



Institutional Review Board

Standard Operating Procedures

Florida International University
Institutional Review Board
Standard Operating Procedures

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I. Institutional Authority

Florida International University (FIU) operates a centralized program to review all human subjects research. The Office of the Vice President for Research at FIU has established an IRB. The IRB reviews projects in a wide range of medical, social and behavioral fields. The IRB is required to meet at least once each year, although more frequent meetings are scheduled.

II. Purpose

The purpose of the FIU IRB is to assure that the rights and welfare of the human subjects are adequately protected in research. To achieve this, the FIU IRB advises investigators in designing research projects in a manner to minimize potential harm to human subjects, review all planned research involving human subjects prior to initiation of the research, approves research that meets established criteria for protection of human subjects, and monitors approved research to ascertain that human subjects are indeed protected.

The FIU IRB also informs and assists FIU and its researchers on ethical and procedural issues related to the use of human subjects in research in order to facilitate compliance with relevant regulations of the United States Government, and provide a framework suitable for continued support by Government agencies, private foundations and the industry for research involving human subjects at FIU.

Primary responsibility for assuring that the rights and welfare of the individuals involved are protected continues to rest with the Principal Investigator (PI) conducting the research. Others engaged in the conduct of 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 subjects. Students are not permitted to serve as the PI on research projects involving human subjects.

III. Principles

All human subjects research (see Section XIX) conducted at FIU is guided by the ethical principles as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled “Ethical Principles and Guidelines for the Protection of Human Subject of Research (Belmont Report)”.

IV. The Authority of the IRB

A. Scope

All human subjects 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. The IRB is guided by the principles of the

Belmont Report and the Common Rule in reviewing all human subjects protocols. The FIU IRB is charged with the protection of human subjects in all research.

FIU IRB reviews projects when:

- 1) the research is sponsored by the institution,
- 2) the research is conducted by or under the direction of any employee, student, or agent of FIU in connection with his or her institutional responsibilities,
- 3) the research is conducted by or under the direction of any employee, student, or agent of FIU using any property or facility of this institution,
- 4) the non-exempt research involves non-FIU investigators using faculty, staff, or students as research subjects for on FIU property.

B. Authority

The authority conveyed to the IRB includes the following:

- a) review all research projects involving human subjects before the involvement of human subjects may begin;
- b) require from investigators revisions in research protocols and Informed Consent documents as a condition for initial or continuation approval;
- c) approve new research projects and the continuation of previously approved projects;
- d) disapprove the initiation of new research projects;
- e) monitor the activities in approved projects including regularly scheduled continuing review at least every twelve months, and verification of compliance with approved research protocols and informed consent procedures;
- f) develop mechanisms for prompt reporting to the IRB of any planned changes in approved projects prior to the implementation of those changes;
- g) develop mechanisms for prompt reporting to the IRB of any adverse experiences occurring in approved projects, or in other projects related in context to the approved projects;
- h) suspend or terminate a previously approved project;
- i) restrict aspects of a research study for the purpose of subject protection;
- j) review and monitor the use of test articles (investigational drugs, biologicals and devices) for the purpose of treatment of serious or life-threatening illnesses.
- k) be available to research subjects' questions or concerns.

C. Exempt Human Subjects Research

Federal regulations recognize certain types of human subjects research as being exempt from IRB oversight. FIU policy requires that all human subjects research be submitted to the Office of Research Integrity (ORI) for review. Upon the ORI's review of the Exempt application, the IRB Coordinator would determine whether the research is exempt. If so, there will be no requirement for continuing review unless explicitly stated by the IRB Coordinator with a written justification.

The PI may request the specific exemption category when submitting the IRB Exemption application. The IRB Coordinator takes this under consideration, but has the ultimate responsibility for making the decision whether the project meets the exempt criteria (see below).

Exemptions are limited to research involving no more than minimal risk to human subjects and the only involvement of human subjects is in one or more of the following categories:

- 1) Research, conducted in established or commonly accepted educational settings (i.e., a school), that specifically involves normal educational practices that are not likely to adversely impact student's opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- 2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
 - i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation; or
 - iii. The information obtained is recorded by the investigator in such a manner that the identify of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 46.111(a)(7).
- 3) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
 - i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
 - iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having

them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

- 4) Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:
 - i. The identifiable private information or identifiable biospecimens are publicly available;
 - ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
 - iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
 - iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

- 5) Research and demonstration projects that are conducted or supported by a Federal department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs; c) possible changes in or alternatives to those programs or procedures; or d) possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that

the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

- 6) Taste and food quality evaluation and consumer acceptance studies: a) if wholesome foods without additives are consumed or b) if a food is consumed that contains a food ingredient at or below the level and or a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the Food Safety and Inspection Service of the U.S. Department of Agriculture.
- 7) Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).
- 8) Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
 - i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);
 - ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;
 - iii. An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and
 - iv. The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

D. Authority of Institutional Officials

The Vice President for Research (or designated Institutional Official) has the authority to review decisions of the IRB. In the case of an approval decision, should the Vice President for Research conclude that a project does not fully comply with policies or obligations of FIU, the project may be disapproved, suspended, or terminated on behalf of the institution. In the case of a decision by the IRB to disapprove, suspend, or terminate a project, the decision may not be reversed by the Vice President for Research or any other officer/agent of FIU, state government, or federal government.

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

A. Compliance with Federal Regulations

FIU (represented by the Office of the Vice President for Research) 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 subjects funded by federal agencies subscribing to the Common Rule.

In studies involving products regulated by the Food and Drug Administration regulations, FIU IRB complies with the requirements set forth in 21 CFR 50, 21 CFR 56, 21 CFR 312, and 21 CFR 812.

