Institutional Review Board Policies and Procedures

2015-2016

Revision 3

Johnson University
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Revision History

Date	Version	• Change
08/01/2011	Revision 0	• Initial Issue
01/12/2012	Revision 1	• Multiple text revisions
01/08/2015	Revision 2	• Changed JU Logo
08/01/2015	Revision 3	• Changed IRB Member • Included guidelines for: ○ Electronic information protection ○ External survey tool: SurveyMonkey to ensure anonymity ○ Records Retention

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Institutional Review Board

A significant component of the culture and atmosphere in an academic institution is the engagement with sound scholarship. To that end, the Institutional Review Board at Johnson University has been established to advance the goal of conducting research with diligence and integrity. The purpose of this committee is to protect the rights and welfare of the human participants who participate in research conducted by students and/or faculty affiliated with Johnson University. This committee is composed of diverse individuals who are charged with the task of reviewing research involving human participants. All research conducted on behalf of or by affiliates of Johnson University shall be evaluated by this committee, which may request modifications to, approve, or reject proposed research. The members of the IRB will be guided by the ethical principles outlined in the Belmont Report (available in the Office of Institutional Effectiveness) and the federal requirements (45 CFR Part 46) as they relate to the mission of the university.

The first principle in the Belmont Report outlines Respect for Persons, indicating that those individuals who are involved in research participate voluntarily and are treated as "autonomous agents." This principle also requires that extra protection be offered to vulnerable individuals such as pregnant women, children and prisoners. The second principle, Beneficence, indicates that the researcher should make every effort to maximize the benefits of the research, while minimizing risks to the participants. Thus, the researcher should "do no harm." Finally, the third principle, Justice, states that both the burdens and benefits of the research process should be spread equitably among the research population and that participants should be treated in a fair manner.

The nature and content of proposed research will be evaluated according to the specific policies and procedures listed below. Please see the IRB schedule for submission deadlines and meeting times.

IRB Chairman, Dr. Trevor Egli email: TEgli@JohnsonU.edu

Membership and Jurisdiction of the IRB

The IRB is an administrative committee established by the Chief Academic Officer to review research conducted under the auspices of Johnson University. Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the University. However, those officials may not approve research if it has been disapproved by the IRB. The IRB functions independently of but in coordination with other committees. The IRB will be composed of between 5 and 7 members who are appointed by the Chief Academic Officer. Members will serve staggered terms of three years. The chair of the committee will also be replaced after serving three consecutive years. At least one member will represent each area of the University that is actively involved in research. Furthermore, at least one

member of the committee will not be employed or related to an employee of the University. The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. However, these individuals may not vote. No IRB member may participate in the review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. The IRB will meet once a month at a regularly scheduled time during the fall and spring semester.

What research projects need to be reviewed by the IRB?

All research involving human participants that is conducted and/or supported by Johnson University students or faculty requires IRB approval. It also includes research conducted by outside individuals or agencies which involve Johnson University faculty, staff or students. The Johnson University IRB retains final judgment as to whether a particular activity must be reviewed by this committee.

What research projects require additional approval?

Research conducted or supported by any federal agency must receive additional approval by federal regulatory boards. In addition, some research activities may require additional review including: school systems, universities, and medical facilities. It is the responsibility of the principle investigator to obtain appropriate approval from both the Johnson University IRB and all participating agencies before starting the research.

What activities do NOT need to be reviewed by Johnson's IRB?

Unless otherwise required by faculty or instructors, the following activities are exempt from review by this committee:

- 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 such a manner that participants cannot be identified directly or through identifiers linked to the participants.
- Research and demonstration projects (e.g., opinion surveys used for instructional purposes and confined to the classroom), which are conducted during the course of regular college courses. However, if the results are to be presented publicly (e.g., thesis or conference) the research must be approved by the IRB prior to data collection.
- Educational or therapeutic activities that are conducted during regular internships or field work.
- Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed, or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, by the Food and Drug Administration, or approved by the Environmental Protection Agency, or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

What is the procedure for reviewing a project?

