University of Texas at Arlington

IRB Standard Operating Procedures

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I. Institutional Authority - The University of Texas at Arlington operates a centralized human participant’s review program under the Office of the Vice President for Research (VPR) at UT ARLINGTON. The IRB reviews projects in a wide range of research protocols in the social, behavioral, educational, and clinical fields.

II. Purpose - The purpose of the UT Arlington IRB is to assure that the rights and welfare of human participants are adequately protected in research. The UT Arlington IRB advises investigators in the design of research projects in order to minimize potential harm to human participants; reviews all planned research involving human participants prior to initiation of the research; approves research that meets established criteria for protection of human participants; and monitors approved research protocols to ascertain whether human participants are indeed protected.

The UT Arlington IRB also informs and assists UT Arlington faculty, staff, and students of ethical and procedural issues related to the use of human participants in research in order to facilitate compliance with relevant federal regulations and to provide a framework suitable for continued support by federal funding agencies, private foundations and industry.

Primary responsibility for assuring that the rights and welfare of research participants are protected continues to rest with the Principal Investigator (PI) conducting the research. Others engaged in the research share this responsibility. Faculty who assign or supervise research conducted by students or staff have an obligation to consider carefully whether those individuals are qualified to safeguard adequately the rights and welfare of participants.
III. Principles - All research at UT Arlington that involves human participants is guided by the ethical principles set forth in the report of the National Commission for the Protection of Human Participants of Biomedical and Behavioral Research entitled “Ethical Principles and Guidelines for the Protection of Human Subject of Research (Belmont Report)”.

IV. Scope and Authority of the IRB – The participation of humans in research carried out at the University or under its auspices must be reviewed and approved by an IRB prior to the start of the research.

A. Scope – The UT Arlington IRB reviews protocols for research involving human participants when conducted by or under the direction of any employee, student, or agent of UT Arlington in connection with his or her institutional responsibilities or using any institutional property or facility. Also, the IRB reviews research protocols of non-UT Arlington investigators when UT Arlington faculty, staff, or students are involved.

B. Authority - The authority conveyed to the IRB includes:

1) Review/approval of new/continuing research protocols involving human participants and associated informed consent documents (ICD) prior to initiation/continuation of research;
2) Monitoring of approved projects including regularly scheduled continuing review at least every twelve (12) months;
3) Verification of compliance with approved research protocols and informed consent procedures;
4) Review of all planned changes to approved protocols prior to implementation;
5) Review of all adverse events occurring in approved projects, or in other projects related in context to the approved projects;
6) Restriction of approved research activities to protect participants when necessary; and
7) Suspension/termination of previously approved protocols for non-compliance with established policies.

C. Authority of Institutional Officials - The VPR (or designated IO) has the authority to review decisions of the IRB. In instances of disagreement, the IO works with the IRB to resolve specific issues.

V. Relationship of UT Arlington IRB to Other Agencies, Institutions and Committees

A. Compliance with Federal Regulations - UT Arlington has filed a Federalwide Assurance (FWA) with the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) affirming that the University is in compliance with 45 CFR 46. This assurance applies to all research involving human participants funded by federal agencies subscribing to the “Common Rule” – (DHHS regulations incorporate the Common Rule as Subpart A of 45 CFR 46).
In studies involving products regulated by the Food and Drug Administration regulations, the UT ARLINGTON IRB complies with the requirements set forth in 21 CFR 50, 21 CFR 56, 21 CFR 312, and 21 CFR 812.

B. Review of Research Activities by Other University Committees - UT ARLINGTON IRB coordinates the review with other institutional committees as described below. None of these committees are a formal part of UT Arlington IRB structure, but there is communication between the committees regarding status of review and/or conditions of approval if there are human participants involved.

1) Institutional Animal Care and Use Committee (IACUC) - The IACUC is responsible for insuring that research involving animal participants complies with the Office of Laboratory Animal Welfare (OLAW) guidelines. Investigators are required to submit a protocol to the IACUC for all research involving animal participants. The protocol must be reviewed and approved by the IACUC prior to the initiation of the research.

IACUC deliberations are normally not shared with the IRB unless there are specific issues involving human participants. In instances where both animal and human participant research issues are involved, investigators should: i) notify the IRB and IACUC chairs; and ii) submit separate protocols to the IRB and IACUC, respectively. In certain instances, the IRB may deem it appropriate to receive notification of the related IACUC approval before approving the IRB protocol.

2) Institutional Biosafety Committee (IBC) - The IBC is responsible for ensuring that recombinant DNA activities comply with the National Institutes of Health (NIH) guidelines. Investigators are required to submit an exemption form and/or an application form to the IBC for all recombinant DNA experiments. The investigator must receive approval from the IBC prior to the initiation of the research.

IBC deliberations are generally not shared with the IRB unless there are specific issues related to human participants. In instances where both biosafety and human participant research issues are involved, investigators should: i) notify the IRB and IBC chairs; and ii) submit separate protocols to the IRB and IBC, respectively. In certain instances, the IRB may deem it appropriate to receive notification of the related IBC approval before approving the IRB protocol.