B. Relationship with Western Institutional Review Board

FIU has a written agreement with Western Institutional Review Board (WIRB) to review specific types of research protocols. The primary function of WIRB is to perform all IRB functions in compliance with applicable federal and state regulations or laws in order to protect the rights and welfare of human subjects. The primary function of Florida International University is the coordination of application materials to be submitted to WIRB for review. FIU reserves the right to withhold any protocol from WIRB review and keep it for review and oversight by the FIU IRB. The FIU IRB may rely on WIRB to provide IRB review for any clinical study that meets one or more of the following conditions:

- 1) Studies involving Drugs, Biologics, (FDA-regulated), single-site and multi-site clinical trials;
- 2) Studies involving Devices (FDA-regulated), single-site and multi-site clinical trials;
- 3) Other Industry-Initiated Research Protocols, single-site and multi-site clinical trials.

All studies not meeting the criteria above will normally be reviewed by the FIU IRB unless determined otherwise by ORI.

C. Review of Research Activities by Other University Committees

FIU IRB coordinates the review with other institutional committees as described below. None of these committees are a formal part of FIU IRB structure, but there is communication between the committees regarding status of review and/or conditions of approval if there are human subject protection issues involved.

1. Institutional Animal Care and Use Committee (IACUC)

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

The deliberations of the IACUC are normally not shared with the IRB unless there are specific subject protection issues involved. It is not a requirement to obtain IACUC approval prior to final approval by the appropriate IRB except when deemed necessary by the IRB.

2. Institutional Biosafety Committee (IBC)

The Institutional Biosafety Committee (IBC) is responsible for ensuring that activities involving Recombinant or Synthetic Nucleic Acid Molecules comply with the National Institutes of Health (NIH) guidelines. The PI is 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.

The deliberations of the IBC are not shared with the IRB unless there are specific subject protection issues raised by the IBC. It is not a default requirement to obtain IBC approval prior to final approval by the appropriate IRB except when deemed necessary by the IRB.

VI. The Membership of the IRB

A. Appointment of Members

The Vice President for Research (or designated Institutional Official) appoints all IRB members and alternates. The length of appointment is at the discretion of the Vice President for Research.

B. Regular Members

The IRB membership is composed of at least five members. The IRB includes at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. IRB members are selected with varying backgrounds of expertise, experience, and diversity to promote complete and adequate review of research activities commonly conducted by the institution.

The IRB also includes at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

C. Responsibilities

Responsibilities of members include determining the type of review (exempt, expedited, full board) for human subject application materials, reviewing protocols to be discussed at IRB meetings, being prepared to discuss issues related to human subjects protections at IRB meetings, serving as primary reviewer at IRB meetings when requested by the IRB Chair, and having an understanding of the specific requirements of human subjects regulations.

IRB members serve at the discretion of the Vice President for Research. Members who do not adequately fulfill their responsibilities as judged by the IRB Chair may be asked to step down from IRB membership by the Vice President for Research.

D. Compensation of IRB Members

IRB members do not receive monetary compensation above their University salary for participation on the board. The IRB Chair may receive compensation from the Office of the Vice President for Research for his/her time commitment.

Community members are provided temporary parking passes, so they do not have to pay the cost of parking during meetings.

E. Member Liability

IRB members function as employees and agents of FIU. As such, when acting in accordance with the FIU IRB Standard Operating Procedures, and within the course and scope of their obligations as IRB members, their actions are covered by FIU general liability coverage.

F. Alternate Members

Alternates, if appointed, are designated for a specific member. If both the alternate and the member attend a meeting, only one of these two may vote. In these cases, the minutes reflect the primary member as the voting member.

G. Non-Voting Members

The Vice President for Research may, at his/her discretion, recruit non-voting (*ex officio*) members from among the academic or administrative staff of FIU, 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 XIX) at the meetings. IRB meeting minutes reflect the presence of non-voting members.

H. Consultants/Ad hoc Reviewers

At its discretion, the IRB may invite scientists or non-scientists from within or outside FIU, who have special expertise, to function as consultants and ad hoc reviewers of a project 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. Conflict of Interest

No IRB member may participate in the IRB initial or continuing review of any project in which the member has a conflict of interest (see Section XIX), 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 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 be absent from 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. The absent member is not counted towards a quorum when the vote on the study in question is taken. Minutes reflect whether or not these requirements have been met.

VII. Management of the IRB Process

A. IRB Chair

The IRB has a chair and, at the discretion of the Vice President for Research (or designated Institutional Official), a co-chair. This individual is a respected, active member of the University community who is well-informed in regulations relevant to the use of human subjects in research. The Vice President for Research appoints the IRB Chair and Co-Chair. The term of service is at the discretion of the Vice President for Research. Whenever the IRB Chair or Co-Chair is not available to conduct IRB business, the IRB Chair or Co-Chair may designate a board member to assume his/her responsibilities during the period of his/her absence.

Responsibilities of the IRB Chair include: making the final determination of the type of review (exempt, expedited, full board), assigning primary reviewers for full board review, running full board meetings, reviewing specific revisions to protocols/consent documents that are required as conditions of approval, signing the application form certifying project approval, and reviewing serious adverse experience reports. In addition, he or she serve as a resource for investigators and IRB members regarding issues related to University and federal policies.

B. Administrative Support - The Office of Research Integrity (ORI)

The Office of Research Integrity, a unit within the Office of Research and Economic Development, has been established to support the IRB process. The Office of Research Integrity:

- 1) assists the IRB in preparing for and monitoring IRB meetings;
- 2) maintains files on all human subjects research (including copies of all correspondence between the IRB and investigators) that takes place at FIU;
- 3) maintains databases for tracking studies;
- 4) assists with preparation of meeting minutes;
- 5) maintains files of minutes of full board and subcommittee meetings;
- 6) screens research applications for completeness;
- 7) acts as a resource for investigators on general regulatory information, guidance with forms, and assistance in preparing an application for IRB review;
- 8) maintains the institution's Federalwide Assurance and the IRB membership rosters;
- 9) provides staff support to the IRB for all written correspondence;
- 10) sends notices of modifications, approvals, study closures, and terminations;
- 11) generates and sends reminder notices to investigators of upcoming continuing reviews;
- 12) maintains information on federal regulations relating to human subjects research;
- 13) provides education regarding the IRB process and regulations to the University community;
- 14) maintains records of IRB membership including training.

