STATEMENT OF ETHICAL PRINCIPLES

John Carroll University is committed to the transmission and extension of human knowledge with the autonomy and freedom appropriate to a university. It recognizes the importance of research in teaching as well as in the development of the teacher and ultimately the student. In keeping with this mission, the University especially encourages research that assists the various disciplines in offering solutions to the problems of faith in the modern world, social inequities, and human needs. John Carroll will not approve or accept any activities that violate human rights, demean human dignity, or operate according to principles directly opposed to those for which the University as a Catholic institution must stand.

For projects involving humans as participants, John Carroll University is guided by the ethical principles regarding all research involving humans as participants as set forth in the *World Medical Assembly Declaration of Helsinki* (*as amended in 2008)* and the report by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research: The Belmont Report*. In addition, the requirements set forth in Title 45, Part 46 of the *Code of Federal Regulations* (CFR) will be followed for all applicable Department of Health and Human Services (DHHS) funded research and, except for the requirements for reporting information to the DHHS, for all other research without regard to source of funding.

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DEFINITIONS

"Research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

"Human subject/participant" means a living individual about whom an investigator (whether professional or student) conducting research: 1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or 2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

"IRB" means an institutional review board established in accord with and for the purpose expressed in this policy.

"Minimal risk" means that 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.

"Written" or "in writing" refers to writing on a tangible medium (e.g., paper) or in an electronic format.

"Non-compliance" is a failure (intentional or unintentional) to comply with applicable federal regulations, state or local law, the requirements or determinations of the IRB, or University policy regarding research involving human participants. This can include, but is not limited to: failure to obtain IRB approval for research involving human participants; inadequate or non-existent procedures for informed consent; failure to follow the approved version of the protocol; failure to follow recommendations made by the IRB to insure the safety of participants; and failure to report adverse events or proposed protocol changes to the IRB.

GENERAL POLICY GUIDELINES

I. ESTABLISHMENT OF IRB: In keeping with the desire of this University to safeguard human participants and in compliance with the federal regulations, an Institutional Review Board (IRB) has been established to review all research projects involving human participants to ensure that:

A. Risks to participants are minimized and reasonable in relation to anticipated benefit, if any, to participants and the importance of the knowledge expected to result. In making these assessments, the IRB will ensure that research procedures are consistent with sound research design and do not unnecessarily expose participants to risks. The IRB will evaluate only those risks and benefits that may result from the specific research study and will not consider possible long range effects of applying the knowledge gained in the research. The direct or potential benefits to the participant, or the importance of the knowledge gained, must outweigh the inherent risks to the individual.

B. Selection of participants is equitable. The IRB will consider the purposes of the research, the setting and the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

C. Informed consent is sought from the participant or from the participant's legally authorized representative and the informed consent is documented according to applicable federal regulations.

D. Privacy and safety rights of participants are protected and the confidentiality of data maintained. Children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged populations are considered especially vulnerable.

II. IRB ADMINISTRATION: The IRB will consist of individuals with various skills and experiences necessary to evaluate human research and its institutional, legal, scientific and social implications. Efforts will be made to ensure that the IRB reflects diversity in race, gender, and cultural backgrounds. The specifics of appointment and activities follow.

A. MEMBERSHIP: Members of the IRB are appointed by the Institutional Official (IO). The Provost and Academic Vice President of John Carroll University serves *ex officio* as the Institutional Official (IO) of the IRB. The members of the IRB are ordinarily appointed for a three-year term and may be reappointed when this initial term expires. Federal regulations stipulate that there must be at least five members on the IRB with one representative from outside of the University, one scientist, and one non-scientist. In addition, it is IRB policy that at least one representative will come from the Boler School of Business and one from the College of Arts and Sciences, but these representatives may fulfill the required scientist and non-scientist roles.

1. The IRB Chairperson: The IRB Chairperson is appointed by the Institutional Official for a three-year term and may be reappointed after each term expires. As a primary representative of the IRB, the Chairperson should have an in-depth understanding of the ethical issues, institutional policy, and federal research regulations that are applicable to human participant studies conducted at the university. The Chairperson will be a full time, tenured faculty member. It is preferred that this person be selected from the pool of current board members or past board members.

