator - A duly qualified faculty member (or a student sponsored by a faculty member) of the University of South Alabama.
- G. Grant - A request for or an allocation of funds to support a project.
- H. Project - A duly defined activity of academic inquiry.
- I. Educational activities - Those activities of a duly qualified faculty member of the University of South Alabama which are related to professional responsibilities in the areas of teaching, research and service.

#### COMPOSITION OF THE INSTITUTIONAL REVIEW BOARD (IRB)

The IRB shall be nominated by the chairman, vice-chairman and administrator of the IRB and appointed by the Assurance signatory, and shall:

- A. Consist of at least five members of sufficiently diverse backgrounds, including consideration of racial and cultural backgrounds of members and sensitivity to issues such as community attitudes;
- B. Include persons who are able to ascertain the acceptability of research applications in terms of institutional commitments, applicable law and professional standards;
- C. Include members of both sexes;
- D. Include at least one member whose primary area of expertise is with handicapped and/or retarded children;
- E. Include at least two members whose primary concerns are in behavioral disciplines;
- F. Include at least one member whose primary concerns are in non-scientific areas;
- G. Consist of members representing more than one profession;
- H. Include a member who is not affiliated or related to a person who is affiliated with the institution;
- I. Include persons who are primarily concerned with the welfare of vulnerable subjects;
- J. Invite individuals with competence in special areas to assist in the review of complex issues;
- K. Not have a member participate in the initial or continuing review of any project in which the member has a conflicting interest.

## RESPONSIBILITIES OF THE IRB

### A. The IRB will:

1. Conduct initial and continuing review of research and report their findings and actions to the investigator and the institution;
2. Determine which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review;
3. Review proposed changes in research activities to insure that changes in approved research, during the period for which IRB approval has been given, has not been initiated without IRB review and approval;
4. Follow procedures to insure that the IRB and Office for Protection from Research Risks (OPRR) of the Department of Health and Human Services (DHHS) receive reports of unanticipated problems involving risks to subjects and others;
5. Conduct its review of research, except when an approved expedited review procedure is used, at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in non-scientific areas;
6. Approve research only with the concurrence of a majority of those members in attendance.
7. Report to the institution and OPRR any continuing or serious matters of non-compliance by investigators with the requirements and determinations by the IRB.

### B. The IRB will maintain:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany proposals, approved sample consent documents, approved advertising or other solicitations for subjects, progress reports and injuries to subjects;
2. Minutes of meetings;
3. Records of continuing review activities;
4. Copies of all correspondence between the IRB and investigators;
5. A list of all members;
6. A compendium of written procedures;
7. Statements of significant new findings provided to subjects;
8. Records required by regulations, which shall be retained for at least three years after completion of the research. The records shall be accessible for inspection and copying by authorized representatives of DHHS, or any agency subscribing to the Common Rule (56.117).

## REQUIREMENTS FOR IRB REVIEW AND APPROVAL OF RESEARCH

### A. The IRB shall:

1. Review and have authority to approve, require modification and/or disapprove all human research activities;
2. Require that information given to subjects as a part of informed consent, including solicitation or advertising for subjects, be in accordance with the requirements for informed consent and that additional information be provided the subject, as deemed necessary by the IRB, to add to the protection of the rights and welfare of the subjects;
3. Require or waive documentation of informed consent;
4. Notify in writing the investigator and the institution of its decision to approve or disapprove the proposed research or of modifications required to secure IRB approval of the research activity;
5. Conduct continuing review of research involving human subjects at intervals appropriate to the degree of risk, but at least once a year;
6. Have authority to suspend or terminate approval of research that is not in compliance with the IRB's determinations or has been associated with unexpected serious harm to subjects.

### B. The IRB shall insure that:

1. Risks to subjects are minimized by using the safest procedures consistent with sound research design;
2. Risks to subjects are reasonable in relationship to anticipated benefits to subjects and importance of the knowledge that may be expected to result;
3. Selection of subjects is equitable, taking into account the purpose of the research;
4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative;
5. Informed consent will be appropriately documented;
6. The research plan makes adequate provision for monitoring the data collected, where appropriate, to insure the safety of the subjects;
7. There are adequate provisions to protect the privacy of subjects and to maintain confidentiality of data;
8. Additional safeguards are taken when vulnerable subjects (minors, mentally incompetent, prisoners, economically and educationally disadvantaged, etc.) are involved in the research in order to protect against coercion or undue influence.

