INSTITUTIONAL REVIEW BOARD (IRB):

DEFINITIONS

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1. **Research** – "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46.102 (d)).

   A. Systematic Investigation – a deliberate approach to obtaining quantitative or qualitative information from or about one or more individuals and planned analysis of data to address a question, describe a phenomenon, or test a hypothesis. Characteristics of a systematic investigation include the articulation of research questions, an articulated plan for data collection, analysis of the data, and conclusions drawn from the data analysis.

   Examples include experimental studies, descriptive studies, program evaluations, and program assessments that involve collection of data through interviews, surveys, observations, testing, focus groups, and other data collection methods involving human interaction.

   B. Generalizable Knowledge – knowledge is generalizable if it has application to people and situations outside of the context of the study. One indication of generalizable knowledge is the intent to make the results available to others through publications, presentations, or other mechanisms. For example, a program evaluation would be a contribution to generalizable knowledge if the results can inform other programs and are published in a professional journal but may not be a contribution to generalizable knowledge if the results are used only to improve the specific program studied. Research for class would be considered generalizable knowledge for courses labeled (a) directed independent study, (b) supervised research, (c) honors theses, (d) masters theses, (e) capstone, or (f) dissertations *if* these courses involve collecting data from human participants (as defined in 45 CFR 46).

2. **Human subject** – "a living individual, about whom an investigator (whether professional or student) conducting research obtains: 1) data through intervention or interaction with the individual, or 2) identifiable private information" (45 CFR46.102(f)).

   A. Intervention – "includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes" (45 CFR46.102(f)(1)(2)).

   B. Interaction –"includes communication or interpersonal contact between investigator and subject" (45 CFR46.102(f)(1)(2)). Please note that the JU IRB considers communication by telephone or an online survey to be interaction.

   C. Private information – "includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual

and which the individual can reasonably expect will not be made public (for example, a medical record)." (45 CFR46.102(f)(1)(2)).

D. **Individually identifiable** - "The identity of the subject is or may be readily ascertained by the investigator or associated with the information" (45 CFR46.102(f)(1)(2)). Information or specimens are considered to be individually identifiable when they can be linked to specific individuals either directly or indirectly.

3. **Protected Health Information** - Individually identifiable health information, held or maintained by an organization or its business associates that is transmitted or maintained in any form or medium. For more information please see the U.S. Department of Health and Human Services HIPAA website.

4. **De-identified Data** - Data are de-identified when it is not possible to reasonably ascertain the identity of a person from that data. Note that HIPAA specifies 18 items that must be removed in order for data to be considered de-identified (see section 164.514(b)(2) HIPAA regulations).

5. **Confidential Data** - Non-anonymous data that a human subject provides to an investigator with the understanding or assumption that the human subject's privacy will be honored. Divulging the source of non-anonymous data to an outside party, or failing to ensure that no outside parties will be able to connect data with their source, normally constitutes a violation of confidentiality.

6. **Anonymous Data** - Data that can never reasonably be connected, by the investigators or anyone else, to the person whose data has been obtained.

7. **Certificate of Confidentiality** – A document which can provide protection against compelled disclosure of identifying information (e.g., court order, subpoena) but does not prevent the voluntary disclosure of identifying information about research subjects by the researcher as specified in the informed consent document. Please note that there are limitations to the protections provided by this document. Please refer to the National Institutes of Health FAQs on Certificates of Confidentiality for more information.

8. **Exempt Review** – Studies that fall into one of six designated categories and that pose minimal risk to subjects may be determined by the IRB to be exempt from further review. This determination can be made only by the IRB based on a review of the study protocol. **Investigators do not have the authority to make an independent determination that human subject research is exempt.** After a project has received approval as an exempt

project, only substantive changes must be submitted for review. Exempt approvals do not typically have an expiration date (JU Standard Operating Procedures IIB). Projects that include interaction or intervention between a researcher and children (46.101(b)(2) or research that includes prisoners cannot fall under exempt review. In making a determination about risk, the IRB considers study population, type of interaction/intervention, sensitivity of information, etc.

