Policy & Procedures Manual

University of Florida
UFIRB02

Revision as of June 2007
# TABLE OF CONTENTS

## I. General Information
- Introduction .............................................................................................................. 4
- Continuous Quality Improvement ........................................................................... 5
- Office Location and Hours of Operation ................................................................. 6
- Structure .................................................................................................................... 6
- Orientation and Training of New Members ............................................................ 7
- Meetings ................................................................................................................... 7

## II. Categories of Review
- Projects requiring the review of full Board .......................................................... 8
- Projects that may receive expedite review ............................................................. 8
- Projects that may be exempt from review ............................................................. 10

## III. The Review Process
- New Protocols ....................................................................................................... 10
  - Full Board Review ............................................................................................... 10
  - Expedite Review ................................................................................................. 12
  - Exempt Review ................................................................................................... 13
  - Indefinite Plans .................................................................................................... 14
- Tabled Protocols .................................................................................................... 19
- Continuing Review ............................................................................................... 14
- Adverse Events ...................................................................................................... 16
- Revisions ............................................................................................................... 17
- Protocol Violations ............................................................................................... 18

## IV. Actions/Decisions
- Protocols Approved as Submitted, No Revisions ............................................... 19
- Protocols Approved Pending Explicit Changes .................................................... 19
- Protocols Tabled .................................................................................................... 19
- Protocols Unable to be Approved ......................................................................... 20
- Appeal Procedure for Protocols Unable to be Approved .................................... 20

## V. Documents and Records
- Agenda Preparation ............................................................................................... 20
- Minutes Preparation .............................................................................................. 21
- Records ................................................................................................................... 21
- Management of IRB Records ............................................................................... 21
- Open Meeting Procedures .................................................................................... 22

## VI. Job Descriptions of Members and Staff
- Chair ...................................................................................................................... 22
- Members ............................................................................................................... 23
- Office Staff ............................................................................................................. 23
- Legal Counsel ....................................................................................................... 25
PREFACE

The University of Florida operates three Institutional Review Boards (IRBs) to safeguard the protection of human participants in research and development. All three boards follow the same federal and university policy guidelines, although each has established slightly different review procedures.

This document sets forth the policies and procedures for the protection of human participants in research, development, and other activities conducted at or sponsored by all units of the University of Florida except University of Florida Health Science Center - Gainesville, the Veterans Administration Medical Center (VA), and the University of Florida Health Science Center - Jacksonville. Faculty, staff, and students should address the University of Florida Institutional Review Board, chaired by Dr. Ira S. Fischler.

In this document, all reference to the University of Florida shall be interpreted as excluding the University of Florida Health Science Center - Gainesville, the Veterans Administration Medical Center, and the University of Florida Health Science Center - Jacksonville.
I. General Information

The President of the University of Florida is responsible for complying with federal, state, and university regulations concerning activities and protections of human subjects in research. The President has delegated this authority to the Vice President for Research, who is legally authorized to act for the Institution and to assume, on behalf of the Institution ("Signatory Official"), the obligations under UF's Federal Wide Assurance (FWA) with the Department of Health and Human Services (DHHS).

UF has designated three internal Institutional Review Boards (IRBs) (IRB-01 Health Science Center, IRB-02 Main Campus, and IRB-03 Jacksonville) and one external IRB (IRB-04, Western IRB or WIRB) to provide oversight for all research conducted under its FWA with DHHS. The IRBs act under the authority of the Vice President for Research.

A. Introduction

1. Purpose

This document sets forth policies and procedures for UFIRB02, (hereafter referred to as the UFIRB). The UFIRB described by this document functions as the review board for research conducted by UF Faculty, staff and students on the UF Main Campus and limited to social, behavioral, and educational research and other studies that involve survey research. The UFIRB described by this document functions as the review board for the University of Florida excluding the Health Science Center - Gainesville, the V.A. Medical Center, and the Health Science Center - Jacksonville.

2. Application

The policies and procedures described herein apply to all research, development, and other activities involving human participants, whether funded or not, for which the University of Florida is responsible. All projects must be conducted or sponsored by members of the University of Florida faculty.

3. General Principle

The UFIRB accepts as basic principles those expressed in the Nuremberg Code (1947), the Declaration of Helsinki (revised 1975), and the Belmont Report (1979), as well as the following documents:

- Title 45 CFR Part 46, OHRP Protection of Human Subjects
- Professional and Ethical Responsibilities of the Society for Applied Anthropology (1974)
- Ethical Standards of Psychologists (1979)
- Code of Ethics of the American Sociological Association (1971)
• Code of Ethics of the National Association of Social Workers (1968)
• Ethical Standards of the American Personnel and Guidance Association (1974)
• International Ethical Guidelines for Biomedical Research Involving Human Subjects, World Health Organization, Geneva, 1993
• OHRP IRB Guidebook, 1993

Copies of these documents are distributed to UFIRB members and are available for review at the UFIRB office.

