Human Subjects Research Application Packet

Guidelines, FAQs, & Application – 2017-18

Daytona State College

Introduction

An integral part of the College's mission is to "foster innovation to enhance teaching and learning." Research is a pathway to achieving this charge and one aspect of the scholarly work undertaken by students, faculty, and staff at Daytona State College. Scholarly research often involves the use of human subjects for data collection and analysis. Daytona State College is committed to protecting human subjects and ensuring the ethical conduct of research. As such, all research projects involving the use of human subjects must be approved by the College's Institutional Review Board (IRB) prior to the commencement of the project. The IRB is the College committee charged with overseeing the procedures for carrying out the College's commitment to protect human subjects in research.

Daytona State College's IRB reviews human subjects research proposals from College personnel to ensure that:

- The rights and welfare of human subjects are protected;
- The risks involved in such research have been considered and are minimized;
- The potential benefits of participation are identified and maximized;
- Participation in research by human subjects is voluntary;
- All human subjects are informed of the risks and benefits before agreeing to participate;
- Human subjects data will be confidential; and
- Research conducted by this institution is ethical and complies with established standards for research.

The IRB does not evaluate the research proposal for the soundness of the study, the merits of the research design, or the potential contribution to the scholarly literature. The focus of the IRB is the evaluation of the research's compliance with ethical standards in regards to human subjects protection (informed consent, confidentiality, risks/benefit to participants). The Institutional Review Board is authorized to review, approve, require modifications in, or disapprove research activities conducted by or through the College.

The following application packet include the Institutional Review Board guidelines, FAQs about IRB, and an application.

INSTITUTIONAL REVIEW BOARD GUIDELINES

The Purpose of the Institutional Review Board

Daytona State College encourages and supports the scholarly endeavors of students, faculty, and staff of the College. Pursuit of scholarly work and research will often involve the use of human subjects for data collection and analysis. The College's Institutional Review Board (IRB) reviews human subjects research proposals to ensure that the rights and welfare of human subjects used in research studies by College personnel are protected, that risks have been considered and minimized, that the potential for benefit has been identified and maximized, that all human subjects only volunteer to participate in research after being provided with legally effective informed consent, and that any research is conducted in an ethical manner and in compliance with established standards.

No research activity involving human subjects shall be undertaken unless an Institutional Review Board has reviewed and approved the activity. Currently, the College has one IRB committee, registered with the Federal Office for Human Research Protections (OHRP) as Institutional Review Board IRB00005372. The College also holds a Federal-wide Assurance (FWA) through OHRP, FWA00010271. As part of this Assurance, the College agrees to consider all research involving the use of humans as research participants as being subject to federal regulations regardless of the source of funding.

The Human Subjects Review Panel

The human subjects review panel includes five members approved by the Vice President of Planning, Development and Institutional Effectiveness and selected to achieve departmental and methodological representation. The IRB comprises members with varying backgrounds and expertise in special areas to provide complete and adequate review of the research. The IRB includes at least one member whose primary concerns are in a science area and one whose primary concerns are in a nonscientific area. The committee will include at least one member external to the College. Members will serve for three-year terms. A chairperson will be appointed by the Vice President of Planning, Development and Institutional Effectiveness. Members with conflicting interests will not vote in any IRB review.

Current human subjects review board members (2017-2018):

- **Dr. Ron Morrison,** Chair
- **Dr. Richard Rogers**, member
- **Dr. Linda Miles**, member
- **Dr. Walter Saviuk**, member
- **Dr. Linda Bradley,** external member (University of Central Florida)

Types of Research Subject to Review

Any research and data collection activities (externally funded, internally funded, unfunded, and conducted by or with the College faculty and students) which involve human subjects or data collected from human subjects must apply to the Institutional Review Board for a review and must request approval before any involvement of human subjects takes place. The IRB review will determine whether the activity/research design will adequately protect the rights and welfare of the subjects.