With the exception of the aforementioned types of study, the Institutional Review Board must review and approve all research projects before they are started. It is the responsibility of the principal investigator(s) to submit a research proposal to the Johnson University IRB committee. Investigators

should refer to the attached document, Checklist for Proposed Research Involving Human Participants, for proposal guidelines. The IRB has two levels of review.

Expedited Review Process

Projects involving minimal risk to participants and traditional forms of assessment may be considered for expedited review. A list of categories for expedited review can be found in Appendix A: IRB Level of Review. Projects reviewed under the expedited process, however, may at the discretion of the reviewer be subjected to full review.

The principal investigator must write a research proposal with an attached cover sheet before seeking approval. The content of the proposal must follow the guidelines outlined in Appendix B: Proposal Checklist. If the principal investigator is a faculty or staff member, the proposal must be reviewed and approved by a member of the IRB.

If the principal investigator is a student, the proposal must be reviewed and signed by a faculty advisor before seeking IRB approval. All proposals must be submitted to the Chair of the IRB who will either review the proposal or forward it to another member of the committee. Members of the IRB will review proposals on a rotating basis, and the Chair of the IRB will determine who will review each submitted proposal. No committee member will be allowed to review proposals if there is a conflict of interest (e.g., faculty advisor to the student researcher). A decision will be made within two weeks after receiving the proposal. A copy of the proposal and board decision will be returned directly to the faculty advisor. If the project has been approved, then the research may proceed immediately. A copy of the approved proposal will be placed on file where it will remain active for a period of five years.

Full Review Process

Projects that involve any of the following must be reviewed by a majority of the IRB: (a) physical or psychological risk, (b) psychological or physiological intervention, (c) deception, (d) surveys on sensitive topics, or (f) research with special populations (e.g., homeless, incarcerated, etc.). A detailed research proposal with attached cover sheet must be submitted at least 10 days before the regular monthly meeting of the IRB. The meeting dates will be set at the beginning of each fall and spring semester. The principal investigator must attend the meeting to present the proposal and be prepared to answer questions about his or her research. When the committee members are satisfied that they have the necessary information to make a decision they will call a vote in the absence of the principal investigator. The final decision will be based on the majority of votes. Although the Chair of the IRB must be in attendance, his or her vote will not carry additional weight. Any board members, including the Chair of the IRB, who have a conflict of interest, will be asked to abstain from the vote. If the research is approved, the study may begin immediately. A copy of the proposal and the board's decision will be placed on file and remain active for five years.

Modifications to Approved Research

Minor changes in the forms or administrative details (e.g., room location, phone numbers) may be changed at the discretion of the faculty researcher or with the approval of a faculty advisor. However, a revised proposal must be submitted to the IRB if any substantive changes are made in the methodology of the research. It is the responsibility of the principal investigator and/or faculty advisor to determine if changes in the study warrant resubmission to the IRB. Modifications that should be resubmitted include

changes such as increased risk for participants, additional assessments or interventions, changes in the types or number of participants, etc. The revised proposal should be submitted directly to the Chair of the IRB for approval prior to changing the protocol.

Informed Consent

Informed consent assures that prospective participants will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. It is an on-going process, not a piece of paper or a discrete moment in time. Informed consent is a critical part of conducting ethical research and the IRB will consider very seriously the manner in which informed consent is provided and obtained. The required elements of an informed consent form or protocol are listed in Appendix C: Informed Consent. As a rule, informed consent will be required for all expedited and full review projects. The IRB recognizes, however, that informed consent may not be feasible or warranted in every study. If full informed consent is impractical or would alter the results of the study, the principal investigator may request modifications to or a waiver of this requirement. To do so, the principal investigator must provide the IRB with sufficient written justification for excluding this step. If full informed consent is to be waived the principal investigator must, at a minimum, provide information about how to contact the investigators for additional information.

Additional Protections for Vulnerable Populations

Incompetent adults cannot give consent. This may include the developmentally disabled, the cognitively impaired elderly, and unconscious or inebriated individuals. Only legally authorized representatives in accordance with state law can give consent for incompetent adults to participate in research. Additionally, when some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards shall be included in the study to protect the rights and welfare of these participants.