In addition, the UFIRB will ensure that potential or perceived coercion is minimized for all research participants. The UFIRB will ensure that principal Investigators are especially sensitive to this issue when dealing with captive and/or potentially vulnerable populations such as students, minors, and prisoners. The UFIRB strongly discourages Principal Investigators from recruiting their own (or their supervisor’s) students as research participants or volunteers.

4. Continuous Quality Improvement

In order to best provide protection of human participants and maintain compliance with all regulatory guidelines, including but not limited to those of the OHRP, State of Florida, University of Florida, and the UFIRB Policy and Procedure Manual and Principal Investigator's Manual, the UFIRB will:

a. Update the UFIRB Policy and Procedure Manual as needed and distribute dated revisions to all members.

b. Update the UFIRB Principal Investigator's Manual as needed and distribute significant dated revisions to all members.

c. Semi-annually (January and July), the UFIRB will select at least 6 protocols from the active files for review. The IRB Chair will direct this review. The Chair may assign other members, alternates, or non-University IRB consultants who are familiar with IRB proceedings to assist in this review.

The procedure will consist of, but not be limited to, reviewing each selected file to verify the completeness of: 1) the approval process; 2) consent process; 3) adverse event reports; 4) debriefing, if deception is involved; 4) the renewal process; 5) reported revisions; 6) ethical issues; and 7) assent procedures when minors are participants.

A written report of the summary of these reviews will be presented to the IRB members and staff, with recommendations listed, if any. Success of this program will be shown by the contents and list of recommendations with each report.
d. Provide continuing education to UFIRB members and Principal Investigators via written and oral communications and attendance at workshops and meetings designed to educate members about new or changed OHRP regulations or guidelines.

B. Office Location and hours of operation

The office for the UFIRB is located in Room 98A of the Psychology Building. The hours of operation are 8:00 am until 4:30 p.m., Monday through Friday except on University of Florida official holidays. The phone number is (352) 392-0433.

C. Structure

The responsibility for compliance with Federal, State and University regulations concerning activities involving human participants rests with the President of the University of Florida. The President has delegated this authority to the Vice President for Research and Graduate Programs. The proper functioning of the UFIRB, including the UFIRB office staff, is the responsibility of the Vice President for Research and Graduate Programs.

The UFIRB consists of two components:

1. Members

Faculty and staff members of the UFIRB are appointed by the University Provost on the recommendation of the UFIRB Chair, Vice President for Research, Technology and Graduate Education, College Deans, and appropriate Departmental Chairs or Directors, for staggered 3-year terms. A Chair shall be appointed by the Vice President for Research and Graduate Programs from among those members who have served on the UFIRB for at least one term.

At least one student member is appointed by the University Provost on the recommendation of the UFIRB Chair and Vice President for Research and Graduate Programs, and will serve a 2-year term.

At least one community member is nominated by current UFIRB members and appointed by the University Provost on the recommendation of the UFIRB Chair and Vice President for Research and Graduate Programs to serve on a year-to-year basis for an indefinite period. These members may not be affiliated with the University and are not part of the immediate family of someone who is.

Alternate members are nominated, appointed and trained in the same manner as full members. The Board maintains at least three faculty alternates to serve on behalf of specific Board members in their absence. Alternate members may not vote unless they are acting on behalf of a full member, or unless they are filling a requirement in accordance with 45
CFR 46 (i.e., prisoner representative). Alternate members may replace full members who resign.

The UFIRB membership shall include at least two members whose primary concerns are non-scientific, as well as members who are able to represent the interest of children, pregnant women, persons with disabilities, and other vulnerable groups of people. A member may satisfy more than one of these categories.

2. UFIRB Staff

The staff of the UFIRB consists of a Grants Specialist, who is an employee of the University of Florida, and part-time employee assisting the Grants Specialist.

D. Orientation and Training of New Members

Each new member of the UFIRB will be provided orientation and training through the following procedures:

1. Completion of assigned readings which include, but are not limited to, 45 CFR 46.111, The Belmont Report, Chapter 3 of the OHRP Guidebook, OHRP FAQ’s on Informed Consent, and UFIRB Policy and Procedure Manual and Principal Investigator’s Manual. Documentation of comprehension of this material will be recorded.


3. Acting as an observer at least two UFIRB meetings prior to voting on any protocol.

E. Meetings

1. Meeting time, place and location

UFIRB meetings are held monthly at a time and place that is subject to change from semester to semester.

2. Deadlines for meeting agendas

Agendas are prepared one week prior to each UFIRB meeting. Protocols and other items requiring action must allow two weeks for this preparation. Items to be reviewed at convened meetings must be received by the first working day of that month.

3. Attendance at UFIRB Meetings

A member who misses three consecutive meetings without sending an alternate or who misses half or more of the meetings in a year, whether sending an alternate or not, forfeits membership on the UFIRB.
4. Meeting Quorum

A UFIRB meeting can be called to order only when a quorum exists. A quorum is defined as a majority of members currently approved by OHRP. The quorum may not consist entirely of men or women, and must have one member whose primary concern is non-scientific. Should a quorum fail during a meeting, no further votes may be taken unless a quorum is restored. A member who abstains from voting because he or she has a conflicting interest cannot be counted toward maintaining the quorum.