Process for Initiating Human Subject Review

Human subjects review will be completed following the standard procedures for review outlined in this document, i.e. submitting the IRB-1 form and any supporting documents (consent forms, data collection instruments to be used in the course of research, grant proposal if submitted to receive external funding). The Chair of the Institutional Review Board will sign the approval form when approval is given.

IRB-1 forms will be reviewed to determine the following:

a) if they are complete and all forms are in order; if not, requests for additional or revised information may be made at this time.
b) if full IRB review is warranted (as in the case of projects which are externally funded or which involve more than minimal risk) or whether the research is exempt from full review.

It is highly recommended that potential investigators discuss the IRB process with the IRB Chairperson prior to submitting an application for review.

Full Board Review Exemptions

The term "exempt" applied to a research project does not mean that the requirement to obtain human subjects approval is waived for that project. The term "exempt" indicates that full committee review is not required. Certain types of research may be exempted from full committee review if the only involvement of human subjects falls within one of the exemption categories listed in the Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects. These research projects may be reviewed and approved by the IRB through its expedited review procedure.

Please note that **researchers are not permitted to declare that their own research projects or those of their students are exempt from review.** For instance, certain types of research involving children, including surveys, interviews, and participant observation, generally cannot be exempted unless the research is conducted in educational settings and involves normal educational practices, such as research on instructional strategies or techniques.

The exemption categories that most frequently apply to research conducted by investigators at community colleges are (http://answers.hhs.gov/ohrp/categories/1564):

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) 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 subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) 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, or agricultural chemical or environmental contaminant at or below the level 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.

A researcher or principal investigator cannot make the determination as to whether a project is exempt from Board review. All projects involving human subjects must be brought to the IRB Chair for a determination of exemption.

The Review Process

For research projects that are clearly exempt from full review, the Chair of the Institutional Review Board or the Chair's designee may, after reviewing the human subjects form and all supporting documentation submitted to them by the researcher, choose to perform an expedited review and grant

approval without review by the full committee. Expedited review, if applicable, will generally be completed within five working days, if the submitted forms and other materials are complete and in order. If the forms or other materials require revision, the researcher will be notified as soon as possible of the revisions to be made. Review of the revised forms will then take place once the forms are resubmitted. Once approval has been granted, an approval letter will be sent to the researcher and report of the approval will be presented to the full committee.

Any cases requiring review by the full Institutional Review Board will be reviewed within thirty days of submission. At each review meeting, careful records will be kept on the disposition of each case. Rulings and requests for additional information will be communicated to the researcher. The researcher and the department chair will be notified of approvals. Copies of all materials will be kept on file for a period of three years or for the duration of the project, whichever is longer. Records containing the name of the researcher, title of the project, starting and ending dates, and funding agency will be maintained indefinitely.

The IRB will be guided by and operate in compliance with applicable sections of Title 45, CFR, Part 46, Protection of Human Subjects, June 23, 2005. For non-exempt multi-year projects, review must be repeated annually. Projects for which the scope of work or activities that involve human subjects change substantially during the project are also subject to renewal application review. In the event that a conflict of interest arises with a member of the IRB related to a project under review, the member will not participate in the review process for that project.

The following types of projects are exempt from IRB review:

- Data gathered for the purposes of fundraising;
- Market research for the purposes of admissions recruiting; recruiting efforts for faculty or staff; and
- Statistical data collected for the management of institutional affairs, including surveys of students, prospective students, and alumni.

A project that does not clearly fall into one of these categories should be brought to the IRB Chair for a determination of whether it is exempt.

Acquiring Human Subjects Training

It is recommended that any researcher proposing research that involves human subjects undergo training in Human Subjects research. Training is available as an online course through the National Institutes of Health's (NIH) Office of Human Subjects Research:

http://phrp.nihtraining.com/users/login.php

The training, composed of seven modules, will take an estimated three (3) hours to complete. Trainees should print a copy of the certificate of completion for their records.

Informed Consent

Researchers must document signed informed consent of human subjects to participate in research. For those less than 18 years of age, the research must obtain the signed informed consent of parents or

legal guardians and all reasonable attempts will be made to obtain each participants' assent, which is defined as the participant's agreement to participate in the study.