C. Resources

The University provides adequate facilities and equipment to support the operation of the IRB and ORI in performing the functions described in this document.

VIII. FIU IRB Organization

A. Health Sciences IRB (HS-IRB)

The HS-IRB reviews all medical and health research protocols involving human subjects, which do not meet the criteria for review by WIRB (see V.B). HS-IRB members come from diverse backgrounds and have a broad range of both scientific and non-scientific expertise.

B. Social and Behavioral IRB (SB-IRB)

The SB-IRB reviews all non-medical research protocols including, but not limited to social, behavioral, humanities, education, anthropology, journalism, history, and environmental studies. The SB-IRB does not review protocols that are regulated by the FDA. SB-IRB members come from diverse backgrounds and have a broad range of both scientific and non-scientific expertise.

C. Referral between IRBs

The FIU IRB Chair and/or the ORI may refer the review of a research project to the other IRB if it is determined that: a) there is a conflict of interest among the investigator(s) and board member(s), or b) more appropriate expertise lies in the other board.

IX. Functions of the IRB

A. Scope of Review

After initial review of applications by the ORI and/or IRB Member for completeness (Section X Part B), IRB review of applications is conducted to:

- 1) determine that the use of human subjects has research relevance and consider ethical issues with regard to the study's design and conduct;
- 2) identify the risks associated with the research, as distinguished from the risks of therapies the subjects would receive even if not participating in research;
- 3) identify level of risk;
- 4) determine that the risks are minimized to the extent possible;
- 5) identify the probable benefits to be derived from the research;
- 6) determine that the risks are reasonable in relation to be benefits to subjects, if any, and the importance of the knowledge to be gained;
- 7) assure that potential subjects are provided with an accurate and fair description of the risks or discomforts and the anticipated benefits;
- 8) determine intervals of periodic review;
- 9) where appropriate, determine that adequate provisions are in place for monitoring the data collected;
- 10) determine the adequacy of the provisions to protect the privacy of subjects and to maintain the confidentiality of the data;

- 11) where the subjects 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 subjects.

B. Special Consideration for Projects Involving Vulnerable Populations

The IRB considers certain groups of human subjects to be particularly vulnerable in a research setting. The IRB 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 children if one of the following conditions is met: a) the research does not involve more than minimal risk to the subject; b) the research is likely to benefit the subject directly, even if the risks are considered to be more than minimal; or c) the research involves greater than minimal risk with no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition.

Requests for approval of any Health and Human Services (HHS) sponsored research that exposes children to risks that do not meet one of the above criteria must be submitted to the Secretary (through OHRP) for review and approval.

Requests for approval of any HHS sponsored research that involves prisoners must receive certification from the Secretary (through OHRP) that the research complies with 45 CFR 46.305(c) and 46.306(a)(1).

An IRB must have present at its meeting a designated prisoner advocate in order to review projects involving the use of prisoners in research. 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 human subjects research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval includes a statement of the reasons for the IRB's action and is reported promptly to the investigator. Federal regulatory agencies are notified in accordance with Section VIII Part E.

D. Noncompliance Investigations and Actions

Information regarding noncompliance in human subjects studies may come to the attention of the IRB through several pathways. These include information contained in new applications, continuing reviews, adverse experience reports, reports from collaborators, employees, subjects, or others.

The IRB has a separate written Standard Operating Procedure (SOP) for the Handling of Non-Compliance with Human Subject Protection Laws, Regulations and Policies. This document is available on the FIU IRB website.

E. Reporting to Federal Oversight Agencies

The Office of Research Integrity notifies the Office for Human Research Protections (OHRP) of any changes to the Federalwide Assurance Statement and IRB Registration.

The Director of Research Integrity and/or the IRB Chair notifies the Office of the Vice President for Research and they together notify OHRP in accordance with the terms of FIU's Federal Wide Assurance (FWA) and the Food and Drug Administration (FDA) (for projects subject to 21 CFR Parts 50 and 56) in a timely manner of any: a) serious or continuing noncompliance; b) unanticipated problems involving risks to subjects or others; or c) suspension or termination of IRB approval for a project. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action.

In cases of corporate-sponsored research, FIU coordinates its notification to federal regulatory agencies with the sponsor.

X. Operations of the IRB

A. Scheduling of Meetings

The SB-IRB and HS-IRB panels have monthly meetings. The schedules can be accessed on the FIU IRB web page. 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.

B. Submission of a New Application

All applications submitted for IRB review are submitted through the online Topaz Electronic Protocol Submission System. The application goes directly to the IRB Coordinator for processing before it is assigned to an IRB member for review.

If the application is incomplete or otherwise not fully prepared for review, it is returned to the investigator or a request is made for necessary changes or to provide additional information. On occasion, the ORI or an IRB Representative may contact the investigator by email, phone, or letter requesting clarification of protocol issues or revisions in consent document(s).

Once a complete submission has been reviewed and approved by the IRB, it is assigned an IRB approval number by the ORI. This number remains with the study until it is terminated.

C. Determination of Type of Review

The IRB Member reviews the entire application and determines the appropriate type of review (expedited or full board review). All applications are assigned to full board review unless (1) they meet the criteria listed in Section X Part E or (2) they meet the criteria listed in Section IV Part C. All projects involving the use of investigational drugs, devices, or biologics for which an Investigational New Drug (IND)/Investigational Device Exemption (IDE) is required receive full board review.

D. Full Board Review Process

1. Primary Reviewer

The member that provided the preliminary review of the protocol typically serves as the primary reviewer at a full board meeting. However, there may be instances where the IRB Chair specifically assigns primary reviewers in advance of a full board meeting. The IRB Chair may, at his/her discretion, serve as the primary reviewer. 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 subjects.