5. Principal Investigator's Participation During UFIRB Meetings

A Principal Investigator or Co-Investigator may not participate in the review and approval process whether a member of the UFIRB or not. The Principal Investigator or Co-Investigator, if present, will be introduced to the Board and may be present only to provide information requested. The Principal Investigator or Co-Investigators will be asked to leave the meeting during the discussion and voting phase of the review and approval process. Such action will be noted in the minutes of the UFIRB meeting.

II. Categories of Review

The UFIRB assessment of risks and anticipated benefits involves: 1) identifying the risks associated with the research, as distinguished from the risks the participants would encounter even if not participating in research; 2) determining that the risks will be minimized to the extent possible; 3) identifying the probable benefits to be derived from the research; 4) determining that the risks are reasonable in relation to the benefits to research participants, if any, and the importance of the knowledge to be gained; 5) assuring that potential participants will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits; and 6) determining intervals of periodic review, and, where appropriate, determining that adequate provisions are in place for monitoring the data collected. In addition, the UFIRB will determine the adequacy of the provisions to protect the privacy of research participants and to maintain the confidentiality of the data, and where the participants are likely to be members of a vulnerable population, determine that appropriate additional safeguards are in place to protect the rights and welfare of these research participants.

A. Projects requiring the review of the full Board at a convened meeting

Projects require review by the full UFIRB at a convened meeting unless they meet the criteria for expedited review (see II.B.) or exemption (see II.C.). Protocols that necessitate review at a convened meeting must be received in the UFIRB office prior to the first work day of the month. Protocols that are substantively complete are sent to UFIRB members at least one week prior to the meeting as part of the meeting packet.

B. Projects that may receive expedited review
Research that involves no more than minimal risk falls within one or more of the following categories can receive expedited review under most circumstances:

- Research conducted in commonly accepted educational settings involving normal educational practices, use of educational tests, survey procedures, interview procedures or observation of public behavior provided that the information obtained is recorded in such a manner that the participants cannot be identified and that any disclosure of the participants' responses outside the research could not reasonably place the participants at risk of criminal or civil liability nor be damaging to the participants' financial standing, employability, or reputation.
- Use of educational tests, surveys and interviews in which the participants are elected or appointed public officials or candidates for public office or when Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- Collection of hair and nail clippings, deciduous teeth, or permanent teeth, which need extraction.
- Collection of excreta, sweat, or uncannulated saliva.
- Collection and recording of data from participants 18 years or older using non-invasive procedures routinely employed in clinical practice (i.e., weighing, testing of sensory acuity, electrocardiography, electro-encephalography, thermography).
- Collection of supra and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
- Voice recordings made for research purposes such as investigations of speech defects.
- Moderate exercise by healthy participants.
- Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development where the Principal Investigator does not manipulate participants' behavior and the research will not involve stress to participants research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.
- Continuing review for research previously approved by the convened IRB if (a) no new participants will be enrolled and all current participants have completed all interventions, but current participants will be followed-up, OR (b) no participants have been enrolled and no new risks identified OR research remaining is limited to data analysis.
- Continuing review where IRB has determined at a convened meeting that the research involves no greater than minimal risk AND no additional risks have been identified.

This means that most projects that involve no more than minimal risk are not otherwise exempt from full IRB review (see below), may receive expedited review. This type of review necessitates that a subset of the full IRB, delegated this authority by the Chair, independently evaluates the protocol, and when all reviewers concur, the protocol is approved. When one or more of these UFIRB members cannot agree to approve a protocol, the protocol is referred to the full IRB for consideration at a convened meeting. Expedited reviews are commonly carried out by the Chair or Vice-Chair of the UFIRB.
The UFIRB Chair determines, on a case-by-case basis, the number of members scheduled to review expedited protocols. UFIRB staff transmits substantively complete protocols to reviewers within 24 hours of their receipt.

C. Projects that may be exempt from review by the full IRB

It may be determined by the UFIRB Chair or Vice-Chair that a research protocol is exempt from full UFIRB review. Research involving the collection of existing data, documents, records, pathological or diagnostic specimens, if these sources are publicly available or if the information is recorded by the researcher in such a manner that participants cannot be identified, are normally approved as exempt from full UFIRB review. Principal Investigators are cautioned that the decision that a protocol meets all of the criteria for exemption rests with the UFIRB.

Other projects where there is no immediate involvement of human participants, such as training grants or where the research protocol is not complete or the research instruments are yet to be developed, generally fall into a special category ("Indefinite Plans") that are reviewed solely by the UFIRB Chair in the same manner as exempt protocols.

When the funded research plan develops to the point that research involving human participants can begin, a detailed protocol describing the research (including the informed consent process and research instruments) must be reviewed and approved by the UFIRB.

III. The Review Process

The UFIRB evaluates protocols in four basic ways: (1) with full Board review; (2) by expedited review; (3) by exemption; or (4) by identifying a protocol as having indefinite plans for the use of human participants (see above). These are described below in detail.