2. The Assistant Chairperson: An Assistant Chairperson of the IRB will be the Director of Sponsored Research and will provide support to the Chairperson and Acting Chairperson. The Assistant Chairperson is an *ex officio* member of the IRB; however, the Assistant Chairperson may not be the sole reviewer of faculty projects or projects in which the principal investigator (or co-investigator) is seeking outside funding.

3. The IRB Administrator: The IRB Administrator will be an *ex officio* member of the IRB. The IRB Administrator will support all members and will report directly to the IRB Chairperson; however, the daily activities of the IRB Administrator will be supervised by the Assistant IRB Chairperson (i.e., the Director of Sponsored Research).

   The IRB Administrator and The Assistant Chairperson are both part of the IRB Office, located within the Office of Sponsored Research. Either the Assistant Chairperson or the IRB Administrator may be voting members of the IRB, but not both. The IO makes all appointments to the IRB, including the assignment of voting rights to either the Assistant Chairperson or the IRB Administrator.

4. IRB Member Training: Under the direction of the Chair, new members are trained by the IRB Administrator or any other experienced current member. Training will consist of reviewing this Policy and general procedures; providing the member with access to all IRB forms, federal regulations, and guidance documents; reviewing the Institutional Review Board: Member Handbook (Amdur and Bankert, third edition), of which each member will receive a copy; and completing the CITI Training course "IRB Members". Ongoing member training will be coordinated by the Chair and the IRB Administrator and may consist of seminars, conferences, webinars, and the sharing of news and journal articles.

If the IRB regularly reviews research that involves a vulnerable category of participants, such as children, students, prisoners, or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced with these participants.

The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

B. MEETING SCHEDULE: The IRB routinely schedules meetings once a month during the fall and spring semesters but the board must meet at least once a semester. The IRB Chairperson will set the dates of the meetings.

C. RECORDKEEPING: The IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

1. Copies of all research applications reviewed, scientific evaluations, if any, that accompany the applications, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to participants.

2. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; 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 controversial issues and their resolution.

3. Records of continuing review activities.

4. Copies of all correspondence between the IRB and the investigators.

5. A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant.

6. Written procedures which the IRB will follow for:
   (a) Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;

   (b) Determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review;

   (c) Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the participant.

   (d) Ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of:

(i) Any unanticipated problems involving risks to participants or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and

(ii) Any suspension or termination of IRB approval.

(e) Ensuring that participants are informed about significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation.

The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research.

D. WHO MUST SUBMIT AN APPLICATION FOR REVIEW: A review of research activities will be made by the IRB for studies sponsored by members of the faculty, staff, or administration of John Carroll University. In those instances where individuals from an institution other than John Carroll University wish to conduct research on its campus, a faculty or staff member of the University must sponsor the application to the IRB. Students attending John Carroll University are bound by the same procedures and policies as the faculty and staff. Moreover, no applications to the IRB from either an undergraduate or a graduate student will be reviewed unless sponsored by a faculty or staff member familiar with the student and the proposed activity.

E. SUBMISSION OF APPLICATION: Any individual or group of individuals intending to conduct research involving human participants has the responsibility to file an *IRB Application for Human Participant Research*. If the research will be conducted by more than one researcher, one individual must be identified as the primary investigator (PI). Human participant research is defined as collecting information about a human participant (i.e., opinions, behaviors, feelings, personal information), regardless of the sensitivity of the data, and generalizing the results (i.e., by publishing–including master's thesis; presenting at a conference; citation in another paper; poster presentations). All individuals who are engaged in the proposed research activity must be listed on the IRB Application as a co-researcher.

If a proposal will be submitted to a funding agency, the application should be sent to the IRB four weeks prior to the deadline for submission to the agency if a decision is required in advance by the funding agency; however, IRB approval may not be necessary prior to submittal of a grant proposal. All research involving more than minimal risk must be reviewed by the full IRB at a convened meeting; exempt or expedited review, as outlined in the regulations, may be granted upon the recommendation of the IRB and would not require review by the full IRB. Research may not be undertaken without IRB approval. Approval cannot be granted retroactively.