9. **Expedited Review** – ***Expedited*** does not mean that the review is less rigorous or happens more quickly than convened review. It refers, instead, to certain types of research considered to involve minimal risk. Research that falls under one or more of the Expedited Review Categories may qualify for expedited review by the JU IRB chairperson and/or by one or more experienced IRB reviewers. Only the IRB may determine whether a project requires expedited or full review. As outlined above, in making a determination about risk, the IRB considers study population, type of interaction/intervention, sensitivity of information, etc. Expedited projects are subject to continuing review at intervals appropriate to the degree of risk, but not less than once per year, or the approval will expire.

10. **Full Board Review** – Research that represents more than minimal risk to participants or others. The inclusion of vulnerable populations (e.g., minors, prisoners, cognitively impaired) or sensitive topics (e.g., deception, illegal behavior, suicide) will sometimes necessitate full board review. Typically, only protocols that are full board projects are reviewed at a convened IRB meeting, and majority of those members present must approve the project. Full board protocols must undergo continuing review at least every 12 months (or more often, if deemed appropriate) or they will expire.

11. **Class Projects** – Class projects at JU are those in which students' involvement is limited to developing the knowledge and skills needed for conducting research with human participants. Class projects might involve interviews in person or by telephone, observations, written or electronic surveys, or analysis of archival data. Given the pedagogical nature of class projects and the inexperience of students conducting class projects, the subject matter of such projects cannot involve more than minimal risk or include vulnerable participants, as defined and described below. This designation as a class project does not apply to courses labeled (a) directed independent study, (b) supervised research, (c) honors theses, (d) masters theses, (e) capstone, or (f) dissertations *if* these courses involve collecting data from human participants (as defined in 45 CFR 46). (JU Procedures for Class Projects) (Policy Pending).

12. **Benefits** – Positive outcomes for society, a scholarly discipline, or to an individual that result directly from the research. For example, one positive outcome for individuals may include receiving individualized treatment or counseling as a result of participation.

Compensation is not considered a benefit of research participation.

13. **Risks** – the probability of negative outcomes to individuals or groups as a result of research. Examples of risks include physical harm, psychological or emotional harm, criminal or civil liability, damage to financial standing, damage to employability, damage to reputation or other harms such as embarrassment, discomfort, or anxiety.

14. **Minimal Risk** – "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (45 CFR46.102 (i)).

15. **Coercion –** "occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance. For example, an investigator might tell a prospective subject that he or she will lose access to needed health services if he or she does not participate in the research" (OHRP, 2011 "What does it mean to minimize the possibility of coercion or undue influence?"). The Code of Federal Regulations requires that "an investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence" (45 CFR 46.116).

16. **Undue Influence** - Offering excessive or inappropriate reward or the use of unjustifiable pressures by a person in authority in order to obtain compliance. Researchers should also avoid the perception of pressures that could create undue influence to participate in research (Belmont Report, 1979).

17. **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."

    Potential participants may be identified as vulnerable if they have cognitive and communication limitations or a serious health condition for which there is no standard

treatment, are economically or socially disadvantaged, or are in a subordinate relationship with those involved in the study (see Bankert & Amdur, 2006; JU Standard Operating Procedures III C).

18. **Prisoner –** Prisoner means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing (45 CFR 46.301).

19. **IRB Approval** – "determination from an IRB that the proposed research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements" (45 CFR 46.111).

20. **Contingent Approval (a.k.a. approval with conditions)** – During review of a new project or amendments to an existing project, the IRB may grant approval pending in one or more of the following scenarios: (a) the Responsible Primary Investigator makes specified changes to the research protocol or informed consent document(s); (b) the RPI confirms specific assumptions or understandings on the part of the IRB regarding how the research will be conducted, or (c) the RPI submits additional documents. Final approval will be granted following receipt of the requested materials or information. Research may not proceed until final approval is granted.