VI. Membership on the UT ARLINGTON IRB
A. **Appointment of Members** - The VPR recommends to the President the appointment of all IRB members and their alternates. IRB members are appointed to three (3) year terms. After their initial appointment, members (and alternates) may be reappointed for no more than two (2) additional consecutive terms. The appointment of members (and alternates) should not exceed three (3) consecutive terms or a total of nine (9) consecutive years of service on the IRB.

Should a member have 3 absences from consecutive IRB meetings, he/she can be removed at the discretion of the IRB Chair.

B. **Regular Members** - The IRB has at least five (5) members with varying types of expertise, experience, and diversity to promote complete and adequate review of human subject research at UT Arlington. At least one member should be from outside UT Arlington (i.e., not otherwise affiliated with UT Arlington and who is not part of the immediate family of a person who is affiliated with UT Arlington) and represent community interests and values.

C. **Responsibilities** - Responsibilities of members include (i) attending IRB meetings; (ii) determining the appropriate type of review for submitted protocols (exempt, expedited, full board); (iii) reviewing protocols to be discussed at IRB meetings; (iv) being prepared to discuss issues related to human participants protections at IRB meetings; (v) serving as primary reviewer at IRB meetings when requested by the IRB Chair; (vi) being informed about the specific requirements regulating the participation of human subjects in research; and (vii) maintaining the confidentiality of IRB meeting discussions.

D. **Compensation of IRB Members** - IRB members do not generally receive monetary compensation above their University salary for participation on the board. The IRB Chair may receive financial compensation and/or release time authorized by the Office of the VPR to ensure a sustained level of high performance.

E. **Member Liability** – IRB members are covered by UT Arlington general liability coverage when acting within the course and scope of their IRB duties.

F. **Alternate Members** – Alternate members of the IRB are appointed three (3) year terms and may be reappointed as alternate members or appointed as a regular member. Total service to the IRB should not exceed three (3) consecutive terms or nine (9) consecutive years.

Alternates serve at-large and only vote when replacing a regular member. If both the alternate and the regular member attend the same meeting, only one vote will be counted. In such cases, the meeting minutes reflect the primary member as the voting member.

G. **Non-Voting Members** - The VPR may, at his/her discretion, recruit non-voting (ex officio) members from among the academic or administrative staff of UT Arlington, whose presence at the meetings of the IRB would aid the IRB in conducting its duties. These members may take part in all meetings of the IRB, participate in the discussions, and make recommendations to influence decisions, but they may not vote on the decisions. Non-voting members are not included in determining or establishing a quorum (see Section IX, Part G) at the meetings. IRB
meeting minutes reflect the presence of non-voting members.

H. **Consultants/Ad hoc Reviewers** - At its discretion, the UT Arlington IRB may invite scientists or non-scientists from within or outside UT Arlington, who have special expertise, to function as consultants and *ad hoc* reviewers of a protocol application. These individuals have access to all documents submitted to the IRB relevant to the specific project under review, may participate at the deliberations and make recommendations on the project, but may not vote.

I. **Conflicts of Interest** - IRB members may not participate in the initial or continuing review of any project in which the IRB member has a conflict of interest, except to provide information requested by the board. In cases where the initial reviewer has a conflict of interest, that study application is re-assigned to another reviewer or taken to the full board. When the investigator-member has a conflicting interest, he or she may be present at IRB meetings, like any investigator, only to provide information requested by the board. He or she must leave the meeting room during the subsequent discussion and voting phases of the review and may not vote (e.g., abstain, table, approve, disapprove) on the study. Members that are absent during the vote do not count toward a quorum. Minutes reflect whether or not these requirements have been met.

VII. Management of the IRB Process

A. **IRB Chair** – The VPR recommends to the President individuals willing to serve as IRB Chairperson. It is the President’s responsibility to formalize the appointment through a written appointment letter. Chairpersons are appointed to a three (3) year term; their appointments may be renewed for additional terms, but should not exceed three consecutive terms or a total of nine (9) consecutive years on the IRB. The Chairperson should be a respected, active member of the University community who is well-informed in regulations relevant to the use of human participants in research. Whenever the IRB Chair is not available to conduct IRB business, he/she may designate a board member to assume his/her responsibilities during the period of his/her absence.

Responsibilities of the IRB Chair include: (i) determining the type of review appropriate for new protocols (exempt, expedited, full board); (ii) insuring that submitted protocols receive expeditious review; (iii) serving as primary reviewer of protocols when appropriate or delegating this responsibility to another IRB member; (iv) conducting the business of full board meetings following basic parliamentary rules, (v) convening expedited review panels when necessary and appropriate; (vi) reviewing on behalf of the IRB, revisions to protocols/consent documents required as a condition of approval, (vii) reviewing serious adverse experience reports; (viii) recommending to the VPR new and/or replacement IRB members; (ix) serve as a member of the Faculty Advisory Committee (FAC); (x) assess and recommend appropriate IRB training for the IRB, investigators, and support staff; (xi) serve as a resource for investigators and IRB members regarding issues related to University and federal policies.