In most cases, class research projects involving human participants are not intended to contribute to generalizable knowledge and therefore do not require IRB review; however,

if a class research project will be generalized (i.e., by publishing–including master's thesis; presenting outside the class; citation in another paper; poster presentation), the *IRB Application for Human Participant Research* must be filed. If IRB approval is necessary and a class will be conducting one basic project, the instructor can file one IRB application covering the entire class. If, however, individual students or small groups of students conduct varying types of projects that require IRB approval, then an IRB application from each student or group is required. Classroom research projects that involve medical patients or employees of an institution other than John Carroll may need to have their research exempted or approved through that institution's IRB prior to initiation of the project.

F. CITI TRAINING: All applicants who are listed on the IRB application, either as principal investigator (PI), co-PI, research sponsor, or co-researcher, must complete a human subjects research training course offered by the Collaborative Institutional Training Initiative (CITI) online program. This requirement includes researchers from other institutions who wish to conduct human subjects research at the University. CITI training must be completed by all researchers who are engaged in the project, including those who are added through an amendment, before the IRB application is submitted, or else the application is not considered complete. Researchers must complete the appropriate training course on the CITI website as required by the IRB. The IRB Administrator serves as the CITI training administrator, monitoring the course requirements and training completion records. CITI certification is valid for three calendar years after training completion, and must be renewed while the research is ongoing.

Researchers who have completed equivalent human subjects research training courses (such as that provided by the NIH or by other Universities) may provide proof of their certification in fulfilment of this requirement. Final approval of alternative human subjects research training certification will be determined by the IRB.

IRB members must complete and stay current with the CITI course "IRB Members" designed to train IRB members.

III. TYPES OF IRB REVIEW: It is the policy of John Carroll University that the IRB will utilize the regulations issued by the Department of Health and Human Services as specified in 45 Code of Federal Regulations 46 when evaluating the proposed research applications. In addition, vulnerable population groups (i.e., children, prisoners, fetuses, human in-vitro fertilization) are covered under specified regulations at §Subparts B, C and D. The following sections elaborate upon the types of IRB reviews (also see **http://sites.jcu.edu/research/pages/irb/review/review-types/**).

A. RESEARCH CONSIDERED UNDER THE "EXEMPT" CATEGORY: In order to establish an individual research project as "exempt," the principal investigator must submit the *IRB Application for Human Participant Research* to the IRB. Copies of supplemental material such as the data instrument, consent form, and solicitation material must be attached. The IRB will maintain this material and all related written communication in a file. The minimal risk exempt categories are codified at 45 CFR 46.101(b).

B. RESEARCH CONSIDERED UNDER THE "EXPEDITED REVIEW" CATEGORY: The principal investigator shall submit the *IRB Application for Human Participant Research*. Copies of supplemental material such as the data instrument, consent form, and solicitation material must be attached. The IRB will maintain this material and all related written communication in a file. Research involving no more than "minimal risk," i.e., risk that is no greater in probability and severity than that ordinarily encountered in daily life during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(i)), to participants and in which the only involvement of human participants falls under any of the categories codified at 45 CFR 46.110.(a) may be reviewed by one or more IRB members following an expedited review process. An application submitted by a principal investigator who is JCU faculty or administration must be reviewed by at least two IRB members following an expedited review process.

C. RESEARCH CONSIDERED UNDER THE "FULL-BOARD REVIEW" CATEGORY: Any research or training project involving the use of human participants which does not fall into the "Exempt" or "Expedited Review" categories must be submitted to the IRB for a full-board evaluation. The principal investigator must complete and submit the IRB Application for Human Participant Research. Copies of supplemental material such as the data instrument, consent form, and solicitation material must be attached. The IRB will maintain this material and all related written communication in a file. The application will be reviewed at a convened meeting.

IV. PROCEDURES FOR REVIEW AND APPROVAL: Specific review and approval procedures of the IRB are as follows:

A. NEW PROJECTS: The principal investigator should be familiar with the IRB Policy before submitting an application. All researchers and sponsors listed on the application should complete the appropriate CITI training course in human subjects protections before the application is submitted. The investigator will complete the *IRB Application for Human Participant Research* form and then submit the application and supporting material to the IRB. Upon receipt, the IRB Administrator will send an email to the principal investigator, research sponsor (if applicable), and his/her Departmental Chairperson or Supervisor confirming the receipt of the application. If the principal investigator's sponsor or Departmental Chairperson or Supervisor has concerns about the project, he/she should notify the IRB Chairperson.