21. **Amendment** - Official request for any change to an expedited or full board approved study or substantive changes to an exempt approved study. All such requests must be submitted and approved by the IRB prior to initiation of the change, except when necessary to eliminate apparent immediate hazards to research participants (Expedited Review #8 and #9). For more information about changes to an exempt study that may be considered substantive, please refer to the JU Standard Operating Procedures.

22. **Revisions** – Revisions are edits made to a packet on IRBNet prior to the project being approved by the IRB. Revisions can be made during the Administrative Review phase, the Modifications Required phase, and the Approved with Conditions phase. The IRB Administrator will relay any recommended revisions via IRBNet and will Unlock the pertinent packet for revisions to be uploaded in the Designer tab. Once the RPI is completed with the necessary revisions, the RPI must change the lock status of the packet to "Locked-Revisions Complete" in order to notify the IRB Admin team.

23. **Modifications Required** – A phase in the review process where the application has passed the Administrative Review phase and has been forwarded to an IRB Reviewer. The IRB reviewer has then relayed recommended revisions back to the IRB Admin to request from the RPI. The IRB Admin will unlock the packet on IRBNet and send a message to the RPI communicating the revisions as well as where to find any supporting documents that may help with the revisions. Once the RPI has made the necessary revisions, they will upload the revised versions of the documents to the Designer tab of their project on IRBNet and change the lock status of the packet to "Locked-Revisions Complete."

24. **Administrative Review** – A phase in the review process that occurs immediately upon submission. The IRB Admin will check the application for completeness and ensure that all documents are attached. If any additions need to be made to the packet, it will be unlocked and marked "Information Required." Once the revisions have been uploaded to the IRBNet packet, the RPI must change the lock status to "Locked-Revisions Complete." The packet will again go through an Administrative Review. Once it passes this review, it will be forwarded to an IRB Reviewer to check it for content. Administrative Reviews can also occur if a project is deemed "Approved with Explicit Changes," by the IRB Reviewer and the RPI only has to upload documents with explicitly written out revisions in order to get approval. This will bypass a second review from the IRB Reviewer and allow the project to be approved in Administrative Review.

25. **Information Required** – A phase in the review process where a submission has not cleared Administrative Review, but is needing certain revisions prior to it being forwarded to the IRB for a review.

26. **Continuing Review** – 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 (2010 HHS Guidance).

27. **Expired Protocol** – If the IRB has not reapproved a research study by the expiration date listed on the approval memo, the research approval will automatically expire. After IRB approval has expired, using, studying, or analyzing identifiable private information is not permitted. Exempt projects at JU do not have an expiration date. Therefore, approval does not expire until closed by RPI or administratively terminated.

28. **Terminated Protocol** - A protocol for which research activities have been permanently discontinued by the researcher or IRB due to approval expiration, unexpected problems involving risk, or other reasons.

29. **Protocol Deviation** - Occurs when a researcher performs activities either different from or in addition to those described in the IRB-approved research protocol, or do not perform activities that were described in the protocol. Protocol deviations should be reported to the IRB by the principal investigator(s) by completing and submitting an Event Report Form promptly upon discovering the deviation.

30. **Non-compliance** - A failure to comply with (a) applicable federal or state laws, rules or regulations, (b) applicable JU policies, procedures, or requirements, or (c) IRB determinations governing the conduct of human subjects research. Examples include, but are not limited to, failure of the principal investigator(s) to obtain IRB approval prior to the initiation of research, inadequate supervision by the principal investigator(s) of those authorized to assist in the conduct of the research, failure of the principal investigator(s) to follow recommendations made by the IRB, and failure of the principal investigator(s) to report unanticipated problems or protocol deviations.

31. **Adverse Event** – a broad term for any physical or psychological harm to a participant in research that occurs at the same time as participation and may or may not be related to the subject's participation in the research. Adverse events may be expected or unexpected and are not always reportable. (See the Office for Human Research Protections site for guidance on Unanticipated Problems Involving Risks and Adverse Events).