A. New Protocols

1. Full Board Review

New protocols require full board review unless they meet the criteria for exemption or expedited review. New protocols for full board review are those which are first time submissions or resubmissions of expired protocols where the Principal Investigator wishes to re-activate the study. New protocols may be submitted at any time. New protocols must conform to the format and must contain the information outlined in the UFIRB Protocol Preparation Guidance. The approval period for a protocol will be determined by the Board, but can be no longer than 12 months from the date of review, and is based on the information available to the IRB reviewers and the perceived risk to the participant as determined by the Board.

Reviewer Responsibilities

a. A packet of information about each new protocol requiring full Board review will be sent to all IRB members. This packet will
contain a copy of the completed IRB form and (where applicable), a description of the informed consent process. The reviewer may contact the UFIRB office, or contact the Principal Investigator directly, if more information is needed.

b. One of the major responsibilities of the UFIRB, and thus the reviewer, is to assess the risks to participants posed by taking part in research. Risk and minimal risk are defined below.

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

**Minimal Risk:** Where “the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests” (45 CFR 46.102[i]).

c. Members are expected to participate in the review of all protocols assigned to them.

d. The reviewers are encouraged to contact the IRB office if further information is needed.

e. Special attention should be taken to identify ethical issues.

f. Members are expected to attend the monthly meeting. Projects to be reviewed at a convened meeting will be forwarded to each member at least one week prior to the meeting. Members are expected to review and be prepared to discuss any and all items on the agenda for that monthly meeting.

g. Members who are unable to attend a scheduled meeting must contact their alternates to determine how best to fulfill their responsibilities. If an alternate is not available, the member must notify the UFIRB office.

**UFIRB Office Procedures**

a. When a new protocol is received, a project identification number is assigned. This project number indicates the year and sequential number of the protocol (i.e., 2007-U-0549). The project number, protocol title, Principal Investigator's name and UFID, and other relevant information are entered into the computer database.

b. The protocol is screened for the following:
   - UFIRB form is complete
   - Description of complete informed consent process
     - All required elements
   - Other information, as appropriate
c. If the protocol is incomplete, it is returned to the Principal Investigator.

d. When the protocol is complete, it is sent out for review and/or placed on the agenda for the next UFIRB meeting.

e. Recommendations made by the Board are recorded in the computer database and in the project file.

f. Appropriate letters are sent informing the Principal Investigator of the action by the Board (see Section IV).

g. Principal Investigators are advised to contact the appropriate departmental offices regarding any specific policies that they are required to follow in connection with the recruitment of University students as research participants.

2. Expedited Review

A description of protocols that qualify for expedited review is specified in Section II. B above. Protocols qualifying for this procedure can be reviewed and approved by the Chair or a subset of members, as directed by the Chair. Protocols can be denied this expedited review and rescheduled for full Board review, but cannot be found to be unable to be approved on behalf of the UFIRB through the expedited review process. If any member votes "unable to approve a protocol" and his/her concerns cannot be satisfactorily resolved, the protocol is scheduled for full Board review. The approval period will be determined by the Board, but can be no longer than 12 months from the date of review, and is based on the information available to the IRB reviewer(s) and the perceived risk to the participant as determined by the Board.

Reviewer Responsibilities

a. The Chair and/or designated subset of the members will receive protocols potentially eligible for expedited review from the staff.

b. If the protocol qualifies for expedited review, the Chair or designee(s) will notify the staff of its approval status by returning a completed review sheet.

c. If the protocol does not qualify for expedited review and is not exempt, the Chair will return the protocol to the staff and request that it be scheduled for full Board review. The staff will forward the protocol to all members.
d. When Principal Investigators submit amendments to existing approved protocols and these amendments are deemed to be minor changes that result in no increase in risk to participants/volunteers, the Chair can use the procedure described in b and c above to review and approve such changes.

e. A written record is kept of the reviewer, date of review and action taken. This information is recorded in the computer database and in the project file.

**UFIRB Office Procedures**

a. All projects potentially eligible for expedited review will be forwarded to the Chair.

b. If the protocol is approved as expedited, approval letters will be sent along with a dated, IRB-approved informed consent document (where applicable). The Chair will report about the action on expedited projects on a semi-annual basis to UFIRB members, alternates, the Vice President for Research and Graduate Programs and appropriate administrators.

c. If the protocol requires revisions, the Chair expresses concerns, or requires additional information; the staff will contact the Principal Investigator(s) by telephone, letter or electronic mail.

d. Principal Investigators will be advised to contact the appropriate departmental offices regarding any specific policies that they are required to follow in connection with the recruitment of University student as research participants.

3. **Exempt Review**

Research deemed exempt from UFIRB review is described in Section II. C above.

**Reviewer Responsibilities**

a. The Chair will receive protocols that are potentially exempt from the staff.

b. If the protocol qualifies for exempt review, the Chair will notify the staff of this status. This information will be recorded in the computer database and made part of the semi-annual report.

c. If the protocol does not qualify for exempt review, the Chair will return the protocol and a completed review sheet to the staff.