Informed consent must include the following information in sequential order and in language that is easily understood by participants:

1. Statement of purpose of the study.
2. Short description of the methodology and duration of participant involvement.
3. Statement of potential risks and benefits of participation.
4. Statement of data confidentiality.
5. Statement regarding the right of the participant to withdraw from the study at any time without negative consequences.
6. An offer to answer any questions the participant may have.
7. Contact information of all Principal Investigators and contact information for Daytona State College's Institutional Review Board chairperson.
8. Line for the participant's signature and/or parent or legal guardian except for questionnaire research in which return of the questionnaire gives implied consent.
9. Statement that the participant is 18 years of age or older unless parent or legal guardian has given consent.

In situations where participants will be decided, items 1 and 2 are omitted and participants are told (on the signed form) that disclosure of the purpose and/or methodology could bias the outcome of the study. In this case, after the study is complete, each participant must be presented with a description of the purpose and methodology as carried out and this document must be signed by the participants "after the fact" in order to guarantee informed consent.

A record of signed informed consent forms must be kept in a secure location.

Frequently Asked Questions About Human Subject Research at Daytona State College

Adapted from the University of Massachusetts Lowell Office of Institutional Compliance

1. What is the IRB?

The Institutional Review Board (IRB) is a committee, comprised of faculty and staff from diverse backgrounds and a community member, that reviews research protocols involving human subject participants to ensure that the rights of the participants are protected, that they are not subject to unreasonable harm (physical and emotional), and that information about them is kept confidential.

2. What is research?

Research means **a systematic investigation, including pilot research, testing and evaluation, designed to develop or contribute to generalizable knowledge**. This includes investigations carried out by faculty and staff for publication and/or presentation and the collection of scholarly materials for theses and dissertations.

3. Why should I submit anything to an IRB? I'm not conducting clinical trials.

An IRB is a federal requirement covering all types of research involving human subjects, including medical, psychological, and educational. Daytona State faculty and staff are extensively involved in educational research—testing new curricula, new modules, new courses, assessing faculty development workshops, assessing student success resulting from program improvements, etc.

4. How do I know if I should submit a research protocol to the IRB?

If your project meets the definition of research (see question #2) and involves human participants, it must be reviewed by the IRB.

5. My research with human subjects is not externally funded with grant money. Do I still have to submit an application to the IRB?

Yes. All research that involves human subject/participants must be reviewed and approved by the IRB.

6. If I begin my activity that involves human subjects before I receive IRB approval, what action may be taken against me?

Any study will be terminated by the IRB, which could result in loss of funding.

7. Can the IRB stop me from conducting my research?

Yes. The IRB has the authority to disapprove, suspend, or terminate research that is not carried out according to its requirements or may be associated with unexpected serious harm to subjects. The IRB will require you to destroy all data.

8. Do student projects that are part of a class requirement have to be submitted to the IRB?

It depends, but typical assignments for a class that are not for generalizable knowledge do not typically need IRB review. Of course, the faculty needs to be aware of the types of information being collected and communicate to students the ethics that guide the collection of information by the students. If there is any question, it is best to contact the IRB chairperson to discuss the specific situation.

9. Do I need IRB approval if my activities will be conducted someplace other than Daytona State campuses? Do I need IRB approval if my protocol is already approved by another IRB?

Yes. Daytona State is still responsible for the activities of its researchers and must comply with federal and college regulations and policies. It is important that the IRB be aware of where and by whom such activities are being conducted, even in another country. The IRB form can be used to designate that an IRB from another institution will be responsible for oversight but the Daytona State IRB still needs to be notified of the activity and keep a copy of the form on file.

10. Who should I contact if I have questions?

Contact the IRB Chairperson, Dr. Ron Morrison at (386) 506-3918 or morrisr@daytonastate.edu .

11. What is informed consent?

Informed consent is usually obtained through a document that fully discloses the nature of the research, explains the risks (both physical and psychological) and benefits and allows the individual to voluntarily decide whether to participate in the research study or not.