Unexpected Harm to Participants

If any participants are suspected of being physically or psychologically harmed during the course of a study, it is the responsibility of the principal investigator to suspend the research and inform the Chair of the IRB. The principal investigator must submit written documentation of the incident and the measures taken to rectify or reduce the harm. The participant(s) will also be informed of their right to submit a statement directly to the IRB. The Chair of the IRB will inform all members of the IRB, as well as the Chief Academic Officer, of any adverse outcomes or incidents resulting from research conducted at or on behalf of Johnson University. If the IRB finds that the study was not being conducted in accordance with its requirements or ethical guidelines, the IRB has the authority to suspend or terminate approval of the research. Any suspension or termination of approval will include a statement of the reasons for the IRB's action, and will be reported promptly to the investigator and the Chief Academic Officer.

CITI Ethics Training

Johnson University utilizes the Collaborative Institutional Training Initiative (CITI) Ethics training, a web-based program, to provide education regarding research ethics. The training program consists of seven modules of study and takes approximately five hours to complete. Upon successful completion of

training, a notice is sent to the Chief Academic Officer and remains in effect for three years. **All faculty, staff, and students doing research are required to take the CITI training. Students within the Ph.D. program take this training as part of CFGS7130 Principles of Research.**

Guidelines for Electronic Information Protection

Electronic Data Security

Researchers have a responsibility to be good data stewards. The majority of data is at some point collected, transmitted, stored, and/or shared electronically. Simply password-protecting a computer may not be sufficient to meet rigorous security standards. Questions include: Is the data identifiable, de-identified (coded) or anonymous? Is sensitive information being collected that could result in harm to participants? What is the risk of harm to the participant or others? Key Terms:

> Anonymous data – data that at no time has a code assigned that would permit the data to be traced back to an individual. Note: IP addresses are considered to be identifiable even though the address is linked to the computer and not specifically to the individual.
>
> De-Identified or Coded data – Identifying information is maintained separately using a code that lllows the researcher to readily ascertain the identity of the individual. The research data is coded with a number, letter, symbol, or combination and a key to decipher the code.
>
> PII – Personally identifiable Information: Any information that can be used to distinguish or trace an individual's identity, such as name, social security number, date and place of birth, mother's maiden name, or biometric records and any other information that is linked or linkable to an individual such as medical, educational, financial, and employment information.
>
> Sensitive Research Data: Data is considered sensitive when disclosure of identifying information could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.

The IRB plan should identify steps taken to protect data during collection, transmission, or storage. Examples of protections include:

- Encryption of data on device to protect against loss/theft of device
- Use of secure data transmission channels to protect against data interception. It is advisable to use a secure transmission process even if the data is anonymous, coded, or non-sensitive.
- Strong passwords to protect against unauthorized access
- Store data behind a secure JU firewall whenever possible
- Ensure strong data security controls on all storage sites

Johnson University's information technology methods for secure login and passcodes meets Federal Requirement 4.8.1 for student identity verification and protection. Use of a JohnsonU.edu information technology (e.g., electronic mail and cloud storage) ensure secure data transmission, strong passwords, and secure data storage).

Survey Monkey (http://www.surveymonkey)
This tool is approved by Johnson University's Institutional Review Board for use in student research provided:

> Survey setup will ensure Secure Transmission per SurveyMonkey recommendations: (a) SSL encryption is **enabled** to protect participant information as it moves along communication pathways between the participant's computer and SurveyMonkey computers. (b) IP address tracking is **disabled** ensuring that a specific participant's response cannot be tracked. The survey design shall include an electronic Informed Consent that records a participant's consent allowing for a "no" or "prefer not to respond" as an option for each question. Furthermore, a participant is given the option to withdraw at any time.

Retention and Destruction of IRB Records

IRB records shall be retained for at least 5 years, and records relating to research which is conducted be retained for at least 5 years after completion of the research. Records may be retained in hardcopy or electronic format. If electronic, appropriate Electronic Information Protection shall be provided.

Additional Standards from your discipline (e.g., HIPAA, FERPA) may be applicable to your data storage plan. Research sponsors may require longer retention periods. You must keep your research records for at least 5 years and possibly longer, depending on the longest applicable standard.

