

**STANDARD OPERATING PROCEDURES OF
THE INSTITUTIONAL REVIEW BOARD**

JACKSONVILLE UNIVERSITY

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I. OVERVIEW OF INSTITUTIONAL REVIEW BOARD

A. The Mission of the Institutional Review Board

Jacksonville University Institutional Review Board (IRB) has the responsibility for protecting the rights and welfare of human participants in all studies and research carried out by University faculty, staff, and students or studies conducted under the auspices of JU. To achieve this, all studies involving human research participants must be conducted in accordance with the Federalwide Assurance (FWA). This legally binding document with the federal government “assures” that all of the institutions under the FWA are guided by the Department of Health and Human Services (HHS) regulations for the protection of human participants, 45 CFR Part 46 (the Common Rule), and are guided by the ethical principles set forth in the Belmont Report, regardless of whether the research is publicly or privately sponsored. In addition to the Public Health Service Regulations 45 CFR 46, the JU IRB is also guided by regulations of the Family Education Rights and Privacy Act (FERPA), the Health Insurance Portability and Accountability Act (HIPAA), the International Conference of Harmonization (ICH), Good Clinical Practice (GCP), and other applicable laws and regulations.

The Belmont Report was completed on April 18, 1979, and the drafters of the document included consideration of rules like the Nuremberg Code in the identification of the broad ethical principles under which human subject research is conducted. The three principles of the Belmont Report, which help guide human subject research at JU:

- Respect for persons;
- Beneficence; and
- Justice.

The principle of *respect for persons* means that each individual should be treated as autonomous, capable of making decisions about themselves and their personal goals. Potential research participants should be given sufficient time and information upon which to base their decisions about participation. Research should be explained so that it is comprehensible to potential participants. Participants should be volunteers who participate without being subject to coercion or undue influence. *Beneficence* means that researchers should maximize the benefits of participating in research studies and minimize the possible risks. Research should be well- designed so that the results are warranted and credible. The principle of *justice* evolves around the question of who ought to receive benefits of research and who ought to bear the burden of possible risks. Vulnerable populations or populations of convenience must not be exploited or coerced into participating.

These three principles of the Belmont Report are implemented through the processes of informed consent, risk/benefit assessment, and fair subject selection.

The Belmont Report and the Code of Federal Regulations regarding human subjects research (45 CFR 46) may be found on the web page of the HHS Office for Human Research Protections (OHRP). Information about the Federalwide Assurance is also posted on the OHRP web site.

B. Role of the IRB in Ethical Review

The purpose of Jacksonville University IRB is to protect the rights and welfare of human research participants and to ensure that research involving human participants is conducted in compliance with applicable federal and state regulations. To achieve this purpose, the IRB must advise investigators in designing research projects that minimize potential harm to participants, review all research involving human participants prior to initiation of the work, approve research that meets established criteria for protection of human participants, and monitor approved research to ensure that the welfare of human participants is appropriately safeguarded.

Guided by the principles set forth in the Belmont Report, OHRP rules and regulations, and ICH, the IRB assures that all of the following stipulations are met:

- Risks to subjects are minimized.
- Risks to subjects are reasonable in relation to the anticipated benefits.
- Selection of subjects is equitable.
- Documented, informed consent is obtained from each prospective subject or the subject's legal guardian or healthcare decision-maker.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative to the extent required by 45 CFR 46.116.
- Informed consent is appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.
- When appropriate, provisions are made for the protection of the privacy of subjects and confidentiality of data is maintained.
- Provisions are made for monitoring the data collected to ensure the safety of subjects.
- Safeguards are included to protect members of vulnerable population groups (45 CFR 46.111).

The IRB consists of scientists, non-scientists, and at least one member unaffiliated with JU who come from varying backgrounds to promote complete and adequate review of research activities commonly conducted at JU. The IRB membership includes professional persons knowledgeable in the areas of institutional commitments, law, welfare of vulnerable participants, and standards of professional conduct and practice. The required diversity of members includes adequate representation from scientific disciplines, non-scientific disciplines, the appropriate minority and gender groups, the academic units of the institution, and the local community though the inclusion of at least one member from outside of the institution. When possible, the IRB will include at least one member from each of the academic colleges within the university. The representative from an academic college should be a tenure-track faculty member.

No member participating in initial or continuing review may have a conflict of interest in the proposed research. The IRB is responsible for assuring that it has the required competence to review protocols, and may add expertise as required.

In exercising its responsibility to ensure that human participants are protected in research conducted by institutional faculty, staff, and students or otherwise under the auspices of the institution, the IRB shall have the responsibility and authority to:

- Review all planned research that involves human participants, including the determination that planned research is exempt from further IRB review (45 CFR 46.101).
- Review and have the authority to approve, require modifications in, or disapprove research activities involving human participants.
- Oversee all research involving human participants that is not exempt from IRB review including the authority to observe or have third parties observe the consent process and the conduct of research.
- Suspend or terminate approval of research that is not conducted as approved or that has been associated with serious unexpected harm to participants. An IRB decision to disapprove, suspend, or terminate a project may not be reversed by any officer or agency of Jacksonville University. However, University officials may, in certain cases, decide that a research study approved by the IRB may not be conducted.
- Report to the institutional official unanticipated problems involving risks to participants and others and serious or continuing noncompliance by investigators.

See [IRB web page](#) for contact information for IRB Chair and Administrator

C. Federalwide Assurance System

Under the FWA system, each IRB must register with Office for Human Research Protection (OHRP) within the U. S. Department of Health and Human Services (DHHS). Each legally separate entity engaged in human subject research must apply for its own FWA. Under federal policy, awardees and their collaborating institutions become engaged in human research whenever their employees or agents intervene or interact with living individuals for research purposes. Although each legally separate institution or entity must file its own Assurance, the institutions are free to designate IRBs under the Assurance that are operated by other institutions or entities.

The FWA requires the development and adoption of policies and procedures for conducting human subject research and the appointment of an institutional official to oversee the University's compliance with federal regulations pertinent to human participants in research. The institutional official at Jacksonville University is designated by the president in written letter.

II. WHAT IS SUBJECT TO REVIEW

A. Scope of Review

Under the provisions of 45 CFR 46, *research* is defined as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” [45 CFR 46.102(d)]. The term *human subject* is defined as “a living individual about whom an investigator...conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information” [45 CFR 46.102(f) (1 and 2)].

By JU policy, all research involving human participants should be conducted under equivalent levels of protection regardless of funding source. All research that uses human participants, tissues/specimens from humans, data/records from human participants, or surveys of human participants requires review and may require approval from the IRB.

Classroom experiences designed to develop knowledge and skills in research methodologies and inquiries designed to inform internal university decision making and program improvement may not be subject to IRB review.

B. Whose Research Is Reviewed?

The requirement for IRB review extends to human subject research conducted by any JU faculty, staff, or student. All JU faculty members, staff, and students must submit protocols for their research involving human participants to the JU IRB. Student research includes, but is not limited to, all honors theses, master's theses, and doctoral dissertations.

Each research study submitted for review can list only one responsible primary investigator (RPI). This RPI must be a full-time, non-visiting JU staff or faculty (9-month or 12-month) who will be considered accountability for the oversight and liability of the project. A principal investigator may be a JU faculty member or a collaborator at another institution. Co-investigators may be faculty members, community faculty, residents, students, collaborators at other institutions, and others who are adequately trained to play a significant role in the research project. For student research other than theses and dissertations, the RPI shall be the faculty member supervising the research.

C. Funded Research

Federal, state, local, and private funding agencies may require documentation of IRB approval for research that involves human participants. JU requires IRB approval prior to the release of funds to support any research involving human participants, regardless of the review category. IRB approval must remain current in order for subsequent funds to be released.

D. Class Projects

If you are conducting class projects that involve research with human participants (as defined in 45 CFR 46) those projects may need to undergo IRB review. For a definition of class projects, please refer to the [JU IRB Definitions](#) document. Only class projects that meet the following criteria do not need to undergo IRB review:

- *Participants from vulnerable groups are not be included.* Class projects shall not involve the use of vulnerable populations, as defined in federal regulations and Jacksonville University IRB Standard Operating Procedures. Additionally, individuals potentially vulnerable to coercion or undue influence (e.g., individuals with whom students in a research methods course have a supervisory relationship) shall not be included.
- *The project involves no more than minimal risk to participants.* Class projects shall not involve topics that involve physical, social, psychological, and/or legal harm to

the participants.

- *Activity is described as a class project rather than as research to prospective participants, other students, university faculty, and university staff.* To the extent that these projects involve practicing and honing skills (e.g., interview techniques, observational methods, and data analysis), projects should be described as exercises in developing and practicing such skills.
- *No dissemination of findings and conclusions in ways that contribute to generalizable knowledge.*¹ Results will never be distributed outside the classroom and/or JU conferences or research symposiums (including NCUR). One exception to this may be community-based class projects in which information is limited to reports to community agencies for which project information was collected. If there is even a remote chance that the data or the report/manuscript will be used in the future for an off-campus conference presentation, or submitted for publication, the research should go through IRB review. If the project is not subjected to IRB review before data collection begins the information will not be permissible for inclusion in future presentations, publications, or research.
- *Provision for informed consent.* Participants in a class project must be fully informed about the nature of the project (including but not limited to its risks and benefits) and must voluntarily consent to participate in the class project. The only exceptions to this requirement for informed consent are projects that only involve (a) the observation of public behavior or (b) the use of archival data (i.e., existing data, records, or documents), provided these data are recorded by students in such a way that the participants cannot be identified.
- *Adequate Provision for Data Monitoring and Storage.* Any data collected as part of class projects must be collected and stored in such a way that the identity of participants cannot be compromised. All information collected from participants in class projects (e.g., surveys, observation notes, and interview transcriptions) must be destroyed or de-identified at the end of the semester. This requirement does not apply to course-related products such as student papers that may need to be retained by instructors as part of the course records.
- *Instructor Responsibility for Student Training.* Given that students in research methods classes are inexperienced with respect to ethical issues in conducting research with human participants, instructors agree to complete the certification required for investigators and to train their students with respect to ethical principles and issues that may arise in interactions with human participants. Also no students will be allowed to be listed as the RPI for a study. [Investigator Assurances](#) page must be signed by the faculty and the student researcher.

Instructors who believe that student activities in a course are class projects that are not subject to IRB review should refer to the [Procedures for Class Projects](#) on the JU IRB Website, as well as the [Human Subjects Research Checklist](#).

