ALFRED UNIVERSITY
INTER-OFFICE MEMORANDUM

TO: All-Faculty, All-Administrators, Research Staff

FROM: Dr. Danielle D. Gagne, Chairperson, Human Subjects Research Committee (HSRC)

RE: AU Policy on Research Involving Human Subjects

DATE: Fall 2019

I. INTRODUCTION

Individuals wishing to conduct research at Alfred University (AU) involving human subjects must conform to applicable federal, state, and local laws and regulations. To oversee and regulate research involving human subjects most effectively, AU maintains a standing committee known as the Human Subjects Research Committee (HSRC). It is the purpose of this committee to review research protocols involving human subjects and evaluate risks to subjects, protection against risks, and potential benefits likely to result from proposed research.

Research is hereby defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition may be funded or unfunded, or may be conducted as a component of another program not usually considered research. For example, demonstration and service programs may include evaluation components that constitute research activities under this definition.

In addition, *student research* (i.e., projects conducted by student investigators who gather data about living individuals outside the class) that involves obtaining data in a systematic investigation about living individuals through intervention or interaction with those individuals, or through the collection of their identifiable private information, are subject to review by the HSRC, even if the activities are not designed to develop or contribute to generalizable knowledge.

The attached policy statement is to remind all faculty, administrators and staff researchers that:

- we have an ethical and legal obligation to protect the interests of human research subjects to the fullest extent possible;
- all supervisors of student research are expected to instruct their students in elements of sound research design, which includes understanding and protecting rights of human subjects; and
- **all physiological and behavioral research involving human subjects must be reviewed** and approved by the HSRC and must comply with informed consent requirements.

Current members of the HSRC are:

Danielle Gagne, Chair, CLAS (Psychology)
Rachel Roth, School of Graduate and Continuing Studies
John D'Angelo, CLAS (Chemistry)
Emrys Westacott, CLAS (Philosophy)
Pamela Schultz, CLAS (Communication Studies)
Mark Whitman, Outside Reviewer (Social and Behavioral Sciences, Alfred State College)

Please direct any questions or comments to any committee member, who will then forward your concerns to the full committee. Please note that all policy decisions involving research with human subjects are rendered by the entire committee, not by any individual member.

II. HUMAN SUBJECTS RESEARCH POLICY at ALFRED UNIVERSITY

Many Alfred University scholars conduct research involving human subjects using in-depth interviews, survey research, direct observation of behavior, and physical experimentation. All Alfred University researchers have a moral and legal responsibility to protect the interests of human research subjects to the fullest extent possible, in accordance with professional standards of ethical conduct. In general, adequate protection of human research subjects requires that the extent of confidentiality be clearly negotiated with the subject and observed by the researcher; that research be reported accurately and completely; and that the subject be fully informed for what purposes data will be used.

University policy requires that all proposals, grants, and behavioral research projects involving human subjects be submitted to the Human Subjects Research Committee (HSRC) for its written approval prior to data collection.

Following federal guidelines, the HSRC will review research that meets the following requirements:

1. risks to subjects are reasonable in relation to the anticipated benefits to subjects or the importance of knowledge that may reasonably be expected to result;

2. research procedures minimize risk to subjects;

3. selection of subjects is equitable;

4. informed consent is sought from each prospective subject or the subject's legally authorized representative; and

5. provisions to protect the privacy of subjects and to maintain the confidentiality of data are adequate.

Legally effective informed consent shall have the following elements:

1. be in language understandable to the subject or the representative;

2. be obtained under circumstances that offer the subject, or the representative, sufficient opportunity to consider whether the subject should or should not participate;

3. not include exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or appears to release the research investigator, the sponsor, the institution or its agents from liability for negligence;

4. explain the purposes of the research and the expected duration of the subject's participation, describe the procedures to be followed, and identify any procedures which are experimental;

5. describe any reasonably foreseeable risks or discomforts to the subject;

6. describe any benefits to the subject or to others which may reasonably be expected from the research;

7. describe the extent to which confidentiality of records identifying the subject will be maintained;

8. explain whether any compensation and medical treatments are available if injury occurs;

9. explain whom to contact for answers to pertinent questions about the research and research subject's rights; and

10. state that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits and that the subject may discontinue participation at any time without penalty.