When research records are to be destroyed instead of stored securely, you should remember to protect your participants' confidentiality throughout the process. Paper records should be shredded and recycled, instead of tossed in the garbage or recycle. Records stored on a computer hard drive should then be erased using commercial software applications designed to remove all data from the storage device. For data stored on USB drives, DVDs, or other storage devices, the storage devices should be physically destroyed. You should keep records stating what records were destroyed, and when and how you did so.

IRB Schedule

Expedited Review

The IRB accepts proposals submitted for expedited review on an on-going basis. Persons submitting proposals for expedited review are to submit 1 electronic copy of their proposal and should expect to wait 2 weeks for a decision from the IRB. Projects reviewed under the expedited process, however, may be subjected to full review at the discretion of the reviewer.

Full Review

The principle investigator conducting research requiring full review must be available and/or present at the meeting the project is evaluated (student researchers are strongly encouraged to have their faculty advisor attend the meeting if possible). Persons submitting proposals for full review are to submit one electronic copy of their proposal. Proposals submitted without the required number of copies will be returned to the applicant.

Full Review Meetings Submission Deadlines:*

* Proposals received after the submission deadline will be reviewed at the next scheduled IRB meeting.

Submit all proposals and supporting documents to: Dr. Mark Pierce (mpierce@JohnsonU.edu).

Appendix A: IRB Level of Review

Please determine the appropriate category for your research project:

__ Expedited Review
This includes the following categories of research:

- ❒ Anonymous, mail, e-mail, or telephone surveys on innocuous topics
- ❒ Anonymous, non-interactive, nonparticipating observation of public behavior
- ❒ Secondary analysis of existing data
- ❒ Research on PK-12 educational curriculum or teaching methods involving educational practices
- ❒ Research involving the use of educational and psychological tests if information taken from these sources is recorded in such a manner that participants cannot be identified and there is no psychological intervention, physiological intervention, or deception
- ❒ Interviews and interactive surveys on innocuous topics
- ❒ Experimental studies that involve no risk or deception
- ❒ Noncurricula, interactive research in schools

__ Full Review
This includes the following categories of research:

- ❒ Research that might put participants at risk (physical, psychological, or social)
- ❒ Research involving psychological or physiological intervention
- ❒ Research involving deception
- ❒ Interviews or surveys on sensitive topics
- ❒ Research with special populations (e.g., minors outside of the normal educational program, prisoners, and mental incompetent)

_____	_____
Signature of Principal Investigator	Date
_____	_____
Signature of Faculty Advisor	Date
_____	_____
Signature of Research Assistant	Date
_____	_____
Signature of Research Assistant	Date
_____	_____
Signature of Research Assistant	Date

Appendix B: Proposal Checklist

REQUIRED FOR ALL PROJECTS

1. A Cover Sheet, clearly indicating:
    a. Title of project.
    b. Names of principal investigators, faculty advisors and research assistants.
    c. Collaborators from outside institutions.
2. Includes general statements of the problem and research question(s) to be tested by the proposed research.
3. Provides a description of the overall plan and procedures and methods. (Attach any questionnaires, interview protocols, and/or testing instruments as well as cover letter or instructions to participant.)
4. Lists relevant characteristics and source of participants. Describes how participants will be recruited.
5. Describes how participants will be selected for participation in the project and any remuneration to be received by the participant.
6. Explains source of funding for project if applicable.
7. States expected starting and completion dates for project.
8. Outlines potential benefit of the project to the individual participant, group of participants, or society in general
9. Outlines potential risks to participants and the measures that will be taken to minimize such risks.
10. Specifies procedures developed with respect to the anonymity of the participants and the confidentiality of their responses. Indicates what personal identifying indicators will be kept on participant. Specifies procedures for storage and ultimate disposal of personal information.
11. Specifies how participants will be informed of the nature of their participation in the project, that their participation is voluntary, and that their responses are confidential. Includes a copy of any written consent forms that will be used or gives an explanation for why written consent is not feasible or necessary.
12. Specifies any special population (e.g., children) involved in the project and describes the procedures for obtaining the appropriate consent.
13. States that documentation of permission from the institution or organization, which has the responsibility for the participants, has been submitted to the Committee before final approval can be given.
14. Specifies how the findings will be used or disseminated (e.g. professional publications, media, employers).