B. **IRB Coordinator** – The IRB Coordinator is part of the Office of Research Administration and provides administrative support to the IRB. The IRB Coordinator is an integral part of the IRB, but serves in a non-voting, ex-officio capacity.
The IRB Coordinator: (i) provides administrative support to the IRB and investigators in all aspects of the IRB process; (ii) assists investigators throughout the protocol submission, review and approval processes, and provides information regarding protocol status; (iii) organizes, coordinates and attends all IRB meetings and records detailed minutes of all meetings; iv) maintains all IRB records (e.g., agendas, minutes, policies, regulations, reference materials and individual protocol files) in a secure environment; (v) maintains the electronic system for tracking IRB protocols (e.g., new protocol submissions, protocol/informed consent modifications, annual continuation applications, safety reports, adverse event documentation, etc.); (vi) coordinates with IRB Chair for follow-thru on all action items resulting from IRB meetings (e.g., modifications to protocol documentation, Informed Consent changes, etc.); (vii) works with IRB Chair/Vice Chair to evaluate investigator responses to documentation changes to determine appropriateness; and (viii) keeps abreast of changes to federal rules/regulations and updates IRB Chair regarding changes.

C. Resources - The University provides adequate facilities and equipment to support the operation of the IRB in the performance of the functions described in this document.

VIII. Functions of the IRB

A. Scope of Review – The IRB reviews all new and continuing protocol applications for the following:

1) determine that the use of human participants has research relevance and that ethical issues have been addressed with regard to the study’s design and conduct;
2) identify the levels of risk and that everything has been done to minimize risk to the extent possible;
3) identify the probable benefits to be derived from the research;
4) balance the risks against the benefits and importance of the knowledge to be gained;
5) assure that potential participants are provided with an accurate and fair description of the risks or discomforts and the anticipated benefits;
6) determine intervals for periodic review;
7) where appropriate, determine that adequate provisions are in place for monitoring the collected data;
8) determine the adequacy of the provisions to protect subject privacy and maintain data confidentiality; and
9) 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 participants.

B. Special Consideration for Projects Involving Vulnerable Populations - The IRB considers certain groups of human participants to be particularly vulnerable in a research setting and considers additional protections for research activities involving pregnant women, human fetuses and neonates, prisoners, children, and cognitively impaired persons. In reviewing these research projects, the IRB ascertains that the inclusion of the vulnerable population is
adequately justified and that safeguards are implemented to minimize risks unique to each population.

The IRB considers for approval research projects involving vulnerable populations if one of the following conditions is met: i) the research does not involve more than minimal risk to the subject; ii) the research is likely to benefit the subject directly, even if the risks are considered to be more than minimal; or iii) the research involves greater than minimal risk with no prospect of direct benefit to individual participants, but is likely to yield generalizable knowledge about the subject's disorder or condition.

Requests for approval of any research that exposes vulnerable populations to risks that do not meet one of the above criteria must be submitted to the Secretary of the Department of Health and Human Services (DHHS) for review and approval.

For review of protocols involving the use of prisoners in research, the IRB must have a designated prisoner advocate present at the meeting. An IRB member may approve new studies limited to retrospective review of prisoner records and minor modifications using expedited review procedures after review and comment by the prisoner advocate.

C. Suspension or Termination of IRB Approval - The IRB has the authority to suspend or terminate approval of research involving human participants that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement of the reasons for the IRB’s action and shall be reported promptly to the investigator, appropriate IOs, and the department or agency head.

D. Noncompliance Investigations and Actions - Information regarding noncompliance in studies involving human participants may come to the attention of the IRB through several pathways. These include internal monitoring of research projects, information contained in new applications, continuing reviews, adverse experience reports, reports from collaborators, employees, participants, or others.

The IRB Chair or his/her designee reviews allegations of noncompliance. The IRB Chair makes a determination as to whether the alleged practices appear to (1) cause injury or any other unanticipated problems involving risks to participants or others, or (2) constitute serious or continuing noncompliance with IRB determinations or federal regulations. In such cases, the IRB Chair shall notify the VPR (or designated IO) and suspend the study procedures pending a timely investigation and review.

Investigations by the IRB focus on the protection of human participants only. Allegations of other types of research non-compliance (e.g., research misconduct) should be referred by the IRB Chair to the VPR for further action. Inquiries or investigations into research misconduct do not preclude IRB review. Depending on the nature of the incident, an ad hoc committee may be established by the VPR. Investigations into research misconduct will follow University guidelines.
Listed below are the recommended procedures for resolving alleged noncompliance:

a) When potential problems are discovered, the IRB Chair asks the IRB Coordinator to compile pertinent background and regulatory information.

b) The IRB Chair determines whether to pursue the matter with the investigator via telephone, e-mail, memo, or in person. The purpose of such contact is fact-finding, i.e., to determine whether the problem is intentional, unintentional, and/or the result of mistake or oversight.

c) Care should be taken to insure that confidentiality is maintained when leaving messages for the investigator via voice mail or with departmental staff.

d) The IRB Chair documents in writing the outcome of all communications and discussions, by either e-mail or memo with a copy to the IRB files. Such documentation should be factual, objective, and include timelines for resolution (e.g., meeting dates, response deadlines).

e) When an initial inquiry does not result in resolution of the matter, a meeting with the investigator should be scheduled as soon as possible.

f) All discussions and efforts to resolve the issue are documented in the IRB files, and presented to the IRB by the IRB Chair.

