# Institutional Review Board
# Policies and Procedures
# 2021

**Revision 6**

**Johnson University**
**7900 Johnson Drive**
**Knoxville, Tennessee 37998**
**http://www.JohnsonU.edu**

**Contact Information:**

**IRB Committee IRB@johnsonu.edu**

**Institutional Effectiveness ewilliams@johnsonu.edu**

| Revision History | | |
|---|---|---|
| **Date** | **Version** | Change |
| **8/1/2011** | **Revision 0** | Initial Issue |
| **1/12/2012** | **Revision 1** | Multiple text revisions |
| **1/8/2015** | **Revision 2** | Changed JU Logo |
| **8/1/2015** | **Revision 3** | Changed IRB Member<br>Included guidelines for:<br>o Electronic information protection<br>o External survey tool: SurveyMonkey to ensure anonymity<br>o Records Retention |
| **11/2/2016** | **Revision 4** | Changed IRB Members, and dates |
| **9/29/2017** | **Revision 5** | Changed IRB Members, and dates<br>Updated JU Logo |
| **3/12/2021** | **Revision 6** | Updated IRB Membership<br>Joined Survey Policy and IRB Policies<br>Survey Policy Edited<br>Added Electronic Submission Information<br>Clarified Ethical Code Expectations |

## *Institutional Review Board Purpose*

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 (IRB) at Johnson University is 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 and research conducted by outside individuals or agencies which involve Johnson University faculty, staff, or students.

This committee is composed of diverse individuals 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 are guided the ethical principles outlined in the Belmont Report (available on the Office for Human Research Protections government site at www.hhs.gov) and the federal requirements (45 CFR Part 46) as they relate to the mission of the university.

The three fundamental ethical principles for using any human subjects for research are:

1. Respect for persons: protecting the autonomy of all people and treating them with courtesy and respect and allowing for informed consent. Investigators must be truthful and conduct no deception;
2. Beneficence: The philosophy of "Do no harm" while maximizing benefits for the research project and minimizing risks to the research subjects; and
3. Justice: ensuring reasonable, non-exploitative, and well-considered procedures are administered fairly — the fair distribution of costs and benefits to *potential* research participants — and equally.

The nature and content of proposed research will be evaluated according to the specific policies and procedures listed below.

## *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 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 is disapproved by the IRB. The IRB functions independently of but in coordination with other committees.

The IRB will be composed of a team of at least 5 members who are appointed by the Chief Academic Officer/Provost. Members will serve terms of three years. The chair of the committee is replaced after serving three consecutive years.

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. The IRB shall have at least one outside member that is in no way affiliated with or renumerated by Johnson University.

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.

## *Research Project Review*

### Surveys

The IRB is separate from, but works in conjunction with, the Office of Institutional Effectiveness to improve the use of existing and new data, coordinate survey schedules, reduce survey fatigue, and maintain consistent IRB protections.

All survey research that is conducted and/or supported by Johnson University students, faculty, or staff and that will take place on the Johnson University campus requires initial approval from Institutional Effectiveness. Examples of surveys that should be approved by the IE office include: 1) A faculty research survey that includes all faculty, or all staff, or all students; 2) A student research survey for a class that seeks to survey students outside of the class, or seeks to survey faculty, staff, or other groups. 3) Staff supervised local or national surveys of broad groups of students, faculty, or staff.

The Institutional Effectiveness office adheres to the criteria for review as set forth by the IRB. When survey projects require additional IRB approval, the principal investigator(s) will be notified of the requirement.

Some exemptions from the requirement for IE review appear below. **Note that the exemptions do NOT apply if the results of the survey will be published or will be presented in a presentation open to the public.** Surveys from external groups not associated with Johnson University, and/or surveys which may be used in public presentations and publications must be reviewed by the IRB, regardless of the exceptions listed below.

Institutional Effectiveness (IE) and IRB approval is not required for:

1. Teaching or advising evaluation forms
2. Faculty surveying students in their own courses
3. Administrators surveying employees they directly supervise
4. Academic administration surveying faculty
5. Surveys for a course in which only students in the same course are surveyed
6. Individual faculty research outside of the university

Those wishing to administer any survey at Johnson University that does not meet the requirements for exemption should first enter the request at

https://websurvey2.johnsonu.edu/cgi-bin/rws5.pl?FORM=JUSurveyRequestForm

From there, the user will be directed to the appropriate forms and procedures.

### Using External Survey Platforms

The use of external survey software platforms (e.g. Survey Monkey, Qualtrics, Typeform, Google Forms, Survey Gizmo) for research with Johnson University affiliated groups is only approved for the situations listed above that do not require IE or IRB approval.

Any cost associated with external software platforms are the sole responsibility of the individual user. Johnson University does not provide payment or reimbursement for access to any external survey software for students, faculty, or staff.

The use of external software platforms is not appropriate for any application other than the ones enumerated above. The following are examples, but not an exhaustive list, of research that requires the use of IE provided survey tools at Johnson University

1. A faculty research survey that includes all faculty, or all staff, or all students
2. A student research survey for a class that seeks to survey students outside of the class, or seeks to survey faculty, staff, or other JU affiliated groups.
3. Staff supervised local or national surveys of broad groups of students, faculty, or staff.

