DEFINITIONS

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-

(e) Ensuring that participants are informed about significant new findings developed

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 currente M$^{\varphi}$ t

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.

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-

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 con912 011 466.p 792 reW*nQ0.00000912 0 6

However, if a project will continue after the third year of its initial approval anniversary, a

IRB POLICY –

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:

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.