g) When a review of relevant documents and meetings as described above do not lead to resolution, the IRB Chair schedules a review by the full IRB at the next available meeting.

h) At this meeting, the IRB shall determine an appropriate course of action.

i) The IRB has the authority to suspend or terminate approved IRB protocols found to be in conflict with institutional policies, state laws, and/or federal laws or regulations. Other sanctions also may be imposed by the IRB and could include, but are not limited to, routine compliance audits, recommendation to the UT Arlington Provost/President regarding letters of reprimand, restrictions on serving as an investigator on future IRB protocols, requirements for further training, etc.

j) The IRB should correspond with investigators in writing regarding the actions/recommendations take, with copies to the departmental executive officer and VPR (or designated IO). To the extent that any action includes suspension or termination, in cases of externally funded programs, federal regulatory agencies must be notified promptly.

E. Reporting to Federal Oversight Agencies

- The VPR (or designated IO) notifies the Office for Human Research Protections (OHRP) of any changes to the Federalwide Assurance Statement and IRB Registration.

The IRB Chair notifies the VPR (or IO) of all instances of noncompliance in human participants research. The VPR is responsible for notifying OHRP in accordance with the terms of UT Arlington’s Federalwide Assurance (FWA) and/or the Food and Drug Administration (FDA) (for projects subject to 21 CFR Parts 50 and 56). This should be done promptly and should inform the federal agency(ies) of: a) serious or continuing noncompliance; b) unanticipated problems involving risks to participants or others; or c) suspension/termination of IRB approval for a research protocol. Notifications of suspensions or terminations of approval shall include a statement of the reasons for the IRB's action.

In cases of corporate-sponsored research, UT Arlington coordinates its notification to OHRP with the sponsor.
IX. Operations of the IRB

A. Scheduling of Meetings - The IRB normally meets once per month. Individual meetings may be cancelled by the IRB Chair due to a) insufficient applications requiring full board review, b) University holiday, c) inability to secure a quorum for attendance, or d) other reasons as may arise that make a scheduled meeting unnecessary or otherwise inappropriate. Following a cancelled meeting, the IRB Chair will work with the IRB Coordinator to schedule an alternate meeting date as soon as possible.

B. Submission of New Applications - IRB applications should be submitted to the IRB Coordinator for IRB review. The IRB Coordinator is part of the UT Arlington Office of Research Administration which is located in room 204 ATI building. The IRB Coordinator can be reached by phone (817-272-2105) or email (irb@uta.edu).

C. Determination of Type of Review - The IRB Chair reviews the entire application and makes determinations as to whether the project constitutes human participants research and, if so, the appropriate type of review (full board review, expedited review, or exempt). All applications are assigned to full board review unless (1) they meet the criteria for exempt (Section IX Part C, i) or expedited (Section IX Part C, iii).

i. Exempt Review - Federal regulations recognize certain types of research involving human participants as being exempt from IRB oversight. UT Arlington requires that all “research” involving humans be submitted to the IRB for review. Upon review of initial applications, the IRB can determine whether the proposed research meets the qualifications for exempt. If so, there is no requirement for continuing review unless explicitly stated by the IRB with a written justification.

Exemptions are limited to research involving no more than minimal risk and the only involvement of human participants falls into one or more of the following categories.

1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special educational instructional strategies, or 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 (a) information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and (b) any disclosure of the human participants’ responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants’ 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 not otherwise exempt under the above two categories if the human participants are elected or appointed public officials or candidates for public office; or 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 if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

5) Research and demonstration projects which are designed to study, evaluate, or otherwise examine public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payments for benefits or services under those programs.

The IRB, at its discretion, retains the right to require continuing review when warranted by the nature of the research and/or inclusion of vulnerable subject populations.

ii. Expedited Review - The expedited review process may be used by the IRB to review applications that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories specified in either 45 CFR 46.110 (OHRP) or 21 CFR 56.110 (FDA).

The investigator may request expedited review of a project when submitting an application by so noting in the IRB Form. However, the IRB Chair has the ultimate responsibility for determining whether it is appropriate to review the application through the expedited process or refer it to the full board.

Approved studies are subject to at least annual review and this information is communicated to the investigator in the approval letter.

Protocols that are reviewed and approved through the expedited process or determined to be exempt are reported to all IRB members on a monthly basis.

The expedited review process may be used for projects involving a) no more than minimal risk, and b) only those procedures listed in one or more of the following categories:

1) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a non disfiguring manner; (b) deciduous teeth at the time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and 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; (i) mucosal and
skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

2) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

3) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non research purposes.

4) Collection of data from voice, video, digital, or image recordings made for research purposes.

5) 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.

6) Continuing review of research previously approved by the convened IRB (a) where the research is permanently closed to the enrollment of new participants, and all participants have completed all research-related interventions, and the research remains active only for long-term follow-up of participants; or (b) where no participants have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

7) Continuing review of research, not conducted under an investigational new drug application or an investigational device exemption where categories “b” through “f” 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.

The expedited review procedure is not used where identification of the participants and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections are implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Even when the above criteria are met, the IRB Chair or another member of the IRB retains the right to require full board review when warranted by the nature of the research.