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.

2. Consultants

At the time of preliminary review of a new project application or modification, the IRB Chair or IRB Member 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 and/or IRB Member in consultation with 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 XIX of this SOP will serve as a consultant for the purposes described in this section.

3. Notification of Meetings and Distribution of Materials

The agenda and application materials are distributed to IRB members sufficiently 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 both new project and continuing review full board meetings, IRB members receive electronic access to the application form, Informed Consent and/or Assent Document(s), recruitment materials, other correspondence with subjects (if applicable), and other materials as determined by the IRB Chair and/or the ORI. The meeting materials are made available to the IRB members via the Topaz Electronic Protocol Submission System.

4. 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 human subjects 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 to allow sufficient time for review prior to the meeting. In most cases, the investigator will be required to attend the meeting to answer any questions that arise during the review of the protocol.

5. Meeting Procedures

The IRB meeting is called to order when a quorum of members is in attendance. The meeting ends or is suspended whenever a quorum of members is no longer present for deliberations. A quorum consists of more than half of the primary members.

At the discretion of the IRB Chair and/or primary reviewer, the investigator(s) may be invited to attend the meeting for the purpose of additional clarification or discussion. The investigator(s) is(are) required to leave the meeting for subsequent discussion and voting.

Voting is by a show of hands. The official meeting minutes record, the number of votes to approve, disapprove, table, or abstain. A 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 any changes required.

6. Meeting Minutes

Minutes are generated that record the following information:

- a) attendance at each meeting;
- b) actions taken by the board;
- c) the vote on actions taken including the number, for, against and abstaining,
- d) the basis for requiring changes in or disapproving research;
- e) the length of time of an approval (if more frequent than 1 year);
- f) a written summary of the discussion of issues and their resolution;
- g) specific comments relevant to inclusion of certain populations;
- h) 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.

E. Expedited Review

The expedited review process may be used in accordance with federal regulations for applications that qualify for expedited review or are exempt. IRB Members are responsible for these reviews. Only those projects involving no more than minimal risk are considered for expedited review.

The PI may request expedited review of a project when submitting an application by so noting in the IRB Form. The IRB Member takes this under consideration, but has the ultimate responsibility for making the decision whether to review through the expedited process or refer to the full board.

Approved FDA-regulated studies are subject to at least annual review and this information is communicated to the PI in the approval letter. Approved studies that are not subject to FDA regulations require a tri-annual review (renewal every three years).

The IRB Member may approve projects as submitted or require modifications prior to approval. They are not empowered to disapprove projects reviewed through the expedited process; in such cases, the application must be submitted for full board review along with the comments and recommendations of the IRB Chair or his/her designee. In cases where the full board concurs with the recommendation, the investigator may appeal the decision as provided below (Section X Part G).

1. Criteria for Expedited Review

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) Research on drugs for which an investigational new drug application is not required or research on medical devices for which a) an investigational device exemption application is not required or b) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- 2) Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows: (a) from healthy, nonpregnant adults, who weigh at least 110 pounds. For these subjects, amounts

- drawn may not exceed 550 ml in an 8 weeks period and no more than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml/kg in an 8-week period and collection may not occur more frequently than 2 times per week.
- 3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring 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.
 - 4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
 - 5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
 - 6) Collection of data from voice, video, digital, or image recordings made for research purposes.
 - 7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
 - 8) Continuing review of research previously approved by the convened IRB (a) where the research is permanently closed to the enrollment of new subjects, and all subjects have completed all research-related interventions, and the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.
 - 9) Continuing review of research, not conducted under an investigational new drug application or an investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

The expedited review procedure is not used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections 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.

F. Revisions Prior to Final Approval

Revisions to new and continuing human subjects applications may be required. Correspondence is sent to the investigator detailing requests for revisions, clarification, or additional information. The investigator typically has 60 days to respond to the revisions 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 changes are requested, the revisions are reviewed by an IRB member and/or the ORI 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 the ORI 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 ORI stamps approved Informed Consent Document(s) with the IRB approval number and the date of approval. These documents are sent to the PI along with a copy of the IRB approval memorandum, which indicates 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.

G. 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 a research activity, it shall include in its written notification a statement of the reasons for its decision, and give the investigator an opportunity to respond in person and/or in writing. An appeal of a disapproved research project must be reviewed at a full board meeting.

As stated Section IV Part D, in the case of a decision by the IRB to disapprove, suspend, or terminate a project, the decision may not be reversed by the Vice President for Research or any other officer/agency of FIU, state government or federal government.

H. Length of Approval

Except for studies determined to be exempt from IRB oversight (Section IV Part C), all human subjects studies are subject to continuing review based on the level of risk as assessed by the board. This review takes place no less than annually for Full Board studies and FDA-regulated studies, and may require more frequent review or reports as determined by the IRB. For Expedited studies that do not fall under the FDA regulations, the review takes place every three years. For projects receiving full board review, the length of approval is calculated from the date of the full board review.

Projects requiring review more frequently may include:

- a) Experimental therapies in which the clear potential for significant adverse experiences have been identified at the time of review;
- b) Non-therapeutic projects based on risk information provided at the time of initial review;
- c) 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
- d) Projects in which local or outside adverse experience reports create new concerns regarding the need for closer project scrutiny.
- e) 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 subjects over a period not to exceed one year.

Investigators are notified via email as to when their projects are due for continuing review.

XI. Monitoring Approved Projects

A. Continuing Review

When a research project is due for continuing review, a courtesy reminder letter is generated by the ORI and sent to the PI via email approximately 30-60 days before the date of continuing review. Lists of investigators receiving these letters are maintained by the ORI. However, it is ultimately the responsibility of the investigator to ensure that his/her project is renewed by the IRB prior to their expiration date.