¹ For more details regarding what JU identifies as “generalizable knowledge,” please refer to the [JU IRB Definitions](#)

E. Institutional Quality Assurance, Quality Control, and Program Evaluation

Whether studies conducted for the purposes of quality assurance, quality control, or program evaluation constitute research with human subjects is not always a simple matter. If such studies are intended solely for use in internal program planning and development or to monitor processes within the organization and are not designed to have application beyond the organization or program that is the target or source of the study, these studies may not be subject to IRB review. The data collection and analysis activities from these studies are not be intended to contribute to generalizable scientific knowledge but are rather used to improve the provision of services to a specific population, organization or program, the studies are not by definition research involving human participants and are not subject to IRB review. If, on the other hand, such studies are intended to inform the field of study and lead to dissemination of the results outside the institution, they are considered research involving human participants and are, therefore, subject to IRB review.

Typically, the following JU internal quality assurance activities do not require IRB review: teaching, faculty, and staff evaluations (but research on such evaluations would require IRB review); performance evaluations; institutional program review; classroom assessment, program assessment, curriculum review; and strategic planning.

By contrast, some quality control studies, needs assessments, or program evaluations may also be designed as research involving human subjects. For example, the study results may be intended to inform the field of study and, thus, may lead to publication of the results in scholarly journals, presentations at professional conferences, and books or monographs that report the findings in a way that impacts the replication of programs or services or the development of public policy.

Such studies should be reviewed by the IRB prior to commencing the study. Principal investigators who are unsure about how the results from a study may be used and who may want to publish results in a scholarly venue because the findings are important and the results warrant dissemination should seek IRB review prior to beginning the study. The IRB will not grant retroactive approval for researchers to publish data that were not collected through an IRB- approved project.

Principal investigators who are planning studies that may not meet the federal guidelines for research involving human participants should submit the appropriate documentation for IRB review. After review of this form, IRB administrative staff will provide official written notification stating whether a project requires IRB approval. Even when the project does not fall under the purview of the IRB, projects must be conducted in compliance with the highest ethical standards and principles.

III. PROCEDURES FOR CONDUCTING INITIAL REVIEW OF RESEARCH

A. The Process of Informed Consent

Conceptualizing the process of informed consent is one of the most important parts of planning a research study. Participants must be able to exercise their right of free will in making the decision to participate. It is equally important that participants be given the correct information, comprehend what is being said and read and have the time to make their own decision about participation. The following elements constitute the consent process:

- Recruitment materials;
- Verbal instructions;
- Written materials;
- Questions/answer sessions; and
- Agreement by documented signature.

Prospective participants may elect to not sign the consent form at the initial time of the consent discussion. It is their option to take the consent form home and discuss it with family and friends. However, prospective participants may not participate in the study until they have signed the consent form or, in the instances in which written informed consent has been waived, otherwise indicated their willingness to participate.

Participants must be informed that it is their right to withdraw from a study at any time without penalty. The consent form must be read to any participants who cannot read. Likewise, for participants who do not read English, the consent form must be prepared in the preferred language or be read and signed by an interpreter in a language the subject comprehends. Children and other vulnerable participants may need information presented as simply and straightforwardly as possible. In cases where the potential subject cannot read the consent form, it must be read to the individual and a witness signature is required on the form. This signature indicates that a witness was present during the reading/interpreting of the consent form and that it was presented in a manner that was comprehensible to the subject.

1. Recruitment Materials

Copies of advertisements, videos, or any other materials used for the recruitment of participants must be submitted with the IRB protocol for approval. The IRB reviews the methods that investigators use to recruit participants because advertising for study participants starts the informed consent and subject selection process. Advertising for participants is considered to be a reasonable recruitment practice as long as the advertisement has been reviewed and approved by the IRB. Examples include materials such as ads in the newspaper and on the radio; posters, flyers, and bulletin board “tear sheets;” e-mail solicitations, and Internet communications designed to reach potential participants. JU faculty should contact the Student Life and/or Marketing & Communications offices for guidance for marketing on campus.

Researchers are strongly encouraged to include the following information in recruitment materials as appropriate:

- The name and address of the investigator or research facility;
- The condition under study and/or the purpose of the research;
- In summary form, the criteria that will be used to determine eligibility for the study;
- A brief list of participation benefits, if any (e.g., a no-cost health examination);
- The time or other commitments required of the participants; and
- The research location and the person or office to contact for further information, including office phone number and/or local (904) area code cell phone number.

Finder's fees (cash or non-monetary payment) for the referral of participants to investigators are considered, in most situations, unethical. This practice has the potential to violate the subject's trust in the referring entity, the investigator, and in the process of research. In instances where it is deemed appropriate the investigator should submit a written justification for offering a finder's fee with the protocol submission. The Board will closely examine studies which include a finder's fee, and decisions for approval will be made on a case-by-case basis.

For additional guidance on recruitment materials, please refer to the [Recruitment Guidelines](#) on the JU IRB's website.

2. Assessing Capacity to Consent

Individual's capacities, impairments, and needs must be taken into account, in order to develop ethical approaches in allowing participation. Even for minimal risk studies, prospective participants must demonstrate that they can make a choice for themselves and understand information relevant to the study. For studies involving greater than minimal risk, the participants should also be able to demonstrate that they understand how this relevant information applies to their own situation and be able to manipulate this information rationally. If the subject is unable to do any of the above, a legally authorized decision maker must give surrogate consent before the study may begin.

3. Required Elements of Informed Consent

The following elements must be included in an informed consent document:

- Statement that the study involves research, explanation of the purposes of the research, description of the procedures to be followed, and identification of any procedures which are experimental. It is essential that the consent process (including consent documents) clearly indicate differences between individualized "treatment" and "research."
- Description of any reasonable foreseeable risks or discomforts to the participant.
- Description of any benefits to the participant or to others.
- Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.

- Statement describing the extent to which confidentiality of records identifying the participant will be maintained.
- For research involving more than minimal risk, an explanation as to whether any compensation is available if injury occurs, whether any medical treatments are available if injury occurs, and, if so, what they consist of or where further information can be obtained.
- Explanation of whom to contact for answers to pertinent questions about the research, the rights of research participants, and whom to contact in the event of a research-related injury.
- Statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled [[45 CFR 46.116\(a\)](#)].

4. Other Elements of Informed Consent

The following elements may be included in an informed consent document as appropriate to the research.

- A statement that the particular treatment or procedure may involve risks to the participant that were unforeseeable at the time the study was initiated.
- Circumstances under which the subject's participation may be terminated by the PI without regard to the subject's consent.
- Any additional costs to the participant that may result from participation in the research.
- Consequence of a participant's decision to withdraw from the research and procedures for termination of participation.
- Statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue will be provided to the participant.
- Approximate number of participants in the study.
- Study treatment(s) and the probability of random assignment to placebo or to each treatment.
- Other information that is required by the IRB because it would meaningfully add to the protection of the rights and welfare of participants. [[45 CFR 46.116\(b\)](#)].

5. Exceptions to informed consent

The IRB may approve a consent procedure that does not include or that alters some or all of the elements of informed consent or waives the requirement to obtain informed consent provided that the IRB finds and documents one of the following two conditions.

- The research is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise

examine public benefit or service programs as described in [45 CFR 46.116\(c\)](#) and the research could not be carried out without the waiver or alteration.

- The research meets the following conditions as described in [45 CFR 46.116\(d\)](#):
 - The research involves no more than minimal risk to participants;
 - The waiver or alteration will not adversely affect the rights and welfare of the participants;
 - The research could not practicably be carried out without the waiver or alteration; and
 - Whenever appropriate, the participants will be provided with additional pertinent information after participation.

The IRB may waive the requirement for the investigator to obtain a signed consent form if it finds that one of the following two conditions apply:

- The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. In these instances, participants should be asked whether they want documentation that links them with the research. Each participant's wish should govern the process.
- The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research [[45 CFR 46.117\(c\)](#)].

B. Determining the Type of Evaluation

A research study will undergo one of three levels of IRB evaluation depending on the level of risk to human participants. These three levels are:

- Exempt from further IRB review;
- Expedited IRB review; and
- Full IRB Board review.

The level of evaluation can only be determined by the IRB, in accordance with federal guidelines. Even if an investigator believes a study is exempt, no research should begin until the IRB reviews the protocol and makes the final determination. Many research studies require expedited or full Board review and approval.

1. Exempt from Board Review

1.1. Type of Research Which May Qualify for Exemption

The Code of Federal Regulations, [45 CFR 46.101\(b\)](#), identifies six different categories of minimal risk research as being exempt from Federal Policy for the Protection of Human Research Subjects. The criteria are briefly described below. JU is required to adhere to the language of [45 CFR Part 46](#), and investigators are encouraged to consult with JU IRB staff with any questions about specific exemption criteria.

- 1) Research conducted in established or commonly accepted educational settings and involving normal educational practices. This includes items such as curriculum design, instructional strategies, and classroom management methods in regular and special education.
- 2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior unless the information is recorded so that human subjects can be identified directly or indirectly and “any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.”
- 3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- 4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in a manner that subjects cannot be identified directly or through identifiers linked to the subject.
- 5) Research and demonstration projects related to public benefit or service programs which are conducted by or subject to the approval of federal department or agency heads or any other officer or employee of any department or agency to whom authority has been delegated.
- 6) Taste and food quality evaluation and consumer acceptance studies conducted under the conditions specified in [45 CFR](#)

[46.101\(b\)\(6\).](#)

1.2. Research that is not exempt:

- Research that involves greater than minimal risk. As defined in the federal regulations, minimal risk means “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.”
- Research with vulnerable populations. The following do not qualify for exempt status: (a) research that involves the survey procedures or interviews with children; (b) observation of the public behavior of children when investigators interact with the children; and (3) research involving prisoners.

Applications that do not meet the criteria for exempt review will be recommended for either expedited review or full board review.

The IRB does not actually approve an exempt study but instead makes a determination that the project meets at least one of the federal exempt categories criteria. Therefore, annual continuing review is not required and no expiration date will be listed on the declaration of exempt status letter.