**iii. Full Board Review Process** - The IRB Chair or a designee of the Chair serves as the primary reviewer for a full board meeting. In selecting the primary reviewer, consideration is given to the individual’s knowledge of the subject area embodied in the proposal.

The primary reviewer reviews the application, Informed Consent Document(s), and all supplemental materials (including, if applicable, the grant application, protocol, and investigator’s brochure). In addition, for continuing review applications, the primary reviewer reviews the complete project file, which includes all modifications and reports of unanticipated problems involving risks to participants.
The primary reviewer may contact the investigator in advance of or during the board meeting for additional information or clarification. The primary reviewer leads the discussion of the new project or continuing review application. The primary reviewer may not have a conflict of interest regarding the project under review and is expected to notify the IRB Chair of any conflict.

Primary reviewers are provided a worksheet to ensure that all criteria for approval of research have been fulfilled.

D. **Consultants** - At the time of preliminary review of a new project application or modification, the IRB Chair may determine that the study requires further review by a consultant with expertise outside of the current IRB membership. This determination may be made based on the scientific design of the study, the ethical issues of the study, the potential risks or benefits of the study, specific privacy and confidentiality concerns, or considerations relative to a particular study population.

Upon identifying the need for a consultant review, the IRB Chair will identify a consultant based on the particular issues to be addressed. For issues requiring only simple clarification, a written set of questions will be developed for submission to the consultant. The consultant’s written response to these questions will be provided to the full IRB for review at the time of the convened meeting. For issues requiring more than simple clarification, the consultant may also be invited to attend the full board meeting during the review of that particular study. The consultant will leave prior to the final vote by the IRB. Documentation of the discussion with the consultant will be included in the meeting minutes.

No person with a conflict of interest as defined in Section XV of this SOP will serve as a consultant for the purposes described in this section.

E. **Notification of Meetings and Distribution of Materials** - Agenda and application materials will be distributed to IRB members with sufficient time in advance of the meeting date to allow time for review, generally one to two weeks in advance. The agenda indicates the date, time, and place of the meeting. For new projects and continuing reviews by the full board, IRB members receive the application form, Informed Consent and/or Assent Document(s), recruitment materials, other correspondence with participants (if applicable), and other materials as determined by the IRB Chair.

F. **Urgent Review of Applications** - Urgent review procedures may be invoked only under unusual circumstances. This does not include urgency that is a result of negligence or delay on the part of the investigator or his/her staff to submit IRB applications in a timely fashion.

On occasion, however, an investigator is faced with an immediate deadline beyond his or her control. If the IRB Chair permits urgent review of a protocol, the materials are distributed as soon as possible to IRB members for review prior to the meeting.
G. Meeting Procedures - IRB meetings are called to order when a quorum of members is in attendance. The meeting is ended by adjournment or suspended whenever a quorum is no longer present for deliberations. A quorum is defined as one half of the voting members of the IRB + 1 member. Alternates can substitute for regular IRB members. When this occurs, the alternate member counts toward the quorum.

At the discretion of the IRB Chair and/or primary reviewer, investigator(s) may be invited to attend the IRB meeting to answer questions, clarification of specific points, or discussion. Invited investigator(s) are required to leave the meeting for subsequent discussion and voting on their protocol.

Voting is by a show of hands. The official meeting minutes document, the number of votes for, against, or abstaining. A simple majority vote of the members present at the meeting is required for approval.

Investigators are notified in writing of the decision of the IRB and suggested modifications that might be required for approval.

H. Meeting Minutes - Minutes are generated immediately following each IRB meeting and must contain the following elements:

i. the names of members in attendance at each meeting;
ii. a record of the vote on actions taken including the number, for, against and abstaining;
iii. the basis for requiring modifications or disapproving of research;
iv. the length of time of an approval (if less than 1 year);
v. a brief summary of the discussion of issues and their resolution;
vi. specific comments relevant to inclusion of certain populations;
vii. in addition to the review of pending applications, meeting minutes may sometimes include information regarding expedited approvals, modifications, terminations, emergency/single patient use, adverse experiences, and any other business appropriate for board meetings.

Revisions to new and continuing human participants applications may be required. Correspondence is sent to the investigator detailing requests for modifications, clarification, or additional information. The investigator has 60 days to respond to the modifications requested. If the investigator does not respond in 60 days, the application is deactivated. If the investigator wishes to conduct a study that has been deactivated, he/she must submit a new application, incorporating comments from the prior IRB review.

When specific modifications are requested, the revisions are reviewed by the primary reviewer and/or the IRB Chair depending on the nature of the revisions. Final approval will not be granted until all of the revisions have been submitted. In instances where a project is tabled at a full board review, the revised documents are returned to the full board for its review and approval. In instances where a project is contingently approved at a full board review, the revised documents are reviewed by an IRB member and/or Chair depending on the nature of the revisions. In either case, the application only receives final approval once all required
changes have been submitted.

Upon receipt of final approval, the IRB Coordinator transmits the IRB approval notification to the investigator that indicates the date of approval, date of expiration, and a summary of investigator responsibilities. If the investigator is a student, copies are sent directly to the Faculty Advisor. The memo reminds investigators that changes in research activity may not be initiated without prior IRB review and approval.