Research investigators must obtain the signature of the subject or the subject's legally authorized representative on an informed consent form approved by the HSRC unless this requirement is specifically waived by the HSRC. The research investigator must make available a copy of the informed consent form upon the request of the subject or subject's representative.

A. Undergraduate and Graduate Research

Students conducting research involving human subjects as a normal class requirement in which the data will be used **for classroom purposes only** are not directly subject to HSRC procedures. Note that this data cannot be used beyond the classroom.

Students conducting major research projects, honors projects, independent studies and master's theses are principal investigators and *are expected* to comply with HSRC procedures.

For student research, advisors must submit all materials in email to the HSRC and copy the student researcher(s). Materials must be free of grammatical and typographical errors.

In all cases, course instructors are expected to instruct their students in elements of sound research design which includes understanding and protecting the rights of human subjects.

B. Ethics Training

As of September 1, 2015, all individuals listed as the Principal Investigator (PI) or who are listed as a faculty sponsor on a submitted proposal must complete a free, on-line training module in Human Subjects Research, which is available through the Collaborative Institutional Training Initiative.

Instructions:

- Go to https://www.citiprogram.org/
- Create a Username and Password
- Add an affiliation: Alfred University
- Modules:
    - Faculty, staff, and students conducting social, behavioral, or educational research with human subjects must select the course labeled *Social and Behavioral Responsible Conduct of Research* (9 modules)

You must score at least 80% on the assessment portion to "pass" and receive your certificate. Upon completion, researchers should print and/or save a certificate of completion, which must be sent to the HSRC with the proposal.

NOTE: Completion of a different training module does not satisfy this requirement.

Additional instructions can be found on the CITI website:
http://citiprogram.desk.com/customer/portal/articles/163300-how-do-i-enroll-in-a-citi-course-for-the-first-time-

C. Ethics Training Recertification

In order to remain in compliance with the Ethics Training requirement, researchers, including faculty/staff sponsors must retake the training modules every three years. Proof of completion should be emailed to the HSRC chair.

D. Submitting Proposals

Those who wish to conduct research need to submit a complete proposal for review. Incomplete proposals will be returned.

Allow at least two weeks for review during the academic terms. Review may take longer during certain times of the year, such as Summer term, Allen term, or during finals weeks.

Please complete and submit the following:

a) proposal cover sheet;
b) research proposal including all required components: background, informed consent, debriefing (if applicable), all questionnaires and instruments (including citations); and
c) copy of the completed CITI ethics training module.

Please send all materials electronically to the HSRC e-mail account at hsrc@alfred.edu. For student research, the proposal must be sent by the faculty sponsor.

III. REVIEW PROCESS

A. Levels of Review

Research with human subjects will fall under one of three categories: Exempt, Expedited, or Full review.

1. Exempt Review.

Exempt Reviews are conducted by one experienced member of the HSRC. Proposals suitable for Exempt Review must involve no greater than minimal risk and fall into one of the categories below:

- research on instructional techniques, curricula, or classroom management methods;
- research using educational tests (cognitive, diagnostic, aptitude and achievement) if information is recorded so that subjects cannot be identified; or
- research involving interview procedures or direct observation of public behavior except where any of the following conditions exist:
  - data are recorded so that subjects can be identified;
  - data, if subjects become known outside of the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; or
  - research that deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or the use of alcohol.

If the HSRC believes that the proposed research is not suitable for Exempt Review, it will be subjected to Expedited or Full Review, as appropriate.

2. Expedited Review

Research that does not meet criteria for Exempt Review, but involves no more than minimal potential harm to participants will undergo Expedited Review. Additionally, federal guidelines stipulate that research qualifying for Expedited Review *cannot* include protected classes or vulnerable populations, such as children, pregnant women, prisoners, and individuals with disabilities, or individuals with mental illness. The Expedited Review is conducted by a subset of the HSRC which involves the Chair and two other committee members.