1.3. Documentation Required for Exemption

Investigators must provide sufficient information about proposed research to determine whether it is exempt. All submissions must be completed online using [IRBNet](#):

- JU Exempt Application
- Informed Consent (as applicable)
- Mentor Agreement Letter (if student researcher)
- Letter for permission to collect data at other institution(s) (as applicable)
- Instruments/Surveys/Questionnaires or other data gathering materials
- Advertising and recruiting materials / messaging / verbiage
- CITI Completion reports
- Documentation regarding internal and external funding applied for or received

1.4. Criteria Used for Evaluation of Exemptions

The IRB Chair or Chair’s designee makes the decision as to whether the study qualifies for exemption from review. If determined to be Exempt, a written memorandum confirming this status will be sent to the principal investigator and/or sponsoring faculty member. Each memorandum includes:

- The investigator’s name;

- The JU IRB number;
- The study title;
- The method of evaluation (e.g., a statement that the study was evaluated by the IRB to be exempt from review);
- Exemption status under which the study qualifies.
- Information about changes that will affect the status of the Exempt project (see also 1.4 below)
- Information about the ongoing protection of human subjects. It will be stated in the memorandum that once data collection under the exempt status begins, the PI agrees to abide by these requirements:
 - All investigators and co-investigators, or those who obtain informed consent, collect data, or have access to identifiable data are trained in the ethical principles and federal, state, and institutional policies governing human subjects research.
 - An informed consent process will be used, when necessary, to ensure that participants voluntarily consent to participate in the research and are provided with pertinent information such as identification of the activity as research; a description of the procedures, right to withdraw at any time, risks, and benefits; and contact information for the PI and IRB Administrator.
 - Human subjects will be selected equitably so that the risks and benefits of research are justly distributed.
 - The IRB will be informed as soon as practicable but no later than 3 business days from receipt of any complaints from participants regarding risks and benefits of the research.
 - The IRB will be informed as soon as practicable but no later than 3 business days from receipt of the complaint of any information and unexpected or adverse events that would increase the risk to the participants and cause the level of review to change. Please refer to section V. B. of the JU IRB Standard Operating Procedures for details about the reporting requirements.
 - The confidentiality and privacy of the participants and the research data will be maintained appropriately.

Once the declaration of exempt status letter is received, the project may begin.

If the study does not qualify for an exemption, the principal investigator will be notified of the reasons the research does not meet the criteria for exempt review and that the protocol must be submitted for either expedited or full board review. Additional information will be requested from the PI in order to facilitate this level of review.

1.5. Revisions of Exempt Research

While the exempt status is effective for the life of the study, if it is modified, all substantive changes must be submitted to the IRB for prospective review. In some circumstances, changes to the protocol may disqualify the project from exempt status. Revisions in procedures that would change the review level from

exempt to expedited or full board review include, but are not limited to, the following:

- New knowledge that increases the risk level;
- Use of methods that do not meet the exempt criteria;
- Surveying or interview children or participating in the activities being observed;
- Change in the way identifiers are recorded so that participants can be identified;
- Addition of an instrument, survey questions, or other change in instrumentation that could pose more than minimal risk;
- Addition of prisoners as research participants;
- Addition of other vulnerable populations;
- Under certain circumstances, addition of a funding source.

Investigators who plan to make any of the above changes should contact the IRB staff so that the review level can be changed as necessary. If investigators are unsure of whether a revision needs to be submitted, they should contact the IRB staff for clarification.

1.6. Audit of Exempt Research Projects

The IRB maintains the authority to audit research determined to be exempt. If the audit reveals that the research activities differ from the application to the IRB for exempt status or if the principal investigators are not fulfilling the agreed-upon assurances for participant protection, the research will be considered in noncompliance and investigators may be required to halt the study pending further IRB review.

2. Expedited Review

2.1. Type of Research Which May Qualify for Expedited Review

In research studies qualifying for expedited review, human participants incur no more than minimal risk. Research activities that may qualify for expedited review are the following:

- Certain kinds of research on drugs and devices, though this category is rarely applicable.
- Collecting blood by stick or venipuncture with limits for age, health, and pregnancy status.
- The prospective collection of specimens for research purposes by noninvasive means.
- Data collected through noninvasive means (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding x-rays and microwaves.
- Materials (e.g., data, documents, records, or specimens) that have been

collected solely for non-research purposes such as medical treatment or diagnosis unless the information is considered sensitive and any breach of confidentiality would not be damaging to the subject.

- Collection of data from voice, video, digital, or image recording made for research purposes.
- Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program or human services evaluation, and quality assurance methodologies.

2.2. Documentation Required for Expedited Review

The required documentation for Expedited review will differ depending on the project activities, study populations, and other details. Please refer to the [Forms Checklist](#) for a list of the required documentation. **All submissions must be completed online using IRBNet.** If you are unsure of which documents to submit, please contact the IRB administrator at juirb@ju.edu.

2.3. Criteria Used for Review of Expedited Studies

Applications for expedited review will be reviewed by the IRB chair or by one or more experienced IRB Board members designated by the chair. The assigned reviewers may exercise all of the authorities of the IRB, except that they may not disapprove the research. Only the full Board may disapprove a study.

The following criteria are used in the review of expedited studies:

- Risks to subjects are minimized.
- Risks to subjects are reasonable in relation to the anticipated benefits;
- Selection of subjects is equitable.
- Documented, informed consent is obtained from each prospective subject or the subject's legal guardian or healthcare decision-maker.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative to the extent required by 45 CFR 46.116.
- Informed consent is appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.
- When appropriate provisions are made for the protection of the privacy of subjects and confidentiality of data is maintained.
- Provisions are made for monitoring the data collected to ensure the safety of subjects.
- Safeguards are included to protect members of vulnerable population groups (45 CFR 46.111).

2.4. Outcomes of Expedited Review

The review of studies by the designated reviewer will result in one of the following actions:

- Approval without changes;
- Approval with modifications;
- Approval contingent upon specific conditions; or
- Not approved.

If the study qualifies for expedited review and is approved, approval documents will be issued to the principal investigator via IRBNet. They can be found in the project's Reviews tab (left hand side of the screen) under the Board Documents section. These approval documents will include:

- An approval memorandum containing the investigator's name; the JU IRB number; the study title; the method of review (i.e., expedited review); the date the study may begin; the period for which the study is approved; and the date the first progress report is due.
- A stamped PDF version of the Informed Consent that must be used for all subjects. No changes should be made to this consent after it is stamped, and subjects should not be solicited to sign an unstamped consent form.
- A stamped version of any advertising materials to be printed or dispersed online.

Once the approval documents are received, the project may begin. The minutes of the Board meeting will reflect the approval of the study through the expedited process. If the study does not qualify for expedited review or if the research does not receive approval by the reviewer(s), a letter requesting additional information/clarification will be sent to the PI or the study will be prepared for full board review at the next scheduled IRB meeting. Additional information may or may not be requested from the PI in order to facilitate this next level of review.

Unless otherwise specified, the approval period for research approved is one year from the date of the approval memorandum sent by the IRB. In certain cases, the IRB may specify a shorter approval period. Such instances might include complex studies, studies that include vulnerable participants, and studies conducted at multiple sites. The IRB may also consider the qualifications of the responsible primary investigator and other members of the research team and the specific experiences of the RPI and other members of the research team in determining the approval period.'

If there is a change in RPI for a project, then the new RPI must re-submit the full Pro-App for the project for reconsideration under the new RPI. Submissions must be through IRBNet.

Any proposed amendments to the protocol or informed consent forms must be approved by the IRB prior to implementation. See Part V. Additional Administrative Actions Requiring IRB Review/Approval, Part A Review of Amendments/Revisions.

Any unexpected or adverse events must be reported to the IRB. See Part V. Additional Administrative Actions Requiring IRB Review and Approval, Part B Reporting Unexpected (Adverse) Events.

3. Full Board Review

3.1. Types of Research Which May Require Full Board Review

Research studies that involve greater than minimal risk for human participants require full Board review. Research that requires full Board review includes:

Some research involving children or other vulnerable populations

- Research that involves experimental drugs or devices.
- Research that involves invasive procedures.
- Some research that involves deception.
- Some survey research or interviews that involve sensitive questions, information about HIV, or result in distress for human participants.

3.2. Documentation Required for Full Board Review

The IRB administrators screen all applications before they are assigned to reviewers. Protocols are placed on the Board Agenda in the order they are received. The sooner a study is submitted in the cycle, the more likely it will be reviewed at the next Board meeting. Incomplete applications are returned to the principal investigator.

The required documentation for Expedited review will differ depending on the project activities, study populations, and other details. Please refer to the [Forms Checklist](#) for a list of the required documentation. **All submissions must be completed online using [IRBNet](#).** If you are unsure of which documents to submit, please contact the IRB administrator at juirb@ju.edu.

3.3. Criteria Used for Review of Full Board Studies

The following criteria are used in the full Board review:

- Risks to subjects are minimized.
- Risks to subjects are reasonable in relation to the anticipated benefits.

- Selection of subjects is equitable.
- Documented, informed consent is obtained from each prospective subject or the subject’s legal guardian or healthcare decision-maker.
- Informed consent will be sought from each prospective subject or the subject’s legally authorized representative to the extent required by 45 CFR 46.116.
- Informed consent is appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.
- When appropriate provisions are made for the protection of the privacy of subjects and confidentiality of data is maintained.
- Provisions are made for monitoring the data collected to ensure the safety of subjects.
- Safeguards are included to protect members of vulnerable population groups (45 CFR 46.111).

3.4. Outcomes of Full Board Review

The review of studies by the full Board will result in one of the following actions:

- Approval without changes;
- Approval with modifications;
- Not approved.

After a study is approved, approval documents will be issued to the principal investigator via IRBNet. They can be found in the project’s Reviews tab (left hand side of the screen) under the Board Documents section. These approval documents will include:

- An approval memorandum containing the investigator’s name; the JU IRB number; the study title; the method of review (i.e., full board review); the date the study may begin; the period for which the study is approved; and the date the first progress report is due.
- A stamped PDF version of the Informed Consent that must be used for all subjects. No changes should be made to this consent after it is stamped, and subjects should not be solicited to sign an unstamped consent form.
- A stamped version of any advertising materials to be printed or dispersed online.

Institutional notice regarding approved protocols will be given through minutes documenting the decisions of the IRB.

If the Board granted “approval with modifications,” then notes with the necessary modifications will be prepared and uploaded to IRBNet on the Reviews tab (left hand side of the screen) under “Board Documents.” Where possible, reviewers will make direct changes and comments to the documents electronically to assist in the revision process. A notice will be sent to the PI that the project has been unlocked on IRBNet and it will have specific

instructions for how to upload revisions and resubmit the packet.

If the changes to the documents are explicit, meaning the board was able to recommend the exact change they want to see, then the board may allow the revisions to be approved in an expedited process prior to the next full board meeting. If significant changes are needed or new language must be added, then the board may require it go back to full board. This will be up to the discretion of the Primary Reviewer assigned to the submission.

Unless otherwise specified, the approval period for research approved is one year from the date of the approval letter sent by the IRB. In specific cases, the IRB may specify a shorter approval period. Such instances might include complex studies, studies that include vulnerable participants, studies with high risk to participants, and studies conducted at multiple sites. The IRB may also consider the qualifications of the principal investigator and other members of the research team and the specific experiences of the PI and other members of the research team in determining approval period.