32. **Unanticipated problem involving risk** - any incident, experience, or outcome that meets **all** of the following criteria: unanticipated in type, severity or frequency; possibly related to participation in the research; and suggests that the research involved greater risk of harm than previously acknowledged.

    If the event meets all three criteria, then the event is an unanticipated problem and must be reported to appropriate entities under the HHS regulations at 45 CFR 46.103. If an investigator determines that an event represents an unanticipated problem involving risk, the investigator must report it promptly to the JU IRB (45 CFR 46.103(b)(5)) by utilizing the Event Report Form that can be found within the Forms and Templates Library in IRBNet. For more information, please see the Office for Human Research Protections site for guidance on Unanticipated Problems Involving Risks and Adverse Events).

33. **Belmont Report** – report issued by the National Commission for the Protection of Human Subjects (1978) that defines the basic ethical principles governing research involving human subjects. Each of these principles is defined below.

A. **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 (Belmont Report; JU Standard Operating Procedures).

B. **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" (Belmont Report; JU Standard Operating Procedures).

C. **Justice** - "revolves 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" (Belmont Report; JU Standard Operating Procedures).

34. **Incidental Finding** - A finding concerning an individual research participant that has potential importance for wellbeing and is discovered in the course of conducting research but is beyond the aims of the study (e.g., suicidal intent, blood pressure readings of greater than or equal to 140/90 mmHg or less than or equal to 90/60mmHg based on medical standards, resting pulse rate of over 100 bpm or under 60 bpm based on medical standards).

35. **Code of Federal Regulations**- The human subject protection regulations issued by the U.S. Department of Health and Human Services are codified in the Code of Federal Regulations (45 CFR 46). The code was first issued in 1974 and has been amended several times. The current version includes five subparts. For more information, feel free to refer to the OHRP Regulations page.

36. **Package** – IRBNet term for a group of documents that are submitted together in IRBNet. A project in IRBNet may be made up of several packages. For example, a new project submitted to IRBNet for review will be identified as package one. If changes are made to those documents, the RPI will create a new package containing the revised documents and that package will be package two of the same project. In the IRBNet ID number the number after the dash represents the package number.

37. **Project** – An IRBNet term for a study that has been submitted via IRBNet. A project may be made up of multiple packages (e.g., initial submission, revisions, amendments, continuing review/extensions, event reports, closing). Each project receives an IRBNet ID consisting of six numbers that do not change throughout the life of the project. The number after the dash

is the package number which will change depending on how many packages have been submitted for one project.

38. **VA Research** - research that is conducted by Veterans Affairs investigators including RPIs, Co-Is, and site investigators on VA time, utilizing VA resources (e.g., equipment), or on VA property including space leased to, and used by VA. The research may be funded by VA, by other sponsors, or be JU funded. (For more information, consult the VHA Handbook)

39. **Researcher** - A person who conducts research whether faculty, staff, or student.

40. **Sample of Convenience** – Recruiting from a specific group because the investigator already has access to these potential human subjects by some means other than an intervention.

41. **Semi-Structured Interview** – A form of intervention that involves scripted questions mixed with general topics that the researcher may ask about in an interview with a human subject. Both the direct questions and the general topics must be approved by the IRB prior to the interview.

42. **Principal Investigator** - The individual who is responsible and accountable for conducting the research. See the JU Standard Operating Procedures for more information about who can be a principal investigator. Click here for HHS guidance on PI Responsibilities.

43. **Informed Consent** - Informed consent is the legally effective voluntary agreement of a participant, or the participant's authorized representative, to participate in research. Informed consent indicates the participant or representative has received full disclosure of and understands the purpose of the study, the procedures to be undergone, information about his or her rights, and the potential risks and benefits of participation and is therefore able to knowledgeably and voluntarily decide whether to participate in the research. Informed consent does not waive the participant's legal rights or release the investigator, the sponsor, the institution or its agents from liability for negligence (see Code of Federal Regulations 45 CFR 46.116 and 45 CFR 46.117 for additional information regarding the general requirements and documentation of informed consent). Research involving children (i.e., a person under the age of 18) requires child assent.