12. What is the difference between anonymous and confidential?

Anonymous means that the data collected by the researcher cannot be linked to the participant. Confidential means that the researcher may be able to identify a participant's data but will not reveal the participant's identity to anyone else. Person-to-person interviews, for example, are never anonymous.

13. Does the IRB serve as a scientific review panel?

No, but if a proposed project appears to lack scientific merit or rigor, or duplicates existing work with more than minimal risk to subjects, the IRB is required to consider whether the benefits to individual subjects and society outweigh the potential for harm to them.

14. Who is responsible for reporting any problems that may occur during the conduct of approved human subject research activities?

Principal Investigators are responsible for reporting promptly to IRB Chair,[name/contact], any serious or continuing noncompliance with federal regulations, college policies, injuring to subjects, unanticipated problems, or changes in research activities. However, anyone who becomes aware of any serious or continuing noncompliance in the conduct of approved research should bring this to the attention of the IRB Chair.

15. What should I do if I know of research that has violated ethics?

You should notify the IRB Chair, [name contact info]. If you have any concerns or are uncertain about what constitutes a violation, contact the IRB Chair.

16. May deception or misrepresentation be used in studies with human subjects?

Yes, if the benefits outweigh the risks to the subjects for participating in such a study, and if the researcher provides a compelling scientific justification for such experimental manipulation. The participants must be informed that some information is being withheld until the end of their participation. For research where deception or misrepresentation is involved, the subjects must receive an explanation (a debriefing) about the nature of the experiment and why such manipulation was critical to its success. Such a form should be included with the materials submitted for IRB review and approval. All research that involves deception must be approved by the IRB.

17. Does the IRB continue to review research once it has been approved?

Yes. The IRB conducts annual/continuing reviews of applications at one year intervals for projects that continue for longer than one year.

18. If I make changes in my protocol, does the IRB have to review and approve it again?

Yes. Any changes must be reviewed and approved by the IRB.

19. When do projects require consent?

Consent is required from any human subject in research unless informed consent has been specifically waived by the IRB. The IRB may waive consent if the project involves no more than minimal risk; the waiver does not adversely affect subjects; the research could not practicably be carried out without the waiver; and, where appropriate, subjects are given information about the project afterwards.

20. Do all projects require written consent?

The IRB may waive written consent if:

- Signed consent is the only record linking the subject to the research and the greatest risk of the research is a breach of confidentiality; or
- The research presents no more than minimal risk and involves procedures for which consent would not normally be obtained outside of the research context.

21. What consent materials are required for research with minors?

Research activities with minors require completion of a parental consent form and an assent form. For more information regarding human subjects research involving children, please visit http://grants.nih.gov/grants/policy/hs/children.htm.

22. What is assent and is it always required?

Assent refers to the agreement by the minor to participate. Assent must be accompanied by consent from a parent or guardian and must be written in the simplest terms possible. Assent must be sought from a child unless: (1) the child is incapable of providing assent (due to age or condition), or (2) the intervention holds out the prospect of direct benefit to the child and the intervention is available only in the context of the study. In these two situations, consent from parent(s) is sufficient.

23. I have a project that involves evaluating data collected about human subjects from databases. The databases I intend to use do not contain any identifiable information (i.e., the identity of the subjects may not be readily ascertained by the investigator or associated with the information) and I am not going to have any intervention or interaction with human subjects. What type of IRB review would this need?

This is not considered human subject research and does not need to be submitted to the IRB for review. It is important to realize that if you conduct a research project that is considered human subject research and you have not had your project reviewed and approved by the IRB before you start your research project, it may be considered scientific misconduct. In addition, scholarly journals are unlikely to publish your study. If there is any question, it is always best to contact the IRB Chair to verify whether you need to have your project reviewed.

24. What should I be concerned about regarding the recruitment flyer for my research project?

The recruitment flyer or advertisement is meant to interest prospective participants but it must provide a rudimentary amount of information that will give a person an understanding of what is to be expected and who is conducting the study, without hype that that raises false expectations.