When the convened IRB disapproves or requires modifications to proposed research, PIs may appeal the IRB decision in writing to the IRB. All appeals of full board decisions will be reviewed by the full board. Only the IRB may change or overturn a decision not to approve a study. The Board is willing to meet with the investigator and discuss alternatives that might allow eventual approval of a rejected study. Written notification is also promptly provided to the institution when a study is not approved by the IRB. Investigators may have the opportunity to resubmit their study and appear before the Board to answer questions or discuss any concerns the Board has with the study.

Any proposed amendments to the protocol or informed consent forms must be approved by the IRB prior to implementation. See Part V. Additional Administrative Actions Requiring IRB Review/Approval, Part A Review of Amendments/Revisions.

Any unexpected or adverse events must be reported to the IRB. See Part V. Additional Administrative Actions Requiring IRB Review and Approval, Part B Reporting Unexpected (Adverse) Events.

C. Special Considerations for Vulnerable Populations

1. Definition of Vulnerable Populations

Federal regulations define vulnerable populations as the following:

- Children, including newborns and minors (anyone under 18 years of age), because of their vulnerability, diminished autonomy and incomplete

- comprehension;
- Pregnant women without regard to stage of pregnancy and viable fetuses, both in utero and ex utero;
- Cognitively impaired persons with conditions that affect their decision-making abilities;
- Incarcerated persons;
- Participants whose economic or educational conditions predispose them to certain incentives.

The IRB may identify potential participants as vulnerable if one or more of the following conditions apply:

- Cognitive or communicative vulnerability. Potential participants may be insufficiently able to comprehend information, deliberate, or express decisions.
- Institutional vulnerability. Individuals, including students, may be subject to the formal authority of others.
- Deferential vulnerability. Potential participants may be informally subordinate to another person.
- Medical vulnerability. Potential participants with serious health conditions for which there is no satisfactory standard treatment may not be able to adequately weigh risks and benefits or may mistake research for treatment.
- Economic vulnerability. Individuals may lack access to adequate income, housing, or health care and, if such benefits are available through research participation, may be unduly influenced.
- Social vulnerability. Stereotyping and otherwise devaluing participant groups may result in a risk/benefit ratio that would not be acceptable to the general population (see Bankert & Amdur, 2006).

The IRB is permitted to appoint expertise to advise the board as needed at any time. Additional advisory experts will not have the right to vote in IRB Decisions, but will serve as non-voting guests to the IRB meetings when considering specific projects.

2. Studies Involving Children

Special considerations must be made when performing research with children (less than 18 years of age)

2.1. 2011 Parental/Guardian Permission and Child Assent

Parental/Guardian Permission Form – For research studies that have greater than minimal risk to children as participants, provide two signature lines for parents/guardians. A reasonable effort must be made to obtain the signatures of both custodial parents. However, one parent’s signature is acceptable if the study is of minimum risk or of more than minimal risk but includes the prospect of direct benefit to participants and in cases where one parent is deceased,

unknown, incompetent, or not reasonably available, or where one parent has legal responsibility for the care and custody of the child. The IRB may waive parental or guardian permission when such permission is not a reasonable requirement to protect the participants (for example, neglected or abused children) provided an appropriate mechanism for protecting child participants is substituted [see [45 CFR 46.408\(c\)](#)].

Assent of the Child – for research studies that involve children ages 8 through 17. It is assumed that children ages 0 through 7 are not capable of giving formal assent but informal assent may be appropriate. The giving of formal and informal assent depends upon the subject’s level of maturity and judgment and should be made on a case-by-case basis.

2.2. Conditions for IRB approval of research involving children

The IRB can approve research involving children only if it meets the criteria for approval of research as outlined in [45 CFR 46.111](#) and it falls into one of the following four categories as described in [45 CFR 46.404-407](#).

- The research involves no more than minimal risk.
- The research involves more than minimal risk but has the potential of direct benefit to the individual participants.
- The research involves more than minimal risk and no prospect of direct benefit to individual participants but is likely to yield generalizable knowledge about the participant’s disorder or condition.
- Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

3. Studies involving Pregnant Women

3.1. Pregnant Women, Fetuses, and Human in Vitro Fertilization

Federal regulations require that IRBs treat pregnant women as a vulnerable population because of the need to avoid unnecessary risk to the mother and fetus. IRBs have additional duties in connection with activities involving fetuses, pregnant women, or human in vitro fertilization. Additional protections for these populations may include the use of witnesses for the consenting process, requiring consultants or patient advocates to monitor the consent process, and limiting the scope of research activities. In addition, principal investigators must give scientific justification for the exclusion of pregnant or potentially pregnant females in research studies [[45 CFR 46.201\(a,b\)](#)].

3.2. Conditions for IRB approval of research involving pregnant women and fetuses

Research involving pregnant women may be exempt if it meets the

criteria outlined in [45 CFR 46.101\(b\)](#) (1) through (6).

Research involving pregnant women or fetuses that is not exempt may be approved only if all of the conditions outlined in the Code of Federal Regulations are met (see [45 CFR 46.204](#)).

Pregnant women may also be enrolled in minimal risk studies when the enrollment of pregnant women is entirely coincidental and bears no relationships to the research.

4. Studies Involving Prisoners

4.1. Definition

A prisoner is defined in federal regulations as “any individual involuntarily confined or detained in a penal institution” [[45 CFR 46.303\(c\)](#)].

4.2 Membership of the IRB if the IRB reviews research involving prisoners

- At least one member of the Board shall be a person with appropriate background and experience to serve as a prisoner representative.
- If the Board does not include such a member, then an individual with appropriate background or experience will be used as a consultant in the deliberation about the proposed research [[45 CFR 46.107\(f\)](#)].

4.3 Conditions for IRB approval of research involving prisoners.

Research involving prisoners may be approved if the conditions outlined in the Code of Federal Regulations are met ([45 CFR 46.305](#)). Special considerations apply to biomedical or behavioral research on prisoners that is conducted or supported by the Department of Health and Human Services ([45 CFR 46.306](#)).

D. Submission Timeline – New Protocols

New protocols can be submitted at any time and will be processed in the order received during regular business hours. New protocols that require full board review are considered by the Board at the next scheduled meeting of the IRB provided they are received (2) weeks prior to the meeting. This gives the IRB members sufficient time to review proposed projects prior to discussion at the full board meeting. New protocols that are reviewed for exempt status and those that are reviewed as expedited will be processed expeditiously and in the order received.

IV. CONTINUING REVIEW

A. Reasons for Continuing Review

IRB review is a continuing process. Research projects that were approved by expedited or full board review are re-evaluated on a regularly scheduled interval, at least once per year, as required by the federal government. The level of risk of a study determines the schedule of review; studies presenting higher levels of risk for participants can be reviewed on a more frequent basis. Studies utilizing investigative devices that pose significant risk can be reviewed on a more frequent basis. Reasons for continuing review include:

- To ensure that the risk/benefit relationship is still acceptable;
- To ensure that participants remain protected from inappropriate risks;
- To determine whether new information that may be important to the subject has surfaced;
- To determine if unanticipated risks were discovered;
- To ensure the protocol that was previously approved is being followed; and
- To ensure that the project adheres to regulations and guidelines, which may have been altered since the project was previously approved.

Unless otherwise specified, the approval period for research approved is one year from the date of the approval letter sent by the IRB. In specific cases, the IRB may specify a shorter approval period. Such instances might include complex studies, studies that include vulnerable participants, studies with high risk to participants, and studies conducted at multiple sites. The IRB may also consider the qualifications of the principal investigator and other members of the research team and the specific experiences of the PI and other members of the research team in determining the frequency for continuing review.

The interval for continuing review (the submission of a progress report) is made at the time of initial IRB approval but may be changed upon subsequent IRB review. The IRB has the authority to suspend, terminate, or place restrictions on a study that has previously been approved for reasons of noncompliance or if deemed necessary to ensure protection of human research participants.

B. Documentation Required for Continuing Review

The following information is required for the submittal of continuing review reports:

- Continuation Request Form
- Research Protocol (most recently approved version)
- Data collection sheet
- Informed Consent – clean copy
- Informed Consent – most recently signed by a subject with date visible but participant's name redacted

If the PI wishes to make amendments to the research protocol, personnel, or procedures then they must complete the necessary steps for an Amendment/Modification, found in Part V.B of this document.

C. Submission Timeline – Continuing Review

Continuing review reports should be submitted with enough time for re-review before the project will expire. The date of a project's expiration is always stated in the previous approval memorandum. A reminder that a continuing review report is due will be sent to the responsible primary investigator (and/or the lead student investigator, if included on IRBNet) before the study will expire via an automated message from IRBNet. This is to allow adequate time for submission and review. It is the responsibility of the responsible primary investigator to submit the continuing review packet before the deadline. It is recommended that investigators, especially those submitting large numbers of protocols, develop their own tracking mechanism for the submission of continuing review reports. Note: Studies that are closed to subject entry but continue to follow participants are still considered to be active studies and must remain in the continuing review process.

D. Consequences of Late Progress Reports for Continuing Review

The IRB has the regulatory responsibility to suspend or terminate approval of research for noncompliance with federal regulations and guidelines and institutional directives regarding continued approval. **The submission of Continuing Review requests is the responsibility of the investigator.**

The regulations permit no grace period after approval expiration. If continuing review is not completed before the expiration date of previous approval, the project will expire and all research activities, including participant recruitment, experimental manipulation/treatment, data collection and data analysis of identifiable private information must cease. An exception may be made if the cessation of treatment poses a threat to the life or welfare of a subject. Failure to cease research activities upon expiration constitutes noncompliance and may jeopardize the investigator's ability to submit further protocols to the IRB and, in the worst case, may result in termination of protocols in the midst of data collection.

After a period of 60 days following expiration, if a status report including an explanation for the lapse has not been received, the protocol shall be administratively closed. After closure, the file is no longer an open record, and a new protocol must be submitted and approved in order for research to continue. The administrative closure of a protocol will be provided in writing and shall include a statement of the reason(s) for the IRB's action. This action will be reported promptly to the investigator and any appropriate sponsoring agency.

E. Evaluation of Continuing Review Packets (Progress Reports)

1. Determining the Type of Review

1.1. Expedited Studies

The review of studies that were originally approved on an expedited basis are screened by the IRB administrators to ensure that risks to participants remain minimal and can be approved on an expedited basis by the IRB chair or designated IRB member.

1.2. Full Board Studies

The review of studies that were originally approved on a full Board basis are screened by the IRB administrators to ensure that the project poses more than minimal risks to participants, therefore requiring full Board review. Some studies originally approved on a full Board basis may qualify for expedited review as a result of the minimal risk associated with remaining study activities. Such studies can be approved on an expedited basis by the IRB Chair or designated IRB member.