All applications submitted for IRB continuing review are submitted through the online Topaz Electronic Protocol Submission System. 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 or IRB Member determines that the study meets the specific criteria for expedited review as outlined in Section X Part E.

For full board continuing review, if a quorum can be obtained, continuing review applications are reviewed following the procedures outlined in Section X Part D.

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 (see Section X Part F). Upon receipt of final approval, the ORI stamps approved Informed Consent Document(s) with the IRB approval number and the date of approval. These documents are sent to the PI along with a copy of the IRB re-approval memorandum, which indicates 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 subjects.

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 subjects 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 the appropriate human subjects application form along with any supporting documentation. Minor modifications may be expedited.

The PI may request that a modification be considered as both a modification and a submission for continuing review. In requesting this action, the submission 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 (see Section X Part F). Upon receipt of final approval, the ORI stamps approved Informed Consent Document(s) that have been modified with the IRB approval number and the date of approval. These documents are sent to the PI along with a copy of the IRB approval memorandum, which indicates 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.

C. Unanticipated Problems Involving Risks to Subjects (Adverse Experiences)

IRB continuing review responsibilities include reviewing reports of any unanticipated problems that involve risk to research subjects or others. Serious and Unexpected Adverse Events Forms must be reported to the IRB within 5 business days. Non-Serious and/or Expected Adverse Event Forms must be submitted to the IRB within 10 business days. The Event Form is submitted through the

online Topaz Electronic Protocol Submission System. All adverse event reports are reviewed by the IRB Chair and/or Full IRB Committee.

For investigational drug/device studies, if a subject is enrolled by FIU investigators, the investigator must report to the IRB either serious adverse experiences or unexpected adverse experiences. In multi-site trials, investigators are required to report adverse experiences that occur in subjects enrolled elsewhere (i.e., by non-University investigators) only when the adverse experience is BOTH serious AND unexpected. Such reports will be filed in the IRB file and may be subject to review by the IRB Chair.

The IRB Chair reviews Event Form 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 subjects be informed of the Adverse Event, 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 Subjects database and filed in the corresponding study file. The ORI or IRB will notify PIs 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.

An adverse experience in a subject enrolled by an FIU investigator that is serious and unexpected and probably or definitely related to the study intervention will be reviewed at a convened IRB meeting in a timely manner. An adverse experience in a non-FIU subject that is serious and unexpected and definitely related to the study intervention also will be reviewed at a convened meeting.

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

D. Other Monitoring Activities

On-site monitoring of projects for which the IRB has determined that verification from sources other than the investigator that no material changes have occurred since previous IRB review occurs at the discretion of the IRB. IRB members, or professional staff in the Office of Research Integrity acting on behalf of the IRB, may conduct a monitoring visit. The reason(s) for on-site review may include, for example, (1) random selections, (2) complex projects involving unusual levels or types of risks to subjects, (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 subjects, 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.

The Types of Reviews Include:

- **Complete Study Review:** All components of the study are reviewed as part of a comprehensive analysis. This type of review is generally only done on studies involving more than minimal risk, but it may also be done on minimal risk studies.
- **Partial Study Review:** A subset of the components of the study will be reviewed. This type of review is generally only done on minimal risk studies, but it may also be done on studies involving more than minimal risk.

Following completion of the quality improvement review, ORI will prepare a written report for the PI. The report may include recommendations for aligning the research protocol, if necessary, with institutional policies and regulatory requirements and/or specify corrective actions, if any.

If the quality improvement review identifies a need for revision of the research protocol or informed consent processes, the PI is responsible for submitting an amendment/modification to the current approved protocol in accordance with IRB requirements.

If the quality improvement review identifies serious or continuing noncompliance, ORI and the PI will adhere to established processes of the FIU Office of Research and Economic Development (ORED) and IRB for the investigation, correction and reporting of any material noncompliance, as may be required or appropriate.

E. Study Closure

The ORI provides through the online Topaz Electronic Protocol Submission System, a form by which an investigator can notify the IRB/ORI that he/she has completed the study.

If the investigator has not received continuing review prior to the expiration date, the ORI sends an email notice to the investigator, explaining that IRB approval has lapsed and cannot be renewed, since it has been permanently closed. This notice explains that no human subjects research activities may be conducted until IRB approval is re-obtained by submitting a new IRB approval form through the online Topaz Electronic Protocol Submission System. This notice 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.

XII. Notification of IRB Activities

Members and alternates of the IRB receive minutes of full board meetings and reports of projects reviewed under the expedited category during the convened meetings. This information is also made accessible to all members and alternates via an online portal.

XIII. Informed Consent Document

Signed informed consent is required on all human subjects research that is not exempt from IRB review (Section IV Part C) except as provided in this section.

The Office of Research Integrity has developed Informed Consent Document templates that provide investigators with guidance in developing the forms. The templates prompt the investigator to add details about the study, levels of risk, and other issues as indicated. The format and language in the templates are in accordance with the federal regulatory requirements. These documents are available from the ORI and may be downloaded from the FIU IRB website.

A. Content of the Informed Consent Document

The Informed Consent Document must address all of the following that are applicable to the particular study in question:

- (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject or to others that may reasonably be expected from the research;
- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens;

- i. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
- ii. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

An Assent Document must also be provided for review when the study involves minors in the 7-17 year old age range.

The IRB may require additional information in the Informed Consent Document regarding:

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

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;

(6) The approximate number of subjects involved in the study;

(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

The Office of Research Integrity and the IRB Member reviews the Informed Consent Document as a part of the triage process to determine if all basic elements of consent are contained in the document. Consent document(s) that are determined to be clearly inappropriate (e.g., significant deficiencies, too complex) are returned to the investigator for re-writing.

The investigator receives written notice via email of required changes in the Informed Consent Document prior to final IRB approval. Final approval is not granted until all required changes have been made and submitted for review and approval (see Section X Part F).

The approved Informed Consent and Assent Documents are stamped with the IRB approval number and the date of approval for all Expedited and Full Board Reviews.