Upon receipt of the application and supporting materials, a qualified IRB Administrator will determine the appropriate review category for the application based on the federal regulations and the degree of risk to participants. The IRB Administrator is considered to be qualified based on training and experience as determined by the IRB Chair. When the IRB Administrator is not considered to be qualified, projects will be classified by at least one IRB member. In addition, any IRB member may request a different review category for a project as he/she deems necessary. The review categories and procedures are as follows:

1. EXEMPT CLASSIFICATION: Certain projects may be classified as Exempt from IRB review by a qualified IRB Administrator.

a. Investigators must submit the *IRB Application for Human Participant Research* form and all supporting materials to the IRB in order for a project to be classified as Exempt.

b. The IRB Administrator or member of the IRB may require revisions to the project before a Notice of Exemption is issued.

c. Certain changes may alter the Exempt status of an ongoing project. Therefore, any proposed changes to an ongoing Exempt project must be submitted to the IRB for review and approval prior to implementation.

d. Continuing review is not required for Exempt projects, unless the research is changed so that it no longer meets the requirements for exemption.

2. EXPEDITED REVIEW: Projects that are considered to fall under the Expedited Review category will be reviewed by one or more IRB members (i.e., review group) and do not require a full-board review at a convened meeting. Applications submitted by JCU faculty or administration will be reviewed by at least two IRB members.

a. Upon submittal of a complete application, the review group will review the application material and send their preliminary review findings to the principal investigator within 14 business days. The submission of disorganized and/or incomplete packets will significantly delay the review.

b. No review group may have a member participate in an initial review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

c. The IRB may approve the project as described in the application unconditionally or request the investigator, for example, to provide additional information regarding the project, to revise and resubmit the application, to revise and resubmit supporting material (e.g., consent forms, solicitation material, data instruments), or to revise the project methodology to safeguard human participants. A review group cannot disapprove a study. Only a full board can decide to disapprove a study. A review group, at their discretion, can request that a project, initially falling under an Expedited Category, be sent to the full board for review or that the project be re-classified as Exempt.

d. In cases where it is deemed necessary by the review group, consultants to the review group may be asked to comment on a proposed research activity.

e. After the investigator has satisfactorily addressed any concerns of the review group, the investigator, research sponsor (if applicable) and his/her Chair/Supervisor will be notified of the approval in writing by the IRB Administrator.

3. FULL-BOARD REVIEW: Projects that fall under the Full-Board Review Category will be reviewed at a convened meeting. Meetings are prescheduled once a month during the academic year.

    a. Projects needing full-board review should be submitted two weeks or more before the next scheduled meeting to allow time for the application to be processed. Complex projects or those requiring the expertise of outside consultants should be submitted well in advance to allow for adequate time to prepare for the full-board review. The submission of handwritten and/or incomplete packets will significantly delay the review.

    b. When conducting a full-board meeting, a majority of the IRB members (i.e., quorum) must be present, including at least one member whose primary concern is in a nonscientific area. A majority of votes must be obtained to approve or disapprove a project or to make a decision regarding the project.

    c. No IRB may have a member participate in a full-board review of any project in which the member has a conflicting interest, except to provide information requested by the Board. That member must recuse himself/herself from discussions at the meeting, may not vote or be counted toward the quorum, and may also not be present during the vote.

    d. An investigator may be asked to appear before the Board to describe the proposed research. In cases where deemed necessary by the Board, consultants may be asked to comment on the proposed research activity.

    e. For projects involving vulnerable population groups (i.e., children, prisoners, , fetuses, human in-vitro fertilization), additional review procedures will be implemented as specified in 45 CFR 46, §Subparts B, C, and D.

    f. The IRB will decide with a majority of its members present:

        i. To approve the project unconditionally;

        ii. To disapprove the project;

        iii. To request substantive clarifications or modifications regarding the project, consent documents, solicitation material, data instruments, etc., to be deferred, pending subsequent review and approval by the convened IRB; or

        iv. To request clarifications or modifications, stipulating specific revisions requiring simple concurrence by the investigator to be reviewed and approved by the IRB Chair or other IRB member(s) designated by the Chair under an expedited review procedure.

g. The IRB Chairperson or IRB Administrator will inform the principal investigator and his/her Chair/Supervisor in writing of the approval/disapproval decision of the Board.

h. In the case of a requested revision, the principal investigator will be informed in writing of the decision of the board. After the investigator has satisfactorily addressed any concerns of the review group, the investigator and his/her Chair/Supervision will be notified of his/her approval or disapproval in writing by the IRB Administrator.

i. There is no appeal to the decision of the IRB unless the project is significantly revised, at which time the researcher must submit a new IRB application. Research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by the IRB.