**Johnson University requires the following protections when using external survey platforms:**

1. SSL encryption is enabled to protect participant information as it moves along communication pathways between the participant's computer and the platform computers.
2. IP address tracking is disabled ensuring that a specific participant's response cannot be tracked.
3. 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.

## Collecting and Storing Survey Data

All data related to surveys must be stored securely and used only for the designated and intended purposes as indicated on the approval form. Data containing participant names, identifying information, email addresses or other confidential information must be saved on computers or drives that belong to the University. This data should not be stored on computers or servers outside the University.

## Research

All other 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. The following activities are generally 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,
    a. if wholesome foods without additives are consumed
    b. 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.

## *IRB Review Process and Procedures*

With the exception of the aforementioned types of research, 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.

***It is imperative that investigators make clear what professional ethical code or specific body of professional ethics will guide their research practices. Johnson University IRB assumes investigators conduct all research in alignment with the most recent code of ethics published by the American Psychological Association (APA), unless another ethical code is identified by the investigator. Research proposals submitted for approval must clearly state their guiding ethical research code, and make protocols align with those principles. Investigators should also be aware of state-based legalities that may govern their research endeavors.***

To determine the required level of review, and access the relevant forms, investigators should go to IRB Level of Review website at

https://websurvey2.johnsonu.edu/cgi-bin/rws5.pl?FORM=IRBLEVELofREVIEW.

### Expedited Review Process

Projects involving minimal risk to participants and traditional forms of assessment may be considered for expedited review. Projects reviewed under the expedited process, however, may at the discretion of the reviewer be subjected to full review. Johnson University utilizes the Collaborative Institutional Training Initiative (CITI) Ethics training, a web-based program, to provide education regarding research ethics. The IRB will determine if CITI training is required prior to the implementation of the project. 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 Office of Institutional Effectiveness and remains in effect for three years.

**Expedited Review Procedures. The principal investigator must fill out an Expedited Research Proposal form before seeking approval.** The content of the proposal must follow the guidelines outlined in *Appendix A: 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 investigator). Proposal review requires a minimum of two weeks, but may be substantially longer depending upon several factors. A copy of the proposal and board decision will be returned directly to the primary investigator. If the primary investigator wants communications from the IRB to be sent to other parties (such as a faculty advisor, program director, or co-investigator) they should indicate as such and provide the appropriate name, role, and email address on the IRB application submission. If the project has been approved, and CITI training is not required, 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.

**Expedited Review Schedule.** The IRB accepts proposals submitted for expedited review on an on-going basis. Proposals are not typically reviewed over the summer semester, although investigators may submit their proposals at any time. Persons submitting proposals for expedited review are to submit 1 electronic copy of their proposal via the online electronic application

As directed on the electronic application, investigators should submit supplemental documents to the JU Institutional Review board at IRB@Johnsonu.edu. In the event that the online electronic application is down or unavailable, full proposals can be submitted via the IRB@johnsonu.edu email address.

Review of proposals requires a minimum of two weeks, and may take longer depending upon the number of proposals currently under review.

Link to the Online Application Portal is:
https://websurvey2.johnsonu.edu/cgi-bin/rws5.pl?FORM=IRBLEVELofREVIEW.

## 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. ). Johnson University utilizes the Collaborative Institutional Training Initiative (CITI) Ethics training, a web-based program, to provide education regarding research ethics. The IRB will determine if CITI training is required prior to the implementation of the project. 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 Office of Institutional Effectiveness and remains in effect for three years.

**Full Review Procedures. The principal investigator must fill out a Full Research Proposal form before seeking approval.** The content of the proposal must follow the guidelines outlined in *Appendix A: Proposal Checklist***.** A detailed research proposal with attached summary form must be submitted with substantial lead time in advance of the project's intended start date.

As directed on the electronic application, investigators should submit supplemental documents to the JU Institutional Review board at IRB@Johnsonu.edu. In the event that the online electronic application is down or unavailable, full proposals can be submitted via the IRB@johnsonu.edu email address.

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.

**Full Review Schedule.** The principle investigator conducting research requiring full review must be available and/or present at the meeting when the project is evaluated (student investigators are strongly encouraged to have their faculty advisor attend the meeting, if possible).

Full reviews are a time-intensive process, and scheduling of project proposal presentations for full reviews require a minimum of 2 weeks. Wait times may be extended beyond this period depending upon the number of proposals currently under review. The full review process often is a protracted process, involving several revisions. Investigators should adjust their proposal timelines appropriately for this process.

**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 investigator 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.

## *Participant Protection*

### 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 B: 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.

### Protections for Vulnerable Populations

Incompetent adults cannot give consent. This may include the developmentally disabled, the cognitively impaired, 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, 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, and may be communicated to the faculty advisor or academic program staff if the investigator is a student at Johnson University.

## Electronic Data Security

Investigators 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?