## POLICIES OF THE INSTITUTIONAL REVIEW BOARD

### A. Ethical policies

Members of the University of South Alabama will conduct all research involving human subjects under the ethical provisions of "The Nuremberg Code" (1949); "Declaration of Helsinki" (1962) and revisions thereto by the World Medical Assembly (1975); "Responsibility and Investigations on Human Subjects" (1964); "AMA Ethical Guidelines for Clinical Investigation" (1966); "Statements on the Use of Human Subjects for Research" (1969); and Code of Federal Regulations 45 CFR Part 46 and 21 CFR 50, 56, 312, 214, 511 and 514, and amendments thereto. These codes are statements of principles concerned with the protection of human subjects and will assist the University of South Alabama in the discharge of its responsibilities for protecting the rights and welfare of subjects participating in research, investigation and care activities.

#### B. Exemptions from IRB review

Some types of research projects qualify for exemption from IRB review. The regulations are difficult to interpret and exemptions are not infrequently challenged by federal granting agencies. In most cases, considerable time and effort may be saved by using the expedited approval process instead.

The IRB, not the investigator determines exempt status, and a letter of exemption is issued by the IRB. A letter of exemption is necessary to release a research application to external funding agencies. The Dean of the Graduate School will also verify that all research involving human subjects described in a thesis or dissertation has been conducted with prior approval or exemption by the IRB.

#### C. Evaluation of technically complicated proposals

Proposals which involve the use of isotopes in any form must first be reviewed and approved by the University of South Alabama College of Medicine Isotope and Radiation Committee. Proposals which are unusual or highly specialized may be referred to consultants within or outside the University of South Alabama prior to consideration by the Committee. Proposals involving investigational new drugs will be reviewed by a qualified physician and/or pharmacist and opinions and consultations from further experts may be obtained prior to the meeting. Rarely, the IRB may request the investigator's attendance at a meeting.

#### D. Expedited review

An expedited review will be conducted by the chairman or designated reviewer. Upon issuance of an approval, the project may be initiated. The action will be presented to the full committee at its next regularly scheduled meeting. In the event the committee requires modification or revision in the protocol at that time, the approval will be rescinded temporarily and the investigator shall cease work on that portion of the project involving humans. The approval may be reinstated upon the investigator's complying satisfactorily with the committee's requests. Expedited review procedures may not be used to disapprove proposed research.

The IRB will permit expedited review under the following circumstances:

1. If the research involves no more than minimal risk and appears on the list of categories of research eligible for expedited review;
2. For minor changes in previously approved research.
3. Categories of research eligible for expedited review:

- a. Collection of hair and nail clippings in a non- disfiguring manner, deciduous teeth and permanent teeth;
- b. Collection of excreta and external secretions, including sweat, saliva, placenta removed at delivery and amniotic fluid at the time of rupture of the membrane prior to or during labor;
- c. Recording of data from subjects, 19 years of age or older, using non-invasive procedures routinely employed in clinical practice. This includes use of physical sensors that are applied to the surface of the body and do not involve input of matter or significant amounts of energy or invasion of the subject's privacy, weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography and electroretinography. It does not include exposure to electromagnetic radiation (x-rays, microwaves);
- d. Collection of blood samples by venipuncture in amounts not exceeding 450 ml in an eight-week period and no more than two times per week from subjects who are in good health and are not pregnant;
- e. Collection of both supra- and subgingival dental plaque and calculus;
- f. Voice recordings made for research purposes;
- g. Moderate exercise by healthy volunteers;
- h. The study of existing data, documents, records, pathologic specimens or diagnostic specimens;
- i. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory or test development where the investigator does not manipulate the subjects' behavior and the research will not involve stress to the subjects;
- j. Research on drugs or devices for which an investigational new drug exemption or an Investigational device exemption is not required.

E. Conflict of interests

No member of this committee shall be involved in either the initial or continuing review of an activity in which the committee member has a professional responsibility except to provide information to the committee.