B. SUSPEND OR TERMINATE APPROVAL: The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or that has resulted in unexpected harm to participants. A list of reasons for any suspension or termination will be provided to the investigator and all appropriate department heads.

C. REVISIONS TO A PROJECT: All substantive revisions (i.e., modifications, addenda, amendments) to a previously approved project must be reviewed and approved by the IRB prior to initiation. Principal investigators should submit a *Revision Request Form* to the IRB at least one month in advance to ensure enough time for it to be reviewed. Project addenda can be reviewed by an Expedited review method; however, a project that was initially reviewed by a full board must be reviewed again by a full board for any addenda. Approval must be granted before any changes can be initiated.

Minor revisions or addenda to a previously approved project (e.g., changes in the researcher's contact information, or any other administrative change that does not increase the level of risk or otherwise change the nature of the research project) may be approved by the IRB Administrator. The IRB Administrator will update the project file to reflect the minor revision.

D. CONTINUING PROJECTS: The IRB will conduct continuing review of a project at intervals appropriate to the degree of risk, but not less than once per year. Project continuing review dates and expiration dates are written on the IRB Notice of Approval sent to the principal investigator. At the discretion of the IRB, minimal risk research projects that are initially reviewed by an Expedited review method may be approved without an approval expiration date, and will therefore not require continuing review unless changes are made to that project that increase the level of risk. Any research project that is approved by the IRB with an approval expiration date will require continuing review before the research activity may continue beyond the expiration date.

If continuing review is required, a principal investigator should submit a *Continuation Request Form* to the IRB at least one month before (i.e., the continuing review date) the project expires to ensure enough time for it to be reviewed. A project is considered open and requires IRB approval to continue beyond the expiration date if: participants are still being recruited; participants are still participating in the research; the research is permanently closed to the enrollment of participants but follow-up with participants may occur; or data is still being analyzed and poses ongoing risk to participants (privacy and confidentiality). Continuing review for a project may be requested each year for two years. However, if a project will continue after the third year of its initial approval anniversary, a new IRB application for the project must be filed with the IRB. A project that was initially reviewed by a full board must be reviewed again by a full board for continuing review. A project that was initially reviewed by an Expedited review method and was given an approval expiration date at the time of the initial approval can be reviewed again by an Expedited review method.

Principal investigators should plan ahead to meet required continuing review dates. If an investigator fails to send a *Continuation Request Form* to the IRB or the IRB has not reviewed and approved a research project by the expiration date specified by the IRB, the research must stop, unless the IRB finds that it is in the best interests of individual participants to continue participating in the research interventions or interactions. Enrollment of new participants cannot occur after the expiration of IRB approval. When continuing review of a research protocol does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. At the discretion of the IRB, a principal investigator who allows a study to expire without requesting a continuation from the IRB may be asked to submit a new IRB application for review to re-activate the project.

V. INFORMED CONSENT: Informed consent must be sought from each prospective participant or the participant's legally authorized representative, in accordance with and to the extent required by 45 CFR 46.116 and will be appropriately documented in accordance with, and to the extent required, by 45 CFR 46.117. The IRB must approve all consent documents, and signed consent forms must be kept on file by the principal investigator for a three-year period following the end of the project. Participants should receive a copy of the consent form or any informed consent document for their records.

A. In compliance with 45 CFR 46.116, the following information must be provided to the participant in clear and non-technical language:

1. The fact that the study is research.

2. The purposes of the research.

3. The expected duration of the research participation.

4. The procedures to be followed.

5. Any reasonably foreseeable risks or discomforts.

6. The benefits to the participant or to others which may reasonably be expected from the research.

7. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.