**UFIRB Office Procedures**

a. All protocols potentially eligible for exempt review will be forwarded to the Chair.
b. If the protocol is exempt from full Board review, the Principal Investigator will be notified. All exemptions will be noted in the semi-annual report.

c. If the protocol is not considered to be exempt by the Chair, it will be returned to the staff to schedule the protocol for an expedited or a full Board review, and distribution as appropriate.

d. All protocols for exempt projects are filed in the UFIRB office.

4. **Indefinite Plans**

Proposals lacking definite plans for involvement of human participants may include (but are not limited to): “institutional type grants when selection of specific projects is the institution’s responsibility, research training grants in which the activities involving participants remain to be selected, and projects in which human participants’ involvement will depend upon completion of instruments” (45 CFR 46.118).

**Reviewer Responsibilities**

a. The Chair will receive protocols with indefinite plans for the use of human participants from the staff.

b. If the protocol falls into this category, the Chair will notify the staff by returning the protocol. This information will be recorded in the computer database and made part of the semi-annual report.

c. If the protocol does fall into this category, the Chair will return the protocol and a completed review sheet to the staff.

**UFIRB Office Procedures**

a. All protocols with indefinite plans for the use of human participants will be forwarded to the Chair.

b. If the protocol falls into this category, the Principal Investigator will be notified. All projects lacking definite plans for involvement of human participants will be noted in the semi-annual report.

c. If the protocol is not considered by the Chair to lack definite plans for involvement of human participants, it will be returned to the staff to schedule the protocol for an expedited or a full Board review, and distribution as appropriate.

d. All projects lacking definite plans for involvement of human participants are filed in the UFIRB office.

**B. Tabled Protocols**  (See section IV. C.)

**C. Continuing Review**

A reexamination of a current project is made when any of the following occurs:
• when the use of human participants in research is expected to continue beyond the original IRB approval period
• when minor changes are proposed
• when the risk associated with the research changes
• when adverse events, unanticipated problems, or complaints about the research are reported.

All protocols approved by the UFIRB are subject to continuing review at intervals appropriate to the degree of risk (as determined by the IRB), but not less than once in the 12 months following approval.

Reviewer Responsibilities

1. Projects will be reviewed to determine the level of risk.

2. Projects proposing minor or no change shall be reviewed in the same manner as the initial review. (If during an initial review by the full Board, the project was determined to be of minimal risk, AND no new risks have been identified, it can qualify for expedited continuing review.)

3. When a proposed change in protocol is not minor or adverse events have been reported, and/or the project was previously reviewed at a convened meeting, reviewer responsibilities outlined in section III.A.1 apply.

4. If the Chair believes a protocol continuing review packet should be reviewed by the full Board, the Chair will return the packet to the staff for the following information to be distributed to all members.
   • Completed continuing review form
   • Current informed consent process
   • Copy of protocol
   • Brief description by the Chair outlining concerns, if applicable

UFIRB Office Procedures

1. At least six weeks prior to the IRB approval expiration date, the staff will send a continuing review form to each Principal Investigator. A copy of this form is placed in the protocol's file. It is, however, the Principal Investigator's obligation to obtain timely renewal.

2. If the UFIRB has not reapproved a research study by a study's current expiration date, the research will be suspended. A letter will be sent to the Principal Investigator indicating this action.

3. If no response has been received within one month following the approval expiration date, the protocol will be terminated. A letter will be sent to

---

1While suspended, new participant recruitment must stop. Interventions under the research protocol must be stopped unless an over-riding concern for the safety or well-being of the participants, or other ethical issues, are involved. In such cases, the Principal Investigator must contact the UFIRB immediately. The suspension will be lifted when and if the protocol is reapproved by the UFIRB. (This statement has been included at the request of DHHS, April, 1995.)
the Principal Investigator indicating this action. The protocol will be deleted from the active projects in the computer database and the paper file will be placed in the inactive files.

4. All continuing review packets (including Principal Investigator’s responses to continuing review memos and current informed consents) will be sent for review in the same manner as the initial review.

5. The UFIRB office will supply the reviewers any additional information requested to help determine current risks to participants.

6. If the protocol is approved by the UFIRB, a reapproval letter will be sent to the Principal Investigator along with a copy of the approved informed consent affixed with the UFIRB expiration date, not to exceed one year from the review date.

D. Adverse Events

Adverse events are undesirable and unintended, although not necessarily unexpected incidents involving risks to participants or others.

The OHRP requires Principal Investigators to report adverse events promptly and in writing to the Chair. This report must be submitted within 5 working days and provide a description of the adverse event, state whether or not changes are needed in the protocol and the informed consent process, and indicate whether or not participants must be notified regarding the event. These revisions will be reviewed by the full Board. The Principal Investigator is also put on notice that if the events submitted are deemed to place participants at increased risk, the Chair may request resubmission of the protocol for full Board review. In a circumstance where the Board perceives the participant(s) may be placed at immediate significant risk, the UFIRB has the authority to suspend or terminate a protocol. Any such action shall include a statement of the reasons for the UFIRB action, and the Chair will contact the appropriate university officials.

Reviewer Responsibilities

Notification of adverse events will be immediately reviewed by the Chair and distributed to all members.