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 in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

- 1) The research involves or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designated 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 authorization.

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 subjects;
- 2) The research could not practicably be carried out without the requested waiver or alteration;
- 3) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
- 4) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- 5) Whenever appropriate, the subjects or legally authorized representatives 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 a signed consent form for some or all subjects, if it finds either:

- 1) That the only record linking the subject and the research would be the consent form, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- 2) That the research presents no more than minimal risk of harm to subjects, and involves no procedures for which written consent is normally required outside of the research context; or
- 3) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was waived.

In cases, in which the documentation requirement is waived, the IRB may require the investigator to provide subjects (or legally authorized representatives) with a written statement regarding the research.

D. Emergency Research Consent Waiver

The IRB may consider an "Emergency Research Consent Waiver" for a class of research consisting of activities, each of which have met the following strictly limited conditions detailed under *either* (a) or (b) below:

(a) Research subject to FDA regulations

The IRB responsible for the review, approval, and continuing review of the research activity has approved both the activity and a waiver of informed consent and found and documented (1) that the research activity *is subject* to regulations codified by the FDA will be carried out under an FDA investigational new drug application (IND) or an FDA investigational device exemption (IDE), the application for which has clearly identified the protocols that would include subjects who are unable to consent, and (2) that the requirements for exception from informed consent for emergency research detailed below have been met relative to those protocols, **or**

(b) Research not subject to FDA regulations

The IRB responsible for the review, approval, and continuing review of the research has approved both the research and a waiver of informed consent and has (1) found and documented that the research *is not subject* to FDA regulations and (2) found and documented and reported to OHRP that the following conditions have been met relative to the research:

- 1) The human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
- 2) Obtaining informed consent is not feasible because the subjects will not be able to give their informed consent as a result of their medical condition, the intervention under investigation must be administered before consent from the subjects' legally authorized representatives is feasible, and there is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the research.

- 3) Participation in the research holds out the prospect of direct benefit to the subjects because subjects are facing a life-threatening situation that necessitates intervention, appropriate animal and other preclinical studies have been conducted and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects, and risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.
- 4) The research could not practicably be carried out without the waiver.
- 5) 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 contacted 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.
- 6) 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 subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible.
- 7) Additional protections of the rights and welfare of the subjects 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 subjects will be drawn, public disclosure to the communities in which the research will be conducted and from which the subjects 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.

E. Screening, Recruiting or Determining Eligibility

An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

- 1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
- 2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

F. Posting of Clinical Trial Consent Form

- 1) For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal website.
- 2) If the Federal department or agency supporting or conducting the clinical trials determines that certain information should not be made publicly available on a Federal website (e.g., confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.
- 3) The informed consent form must be posted on the Federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

G. Alteration or Waiver of HIPAA Authorization

The IRB may approve an alteration or waiver of HIPAA Authorization provided that the research meets the criteria outlined in 45 CFR 164.512(i)(2)(ii). Alterations or waivers of HIPAA Authorization are documented in the IRB approval letter.

XIV. Research Using Food and Drug Administration (FDA) Regulated Products

A. Determination of Significant Risk (SR) vs. Nonsignificant Risk (NSR) for Non-Exempt Medical Devices

For determination of the need for an IDE, the convened IRB will address the applicability of FDA regulations under 21CFR812.2 and, if necessary, make a significant risk determination.

A Significant Risk (SR) device study is one that presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

A Nonsignificant Risk (NSR) device investigation is one that does not meet the definition for a SR study.

The risk determination is based on the proposed use of a device in an investigation, and not on the device alone. In deciding if a study poses an SR, the IRB considers the nature of the harm that may result from use of the device. Studies where the potential harm to subjects could be life-threatening, could result in permanent impairment of a body function or permanent damage to body structure, or could necessitate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to body structure is considered SR. Also, if the subject must undergo a procedure as part of the investigational study, e.g., a surgical procedure, the IRB considers the potential harm that could be caused by the procedure in addition to the potential harm caused by the device.

FDA has the ultimate decision in determining if a device study is SR or NSR.

If an investigator or a sponsor proposes the initiation of a claimed NSR investigation to an IRB, and if the IRB agrees that the device study is NSR and approves the study, the investigation may begin at that institution immediately, without submission of an IDE application to FDA.

To help in the determination of the risk status of the device, an investigator is asked to include the sponsor's (including the investigator on investigator-initiated studies) assessment of whether or not a device study presents a significant or nonsignificant risk. The investigator must provide the IRB with a description of the device, reports of prior investigations with the device, the proposed investigational plan, a description of subject selection criteria, and monitoring procedures. The investigator must inform the IRB whether other IRBs have reviewed the proposed study and what determination was made. The investigator must inform the IRB of the FDA's assessment of the device's risk if such an assessment has been made. The IRB may also consult with FDA for its opinion.

The IRB may agree or disagree with the investigator/sponsor's initial NSR assessment. If the IRB agrees with the sponsor's initial NSR assessment and approves the study, the study may begin without submission of an IDE application to FDA. If the IRB disagrees, the sponsor should notify FDA that an SR determination has been made and the initiation of the study must be delayed until FDA approval of an IDE application has been granted.

If the IRB decides the device/study is significant risk, it notifies the investigator and sponsor of this decision. The IRB must be provided with notice that an IDE has been granted, and the IDE number must appear on the investigator's IRB application prior to final full board review.

Once the SR/NSR decision has been reached and proper documentation provided, the IRB considers whether the study should be approved or not. Full IRB review is required for all studies involving investigational devices. The criteria for deciding if SR and NSR studies are approved are the same as for any other study. After the IRB has made the SR/NSR determination, the IRB can elect to have the study go through an Expedited review if the protocol involves no more than minimal risk and falls under one of the Expedited review categories. Minutes of IRB meetings document the rationale for SR/NSR and subsequent approval or disapproval decisions for the clinical investigation.