2. Criteria Used for Continuing Review

The criteria for the continuing review of projects are the same as those for initial review.

- Risks to subjects are minimized.
- Risks to subjects are reasonable in relation to anticipated benefits to subjects and to research in this area.
- Selection of subjects is equitable.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with [45 CFR 46.116](#).
- Informed consent will be appropriately documented in accordance with [45 CFR 46.117](#).
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- When appropriate, adequate provisions are made to protect the privacy of subjects and to maintain the confidentiality of data.
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence (such as children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons), additional safeguards have been included to protect the rights and welfare of these participants ([45 CFR 46.111](#)).

3. Outcomes of Continuing Review

The continuing review of studies by the full Board will result in one of the following actions:

- Approval without changes;
- Approval with modifications; or

- Not approved (a decision that can be made only by the full board).

After a study is approved, a notice is sent to the principal investigator informing of the continued approval of the study by the IRB and the institution is notified via the IRB Minutes. Each approval notice includes the following stamped and dated documents:

- An approval memorandum containing the investigator's name; the JU IRB number; the study title; the method of review; the effective date of the continuation; the period for which the study is approved; and the date the next progress report is due.
- Any new study documents approved such as a revised research protocol, revised consent and assent forms, revised instruments, and revised recruitment materials.

If modifications are requested, the notice should identify changes to be made to appropriate study documents.

When the IRB disapproves or requires modifications to continuing research, PIs may appeal the IRB decision in writing to the IRB. All appeals of full board decisions will be reviewed by the full board. Only the IRB may change or overturn a decision not to approve a study. The Board is willing to meet with the investigator and discuss alternatives that might allow eventual approval of a rejected study. Written notification is also promptly provided to the institution when a study is not approved by the IRB. Investigators may have the opportunity to resubmit their study and appear before the Board to answer questions or discuss any concerns the Board has with the study.

V. ADDITIONAL ADMINISTRATIVE ACTIONS REQUIRING IRB REVIEW/APPROVAL

A. Review of Revisions/Additional Information

Revisions are changes made to a project that has not yet received IRB approval or an exemption in order to receive an approval or an exemption. Revisions or additional information will be requested in a message from the IRB Administrator via IRBNet with specific instructions on how to access the reviewer comments and documents, as well as how to upload revisions and resubmit.

1. Information Required

Investigators will receive a written notice with this status if a document or specific information is missing from a submission. This status only occurs during the Administrative review stage, prior to the packet being forwarded on for a member of the IRB's review. Investigators will need to submit updated versions of any documents revised since the previous package submission and any new information or documents not submitted in previous packages. If a document remains unchanged from the initial submission package and no revisions were requested to that document, it will not be necessary to submit an updated version of that document in subsequent packages.

2. Modifications Required

Investigators will receive a written notice with this status if an IRB Reviewer has gone through the submission and requested specific revisions or additions to the packet. This notice will include specific instructions of how to access the revisions requested and how to resubmit the packet as needed. If a document remains unchanged from the initial submission package and no revisions were requested to that document, it will not be necessary to submit an updated version of that document in subsequent packages.

3. Timeline for Revisions

Revisions and/or additional information as described above must be submitted within 90 days of written communication to investigator. The investigator can email an IRB administrator (juirb@ju.edu) to request additional time if that request is submitted at least 7 days before the 90 day deadline. If the revisions are not submitted within 90 days and the investigator has not contacted an IRB administrator within the appropriate period to request additional time, the project will be administratively withdrawn.

B. Review of Amendments

An amendment is a change made to a project that was previously approved or declared exempt. Any proposed changes to the protocol, advertisements, consent form(s), or other study related material must be promptly submitted to the IRB for review. Changes in approved research cannot be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards.

1. Documentation Required

Changes in an IRB-approved protocol and IRB-approved consent documents should be initiated by completing the [Amendment Request Form](#). Changes should not be implemented prior to receipt of IRB approval.

Along with the Amendment Request, any documents that have content affected by the amendment should also be uploaded and reflect the changes necessary. This includes any changes in protocol, personnel, or procedure. These documents will be uploaded as a new packet, but a part of the same project on IRBNet. For clarification on this, please contact the IRB Administrator (juirb@ju.edu).

2. Type of Review

The decision regarding whether an amendment will be reviewed as expedited or by the Full Board is made by the IRB administrators in consultation with the IRB chair and/or Vice Chair.

2.1. Administrative – for minor changes to Exempt studies or for personnel changes to Expedited/Full Board only.

Minor changes to Exempt may include:

- Change in personnel
- Change in inclusion criteria (but still same type of data collection / intervention)

2.2. Expedited – if the project was initially Expedited/Full Board and the changes are minor.

Minor changes may include:

- Changes in the investigatory team;
- Administrative changes (e.g., names of contact individual's phone numbers, and addresses);
- Changes in study-related activities (e.g., extra visits, additional questionnaires or subject diaries, or additional low risk activities such as blood draws).

2.3. Full Board – if the project was initially Full Board and changes are found to be significant.

Significant changes may include:

- Fundamental changes in the study design;
- Some new dosing regimens;
- Addition of substantial numbers of new participants; or
- New treatment groups.

The actions of the Board are noted in the minutes.

C. Reporting Unexpected Adverse Events

Investigators must report to the IRB any unanticipated problems involving risks to participants or others. It is important to delineate the definitions that inform reporting requirements. In particular, it is important to understand the difference between unanticipated problems and adverse events because many adverse events are not reportable.

1. Definitions

1.1. Unanticipated Problem.

According to federal guidance, unanticipated problems involving risks to participants or others refers to any incident, experience, or outcome that:

- Is unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Is related or possibly related to a subject's participation in the research; and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

1.2 Adverse Event.

An adverse event is any undesirable and unintended consequence of, or reaction to, procedures experienced by the research participant/subject. These incidents may involve (but are not limited to) the conduct of the study, or the subject's participation (i.e., problems with recruitment and/or consent process). Such events do not have to be physical in nature; an event may involve psychological harm and threats to privacy or subject safety.

1.3 Differentiating between an Unanticipated Problem and an Adverse Event.

By definition, an unanticipated problem is unexpected, whereas an adverse event may be anticipated or unanticipated. Additionally, an unanticipated problem may involve the increased risk of harm whether or not any actual harm occurred. Examples of unanticipated problems that should be reported to the IRB include the following:

- Publication in the literature, data safety monitoring report, interim result, or other finding that indicates an unexpected change to the risk/benefit ratio of the research.
- Breach in confidentiality resulting from a disclosure of confidential information or from lost or stolen confidential information that may involve risk to that individual or others.
- Complaint of a participant or family member that indicates an unanticipated risk;
- Disqualification or suspension of investigators.
- Accidental or unintentional change to the IRB-approved protocol that involves risks or has the potential to recur.
- Deviation from the protocol taken without prior IRB review to eliminate apparent immediate hazard to a research participant.
- Any deviation from the IRB-approved protocol that increases the risk or affects the participants' rights, safety, or welfare.

2. Required Reporting of Unanticipated Problems.

Reporting is required of all unanticipated problems, including those which may occur after the participant has completed or has withdrawn from the study. This reporting is carried out through a written notice to the IRB administrators using the [Event Report Form](#).

- Unanticipated problems involving increased risks to participants or others shall be reported to the IRB within 3 business days or as soon as practicable after the investigator has become aware of the event.
- Any other unanticipated problem shall be reported to the IRB within 1 week of the investigator becoming aware of the problem.

3. IRB and Institutional Responsibilities.

The chair or designee(s) of the IRB will review all reports of unanticipated problems. If a reported event poses serious risk to subject safety, the chair or designated subcommittee may immediately suspend the study.

Any unanticipated problem involving more than minimal risk(s) to participants or others will be reviewed by the convened IRB. For unanticipated problems

referred to the convened IRB, all members will receive the application and consent form, where relevant, and materials describing the unanticipated problem as well as any correspondence with the investigator to date.

- In most cases, the chair or designee(s) of the IRB will review a corrective action plan with the PI in order to resolve the immediate scenario and prevent future occurrences.
- Documentation of these events and their resolution will be recorded in the minutes of the next convened IRB meeting.
- The IRB has the authority to suspend or terminate IRB approval of protocols that are found to pose unanticipated or heightened risk.
- Other actions that may be required by the IRB include but are not limited to:
 - Modification of the research protocol;
 - Modification of the information disclosed during the consent process;
 - Additional information provided to past participants;
 - Notification of current participants, which is required when such information might relate to participants' willingness to continue to take part in the research;
 - Requirement that current participants re-consent to participation;
 - Modification of the continuing review schedule;
 - Monitoring of the research;
 - Monitoring of the consent;
 - Obtaining more information pending a final decision;
 - Referral to other organizational entities (e.g., JU General Counsel, Institutional Official); and
 - Requirements for additional training for investigators and/or research staff.

Determinations from the convened IRB meeting are documented in the minutes.

The Institutional Official is responsible for all required reporting of unanticipated problems involving risks to participants or others and the resulting IRB actions to the appropriate federal agencies.

VI. CLOSING OUT A STUDY

Filing a closing report is an important element of the research study process. Besides informing the IRB that a study has concluded, it provides data on local subject ethnicity and gender, adverse events, and other information accumulated during the study. Federal guidelines require that terminated studies be reported to the FDA and OHRP, as well as to the sponsor and other institutional officials. The procedure for a closing reporting is very similar to that of continuing review. The same documentation required for continuing review is used. Data on subject recruitment, adverse events and other information must be provided when this final report is filed. Closing reports are reported to the Board.

For research projects approved as expedited or full IRB, close of the study should be reported at the conclusion of all study related activities. Once a study is closed, the file is withdrawn from the active IRB files and placed in archive for a minimum of three (3) years. The university is required to

maintain files until a specified period of time has passed after completion of the study or project. Thus, it is essential that closing dates be provided to the IRB.

VII. PROTOCOL DEVIATION

Any protocol deviation that results in a change to the risk/benefit ratio or affects the integrity of the study should be promptly reported to the IRB by the investigator. In addition, the deviation should be reported to any other required entity (e.g., the funding agency) by the investigator. In addition, any deviations that will become implemented into the project protocol must be submitted via and Amendment Request Form, as mention in section IV.B.

VIII. MONITORING OF STUDIES AND/OR REPORTING NONCOMPLIANCE

The IRB has the authority to monitor study records to:

- Verify that no material changes have occurred since the previous IRB approval;
- Verify compliance with the approved protocol;
- Verify the informed consent;
- Exercise appropriate administrative overview to ensure that JU policies and procedures designed for the protection of the rights and welfare of human participants are being effectively applied; or Verify compliance with IRB policies and procedures and federal regulations.