I. **Appeal of IRB Decisions** - Investigators may appeal the IRB requirement for specific changes in the protocol and/or consent document(s). At the discretion of the IRB Chair, the investigator may make such an appeal in person and/or in writing to the IRB.

If the IRB decides to disapprove an application for research involving human participants, the investigator(s) shall be notified in writing of the decision of the IRB along with a detailed statement summarizing the IRB concerns that led to the decision. The investigator(s) must be afforded an opportunity to respond to the decision in person and/or in writing. An appeal of a disapproved research project must be reviewed at a full board meeting.

A decision by the IRB to disapprove, suspend, or terminate a project is not subject to reversal by the VPR or any other officer/agency of UT Arlington, state, or federal government.

J. **Length of Approval** - Except for exempt studies, all research involving human participants is subject to continuing review based on the level of risk as assessed by the board. This review takes place no less than annually, and may require more frequent review or reports as determined by the IRB. For projects receiving full board review, the length of approval is calculated from the date of the full board review.

For projects approved via the expedited process, the IRB Chair determines the length of approval.

Projects requiring review more frequently than annually may include:

i. experimental therapies in which the clear potential for significant adverse experiences have been identified at the time of review;
ii. non-therapeutic projects based on risk information provided at the time of initial review;
iii. projects in which new information provided during the duration of the study (including at the time of continuing review) indicates a high probability of significant adverse experiences not previously reported; or
iv. projects in which local or outside adverse experience reports create new concerns regarding the need for closer project scrutiny (in such cases, approvals may be granted for time periods less than one year or, as may be more appropriate, for a limited number of participants over a period not to exceed one year).

Investigators shall be notified via regular campus mail and email when their projects are due for continuing review.
X. Monitoring Approved Projects

A. Continuing Review - When a research project is due for continuing review, a courtesy reminder is generated by the IRB Coordinator and sent to the investigator via email at 60 days from the protocol expiration date and again 30 days before the date of continuing review. Lists of investigators receiving these emails are maintained by the IRB Coordinator. **It is the responsibility of each investigator to insure that his/her project is renewed by the IRB prior to the expiration date.**

Applications intended for IRB continuing review are submitted to the Office of Research Administration (ATI 204) for processing. Investigators can access and download the necessary IRB application(s) from the IRB website (http://www.uta.edu/ra/oric/formsdepot.htm). Research approved previously by expedited review is considered eligible for expedited review at the time of its regular continuing review, if, during the course of the study, the risks of the study have not increased. Projects that were initially reviewed by the full board continue to receive full board review unless the IRB Chair determines that the study meets the specific criteria for expedited.

Investigators are notified in writing of the decision of the IRB and any changes required. Final approval is not granted until all required changes have been made and submitted for review and approval. Upon final IRB approval, the IRB Coordinator transmits the approval notification, approved Informed Consent Document(s), and re-approval memorandum that details the date of approval, date of expiration, and a summary of investigator responsibilities. The memo reminds investigators that changes in research activity may not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to participants.

B. Modifications - Investigators must report planned changes in the conduct of a study and receive approval from the IRB prior to implementing these changes. The approval documentation sent to investigators of exempt, expedited, and full board studies notifies them of the need for submitting any changes in their research projects to the IRB for review and approval. Modifications include, but are not limited to, procedural changes to a protocol, adding or removing investigators, requesting additional participants beyond the approved number, change in funding, and changes in Informed Consent Document(s). When an investigator wishes to modify a protocol, he or she must submit these modifications on IRB Form #4 along with all supporting documentation. Minor modifications may be expedited.

Investigators may request that a modification be considered as both a modification and a submission for continuing review. In requesting this action, submission materials must include all items required at time of continuing review as well as the details of the requested modification. Such applications are processed through the Continuing Review system. In these cases, the IRB may consider this as appropriate and “reset” the clock for continuing review.

Investigators are notified in writing of the decision of the IRB and any changes required. Final approval is not granted until all required changes have been made and submitted for review and approval. Upon receipt of final approval, the IRB Coordinator stamps approved on the Informed Consent Document(s) that have been modified with the IRB approval number and the
date of approval. These documents are sent to the investigator (or Faculty Advisor) along with a copy of the IRB approval memorandum, which indicates the date of approval, date of expiration, and a summary of investigator responsibilities. If the investigator is a student, then the copies are sent directly to the Faculty Advisor. The memo reminds investigators that changes in research activity may not be initiated without IRB review.

C. **Unanticipated Problems Involving Risk to Participants (Adverse Events)** - IRB continuing review responsibilities include reviewing reports of any unanticipated problems that involve risk to research participants or others. Serious and Unexpected Adverse Events Forms must be reported to the IRB within five (5) business days. Non-Serious and/or Expected Adverse Event Forms must be submitted to the IRB within ten (10) business days. All adverse event reports are reviewed by the IRB Chair and/or Full IRB Committee.

The IRB Chair reviews “serious adverse event” and “unexpected adverse event” reports that meet the above criteria and may at his/her discretion add the event as an agenda item of a convened full board meeting. The IRB may require that enrolled participants be informed of the AE, that the Informed Consent Document be modified, or that other changes to the protocol be made.

