STATEMENT OF ETHICAL PRINCIPLES

John Carroll University is committed to transmitting and extending

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 accordance 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 cdiu psto.9 (, o-iite)6 (y)30 (ong hu)-10 (m)-2 (a)4 (n pa)4 (r)3 (t)-2 (i)-2 ((()3 (i)-2 (nt

The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that

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

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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 projedr(j)-6 (e)4 (r)3 (,)]TJ -0.004 Tt4 Tw [(r5l [(r5l [(r5 6 (o)-e (d)-4 (t)-44 ( )]6 (6)-4

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

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by the IRB Chair or other IRB member(s) designated by the Chair under an expedited review procedure.d e .

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. -0.002 Tw 1.9ar

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, institut

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 their 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 [illegible]

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