25. How do I document that I have received Human Subjects training?

If you have already undergone human subjects training, you will need to provide a copy of the certificate of completion. If you have not taken human subjects training, you can access a free online course through the National Institutes of Health (NIH): http://phrp.nihtraining.com/users/login.php. The training takes about three (3) hours. Print a certificate of completion for your records when you have completed the training.

26. I think my research is exempt. Do I need to seek IRB approval?

Yes. You must submit an IRB-1 Protocol Form to receive "exempt" or expedited review. Only the IRB Chair can make that determination, *not* the Principal Investigator(s).

APPENDICES

Daytona State College
IRB-1 Protocol Submission Form

Instructions: The principal investigator should complete each section of this form. Incomplete forms will not be reviewed. Upon completion of the form, the principal investigator must submit to the IRB chairperson the original, signed form along with all necessary support documents, including the research proposal (if externally funded), all consent/assent forms, and any research instruments (i.e. questionnaires, interview protocols, etc.). Please make a copy for your records. An incomplete form will be returned to the principal investigator without review.

Any questions regarding the IRB process or this form should be directed to the IRB chairperson.

IRB Chairperson:	Dr. Ron Morrison
Phone:	506-3918
Email:	ronald_morrison@daytonastate.edu

By submitting the form and supporting materials to the IRB, the PI agrees to the following:

- This study will be conducted in the manner described in the submission. No changes to this study will be implemented until a revision form has been submitted and approved by the IRB.
- This study will be conducted during the one year IRB approval (or less as stipulated by the IRB). If the study will exceed the approval period, the PI will submit a Continuation/Renewal/Revision form in a timely manner (but prior to the renewal date).
- The PI will provide a copy of the signed consent form to the subject.
- The PI will retain all signed informed consent documents for a minimum of three (3) years (or longer as stipulated by the funding agencies) from the date the study is concluded.
- The PI will report in writing any serious or adverse events to the IRB chair within 24 hours.
- The PI will provide participants with any significant new information obtained during the course of the study.
- If the study has been approved at the Expedited or Full Review levels, the PI will report to the IRB when this study has closed. This report will be provided no more than 90 days from the end of the study.

Daytona State College
IRB-1 Protocol Submission Form

Title of Research Protocol: _____

SECTION 1: Investigators

Principal Investigator (PI): _____

Title: _____

Department: _____

Campus Location: ☐ **DB** ☐ **Deland** ☐ **Deltona** ☐ **Flagler/PC** ☐ **ATC** ☐ **NSB**

Campus address: _____

Email: _____ **Phone:** _____

Completed Human Subjects/IRB training: ☐ **YES (attached certificate)** ☐ **No**

I certify that the protocol and method of obtaining informed consent as approved by the Daytona State College IRB will be followed during the period covered by this research project. Any future changes to the research project will be submitted to the IRB for review and approval prior to implementation.

PI Signature: _____ **Date:** _____

Co-Principal Investigator (Co-PI): _____

Title: _____

Department: _____

Campus Location: ☐ **DB** ☐ **Deland** ☐ **Deltona** ☐ **Flagler/PC** ☐ **ATC** ☐ **NSB**

Campus address: _____

Email: _____ **Phone:** _____

Completed Human Subjects/IRB training: ☐ **YES (attached certificate)** ☐ **No**

I certify that the protocol and method of obtaining informed consent as approved by the Daytona State College IRB will be followed during the period covered by this research project. Any future changes to the research project will be submitted to the IRB for review and approval prior to implementation.

Co-PI Signature: _____ **Date:** _____

Please list additional Co-PIs on a separate page

SECTION 2: General Project Information

Proposed start date: _____ **Proposed end date:** _____

Total project duration: _____

Performance site(s): _____

Source of Funding:

- ☐ **Grant (specify source)** _____
- ☐ **Other (specify)** _____
- ☐ **Unfunded**

SECTION 3: External Collaboration

Projects involving collaboration with researchers/personnel from institutions other than Daytona State College should complete the following section. Each participating institution is responsible for safeguarding the rights and welfare of human subjects and for complying with all regulations. ***If the research does <u>not</u> involve external collaboration, please check the "not applicable" box below.***

☐ This section is <u>NOT APPLICABLE</u> for this application.