F. Scientific merit and ethical acceptability

The committee, with advice from outside experts at its discretion, may determine if the proposed research involving human subjects may be conducted at the University of South Alabama. This determination may be made on the basis of ethical considerations, scientific merit, or other criteria.

POLICY ON INFORMED CONSENT

Information conveyed in the consent procedure shall include:

- A. A reasonable opportunity for the subject to consider participation.

- B. Be expressed in understandable language;
- C. Exclude exculpatory language;
- D. Contain a reasonable explanation of the research, its purposes, procedures and duration of participation, to include discomfort and risk;
- E. Describe any benefits to the subject or mankind;
- F. Describe alternative procedures, when appropriate;
- G. Describe the extent to which confidentiality of records will be maintained;
- H. Explain the availability of compensation and availability of treatment, if injury occurs;
- I. Contain instructions concerning who may be contacted for answers to pertinent questions;
- J. State the conditions of participation. Where appropriate, one or more of the following elements shall also be provided:
  - 1. State that the procedure may involve unforeseeable risks;
  - 2. State circumstances for termination of a subject's participation by the investigator;
  - 3. State possible additional cost to the subject;
  - 4. Describe consequences of a subject's withdrawal from participation, specifically, that the subject is free to withdraw from the project at any time without prejudice.
  - 5. State that significant new findings will be made available to the subject;
  - 6. In studies to be submitted to the Food and Drug Administration, a statement shall be included informing the subject that research records may be subject to inspection by the FDA.
- K. Methods of recruitment of subjects, such as newspaper or broadcast media advertising, posters, flyers, interviews, etc. are considered an extension of the consent process and must receive prior approval by the IRB.
- L. The IRB may approve a consent procedure which does not include or which alters some of the elements of consent if the amount and complexity of information to be provided in the consent process are modified for potential subjects with impaired or limited capacity to understand. These alterations or waivers will be approved if:
  - 1. The subjects are functionally and legally competent to give consent;
  - 2. The purpose is to insure that these subjects receive information they can reasonably be expected to understand to allow them to make a knowledgeable decision regarding their participation in research.

M. Procedures must be developed to insure consent is sought from subjects at a time when they can make a reasonable judgment.

N. Documentation of informed consent shall:

1. Consist of a written consent form containing a current official IRB approval stamp, signed by the subject or the subject's representative and a copy given to the person signing the form;
2. Be a written consent form defining the elements of informed consent which may be read to the subject or the subject's authorized representative;
3. Be waived if:
  - a. The only record linking the subject and the research is the consent document, and the principal risk is the potential harm that would result from a breach of confidentiality;
  - b. The research presents no more than minimal risk or harm to the subject and involves no procedures for which written consent is normally required.
4. Never be waived for IND, IDE or other FDA regulated studies.

O. Consent for patients unable to provide informed consent.

This relates to children, minors, prisoners, inmates of mental institutions, the educationally disadvantaged, etc. A uniform policy which will cover all eventualities under which legitimate research activities may be conducted with the above subjects is difficult to define.

It will be necessary for the committee to review carefully each proposal with due consideration for the significance of the activity and the balance of potential benefits and risks to any subject. These guidelines will be followed:

1. Initial studies requiring the participation of subjects unable to give informed consent may be performed only on subjects for whom consent can be provided by a reasonable relative;
2. Procedures on subjects unable to provide informed consent should be such that probable immediate and/or long-term benefits significantly outweigh probable risks. Similarly, procedures which are essentially substitutions for established procedures with known benefit/risk ratios must offer a substantial probability of better outcome than the established procedures for which they are substituted;
3. In all circumstances involving subjects unable to provide informed consent and under circumstances in which informed consent of responsible relatives is also not available, investigators must obtain an agreement to such procedures from two senior physician consultants who are not involved in the research;
4. Minors--married persons are legally capable of consent regardless of their ages. Other individuals under the age of 19 are legally incapable of consent; their legal guardians must be petitioned for consent to secure informed consent from the minor to the extent that the minor seems capable of comprehending the experimental procedure and its implications. There is no question that legal guardians can consent to the participation of the minor in experiments that have the potential of yielding direct benefit

to the minor. Whether the guardian can consent to research which offers no potential benefit to the minor is a subject of current controversy. A guardian who is asked to consent to such research must be informed that the outcome of litigation in which the right to have consented might be challenged by the subject at some future date cannot be predicted.