The IRB plan should identify steps taken to protect data during collection, transmission, or storage. Johnson University requires the following protections:

- Encryption of data on device to protect against loss/theft of device. (Note: Data on portable devices such as smartphones or tablets is not encrypted.)
- 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. (Note: All data transmitted within JohnsonU.edu is secured with encryption during transmission without exception.)
- Strong passwords to protect against unauthorized access.) Note: Password protection includes a minimum of 8 characters in length, at least one upper case character, at least one lowercase character, and at least one number or symbol.)
- Store data behind a secure Johnson University firewall whenever possible. (Note: All internal data is stored behind a Meraki Firewall on both campuses. All information stored in the cloud is securely stored behind similar appliances.)
- Ensure strong data security controls on all storage sites. (Note: Access to internal storage is heavily regulated and is typically only available while on a Johnson University campus.)
- External storage devices used to store data such as hard drives, usb flash drives, etc. must be encrypted and password protected. Procedures for storing passwords separately from the storage device and under secure conditions is required.

Johnson University's information technology methods for secure login and passcodes meet 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). All data within Johnson's network is secured with encryption during transmission without exception.

## Retention and Destruction of IRB Records

IRB records shall be retained for at least 5 years, and records relating to research which is conducted shall be retained for at least 5 years after completion of the research, or in accordance with the relevant ethical code and state law, whichever is longer. 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 data storage plans. Research sponsors may require longer retention periods. Investigators must keep research records depending on the longest applicable standard.

When research records are to be destroyed instead of stored securely, investigators must protect participants' confidentiality throughout the process. Paper records should be shredded and recycled, instead of tossed in the garbage or recycled. 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. Investigators should maintain records stating what records were destroyed, and when and how the data was destroyed.

## Appendices

Appendix A: Proposal Checklist
Appendix B: Informed Consent

# Appendix A: Johnson University Proposal Checklist

Investigator's should submit project proposals online at:

https://websurvey2.johnsonu.edu/cgi-bin/rws5.pl?FORM=IRBLEVELofREVIEW.

**REQUIRED FOR ALL PROJECTS**

1. **Title of Project**

2. **Names of Principal Investigators, Faculty Advisors and Research Assistants**.

3. **Collaborators from Outside Institutions (If Applicable)**

4. **Statement of the Problem and Research Question.** General statement(s) of the problem and research question(s) to be investigated by the proposed research.

5. **Methodology**. Provide a description of the overall plan and procedures and methods. (email any questionnaires, interview protocols, and/or testing instruments, as well as cover letter or instructions to participant to IRB@johnsonu.edu)

6. **Sampling.** List relevant characteristics and source of participants. Describes how participants will be recruited. Describe how participants will be selected for participation in the project and any remuneration to be received by the participant. If investigator is accessing personal contact information, demonstrate how information is in public domain, or investigator has permission from proper authority to access such records.

7. **Funding**. Explain source of funding for project. All projects have costs. Specify if self-funded or any outside resources.

8. **Timeline**. Expected starting and completion dates for project.

9. **Benefits and Risks.** Outline potential benefit(s) of the project to the individual participant, group of participants, and/or society in general. Outline potential risks to participants and the measures that will be taken to minimize such risks.

10. **Protection of Participants**. Specify procedures developed with respect to the anonymity of the participants and/or the confidentiality of their responses. Indicate what personal identifying indicators will be kept on participant. Specify 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. Include a copy of any written consent forms that will be used or gives an explanation for why written consent is not feasible or necessary.

11. **Electronic Information Security and Data Protection protocols.** Specify procedures for storage and ultimate disposal of personal information and research data, including how such procedures match an identified ethical code and/or state laws (whichever is more stringent).

12. **Special Protections.** Specify any special population (e.g., children) involved in the project and describe the procedures for obtaining the appropriate consent.

13. **Permissions.** State what documentation of permission from the institution or organization, which has the responsibility for the participants, has been submitted to the Committee via email. Before final approval can be given, the researcher must provide any relevant and/or applicable permissions for use of particular study participants, populations, research instruments, or applicable forms.

14. **Projected Uses of Findings**. Specify how the findings will be used or disseminated (e.g. professional publications, media, employers). Verify that information in this section is consistent with all informed consent documents and previous reported methodologies.

15. **Participant Feedback**. Describe plans for investigators to provide some summary of findings to participants or a rationale for why this is not tenable.

16. **Psychological Interventions.** Describe 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. (REQUIRED FOR FULL REVIEW PROJECTS)

17. **Follow-Up and Debriefing.** Describe procedures for follow-up and/or debriefing. Verify these procedures are consistent with previous described methodology and informed consent.

18. **Risk Mitigation and Recourse.** Specify procedures that will be designed to address any adverse effect from participating in the study.

# Appendix B: Johnson University 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 investigator and faculty advisor (when applicable)
- ❒ Contact information for the primary investigator
- ❒ Name of the human participant
- ❒ A statement that the human participant is not asked to relinquish the right to hold the investigator, 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 | Participant's Name (printed) | Date |
| _____ | _____ | _____ |
| Witness Signature (if necessary) | Witness's Name (printed | 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 | Name (printed) | Date |