1. The Chair will review the adverse event letter, current informed consent, the currently approved protocol, and, if applicable, the last continuing review report to determine if there is any increased risk.

2. The staff will assist in obtaining information to assess current degree of risk.

---

2When a protocol is terminated, no further participants may be recruited into the study and all participants currently enrolled must be notified of the protocol’s termination. Participants may not be followed for research observation or data collection after such termination. (This statement has been included at the request of DHHS, April, 1995.)
3. The Chair will make a recommendation to the members at the regularly scheduled meeting about the results of the review and record made in the project file. One or more of the following must be recommended:
   a. No action is needed.
   b. Changes are needed in the informed consent.
   c. Current participants must be informed of this new information and risk.
   d. The protocol needs to be revised due to this new information.
   e. The protocol is put on "suspended" until more information is made available.

4. In the event a protocol is suspended, the Chair will contact the Vice President for Research.

**UFIRB Office Procedures**

1. When notice of adverse events is received by the UFIRB office, the notice and the active protocol file are immediately brought to the attention of the Chair.

2. The adverse event letter, copy of the currently approved protocol, the last continuing review report (if applicable), current informed consent document, and any additional relevant documents are sent to all UFIRB members for review.

3. The project is placed on the agenda for the next regularly scheduled meeting (or a special meeting is set if directed by the Chair).

4. After the meeting, a letter is sent to the Principal Investigator indicating what action (if any) was taken.

**E. Revisions**

Changes to a protocol or informed consent process may originate from the Principal Investigator or the sponsor. The Principal Investigator is responsible for contacting the UFIRB when protocol changes are proposed; a change in risk associated with the research occurs; and/or adverse events, unanticipated problems, or complaints about the research are reported. A written description of proposed changes to the protocol, informed consent process and/or research instruments must be submitted to the Board for review and approval prior to implementation. The form for revision submission is located on the IRB02 website. Only in the rare circumstance when it is necessary to eliminate apparent immediate hazards to the research participants, as noted in 45 CFR 46.103(b)(4)(iii), is a researcher permitted to modify an approved protocol without the prior review and approval of the UFIRB. In this case, the UFIRB must be informed within 5 days of the change following its implementation. The change will be reviewed to determine that it is consistent with protection of human participants.

1. Changes, which do not increase the risk for previously approved projects, are minor changes to a protocol. These may involve changes to the number of participants, venue of the data collection, etc). Minor changes
need the approval of the Chair under the expedited format (see procedures II.B).

2. Major changes are those which increase risk to participant. These changes need the review of the full Board. The project is placed on the agenda and the revision request forwarded to all members (see procedures II.A).

**Reviewer Responsibilities**

**Minor Changes**

1. The Chair receives requests for minor changes in a current protocol from the staff.

2. If the changes are approved, the Chair will make a written, dated note on the request and return the project file to the staff.

3. If the changes are not felt to be minor, the Chair will return the project file to the staff to be distributed to full Board.

**Major Changes**

1. The full Board will receive a copy of the request; original protocol and current consent process.

2. The request must be reviewed with the same criteria for concern of human participants as used in the review of a new protocol, assessing risks to the participants (see II.A).

3. The project is placed on the agenda and the revision request forwarded to all members (see II.A. UFIRB Office Procedures).

**UFIRB Office Procedures**

1. Date requests for revisions or amendments at time of receipt and attach to the current approved protocol file.

2. Ascertain if the request requires immediate attention. If so, inform the Chair.

3. Send out to full Board for review and enter on the next agenda.

4. Notify the Principal Investigator of the Board’s action.

5. Update protocol file and database to reflect the action and this revision.

**F. Protocol Violations**

**Protocol violations involve** research that is not being conducted in accordance with the UFIRB's requirements.
UFIRB Office Procedures

1. If a protocol violation occurs or is suspected, the Chair will notify the Principal Investigator in writing of the event in question. UFIRB approval for the protocol may be withdrawn until the issue is resolved. The Principal Investigator will have 5 working days to respond in writing to the inquiry.

2. If no response is received from the Principal Investigator, a second letter will be sent to the Principal Investigator, the Department Chair, and the Vice President for Research and Graduate Programs.

3. Once the response is received, the Chair will decide what further action, if necessary, will occur. This could include a recommendation to withdraw IRB approval for the study, reinstatement of the study, review by full Board, or a recommendation to the Vice President for Research and Graduate Programs.

4. If the Chair feels the IRB approval for the study should be withdrawn, this recommendation will be brought to the full Board for final review.

5. The staff will notify the Principal Investigator of the Board’s decision in writing.

6. The UFIRB will notify the Vice President for Research and Graduate Programs of any instances of serious or continuing non-compliance and any suspension or termination of approval to meet the requirements at 45 CFR 46.103(b)(5) and the University of Florida’s MPA.

IV. Actions/Decisions

A. Protocols Approved as Submitted, No Revisions

Approval letters are generated by the staff at the completion of the review period or, when feasible, the same day as the UFIRB meeting. Approval letters are the first priority of the UFIRB staff. A copy of the UFIRB approved informed consent document with the expiration date affixed will be included with the approval letter sent to the Principal Investigator.