Serious and unexpected adverse experiences that meet the above criteria are entered into the Human Participants database and filed in the corresponding study file. The IRB Chair – through the IRB Coordinator - will notify investigators regarding their Serious and/or Unexpected Adverse Event Reports if there are concerns, issues requiring clarification, and/or protocol related changes needed as a result of the reported event. Investigators may request a confirmation of receipt from the IRB Coordinator for their Adverse Event Report submissions.

An adverse event with any human participant enrolled by an investigator that is serious or unexpected, and may be related to the study intervention will be reviewed at a convened IRB meeting in a timely manner.

The IRB notifies investigators of their reporting requirements to OHRP/FDA/funding sponsor of adverse experiences that are serious and unexpected and probably or definitely related to the study intervention. Investigators may have additional reporting responsibilities outlined in individual contracts that are not covered by this procedure.

If the IRB suspends or terminates a study due to reported adverse experiences, the University notifies federal regulatory agencies in accordance with Section VIII Part E.

D. **Other Monitoring Activities** - IRB members may conduct monitoring visits. The reason(s) for on-site review may include, for example, (1) random selection, (2) complex projects involving unusual levels or types of risks to participants, (3) projects conducted by an investigator who previously failed to comply with IRB determinations, or (4) projects where continuing review or reports from other sources have indicated that changes without IRB approval may have occurred.
An on-site review may include (1) requests for progress reports from investigators, (2) examinations of research records, including signed Informed Consent Documents, protocol amendments, and serious and/or unexpected adverse experience reports, (3) contacts with research participants, or (4) observation of the consent process. Examples of when observation of the consent process could occur are: (1) the full board IRB determines during review of a project that a conflict of interest exists such that the informed consent process should be observed by a neutral party; (2) the IRB is made aware of a complaint or concern with regard to the informed consent process; or (3) the IRB determines as a result of the monitoring process that the consent process is insufficient and education/training is required for conduct of consent.

A written record of monitoring activities is maintained in the study file and in the Office of Research Administration.

Any of the following may occur as a result of a monitoring report:
(1) If the IRB Chair determines that the issues identified do not reflect serious or ongoing noncompliance and they do not involve risk to participants, the IRB Chair may approve the report that is then sent to the investigator (or Faculty Advisor) for response and resolution of any outstanding issues.

(2) If the IRB Chair cannot make a clear determination with regard to the findings, or if the findings clearly reflect either serious or ongoing noncompliance, or risk to participants, the VPR (or designated IO) is notified and the findings are referred to full board for review.

(3) The IRB Chair may temporarily halt enrollment and/or data collection until full board review occurs (with consideration of effect in therapeutic trials).

(4) The IRB Chair may immediately refer the findings to the full board IRB.

Note: The auditor should communicate with the IRB Chair on the findings, but the IRB Chair should not be the person actually conducting the audit.

E. Study Closure
(1) The IRB provides, upon request or through their website, a form by which an investigator can notify the IRB that he/she has completed an approved IRB study.
(2) If the investigator has not received continuing review prior to the expiration date, the IRB Coordinator sends a memo to the investigator, explaining that IRB approval has lapsed and cannot be renewed, since it has been permanently closed. This memo includes a notice that no human participants research activities may be conducted until IRB approval is re-obtained by submitting a new application submission. This memo also clarifies that the new submission will be treated as a brand new project based on the remaining activities in the project. That new submission will receive a new IRB approval number after it has been reviewed and approved by the IRB. The IRB does not approve continuing review applications that are received beyond the one-year expiration date.

XI. Notification of IRB Activities - Members and alternates of the IRB receive minutes of full board meetings and reports of IRB business. Reports include written notification of all new projects approved (full board and expedited), projects determined to be exempt, and continuing reviews (full board and expedited).

XII. Informed Consent Document - Signed informed consent is required on all human participant’s research that is not exempt from IRB review (Section IX Part C) except as provided in this section.

A. Content of the Informed Consent Document (This section needs to be rewritten to reflect a focus on the Informed Consent Process and a revised Informed Consent form.)

B. Waiver of Consent or Elements of Consent - The IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided the IRB finds and documents that:

1) the research or demonstration project is to be conducted by, 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 could not practicably be carried out without the waiver or alteration.

The IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

1) the research involves no more than minimal risk to the participants;
2) the waiver or alteration will not adversely affect the rights and welfare of the participants;
3) the research could not practicably be carried out without the waiver or alteration; and
4) whenever appropriate, the participants will be provided with additional pertinent information after participation.
C. Waiver of Documentation of Consent - The IRB may waive the requirement for the investigator to obtain signed consent forms for some or all participants, if it finds either:

1) the only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
2) the research presents no more than minimal risk of harm to participants, and involves no procedures for which written consent is normally required outside of the research context.

In cases, in which the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research that includes the following:

1) The research could not practicably be carried out without the waiver.

2) The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, to asking the legally authorized representative for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review.

3) The IRB has reviewed and approved informed consent procedures and an informed consent document. These procedures and the informed consent document are to be used with participants or their legally authorized representatives in situations where use of such procedures and documents is feasible.