8. The extent to which confidentiality of data and privacy of the participants will be maintained.

9. For research involving more than minimal risk or if injury occurs as a direct result of the research, the type of compensation and the availability of medical treatment will be described and the financial costs that the University will be responsible for specified.

10. Who to contact for answers to pertinent questions about the research, participants' rights, and research related injury to the participant.

11. The fact that participation is voluntary and that the participant may withdraw his or her consent at any time without penalty or loss of benefits which will be prorated to the time of withdrawal.

B. Based on this regulation, legally effective informed consent shall:

1. Be obtained from the participant or the participant's legally authorized representative;

2. Be in language understandable to the participant or representative;

3. Be obtained under circumstances that provide the participant with opportunity to consider whether or not to participate, and that minimize coercive influences;

4. Not include language through which the participant is made to waive any of his/her legal rights or releases the investigator, sponsor or institution from liability or negligence.

C. Voluntary and informed consent must be obtained by all participants, unless the requirement or parts of the requirement are waived by the IRB. Specific conditions for the complete or partial waiver of informed consent can be found at 45 CFR 46.116.

VI. RESPONSIBILITIES OF INVESTIGATORS: It is the responsibility of the investigators to:

A. Familiarize themselves with these guidelines and to discuss with members of the IRB any questions regarding proposed research activities.

B. Submit a completed *IRB Application for Human Participant Research* form and the necessary supporting documents for review by the IRB.

C. Notify the IRB of any injury—physical, psychological, or social—that is suffered by participants because of their participation in a research activity.

D. Request a continuing review if the research is judged by the IRB to involve more than "minimal risk" or extends beyond an assigned expiration date.

E. Make provisions to keep records, documents, and informed consent forms normally for at least three years following the completion of the project or activity, or for a longer period as judged necessary.

F. Take proper measures to insure confidentiality and security of all information obtained from the participants. Include a written explanation of these measures with the application to the IRB for review.

VII. ADVERSE EVENTS AND UNANTICIPATED PROBLEMS: Any adverse event or unanticipated problem must be reported immediately to the JCU IRB Chairperson. Adverse events and unanticipated problems can include injury to participants, investigators, and research assistants; breaches of confidentiality; stolen or lost data; etc. The IRB Chairperson, at his/her discretion, will report any problem to the Institutional Official (i.e., JCU Provost/Academic Vice President) or any other Dean, Chairperson, university official or regulatory agency deemed necessary to resolve any problems or conflicts. The IRB Chairperson may also request that substantive changes in the research protocol or informed consent process be made, that the study be stopped until further review by the IRB, or that other corrective actions be taken to protect the safety, welfare, or rights of participants or others.

VIII. NON-COMPLIANCE: Incidences of non-compliance should be immediately reported to the IRB Chairperson or anonymously through the web-based EthicsPoint Reporting System**.** Non-compliance is a failure (intentional or unintentional) to comply with applicable federal regulations, state or local law, the requirements or determinations of the IRB, or University policy regarding research involving human participants. This can include, but is not limited to: failure to obtain IRB approval for research involving human participants; inadequate or non-existent procedures for informed consent; failure to follow the approved version of the protocol; failure to follow recommendations made by the IRB to insure the safety of participants; and failure to report adverse events or proposed protocol changes to the IRB. The IRB Chairperson will investigate allegations of non-compliance in a manner determined by the seriousness of the allegations and the probability of or occurrence of harm to participants. All non-compliance issues will be handled by the Chairperson. The Chairperson may seek assistance from the IRB as necessary. The Chairperson, at his/her discretion, will involve the necessary people (e.g., departmental chairperson, dean) to resolve any non-compliance issue. Any individual, including the Chairperson, who is responsible for carrying out any part of the non-compliance investigation and decision, shall not have unresolved personal, professional, or financial conflicts of interest with the principal investigator. Should the Chairperson be

recused from the investigation, the Assistant Chairperson shall act for the Chairperson in accordance with this policy.

Under federal regulations, the IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's policies or that has been associated with unexpected serious harm to participants. This judgment cannot be overturned by any other University authority or policy. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

Non-compliance issues relating to the IRB may also fall under the purview of the University's *Misconduct in Scholarship and Grants Management Policy & Procedures*. However, the federal regulations stipulate that the IRB still maintains the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's policies or that has been associated with unexpected serious harm to participants.