B. Protocols Approved Pending Explicit Changes

Letters requiring specific revisions necessitating simple concurrence by the Principal Investigator are prepared based on the comments and/or concerns submitted by reviewers during the review period and/or the decision made by the members at the meeting. Protocols approved with explicit changes are the second priority of the UFIRB staff.

The Principal Investigator’s response is reviewed by the Chair, or designated, experienced member, for completeness and, if appropriate, the approval letter
and approved informed consent document with the expiration date affixed is sent to the Principal Investigator.

C. Protocols Tabled

Definition: Any protocol under review by the UFIRB in which additional information or substantive protocol modifications or informed consent document revision(s) are required in order to complete the review process.

Reviewer Responsibilities

Reviewers must write "Tabled" on the IRB protocol form and keep the original packet of material (the protocol, informed consent and other related material) for the next meeting.

UFIRB Office Procedures

1. A letter stating the issues raised is sent to the Principal Investigator following the meeting. The issues are recorded in the minutes.

2. When a response is received from the Principal Investigator, a copy of that response and the letter to the Principal Investigator are sent to the members for the next meeting.

3. Tabled protocols will be listed on the agenda for the next meeting, along with the issues raised.

D. Protocols Unable to be Approved

When the Board feels it is unable to approve a protocol, a letter is prepared by the staff to inform the Principal Investigator of the Board’s decision and the reasons. Drafts of letters are reviewed by the Chair. Final copies are signed by the Chair prior to their being sent.

E. Appeal Procedure for Protocols Unable to be Approved

Any person or entity which demonstrates a genuine interest in the result to be obtained may appeal any aspect of the UFIRB review and decision to an administrative review committee consisting of the Provost, Vice President for Research and Graduate Programs, the University Attorney responsible for the legal aspects of research involving human participants, and the pertinent College Dean. The finding of the IRB will be reported to this administrative review committee by the IRB Chair. It will be the responsibility of the administrative review committee to ensure that the guidelines followed are consistent with 45 CFR 46 as well as the policies and practices of this institution. Upon the recommendations of this committee, appeals will be referred to the IRB for disposition as the final authority.

V. Documents and Records

A. Agenda Preparation
The agenda for UFIRB meetings will group the different protocols and business items into logical categories. Protocols will be listed in ascending protocol numbers, unless there is reason to do otherwise. Copies of the agenda and materials related to protocols on the agenda are prepared ten days prior to the meeting and distributed via campus mail. Mail to community members is distributed via the U. S. Postal system.

B. Minutes Preparation

The minutes will include the names and titles of each initial and continuing review application or application for revision, a summary of the actions taken and a summary of the discussions as they relate to the approval of applications, which includes documenting ethical issues, level of risk as assessed by the UFIRB, and issues involving consent/assent. When minors are participants in a research protocol discussed at a convened meeting, the requirements at 45 CFR 46.404-407 will be discussed and documented in the minutes by citing the appropriate category.

The minutes will also include the basis for requiring changes in the research protocol and informed consent, the number of members voting for, against or abstaining, the length of approval time given, not to exceed one year, and, if appropriate, a notation specifying actions taken to avoid conflict of interest (i.e, a UFIRB member/Principal or Co-Investigator left the room prior to the discussion and voting).

The minutes will note if a quorum is present and if a non-scientist is present for voting purposes. Should a member leave or enter the room after protocol discussions have begun, a record of this fact will be made in the minutes. Additionally, a note will be made if the exiting member affects the status of the quorum for voting purposes.

C. Records

The minutes and agendas for each meeting are to be retained in the permanent files of the UFIRB office. Records required by 45 CFR 46.115 are also maintained.

Individual project files shall be maintained for each project submitted to the UFIRB. Each file shall contain the original application packet (see section II.A.), all correspondence, approval, notes from the meetings, a copy of the approved consent form and all continuing review information. These records are maintained for at least three years after completion of the study. UFIRB minutes and agendas are also maintained as a documentation of UFIRB actions.

D. Management of IRB Records

1. Protocols
All files are kept in the UFIRB office. Files are secured when the office is closed. Project files are destroyed three to five years after being removed from the active files.

2. Requests for Information

The UFIRB office operates under the same State Public Records Rules and Regulations as do the other University offices. All requests for UFIRB records must be submitted to the UFIRB office. Records and files that are not public records or are exempted from public disclosure are not released to the public. Decisions regarding what documents are public are made in consultation with the University Counsel.

When the OHRP or members of the public or media request copies of UFIRB records and files, the Principal Investigator, University Counsel and the Vice President for Research and Graduate Programs are immediately notified.

E. Open Meeting Procedures

The UFIRB meetings are conducted under the same State Public Meeting Rules and Regulations as are other University committee meetings. Announcements of the meeting are circulated and seating for guests and visitors is provided. Guests should make their presence known to both the Chair and UFIRB staff for introduction and proper recording.