4) Additional protections of the rights and welfare of the participants will be provided, including consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the research will be conducted and from which the participants will be drawn, public disclosure to the communities in which the research will be conducted and from which the participants will be drawn, prior to initiation of the research, of plans for the investigation and its risks and expected benefits, public disclosure of sufficient information following completion of the research to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results, establishment of an independent data monitoring committee to exercise oversight of the research, and if obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a legally authorized representative, and asking whether he or she objects to the subject's participation in the research. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.
In addition, the IRB is responsible for ensuring that procedures are in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the research, the details of the research and other information contained in the Informed Consent Document. The IRB shall also ensure that there is a procedure to inform the subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. If a legally authorized representative or family member is told about the research and the subject's condition improves, the subject is also to be informed as soon as feasible. If a subject is entered into research with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the research is to be provided to the subject's legally authorized representative or family member, if feasible.

XIII. Record Retention Policy - The UT Arlington Office of Research Administration maintains file copies of all research proposals reviewed, scientific evaluations, if any, approved sample Informed Consent Documents, progress reports, adverse experience reports, meeting minutes showing attendance, action taken, vote with number of members voting for against, abstaining, the basis for requiring changes in or disapproving research, a written summary of the discussion of controverted issues and their resolution, and other correspondence pertaining to IRB operations.

Paper records on human participants’ research are maintained by the ORS for at least three (3) years after study termination.

XIV. Education and Training - The IRB and ORS provide services to inform the research community on issues related to use of human participants in research and ethics in research, and to make researchers aware of applicable Federal regulations.

A. Educational Activities Aimed at the Research Community at Large - UT Arlington ORS maintains an internet website that contains detailed information on the human participants review process as well as links to federal regulations and regulatory agencies, the OHRP Institutional Review Board (IRB) Guidebook, and other guidance documents.

ORS also maintains a small library of materials that includes the OHRP Institutional Review Board (IRB) Guidebook, federal regulations, and other books and videotapes discussing ethical and regulatory issues relating to human participants research.

Application materials are provided with appropriate guidance (e.g., templates) as a means of educating investigators regarding the proper process for conducting research with human participants.

ORS schedules and advertises numerous educational workshops throughout the calendar year directed at investigators and their research associates. These workshops cover topics that include UT Arlington policies and procedures as well as federal regulatory requirements.
Members of the IRB or ORS staff may present information at meetings in academic departments or give scheduled lectures to emphasize selected aspects of human subject research, and to keep various constituencies abreast of activities of the IRB.

B. Educational Activities Aimed at Members of the IRB - At the time of induction of a new member, the IRB Chair and/or a professional staff member from ORS provides the individual with the procedures of the IRB and the general regulatory framework from which procedures and policies are derived.

UT Arlington provides the opportunities for IRB members to participate in continuing education/training, and to attend conferences/workshops on human participant issues in research. Upon return, these individuals will be expected to provide relevant information to all board members and, as appropriate, the rest of the University community.

XV. Definitions

Conflict of Interest – an IRB member may not vote on a project, and is not counted towards a quorum, when s/he serves as a co-investigator or other member of the research team or when s/he or an immediate family member has a conflict of interest with a project being reviewed. Conflicts are, defined as:

i. Receiving payments in excess of $10,000 including salary, consulting fees, royalty or licensing payments from intellectual property, honoraria and/or gifts from the study sponsor over the past 12 months or anticipated for the next 12 months (excluding salary and other payments for services from UT ARLINGTON); or

ii. Having equity interest worth more than $10,000 or more than 5% of the business entity as determined by reference to publicly listed prices (excluding mutual funds); or

iii. Having any equity interest if the value cannot be determined by reference to publicly listed prices (e.g., start-up companies); or

iv. Holding a position as director, officer, partner, trustee, employee, or any other position of management; or

v. Holding patent rights or royalties from such rights whose value may be affected by the outcome of the research, including royalties under any royalty-sharing agreements involving UT Arlington.

Human Participant – a living individual about whom an investigator (whether professional or student) conducting research obtains a) data through intervention or interaction with the individual, or b) identifiable private information.

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.

Minor Modifications – modifications to a research project and/or consent documents that pose no additional risk to participants; or modifications that maintain similar or increased safeguards to protect the subject.
**Principal Investigator** – the principal investigator (PI) is the person who directs a research project or program. The principal investigator usually writes and submits the grant application, oversees the scientific/technical aspects of the grant, and has responsibility for the management of the research.

**Quorum** – a majority of voting members of an IRB usually interpreted to mean half of the, including at least one member whose primary expertise is in a nonscientific area.

**Research** - a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research even if they are a component of a larger non-research activity (e.g., instruction, demonstration).

**Risk** – the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude may vary from minimal to significant.

**Serious Adverse Experience (SAE)** – Any adverse experience associated with the use of the drug/device that results in any of the following outcomes: death, a life-threatening adverse experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed above.

**Unexpected Adverse Experience (UAE)** – Any adverse experience associated with the use of the drug/device, the specificity or severity of which is not consistent with the current investigator brochure; or, if an investigator brochure is not required or available, the specificity or severity of that is not consistent with the risk information provided to participants and the IRB.