Under certain conditions, the IRB may seek verification from sources other than the principal investigator to ensure that measures for the protection of human participants are being followed and appropriately documented and that no material changes have been made to a protocol and affiliated documents since previous IRB review. Such verification may be sought for a random selection of studies, for studies which are highly complex, or for protocols or principal investigators with a history of concerns regarding compliance.

The IRB has the authority to suspend or terminate protocols that are found to be non-compliant with institutional policies and procedures, state laws, and/or federal laws or regulations. Other sanctions imposed by the IRB may include, but are not limited to, compliance audits, letters of reprimand, and restrictions on serving as an investigator on human subjects protocols. The IRB is responsible for reporting to appropriate officials, the FDA (if appropriate), and OHRP (if appropriate):

- Any unanticipated problems involving risks to human participants or others;
- Any instances of serious or continuing noncompliance with regulations or determinations of the IRB; and
- Any suspensions or termination of IRB approval.

The chair of the IRB will review allegations of noncompliance. The chair makes a determination as to whether the alleged practices appear to (1) cause injury or any other anticipated problems involving

risks to participants or others or (2) constitute serious or continuing noncompliance with IRB regulations. The IRB chair will consult additional Board members to discuss the need for a suspension. Following the consultation, the chair could suspend the study until a timely investigation and review by the convened IRB.

IX. IRB ADMINISTRATION

A. Resources

Jacksonville University provides staffing, office space, computer equipment, filing cabinets and sundry supplies to support the effective administration of the IRB. The Office of Research and Sponsored Programs is responsible for the administrative support of the IRB.

As appropriate and when institutional resources permit, a faculty associate may be appointed to work with the IRB staff and members. The faculty associate may provide training for staff members, IRB members, faculty, and students and will serve as a liaison to faculty and departments within the institution.

B. IRB Relationship to JU

The IRB is comprised of individuals who serve voluntarily from JU and the community. Board determinations are made autonomously, without influence from JU administration. No officials, committees, or others have the authority to approve any human subject research that has not been approved by the JU IRB. This includes the Institutional Official. The IO has the authority to request a re-review of a project submission if they have reason to believe the review was not conducted according to the JU IRB's standard operating procedure. However the IO cannot approve research solely.

C. Membership

No fewer than five (5) members of varying backgrounds shall be appointed to the IRB as described in section I.B of this document. Each faculty member should be tenure-track.

Alternate members may be appointed to the IRB following the same procedures that apply to members. Alternate members are appointed to serve only for named members or roles of the IRB (e.g., nonscientist, community member). Alternate members may vote only when they are representing the named member.

The IRB may, at the request of members or the discretion of the chair, invite individuals with competence in specific areas to assist in the review of issues that require expertise in addition to that available on the IRB. No consultant shall be employed who has a relevant conflict of interest in reviewing the research at issue. Consultants may provide comments in writing or in person at a convened meeting of the IRB. Consultants may not vote with the IRB.

1. The Chair

1.1. Appointment

The Institutional Official appoints the chair of the IRB, typically for the term of two years. Under special conditions, a one-year appointment may be made. The IO may remove the chair for nonperformance of his/her IRB (or other associated) duties. The chair is required to have a faculty commitment to the Institution. As appropriate and agreed upon by the chair, the chair's department chair, and the IO, the chair may be compensated for service through reassigned time or receipt of a stipend.

1.2. Responsibilities

The IRB Chair is required to complete mandatory OHRP training associated with the federal assurance process and to maintain current certification through the Collaborative Institutional Training Initiative (CITI) modules or other IRB-approved training. The IRB Chair should participate in other training as available and appropriate.

The responsibilities of the IRB chair are defined as follows:

- Convene and chair the IRB meetings.
- Communicate the decisions of the Board to the investigators.
- Develop and initiate appropriate changes in IRB policy in consultation with the institutional official.
- With the assistance of the IRB administrators, prepare the annual report to the IO, which includes a list of the members, accomplishments, recommendations, problems, concerns and future strategies.
- Review continuing review reports that may be reviewed on an expedited basis (45 CFR 46.110 and 21).
- Appoint appropriate Board members to review continuing review reports and serve as primary reviewer for full Board presentation of continuing review reports that require full Board review.
- Determine which studies need verification from sources other than the investigators that no material changes have occurred since the previous IRB review.
- Review and approve closing reports.
- Provide expedited review of new protocols in conjunction with other members of the board.
- Review and approve requests for exemption from review.
- Represent the IRB, in collaboration with the IO, in intra- and extra-mural deliberations with individuals or agencies regarding IRB activities or protocol management.
- Monitor federal regulations and changes therein that impact the Board activities and administrative management of protocols and report these changes, as appropriate, to all IRB members.
- Make recommendations for Board membership.

2. Board Members

2.1. Appointment

The Institutional Official appoints board members for a term of up to three years. The Board shall include sufficient numbers of members to provide adequate review of protocols. Expertise shall be appropriate to the types of protocols reviewed and, in addition, there shall be expertise in legal, ethical, and behavioral areas.

Appointment will take the form of a written letter, signed by the IO, detailing the specific role and parameters of the appointee.

2.2. Recruitment

The key mechanism for recruitment of IRB Members will be appointing substitute members. These substitutes will either become full board members or assist in the nomination of other persons to fill the vacancy when a current full board member rolls off. Details of the role and responsibilities of Substitute Board Members are detailed in section VII.C.3 of this document.

When additional new members are needed outside of just rolling a Substitute Board Member into a Full Board Member seat, the IRB Administrator will approach the IRB, asking for recommendations/nominations at a full board meeting. Recruitment will be exclusively by IRB nomination. The nominee will then be contacted by the IRB Administrator and appointed by the IO.

2.3. Responsibilities

2.2.1 Attendance

It is the responsibility of each member to attend all meetings of the IRB. In the event that a member cannot attend, the IRB administrator should be notified prior to the distribution of protocols for review. Members who miss successive meetings or have a high incidence of absenteeism will be contacted with regard to future service on the committee, and may be replaced.

2.3.2. Full Board Review

Full Board Reviews involve all members of the IRB reviewing the documents for a protocol. However, one member will be assigned as the "Primary Reviewer." This person will scrutinize the project the most and will ultimately make a recommendation to the rest of the IRB as to what the determination should be. It is critical that members review those protocols for which they are responsible as soon as they are received so that they may contact other members of the IRB, contact the investigator, or ask the IRB Chair or IRB coordinator to contact the

investigator, if necessary, to clarify any issues well before the meeting. A lead reviewer will be appointed by the IRB administrators in consultation with the IRB chairs for each protocol requiring full board review.

2.3.3. Expectations of Lead Reviewers

Lead reviewers are expected to do the following:

- Present the protocol to the rest of the convened Board at the meeting and provide a recommendation for approval, approval with modifications or disapproval based on the evaluative criteria defined in [45 CFR 46.111](#).
- Assess risks to subjects are minimized.
- Assess risks to subjects are reasonable in relation to the anticipated benefits.
- Ensure selection of subjects is equitable.
- Ensure that documented, informed consent is obtained from each prospective subject or the subject's legal guardian or healthcare decision- maker, to the extent required by [45 CFR 46.116](#).
- Ensure that informed consent is appropriately documented, in accordance with, and to the extent required by [45 CFR 46.117](#).
- Verify that appropriate provisions are made for the protection of the privacy of subjects and confidentiality of data is maintained.
- Verify that provisions are made for monitoring the data collected to ensure the safety of subjects.
- Ensure that safeguards are included to protect members of vulnerable population groups ([45 CFR 46.111](#)).
- Review all consent forms for general adherence to IRB guidelines and for ethical/scientific concerns and provide written editorial comments as appropriate on the consent forms for the protocols that they are charged with reviewing.
- Complete any IRB reviewer checklist with respect to the protocol and subject consent form and its contents.
- Treat all material as strictly confidential. None of these materials are to be treated as refuse, but must be either shredded or returned to the IRB office for shredding.
- Evaluate scientific validity to the extent that if the project is judged as frivolous (e.g., clearly provides no scientific or clinical benefit), the study is not acceptable ethically because the risk-benefit ratio for subjects would not justify approval for participation.
- Seek additional information or clarification about the project as needed by contacting the principal investigator directly or

through the IRB Chair or IRB administrator prior to the meeting. If the questions or issues are not adequately addressed in that interaction, the reviewer should confer with the Chair

- Notify the chair if an outside consultant is needed. The consultant may be invited to attend the meeting to discuss the protocol. In either case, the consultant will be acting as an ad hoc member and will not be afforded voting privileges.
- Notify the IRB administrator if the investigator should be invited to the Board meeting to provide clarification of a study.
- Lead discussion of the protocol and supporting materials at the meeting and respond to questions from other members.

2.3.4. Expedited Review

Members are not required to review Expedited Review projects, though it is strongly encouraged. When a member is first appointed, there will be a probationary period of six (6) months where the new member will be assigned to Expedited Reviews in tandem with a Full Board Member that is approved to review Expedited Reviews. At the end of this six month period, the tandem Full Board Member can recommend the IRB grant Expedited Review privileges to the new member.

Expedited Reviews must be conducted within 5 to 7 business days after the project is assigned to the reviewer. If the reviewer is not able to conduct the review in that time period, it can be re-assigned to another member of the IRB.

In Expedited Reviews, the assigned member of the IRB that is the “Primary Reviewer” goes through all the documentation of the submission and checks it for completion and compliance issues. They provide any necessary feedback to the RPI via the IRB Administrator, so as to maintain anonymity. Finally the Primary Reviewer will make a determination and the IRB Administrator will issue documents accordingly. The review will be documented in the agenda of the next meeting as notice to the rest of the IRB that the review took place. At that time, anyone in the IRB can challenge the review or request more detail.

2.3.5. Responsibilities in Voting for All Board Actions

After presentation of a protocol and consent form at the meeting, any member may make a motion to:

- Approve the study;
- Approve with modifications to the study; or
- Disapprove the study in current form, providing feedback for revisions

Following standard rules, a vote will be taken and the numbers of ayes,

nays and abstentions recorded along with the members who are voting on the motion. A majority is more than one-half of the members in the room. The IRB Chair's vote will count twice in the situation of a "tie vote" by the Board. Proxy votes are not allowed. Any member who is out of the room is neither counted in the quorum nor counted in the vote.

No additional review/approval of IRB actions by others within the institution is required, and override of disapprovals is prohibited.