#### P. IRB Involvement in Consent Form

The consent form will include a phrase informing the participant that in case of any concerns pertaining to participation in the research, the subjects may contact the IRB, and the IRB's phone number will appear on all consents. .

### APPROVED PROJECTS AND ACTIVITIES

A. Approval of a project or activity by the committee will be for a period of one year unless a shorter approval period is specifically designated by the IRB.

B. All projects and activities will be reviewed by the committee annually. It is the responsibility of the investigator to initiate the annual review. A reminder will be sent by the IRB to the investigator prior to the date of resubmission of the project.

C. All untoward effects of projects or activities will be reported immediately in writing to the committee. Upon review of the circumstances surrounding the complication, the committee may:

1. Suspend that portion of the project responsible for the complication;
2. Recommend modification of the project and approve its continuation;
3. Recommend that the project or activity continue unchanged.
4. Withdraw approval of the project.

D. Although the IRB may approve a study, other institutional officials may disapprove it. This may occur for several reasons:

1. The institution may have limited space or resources and therefore gives priority to other studies.
2. The study may be in an area in which the institution does not want to participate, or the study may not meet the ethical, educational, service or research standards endorsed by the institution.
3. The institution may be adversely financially impacted by a study and is unable or unwilling to assume the costs of the study.

### POLICY ON CHANGE OF PROTOCOL

Investigators who desire to change the procedures in a research protocol must submit such details in writing to the committee. In most cases expedited review procedures can be applied to such changes. Written approval from the IRB must be issued before any changes may be implemented.

### PROVISIONS TO PROTECT THE HEALTH AND SAFETY OF HUMAN SUBJECTS

It is the responsibility of the committee to insure that the setting and conditions of all projects and activities involving human subjects are such that any necessary resources of the medical center are available if required.

#### NOTIFICATION

Investigators will be promptly notified in writing by the committee of the results of its review of any proposed project, renewal request or change in protocol. Such notifications will clearly state approval, disapproval or the provisions under which such proposals will be acceptable.

#### RECORDS

The administrator of the Institutional Review Board will maintain records of its meetings and all reviews and decisions concerning projects and activities involving human subjects. Such records will include all of the written information submitted to the committee with any request for approval of review of a project or activity; any questions or requests for additional information made by the committee; the pertinent discussion and the reports of any other subcommittees that relate to the proposal. Such records will also include recommendations of the departmental research committees, chairmen or other consultants.

#### MONITORING

The committee may request reports from an investigator to periodically evaluate research that presents high risk to the human subjects or involving vulnerable subjects such as children, institutionalized or hospitalized persons at intervals determined by the IRB at the initial review.

#### MECHANISM AND RIGHT OF APPEAL FOR PRINCIPAL INVESTIGATOR ON UNFAVORABLE DECISIONS BY THE COMMITTEE

An investigator who receives an unfavorable review by the committee has the right of appeal. This appeal is initiated by filing a notice of appeal in writing with the dean of the College of Medicine within thirty (30) days from the date that the committee issued its unfavorable report. It shall be the duty of the appellant to include in the notice of appeal copies of any and all documents submitted to the committee. The dean of the College of Medicine can either affirm the unfavorable report of the committee, in which case the decision is final, or request re-review of the proposal at the next scheduled meeting of the committee. Neither the dean, nor any other institutional official may reverse an IRB decision of non-approval.

The committee shall notify the investigator of the rehearing, and the investigator shall have the right to appear at the rehearing to defend the proposal.

#### RIGHT OF APPEAL OF SUBJECT PARTICIPATING IN A PROJECT OR PROGRAM

Any subject involved in a project or program has the right to voice complaints or concerns directly to the chairman of the committee through the IRB administrator. In case of an appeal to the committee by a subject, the committee will determine the validity of the complaint and will notify the investigator or project director of its judgment in the matter. The latter will abide by the decision of the committee.