B. Determination of Need for an Investigational New Drug (IND)

Studies that involve FDA-regulated products that are submitted without a valid IND number will be reviewed with respect to determining the need for an IND, based on the investigator's response to questions contained in the IRB application form.

If the IRB determines that the study is exempt from an IND and approves the study, the study may begin without submission of an IND application to FDA. If the IRB determines that an IND is needed, the investigator/sponsor must submit an IND application to the FDA and provide documentation of the outcome of the FDA determination to the IRB before the IRB approves the study.

The IRB may consider a study using a drug product that is lawfully marketed in the United States to be exempt from the requirements for obtaining an IND if all the following apply: (i) The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug; (ii) If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product; (iii) The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product; (iv) The investigation is conducted in compliance with the requirements for institutional review and with the requirements for informed consent; and (v) The investigation is conducted in compliance with the requirements with regard to promotion and charging for investigational drugs in 21CFR312.7

A clinical investigation involving an in vitro diagnostic biological product that is a blood grouping serum, reagent red blood cells, or anti-human globulin is exempt from the requirements for an IND if (a) it is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure and (b) it is shipped in compliance with 21CFR312.160.

A drug intended solely for tests in vitro is exempt from the requirements of an IND if it is shipped in accordance with 21CFR312.160.

A clinical investigation involving use of a placebo is exempt from the requirements of an IND if the investigation does not otherwise require submission of an IND.

XV. Emergency Use of an Investigational Drug/Device

The FDA human subjects regulations allow for an investigational drug/device to be used in emergency situations without prior IRB approval. Emergency use is defined as a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval for the use. The investigator is still required to obtain informed consent under these circumstances. The emergency use must be reported to the IRB in writing within 5 working days.

The written report submitted to the IRB must include a cover letter explaining the medical condition, reason for use, and date administered as well as a copy of the signed Informed Consent Document. The investigator must also include any manufacturer information available on the product (e.g., drug brochure). Once the investigator has provided written notice, the IRB Chair or his/her designee responds in writing that the information has been received.

Written informed consent must be obtained prior to administration or use unless the emergency situation makes it not feasible to obtain informed consent prior to using the test article. Exemption from the informed consent requirement is granted only when: (1) a life-threatening situation necessitates use of the test article; (2) the subject is unable to provide effective consent; (3) there is insufficient time in which to obtain consent from the subject's legal representative; and (4) there is no available alternative method of approved or generally recognized therapy of equal or greater likelihood of saving the subject's life.

The investigator must document the infeasibility of obtaining consent as follows: The investigator and a physician who is not participating in the clinical investigation must certify in writing the existence of all four conditions listed above before use of the test article. If in the investigator's opinion immediate use of the test article is necessary to save the life of the subject and there is insufficient time to obtain the independent determination before using the test article, the investigator is to make his or her own written determinations, then obtain the written review and independent evaluation of a physician who is not participating in the clinical investigation. The documentation of the infeasibility of obtaining informed consent must be submitted to the IRB within five working days after the use of the test article.

The investigator's report is presented at the next IRB meeting. When an IRB receives a report by an investigator of an emergency use, the IRB examines the case to assure that the emergency use was justified. Since prior IRB approval is not obtained, the patient may not be considered a research subject and data regarding care may not be included in any report of research activity.

Although this procedure is designed to permit only a single emergency use of a test article for the treatment of one patient by one physician within the University, it is not intended to limit the authority of a physician to provide emergency care in a life-threatening situation. Should a situation arise which would require the emergency use of the test article for a second patient, either by the

same or a second physician, for the same test article, subsequent emergency use should not be withheld for the purpose of gaining IRB approval. If it appears probable that similar emergencies will require subsequent use of the test article at the University, every effort should be made either to sign on to the sponsor's protocol or to develop a protocol for future use of the article at the institution. Either of these protocols would need to be prospectively reviewed and approved by the IRB for future use of the test article.

The use of a test article in an investigation designed to be conducted under emergency conditions (e.g., emergency room research) usually does not qualify for the emergency use exemption (see Section IX Part D).

The investigator is asked to provide an update on the status of the subject three months after the emergency use.

XVI. Treatment Use of an Investigational Drug/Device

The IRB reviews the use of investigational drugs/devices if the investigator provides evidence that a treatment IND/IDE has been obtained or as single patient use (below). In all cases, treatment use of an investigational drug/device requires prospective IRB approval as well as subject informed consent.

A. Single Patient Use

In non-emergency situations, single patient use allows a physician to obtain access to an investigational drug upon receiving approval from the IRB. This approval is granted for the treatment of a single patient. When an investigator desires to obtain single patient use approval, the investigator submits an application and the study is assigned a FIU IRB identification number and sent through the new application procedure. The treatment use may occur only after IRB approval is obtained. The investigator is asked to provide an update on the status of the subject three months after approval. Subsequent treatment use requires FDA approval for a treatment IND/IDE.

B. Humanitarian Use

Humanitarian use of investigational devices is prospectively reviewed by the IRB. The investigator is required to submit a new application for review. Included in the application must be evidence that the investigator/sponsor has obtained a Humanitarian Device Exemption (HDE) from the FDA. These projects are subject to the same new and continuing review requirements as research projects as outlined in this document.

XVII. International Research

A. Investigator Responsibilities

Local IRB Review

In addition to obtaining FIU IRB approval, the FIU investigator must seek review of his/her human research protocol by a local IRB, Ethics Board or Independent Ethics Committee (IEC) whenever possible. The local IRB, Ethics Board, or IEC must be knowledgeable about and sensitive to local community composition, mores, laws, and standards of conduct. In the event that no such local IRB, Ethics Board, or IEC exists or when such a local ethics board is unable or unwilling to review the research, the PI must take steps either to identify a review board within the general region or to identify a local institution that can serve in a comparable capacity (e.g., a tribal council, school board, town committee, or hospital board). Research that is particularly complex or presents significant risk to subjects may require consultation with the FIU legal counsel to ensure that the rights of subjects are appropriately protected, and that the research is conducted in conformance with local law. A copy of the local IRB or IEC approval must be submitted to the FIU IRB.