2.3.6. Conflict of Interest

Members; that are investigators on a project, or; with whom an investigator is a partner, or; who works closely with the investigator may wish to abstain from deliberations and voting. There will be no specific requirement to abstain simply by virtue of departmental or divisional affiliation. However, members should seriously consider their collaborative relationships with investigators and act responsibly and in accordance with state law and university policy with regard to conflict of interest.

Any individual with a personal conflict of interest must abstain from the vote and should not be present during discussion of the protocol unless requested to provide information by the IRB [45 CFR 46.107(e)]. The only required absence from the meeting room during discussion about the study and voting is that of investigators on the protocol and those with a conflict of interest. A notation in the minutes will be made of any member who chooses to abstain for reasons of conflict of interest (COI).

2.3.7. Educational Responsibilities

Members are required to maintain current certification through CITI and other requirements as established by the Office of Human Research Protection or through other federal and state regulations. Members are given an IRB manual of regulations and supplementary materials. Members are expected to attend scheduled sessions for education in ethics and regulatory compliance. These sessions are designed to ensure that all members have sufficient background and awareness of trends in both the principles of and regulations for protecting human research participants.

3. Substitute Board Members

3.1. Appointment

The IO appoints substitute board members for a term of up to three years. The Board shall include sufficient numbers of members to provide adequate review

of protocols. Expertise shall be appropriate to the types of protocols reviewed and, in addition, there shall be expertise in legal, ethical, and behavioral areas. Substitute Board Members should have a similar expertise to a corresponding Full Board Member for which they can sit-in to perform board actions.

3.2. Recruitment

Substitute Board Members will be nominated by their corresponding Full Board Member. Recruitment will be word of mouth until brought before IRB Board for public nomination. Upon the agreement of the IRB to nominate a Substitute Board Member, the IRB Administrator will then contact the member and proceed to obtain written appointment by the IO.

3.3. Responsibilities

3.3.1. Attendance

Substitute Board Members must be able to attend any meetings which their corresponding Full Board Member cannot attend. If their Full Board Member is never absent, the Substitute Member still must attend two IRB meetings in a given calendar year to remain in good standing with the IRB.

3.3.2. Full Board Review

Substitute Board members are required to review any Full Board Review projects on the agenda for a given meeting where the Substitute is sitting in for the Full Board Member. The Substitute Member is expected to be have read and reviewed the materials provided, and be prepared to give insight based on the expertise of that given seat on the IRB.

3.3.3. Expedited Review

Substitute members are not required to review Expedited Review projects, though it is strongly encouraged. When a substitute member is first appointed, there will be a probationary period of six (6) months where the Substitute Member will be assigned to Expedited Reviews in tandem with a Full Board Member that is approved to review Expedited Reviews. At the end of this six month period, the tandem Full Board Member can recommend the IRB grant Expedited Review privileges to the Substitute Member. Expectations for a Substitute Member conducted Expedited Reviews are the same as for a Board Member.

3.3.4. Responsibilities in Voting in All Board Actions

Substitute Members only hold the power to vote at Full Board Meetings where their corresponding Full Board Member is not present. In those situations where a Substitute Member is sitting in for a Full Board

Member, their voting responsibilities will be the same as if they were the Full Board Member.

After presentation of a protocol and consent form at the meeting, any member may make a motion to:

- Approve the study;
- Approve with modifications to the study; or
- Disapprove the study in current form, providing feedback for revisions

Following standard rules, a vote will be taken and the numbers of ayes, nays and abstentions recorded along with the members who are voting on the motion. A majority is more than one-half of the members in the room. The IRB Chair's vote will count twice to break a "tie vote" by the Board. Proxy votes are not allowed. Any member who is out of the room is neither counted in the quorum nor counted in the vote.

No additional review/approval of IRB actions by others within the institution is required, and override of disapprovals is prohibited.

3.3.5. Conflict of Interest

Substitute Members; that are investigators on a project, or; with whom an investigator is a partner, or; who works closely with the investigator may wish to abstain from deliberations and voting. There will be no specific requirement to abstain simply by virtue of departmental or divisional affiliation. However, members should seriously consider their collaborative relationships with investigators and act responsibly and in accordance with state law and university policy with regard to conflict of interest.

Any individual with a personal conflict of interest must abstain from the vote and should not be present during discussion of the protocol unless requested to provide information by the IRB [45 CFR 46.107(e)]. The only required absence from the meeting room during discussion about the study and voting is that of investigators on the protocol and those with a conflict of interest. A notation in the minutes will be made of any member who chooses to abstain for reasons of conflict of interest (COI).

3.3.6. Educational Responsibilities

Members are required to maintain current certification through CITI and other requirements as established by the Office of Human Research Protection or through other federal and state regulations. Members are given an IRB manual of regulations and supplementary materials. Members are expected to attend scheduled sessions for

education in ethics and regulatory compliance. These sessions are designed to ensure that all members have sufficient background and awareness of trends in both the principles of and regulations for protecting human research participants.

D. IRB MEETINGS

IRB meetings will be scheduled for at least once a month during the academic year and once a month in May, June, and July. The IRB will not meet during August unless needed. The schedule of IRB meetings for the semester will be posted on the IRB web site. Guests may attend the meetings with the permission of IRB administrative staff and the IRB chair. Project RPIs and investigators may attend meetings but must leave the room during deliberation of their project.

The duration of the meeting is 2 hours standard in the case of full board review(s) and 1 hour standard for meetings with no full board reviews. All members should expect to be available for the entire meeting. Attendance is required by at least one non-scientist for the IRB to obtain a functional quorum. A quorum for each IRB meeting is greater than one-half of the number of voting IRB members. Any decision made by an IRB must be made with both a numerical and a functional quorum. If either quorum is lost, no decisions can be made until a quorum is reconstituted. Otherwise, the meeting must be adjourned.

As approved by OHRP, the Board reserves the option of holding a convened IRB meeting via a telephone conference call or videoconferencing. For such a meeting, each member must 1) receive all pertinent material prior to the meeting and 2) be able to actively and equally participate in the discussion of all studies. Minutes of such meetings must clearly document that these two conditions have been satisfied in addition to the usual regulatory requirements (e.g., attendance; initial and continued presence of a majority of members including at least one non- scientist member, and individual from outside the institution; actions taken by the IRB; the vote on such actions; discussion and resolution of controverted issues).

All members receive the following documentation for review before the meeting: the meeting agenda; minutes from the previous IRB meeting; documentation for each protocol to be reviewed by the Full Board via IRBNet.

The lead reviewer for a study funded by Health and Human Services (HHS) or other federal grant may receive a copy of the grant application. The complete documentation is available to all Board members for their review, both before and during the meeting via IRBNet.

Minutes are maintained for all IRB meetings as outlined in subsection E. Minutes are a primary way the IRB informs institutional members, including the institutional official and university administrators, about IRB deliberations, considerations, and actions.

E. IRB Recording Requirements

The ORSP shall maintain the following records and documents:

- A list of the current IRB members and their qualifications (e.g., earned degrees, representative capacity, indications of experience such as Board certifications and licenses sufficient to describe each member's anticipated contribution to IRB deliberations and any employment or other relationship between members and JU).
- Written standard operating procedures for the IRB.
- The most recent version of IRB forms.
- Agendas and minutes of the meeting including attendance of members, recorded discussion of issues including discussion of controverted issues, records of IRB decisions, and records of the vote along with the members who are voting on the issue. Minutes should provide sufficient detail to show attendance (including any consultants/guests shown separately) at the meetings; absences during the meeting; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution. The minutes should include documentation of actions since the last convened meeting, including exemptions granted, expedited protocols approved, and protocols requiring continuing review that have been extended.
- All documentation surrounding federal assurances.
- Any agreement documents generated in the conduct of the IRB policy and procedures.
- Archival copies of study files up to 5 years after close of the study for federally funded studies and 3 years for non-funded projects.
- Records of complaints regarding IRB policy and regulation.
- FWA and related documents and correspondence.
- All IRB files, open and archived, including the following information:
 - All research proposals, investigator brochures, consent forms, adverse events reports, budgets, copies of correspondence, including verification of review, between the Board and the investigator, and any other correspondence relevant to IRB business;
 - Statements of significant new findings provided to participants whenever appropriate; and
 - Records of continuing review activities.

F. Appeal of IRB Decisions and Processes

When the convened IRB disapproves or requires modifications to proposed research, PIs may appeal the IRB decision in writing to the IRB. All appeals of full board decisions will be reviewed by the full board. Only the IRB may change or overturn a decision not to approve a study. Institutional officials may, however, overturn approval of a protocol by the IRB.

Appeals on procedural matters should be directed by the institutional official. The IO is responsible for matters of research integrity and the IO has the authority to require an IRB to reconsider a protocol if evidence suggests that the IRB did not follow established procedures

or acted in violation of federal regulations or JU institutional policy.

G. Internal Monitoring of Compliance and Annual Reports

1. Internal Audit Procedures

The IRB can vote to audit any project in their oversight, active or closed, at any time. The Institutional Official can also request an audit of any project where they believe the oversight has not been conducted according to established procedure or in accordance with federal regulation. In the process of an audit, the RPI and any other investigators are required to comply and turn over any documents that are a part of the research or that the IRB perceives as being pertinent to a review of the study. The IRB reserves the right to suspend or withdraw approval from a study at any time.

Should an investigator feel that the review of their project by the IRB has been unfair, they may appeal the decision to the Institutional Official in written notice with the IRB Administrator and the IRB Chair included in carbon copy. The IO cannot approve any study.

2. Revisions to Standard Operating Procedures

The standard operating procedures are reviewed annually by the IRB administrators in conjunction with the IRB chair and revised when warranted. Approval of the standard operating procedures, either new or revised, requires review and signature of the (a) the institutional official and (b) the JU General Counsel. Each revised standard operating procedure will supersede all previously-approved versions and will be effective on the date of the most recent signature.

3. Revisions to IRB forms

IRB forms are reviewed annually by the IRB administrators in conjunction with the IRB and revised when warranted. Approval of IRB forms, either new or revised, will be effective when approved by the IRB Chair.