15. Describes plans for researchers to provide some summary of findings to participants or a rationale for why this is not tenable.
16. Describes Electronic Information Security and Protection protocols
17. Describes records retention and destruction protocols

ADDITIONAL REQUIREMENTS FOR FULL REVIEW ONLY

18. Describes if the participants will be exposed to any psychological interventions such as deception, contrived social situations, manipulations of attitudes, opinions, or self-esteem, psychotherapeutic procedures, or other psychological influences.
19. Describes procedures for follow-up and/or debriefing.
20. Specifies any procedures that will be designed to address any adverse effect from participating in the study.

Appendix C: Informed Consent

Informed consent is recommended for all research studies but is required for Expedited and Full Review projects. Every informed consent should include all of the following as they apply.

- ❒ Johnson University letterhead, or the letterhead of the sponsoring institution
- ❒ Title of study
- ❒ Name of the primary researcher and faculty advisor (when applicable)
- ❒ Contact information for the primary researcher
- ❒ Name of the human participant
- ❒ A statement that the human participant is not asked to relinquish the right to hold the researcher, institution, and/or funding agency liable for negligence
- ❒ Contact information for questions about the research
- ❒ Contact information for questions about a participant's rights
- ❒ A clear statement of the research
- ❒ An explanation of the purpose of the research
- ❒ A description of research procedures
- ❒ Identification of any procedures or treatments that are experimental
- ❒ The approximate number of study participants involved in the research
- ❒ The expected duration of the research
- ❒ A clear description of any reasonably foreseeable risks and/or discomforts to the participant associated with routine or experimental procedures
- ❒ Whom to contact in the event a research-related injury occurs
- ❒ Compensation and/or medical treatment in the event of injury
- ❒ Description of the medical treatment
- ❒ Where to obtain further information
- ❒ A clear statement of confidentiality that under no circumstances will information be disclosed to another entity for any purpose without specific and expressed agreement from the participant and a description of methods for assuring confidentiality
- ❒ A statement that participation is voluntary and refusal to participate or withdrawing from the study at any time involves no penalty or loss of benefits to which the participant is otherwise entitled
- ❒ Anticipated circumstances under which the participation may be terminated by the investigator without regard to the participant's consent

- ❒ The consequences, if any, of a participant's decision to withdraw from the research
- ❒ Procedural instructions for how the participant withdraws from the research
- ❒ Disclosure of any alternative procedures or courses of treatment that might be advantageous to the participant
- ❒ Details regarding reasonable benefits of the research and/or participation in the research
- ❒ Any cost that may be incurred by the participant as a result of participation in the research
- ❒ A statement assuring that if significant findings are developed that may relate to the participant's willingness for continued participation, the information will be provided to the participant who may choose to withdraw from the study
- ❒ For research using medical records, the following are addressed:
  - Time limit of review of the record (e.g., two months following consent)
  - The data or information that will be extracted from the record
  - A clear description of how the data or information will be used in the study
  - Permission language for contacting the participant in the event that the participant meets the research criteria
- ❒ The paragraph immediately preceding the signature/date line includes the following verbiage:

  By signing this consent form, I verify that I understand this research protocol and the risks that I may be exposed to as a participant the study. I have had the opportunity to ask questions for clarification about all aspects of the study. I realize that I have the right to ask questions and/or withdraw from the study at any time without penalty. If the study protocol changes in a way that would significantly affect the participants, I will be notified and asked to sign a new Informed Consent. Signing this form does not imply that I give up any legal rights in relation to the study. I will receive a copy of the signed consent form.

_____ _____
Participant's Signature Date

_____ _____
Witness (if necessary) Date

INVESTIGATOR'S AFFIDAVIT
The participant has been provided with the research study information detailed in this Informed Consent and has been given the opportunity to ask questions and receive clarification regarding any component of the study. I attest that the participant appears to understand the ramifications and risks of participating in the study. To the best of my knowledge, a medical, language, or other communication barrier has not hindered the participant's understanding of the proposed involvement in the research.

_____ _____

Signature of Principal Investigator Date