Informed Consent

The PI and other IRB-approved study personnel must obtain the voluntary informed consent of the prospective participant or, in the case of an individual who is not capable of giving informed consent, the permission of a legally authorized representative or surrogate in accordance with applicable local law. Informed consent processes must be sensitive to local cultural norms. The informed consent discussion and all consent documents must be in the language understood by participants. If participants are likely to be unable to provide written consent, then the investigator, when submitting a protocol for IRB approval, must provide justification for a waiver of written consent and propose an acceptable alternative method of obtaining oral consent that is appropriate to both the participants and their culture.

Appropriate Resources and Facilities

The protocol must provide evidence of sufficient local resources and facilities to support the proposed human subjects protocol in compliance with this policy and local law. The FIU investigator and the foreign institution or site are responsible for ensuring that the resources and facilities are appropriate for the nature of the research, and are responsible for the ongoing monitoring of the research, including the ability to respond to emergent issues that occur during the course of the research.

HIPAA Applicability

HIPAA regulations do not apply to health information obtained and held at international sites; however, researchers must comply with all applicable local privacy laws. However, if identifiable health information collected at an international site is brought back to the United States, then it may be subject to HIPAA regulations.

B. IRB Responsibilities

IRB Review of Research

The IRB ensures the ethical and equitable treatment of research volunteers and protects the rights and welfare of those who participate in research. For international research involving human subjects, the IRB review must include confirmation of local IRB/IEC approval as applicable, current host institution FWA approval as applicable, and compliance with adverse event reporting and other FIU policies as they apply to human subjects research.

Knowledge of Local Research Context

In order to approve a protocol being carried out at a foreign site and to make an informed judgment about the level of risk to potential research participants, the FIU IRB must demonstrate that it has sufficient information about the local research context and local law by its review of written material, or through discussions with either IRB members knowledgeable about the local context or appropriate expert consultants. The level of knowledge about the local context and local law required for approval is based on the degree of risk to potential research participants. Higher risk studies require more thorough considerations of local context and inclusion of strategies to mitigate harm than do minimal risk studies.

Informed Consent Process

The FIU IRB will review the consent process, paying special consideration to maintaining sensitivity to local cultural norms and applicable law, including issues such as the following: disclosure of scientific and/or medical facts to individuals who may be unfamiliar with and distrustful of the concepts to be studied; differences in cultural and societal norms; differences in the role of women in society; differences in the role of family and community in the consent process; multiple local languages; and literacy level.

XVIII. Record Retention Policy

The ORI 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. These records are maintained by ORI for at least three years after study completion.

Investigators need to maintain research records (e.g., signed informed consent forms) for at least three years after study completion. Signed HIPAA Authorization Forms need to be maintained for at least six years from the date of creation or the date when it was last in effect, whichever is later.

XVIX. Education and Training

The IRB and ORI provide services to inform the research community on issues related to use of human subjects 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

The ORI maintains a website that contains detailed information on the human subjects review process as well as links to federal regulations and regulatory agencies, the OHRP Institutional Review Board (IRB) Guidebook, and other guidance documents.

The ORI 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 subjects research.

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

The ORI schedules and advertises numerous educational workshops throughout the calendar year directed at investigators and their research associates. These workshops cover topics that include FIU policies and procedures as well as federal regulatory requirements.

Members of the IRB or ORI 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.

All researchers that are engaged in conducting research with human subjects are required to complete the web-based CITI IRB Human Subjects Research training course. All researchers that will be working with protected health information (PHI) are required to complete the web-based CITI Health Information Privacy and Security (HIPS) training course. All researchers that will be conducting an NIH funded or FDA regulated clinical trial are required to complete the web-based CITI Good Clinical Practices training course.

B. Educational Activities Aimed at Members of the IRB

At the time of induction of a new member, the IRB Chair and/or professional staff from the ORI provide the member with the procedures of the IRB and the general regulatory framework from which procedures and policies are derived. This process involves an orientation workshop that focuses on all of the responsibilities and duties for new members.

Instruction by the ORI also includes reviewing specific areas of the FIU human subjects website for detailed information on FIU human subjects review process as well as links to federal regulations. In addition, all new IRB members are required to complete the online CITI IRB Member Training Course and CITI Health Information Privacy and Security (HIPS) Course and provide copies of their certificates to the ORI.

New members must also provide the ORI with a copy of their Curriculum Vitae. New members are required to have a senior IRB mentor co-sign on their first three Expedited reviews to ensure that they are reviewing the protocols in compliance with federal regulations before they are officially appointed as an Expedited reviewer.

FIU provides the opportunity for the IRB members to attend, at least annually, a conference, workshop, or webinar on human subject issues in research. Upon completion of the training, these individuals provide relevant information to all board members and, as appropriate, the rest of the University community.

C. Educational Activities Aimed at Members of the University Administration

FIU provides the opportunity for staff members of the Office of Research Integrity to attend, at least annually, a conference or workshop on human subject issues in research. Upon return, these individuals brief appropriate members of the University community on relevant information obtained.

XX. 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:

- a) 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 FIU); or
- b) 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
- c) Having any equity interest if the value cannot be determined by reference to publicly listed prices (e.g., start-up companies); or
- d) Holding a position as director, officer, partner, trustee, employee, or any other position of management; or
- e) 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 FIU.

Human Subject – a living individual about whom an investigator (whether professional or student) conducting research: a) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or b) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

IRB Chair – Chair or Co-Chair, as designated on IRB roster submitted to OHRP.

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 subjects; 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, 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 whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

- i. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focuses directly on the specific individuals about whom the information is collected.
- ii. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- iii. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- iv. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

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 which is not consistent with the risk information provided to subjects and the IRB.