X. RESPONSIBILITIES OF KEY INDIVIDUALS

The following are responsibilities of individuals who are associated with the IRB or who conduct research using human participants:

A. Responsible Primary Investigators

The responsible primary investigator (RPI) is the individual directly held responsible for the conduct of research and, as such, must personally conduct or supervise the research. The definition and requirements for the term “RPI” can be found in the [JU IRB Definitions](#). RPIs have the following responsibilities related to the IRB review process:

- Obtain and maintain certification through CITI before initiating research involving human participants.
- Review training materials and federal regulations regarding the protection of human research participants. Attend training sessions when provided by the institution.
- Review relevant federal regulations, legislation, and institutional assurance documents pertinent to the proper conduct of research in human participants, particularly those that are pertinent to subject populations involved in investigator's research studies (e.g., children, cognitively impaired individuals, the emergently ill, pregnant women, fetuses and others).
- Submit and maintain active research protocols for human subjects research.
- Provide timely submission of continuing review reports so that there is not a lapse in approval for the research
- Train project staff members appropriately to ensure they are acting in congruence with current IRB policies and procedures.
- Submit timely IRB documentation.
- Assure the accuracy and completeness of all documents to the IRB.
- Use the most current version of IRB forms.
- Communicate IRB approvals to sponsors, unless sponsor requests a direct response
- Ensure that permission is obtained to use copyrighted materials
- Ensure that changes in approved research are not initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards.
- Provide written notification of a change in association with a research study or with the institution. These changes are recorded in the Board minutes.
- Promptly notify the IRB of protocol deviations that affect the risk/benefit ratio to participants or the integrity of the research study.
- Promptly inform the IRB of unanticipated problems involving risks to human participants or others. RPIs must notify the IRB when there is to be a review of their study by any regulatory agency. Routine "site visits" and the outcomes must be reported on the Continuing Review Form or Closure Request Form. A copy of all correspondence relating to the investigation must be submitted to the Board.

B. IRB Administrators

Responsibilities of the IRB administrators and other assigned Office of Research and Sponsored Programs staff as necessary and appropriate are as follows:

- The IRB administrators must complete mandatory OHRP training associated with the federal assurance process. CITI Training
- Participate in other training as such training is available and appropriate.
- Receive, log in, and distribute for review all protocols to ensure that all necessary documentation is provided at the time of submission.
- In cooperation with the IRB chair, prepare the agenda for each meeting.
- Attend all IRB meetings and provide accurate and complete minutes of the meeting, which serve as the official, permanent record of IRB actions. The draft minutes should be forwarded to the chair prior to distribution.
- Distribute the minutes to Board members, with the protocols for the next meeting,

- for their review prior to the convened Board meeting.
- Collect comments and concerns from the reviewers. When appropriate, return materials to the principal investigator.
- Distribute, as needed, the IRB Standard Operating Procedures to faculty and departmental representatives.
- Receive and prepare all communication between the IRB and the principal investigator. This includes new protocols, IRB requests for additional information, continuing review reports, closing reports, amendments, adverse event reports and any other general correspondence generated by the members of the IRB.
- Maintain all IRB files, both open and archival.
- Provide review of submissions for final approval, checking against the formal documentation from the meeting and the correspondence surrounding the approval process.
- Assist Chair in the interpretation of the federal regulations and in the development of appropriate institutional instruments to maintain compliance.
- Manage the IRBNet database,
- Provide consultation to the Board at the meetings in areas of regulatory compliance.
- Direct and monitor the continuing review process.
- Regularly report to the Institutional Official and other University officials on the status of IRB work and decisions and prepare any reports requested by the IO and other University officials.
- Develop and implement educational programs relating to the protection of human research participants, for all individuals involved in research under the FWA.
- Monitor IRB policies and procedures for compliance with applicable regulations and state laws.
- Audit IRB operations regularly.

C. Institutional Official

The Institutional Official is designated by Jacksonville University Federalwide Assurance as having the authority and responsibility to ensure that appropriate policy and procedures are in place to ensure the adequate protection human participants in research conducted under the auspices of the university. The IO is the president of the university by default, but another member of the university's administration can be appointed as IO by written letter of the president. The responsibilities of the IO include:

- Complete mandatory OHRP training associated with the federal assurance process.
- Serve as a consultant to the IRB.
- Oversee the work of the IRB administrators.
- Oversee policy and procedure issues.
- Serve as consultant for federal regulatory authorities.
- Serve as authorized individual (Institutional Official) in compliance and regulatory matters.
- Provide recommendations for committee structure and function.
- Regularly review IRB minutes and records.

- Hear and respond to appeals on procedural matters regarding the IRB.
- Be responsible for all required institutional reports to sponsors and federal agencies.
- Appoint members of the IRB and the chair
- Receive regular reports from IRB administrators and the IRB chair on the operations and operational needs of the unit.
- Maintain familiarity with the federal requirements for IRB oversight of research.
- Ensure that university policy is reviewed and revised as needed so that the university is in compliance with federal regulations and the intent of the federalwide assurance.

XI. COOPERATIVE RESEARCH

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human participants and for complying with this policy. With the approval of appropriate department head/organizational authority, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

When JU agrees to provide oversight to external investigators, they effectively become JU RPIs for the purposes of this study or studies and are expected to meet JU standards. Among other things this means that they must comply with the same training requirements (e.g., CITI training) as JU investigators, unless they come from an institution that has similar requirements that we accept.

Two types of external agreements may be used by the IRB: Individual Investigator Agreements (IIA) and IRB Authorization Agreements (IAA). Each serves a different purpose and is used in different situations.

A. Individual Investigator Agreement

Occasionally, JU may be asked to provide IRB review for outside investigators who are not affiliated with JU nor with an institution that has an IRB. This would typically involve studies based at JU in which the outside investigator is engaged in human subjects research. In general we would not extend IRB oversight to research by outside investigators in which JU is not otherwise engaged. Thus, outside investigators must seek a JU faculty or staff member to serve as the RPI for the proposed research.

This agreement is used for two types of individual external investigators:

1. Independent Individual Investigators – those who conducting independent research and act outside any business, institutional, or organizational role they may have. For this type of investigator agreement, the following documents should be included and placed in the JU IRB record:
 - External Investigator’s curriculum vitae, including full name and credentials, mailing address, phone number and e-mail address if this information is not

included on the CV;

- Written letter or e-mail indicating that the IRB accepts oversight of the external investigator and the use of this type of agreement, that the curriculum vitae of the investigator is on file with IRB, and that research ethics training requirements have been met for this individual.

2. Institutional Individual Investigators – those who act as agents of a business, agency, institution, or organization for which they work and which does not have a federalwide assurance. This would include any graduate level students whose institution does not its own IRB and that are conducting research at JU (or with human subjects affiliated with JU). For this type of investigator agreement, the following should be included and placed in the JU IRB record:

- Written confirmation from appropriate authority of organization where external investigator works/studies confirming that this research is permitted;
- External Investigator’s curriculum vitae, including full name and credentials, mailing address, phone number and e-mail address if this information is not included on the CV;
- Letter or e-mail indicating that the IRB accepts oversight of the external investigator and the use of this type of agreement, that the curriculum vitae of the investigator is on file with IRB, and that Research Ethics training requirements have been met for this individual;

Regarding the timing of final IRB approval in relation to execution of the agreement, the JU IRB has the discretion to either provide contingent approval for the study pending the finalization of the agreement (necessitates return for final approval) or provide final approval for the study noting the need for completion of the agreement to proceed with research activities involving the external.

In either of these types of Individual Investigator Agreements, the JU faculty/staff member must be listed as the RPI on the Pro-App. The external investigator should be included on the Research Team Attachment. The RPI will be held fully responsible for the research conducted and will be the point of contact for any continuing review or closures.

B. IRB Authorization Agreements

When two institutions, both holding FWAs, are engaged in the same research study, it *may be* appropriate for one institution to rely on the IRB of another institution for review and continuing oversight of that research (i.e. this would typically involve studies primarily based at one institution, with somewhat peripheral involvement by investigator(s) at the other). This type of agreement is executed between institutions to document the delegation of IRB oversight- either reciprocal, joint oversight. Reciprocal oversight would indicate that one institution is relying on the other one to provide IRB oversight of the research. Joint oversight refers to when both institutions are actively overseeing the research activities and continued approval. These arrangements may be considered but cannot be forced on either collaborating institution. This agreement is used in five types of situations:

1. JU IRB relies on (i.e., defers to) the IRB of an external, assured institution that will handle all elements of oversight of research activities and approval/closure;
2. The IRB of the external, assured institution relies on (i.e., defers to) JU's IRB for oversight of research activities and approval/closure;
3. The JU IRB reciprocates the external IRB's approval but still maintains joint oversight of research activities and approval/closure;
4. The external assured institution does not have their own IRB and needs to use JU's IRB(s) as the IRB of record in order to be engaged in the research.
5. External IRB's for Industry-Sponsored Contracts (see details in section below)

For all IRB Authorization Agreements, the following documents will be required for the JU IRB's consideration:

- Cover letter from principal investigator explaining the nature of the research and the relationship between JU and the external institution, and who will be the contact person for the research study
- Approval letter from the external IRB, including name, contact information, and FWA number;
- Study title and number;
- All study-related documents that the external IRB reviewed in order to deem the study approved;
- Training credentials on CITI or other applicable training platform for all investigators interacting with human subjects or identifiable data;
- Sponsor or funding agency and the award number

Regarding the timing of final IRB approval in relation to execution of the agreement (i.e. signed by both JU and IO of external site), the IRB has the discretion to either provide contingent approval for the study pending the finalization of the agreement (necessitates return for final approval) or provide final approval for the study noting the need for completion of the agreement to proceed with research activities involving the external collaborator/site (documentation filed, but approval already granted).

C. Industry Sponsored Contracts using External IRB

Jacksonville University utilizes a Master Services Agreement with Western IRB as a third-party oversight source for research studies that involve industry sponsored contracts. The goal of this is to allow these studies to be reviewed with sufficient expertise, expediency, and also to remove any possible perceived conflict of interest because of university faculty/personnel receiving funding for the research.

Any research proposal looking to utilize this agreement with WIRB must be working directly with the Office of Research & Sponsored Programs to draft their budgets and contracts. The ORSP will ensure that the fee for the review by WIRB is built into the contract's budget and covered by the sponsor. Once the ORSP is included in the contract process, they will provide a Memorandum of Understanding for the RPI to include in the submission to WIRB that acknowledges the study and verifies JU's ORSP is aware of/collaborating with the design of the

sponsored research. WIRB will not review any submissions from JU personnel that does not include this Memorandum of Understanding.

The ORSP will walk the RPI through the proper submission process to WIRB. Once WIRB notifies the JU ORSP that the project design has been approved, then the IRB Administrator will send the WIRB approval documents of the study to a JU IRB reviewer for expedited review. A determination will be made by JU's IRB within seven (7) business days.

XII. APPROVAL OF THE JU IRB STANDARD OPERATING PROCEDURES

The Standard Operating Procedures of the IRB are to be approved by the University's General Counsel, the Institutional Official, and the Chair of the JU IRB. Signature below is assurance that each has read through the SOP document, accepts the responsibilities posed therein, and sees them as suiting for protecting the interests of human subjects and Jacksonville University in research endeavors.

General Counsel

Date

Institutional Official

Date

Chair of the Jacksonville University IRB

Date