VI. Job Descriptions of Members and Staff

A. Chair

The Vice President for Research and Graduate Programs shall appoint a Chair from among those members who have served on the UFIRB for a period of at least one term. The Chair shall be responsible to the Vice President for Research and Graduate Programs for the general supervision of the activities of the UFIRB. The University will provide orientation and training opportunities at the local and/or national levels in UFIRB matters. The Chair, with administrative and communication skills, provides leadership and promotes an environment conducive to scholarly research and activities that protect human participants who take part in research. The Chair shall serve for a three-year term and may be reappointed. The duties of the Chair are as follows:

1. Presides at all meetings of the UFIRB.
2. Calls special meetings of the UFIRB.
3. Conducts reviews of all protocols submitted to the UFIRB proposing use of human participants in research.
4. Advises and counsels Principal Investigators referred by the UFIRB staff and UFIRB members.
5. Screens potential UFIRB members and present acceptable nominees to the Vice President for Research and Graduate Programs for review.

6. Makes decisions on emergency conditions as they relate to the UFIRB's protection of human participants in compliance with Federal regulations.

7. Keeps the UFIRB informed of developing problems in the area of human research on any current or pending project.

8. Communicates regularly and frequently with the UFIRB staff concerning UFIRB matters.

9. Supervises the UFIRB staff.

10. Performs functions delegated to an official of the UFIRB in accordance with University, State and Federal regulations.

11. Appoints alternate members or a Chair designee.

B. Members

The University will provide orientation and training opportunities at the local and/or national levels in UFIRB matters. The duties of the UFIRB members are as follows:

1. Attend all meetings.

2. Contact an alternate who can attend the meeting when the member is unable to do so to act in place of the member.

3. Review materials before each meeting.

4. Review all introductory and regulatory documents relating to the use and protection of human participants.

5. Disqualify themselves from participating in the review of, or voting on any activity in which he/she has a conflict or interest or even the perception of a conflict of interest.

6. Contact the UFIRB office if unable to attend a meeting.

7. Willingly participate in subcommittee activities as time and interests allow.

8. Protect the confidentiality of the records and information provided to him/her.

C. Office Staff

The staff of the UFIRB consists of a Grants Specialist and one graduate research assistant. The University will provide orientation and training to the
Grants Specialist at the local and/or national levels for matters pertaining to the UFIRB.

The duties of the UFIRB staff/graduate assistant are as follows and shall be delegated at the discretion of the Grants Specialist:

1. Receive and perform initial screening of all research protocols submitted to the UFIRB. Distribute protocols to appropriate member(s) for review.

2. Arrange and coordinate all aspects of UFIRB meetings, records and communications. Attend, as ex-officio member, all meetings of the UFIRB. Prepare and distribute an agenda indicating the protocols to be discussed prior to each scheduled meeting. Take and distribute minutes of UFIRB meetings that record the attendance and actions of the UFIRB.

3. Maintain communication with Principal Investigators regarding the status of and actions taken on their protocols.

4. Provide such information to UFIRB members as shall be required.

5. Maintain complete records of all UFIRB deliberations and actions.

6. Maintain accurate records of all protocols, including relevant discussions, correspondence, modifications and final actions.

7. Serve as liaison between UFIRB members and Principal Investigators, relay information concerning review procedures to student, faculty, and staff experimenters and administrators in need of information concerning forms and procedures.

8. Direct Principal Investigators to appropriate information sources.

9. Circulate new regulations, laws, and information to UFIRB members.

10. Provide liaison with the Office of Research and Graduate Programs, IRB Coordinator, University Counsel, College and Departmental offices, and cooperating and affiliated institutions.

11. Conduct periodic reviews and close protocols that have expired.

12. Furnish such information and reports as are required by the UFIRB, the University, OPRR, FDA, and others.

13. Present detailed formal instructional workshops to classes across campus regarding ethical principles, submission and review procedures.

14. Assist in the development of materials for the orientation and continuing education of UFIRB members and alternates.

15. Develop and assist in the orientation and continuing education of faculty, staff and students with UFIRB procedures and policies.

16. Analyze opportunities to improve services and implements enhancements.

17. Develop and the Policy and Procedure Manuals for the UFIRB in accordance with OHRP, FWA, and University of Florida requirements.
18. Prepares, semi-annually, a written report to the Vice President for Research and Graduate Programs of the status of all current and pending protocols processed during that six-month period.

19. Assists in the development of the annual budget, initiating paperwork for all purchases and expenditures for the UFIRB.

20. Assists the Chair in handling telephone messages, making appointments and travel arrangements.

D. Legal Counsel

The Vice President for Research and Graduate Programs will appoint University legal counsel for the UFIRB. The University will provide orientation and training at the local and/or national levels in UFIRB matters. Legal counsel will have speaking privileges at all UFIRB meetings, and will serve as an ex-officio member (no vote). The duties of the legal counsel include the following:

1. Inform and advise the UFIRB concerning legal issues involving research on human participants.

2. Provide legal advice to the UFIRB on an on-going basis by addressing issues and questions raised at the UFIRB meetings.

3. Advise the UFIRB on the legal implications of UFIRB policies.