External Researcher: _____

Title: _____

Institution/Organization: _____

Has this proposal been submitted to another IRB? ☐ YES ☐ NO

IF YES, IRB Decision:

Please include a brief description of the external researcher's role:

SECTION 4: Research Description

A. Briefly describe the project's research methodology using non-scientific language.

1. Abstract
2. Goals, Objectives, and Significance of Research:
3. Procedures: *Briefly describe the participants, the location(s) of the project, the procedures to be used for data collection, whether data will be confidential or anonymous, disposition of the data, who will have access to the data*.
4. Participant Selection Methods: *Describe the methods you will use for a) selecting research participants and b) ensuring that their participation is voluntary.*

B. Participants/Human Subjects

Subjects will be: ☐ Daytona State College Students
☐ Adult, non-students
☐ Non-adult, non-students

Number to be recruited: _____

Special Populations (Check all that apply)
☐ Prisoners
☐ Mentally challenged
☐ Mentally ill
☐ Elderly
☐ Other (specify): _____

Approximate time commitment per subject: _____

Will compensation be provided to subjects? ☐ YES ☐ NO

If YES, specify the form and amount of compensation per subject: _____

_____

SECTION 5: Review and checklist

Based on review of the Daytona State College Institutional Review Board Guidelines, check one of the following:

A. I request that this research be considered **exempt** from IRB review: ☐
B. I request that this research be considered for **expedited** IRB review: ☐
C. I believe this research is subject to **full** IRB review: ☐

Checklist:

Please ensure that the following items are included in this application:

1. Research proposal narrative ☐
2. All consent and assent forms: ☐
3. Data collection instruments: ☐
4. Collaborative IRB Approval letters (if applicable): ☐
5. Human subjects training certificate: ☐
6. Any additional support documents (please label): ☐

To be completed by the IRB Chairperson					
IRB File Number:					
	Approved		Approved with conditions		Refer to full committee review
Comments:					

Sample Informed Consent Form

The following sample informed consent form is offered as a guideline for developing an informed consent form. The exact language to be used is the decision of the researcher. Additional requirements for the informed consent form may depend on the specifications of the research to be conducted.

Project Title: Student Mental Health Awareness

Project Director: Dr. Jane Smith, faculty, Department of Psychology

Purpose: The purpose of this study is to learn what promotes and prevents students from seeking help for mental health needs. This study involves interviews with students to learn more about these issues. An interview will last 1-2 hours and will be recorded and transcribed.

Risk and benefits: Foreseeable risks and potential adverse effects include emotional distress prompted by discussions regarding mental health topics. To provide protection against such risk, the interview will be conducted by faculty or a licensed mental health professional. In addition, you will receive contact information for on-campus or off-campus counseling services, should you desire assistance after participating in the interview. If you experience immediate distress at any point during the interview, you may discontinue the interview at any time without consequences.

You may find it beneficial to discuss mental health. The interview may be useful for helping you to think about important issues related to mental health and the services that are available to you.

Voluntary and confidential participation: Your participation in this interview is complete voluntary. You may skip any questions you do not wish to answer. If you decide to conclude your participation at any point, you may withdraw without consequence. Your participation is confidential. All interviewees will be given a code number and potentially identifying information will be removed from the interview transcript. All records of research will be kept in a locked office and only the project team will have access to the records.

If you have questions: You may ask any questions about your participation in the project now or at a later point. You may contact Dr. Jane Smith at (386-555-1234 or smithj@College.edu) to discuss any questions or concerns about the project. If you have questions or concerns regarding your rights as a participant in this study, you may contact the Institutional Review Board at (385) 555-2233.

I understand the study described above and have been given a copy of the description as outlined above. I am 18 years or older and I agree to participate.

_____ _____

Signature of Participant Date

_____ _____

Signature of research/witness Date