44. **Waiver of Informed Consent** - Grants permission to conduct research without obtaining consent from the subject following the IRB's determination that (a) the research

involves no more than minimal risk to the subjects, (b) the waiver will not adversely affect the rights and welfare of the subjects, (c) the research could not practicably be carried out without the waiver; and (d) whenever appropriate, the subjects will be provided with additional pertinent information after participation. See section 45 CFR 46.116 of the federal regulations for more information.

45. **Waiver of Documentation of Informed Consent** - Grants permission to conduct research in which subjects consent to participate, but do not sign a consent form. The researcher must still provide the subjects with information about the research that is understandable and that permits them to make an informed and voluntary decision about whether or not to participate. The IRB may waive the requirement for obtaining a signed informed consent document if (a) the only record linking the participant and the research is the consent document and the principal risk of the research would be potential harm resulting from a breach of confidentiality or (b) the research presents no more than minimal risk of harm to the participants and involves no procedures for which written consent is normally required outside of the research context. See 45 CFR 46.117 of the federal regulations for more information.

46. **Child Assent** – a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent (Assent Guidance). In order for a child to take part in research parental or guardian permission is required.

47. **Permission** – the agreement of parent(s) or guardian to the participation of their child or ward in research (45 CFR 46.408).

48. **Parent** - a child's biological or adoptive parent (45 CFR 46.402(d)).

49. **Guardian** - an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care (45 CFR 46.402(e)).

50. **Legally authorized representative** - an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research (45 CFR 46.102(c)).

51. **Deception** – Deception relates to research in which participants are intentionally deceived or given false information about the research (e.g., participants are provided with false information about their performance on a test; the use of a confederate posing as a participant). Deception is sometimes used in social behavioral research. The rationale for deception is that

a non-deceptive procedure would make it impossible to obtain accurate data. Additionally, the scientific, educational, or applied value of the research must outweigh the risks associated with the use of deception and deception should only be used when the research cannot be conducted without it (see American Psychological Association, Ethical Principals of Psychologists and Code of Conduct, Standard 8.07 Deception in Research).

52. **Incomplete Disclosure** - Incomplete disclosure involves withholding information about the true purpose or nature of the research (e.g., participants in a study about word learning are given a surprise memory test). The rationale for incomplete disclosure is to avoid biasing results. Incomplete disclosure is similar to deception and requires debriefing.

53. **Debriefing** – Debriefing is necessary when deception or incomplete disclosure has been used in research. It involves the researcher providing a full account and justification of the research activities after the research session is over.

54. **Research Personnel** – Any person working on the research project in any way. This will include anyone with primary contact with the human subjects, those who do not contact with the human subjects, those working with identifiable data, and those only working with de-identified data. All persons associated with the research project are considered research personnel.

55. **Investigator** – An investigator is defined by the U.S. Department of Health & Human Services as such: "OHRP interprets an "investigator" to be any individual who is involved in conducting human subjects research studies... Investigators can include physicians, scientists, nurses, administrative staff, teachers, and students, among others. Some research studies are conducted by more than one investigator, and usually one investigator is designated the "principal investigator" with overall responsibilities for the study. In every human subjects research study, investigators have certain responsibilities regarding the ethical treatment of human subjects." Investigator Responsibilities FAQs. In this sense, all investigators would be research personnel, but not all research personnel would be considered investigators.

56. **Responsible Primary Investigator** – This is an internal term used by Jacksonville University to refer to the person who will be held responsible for a research project from a liability and auditing perspective. RPIs must be a non-visiting, full time (9-month or 12-month) faculty or staff of Jacksonville University. This person will be the main contact for any submissions, oversight, auditing, and liability.

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