3. Full Review

Any research not qualifying for Exempt Review or Expedited Review is subject to Full Review by the HSRC. If desired the researcher and sponsor (if applicable) is welcome to attend the HSRC review meeting and provide justification as to why they feel the proposal should be approved.

Regardless of the level of review (Exempt, Expedited, or Full), researchers should expect that review of HSRC proposals will take at least 2 weeks (or longer if submitted during "off" times as described in Section II Subsection D). This does not account for any revisions required to the proposal. Please plan accordingly.

B. Review Process

Pre-review. Only complete and properly constructed proposals are forwarded to the HSRC for review. Proposals which are incomplete, contain errors, or were not submitted properly will be returned to the researcher(s) without review.

Notification. The outcomes of Exempt and Expedited Reviews will be provided to researchers via email. If revisions are required, they will be detailed in this communication. If Full Review is needed, the HSRC Chair will contact the researcher and sponsor (if appropriate) to determine whether an in-person meeting is needed or desired. **Researchers cannot begin to collect data until HSRC approval is granted.** Unless otherwise noted, approvals will be valid for one year, after which researchers must contact the HSRC to request a renewal of the initial approval. Depending on the review level of the initial proposal, re-review may be necessary.

IV. NONCOMPLIANCE

All Alfred University researchers must comply with HSRC policies.

Failure to comply with HSRC policy may constitute a serious legal and/or ethical breach and therefore, must be reported to the HSRC immediately if discovered. Examples of noncompliance include, but are not limited to:

- Failure to conform to approved research protocol(s)
- Disclosure of participants' information to unauthorized parties
- Changing research protocols without HSRC approval
- Conducting research before formal approval is given (or without seeking approval at all) or after approval has expired
- Failure to provide accurate and truthful information to the HSRC or participants

If noncompliance with HSRC standards is suspected, please contact the HSRC chair directly at hsrc@alfred.edu. If upon consultation with HSRC members and/or the Provost's office it is determined that researchers have not complied with HSRC policies, researchers must cease all research activity immediately. Written notification of the order to cease research will also be provided to the researchers' division head, dean, and/or faculty members, as deemed appropriate.

V. PROPOSAL

Your proposal must include all of the sections.

A. Cover Sheet (see end of packet)

B. Major purpose/Background

This section must provide sufficient non-technical background so that the committee can understand the motivation for the proposed research, the benefits and risks associated with the proposed research, and how the results of the research will be used. Citation of relevant scholarly literature and research question(s) or hypothesis(ses) under investigation are expected.

C. Subjects and procedures

Describe the research procedures, participant recruitment procedures, and any possible remuneration/compensation. Identify the targeted participants with respect to age, gender, and other defining characteristics.

D. Safeguards for subjects

Describe any potential negative consequences incurred through participation (or, state that minimal risk is expected). Indicate how risk or negative consequences will be minimized for participants. Be sure to include the contact information for the principal investigator, faculty sponsor (if applicable), and chair of the HSRC.

E. Time frame

Provide the time frame for the participation of the subject, and the overall timeline for completion of the project.

F. Care and use of results

Indicate steps taken to ensure confidentiality: Password-protected and/or encrypted computer files, locked filing cabinets, locked offices, non-identifying participant key codes, etc. Describe how the results of the research will be used (e.g., presentation at conferences, publication, etc.) and how the data will be maintained and destroyed (if applicable).

G. Appendices

1. Informed consent form
2. Debriefing statement
3. Any other instruments (e.g., questionnaires, forms, etc)

INFORMED CONSENT CHECKLIST

- Describe the research broadly, offering the subject or the representative sufficient opportunity to consider whether the subject should or should not participate.

- Explain the purposes of the research and the expected duration of the subject's participation, describe the procedures to be followed, and identify any procedures which are experimental.

- Describe any reasonably foreseeable risks or discomforts to the subject.

- Describe any benefits to the subject or to others which may reasonably be expected from the research.

- Describe the extent to which confidentiality of records identifying the subject will be maintained.

- Explain whether any compensation and medical treatments are available if injury occurs.

- State that participation is;
    - voluntary,
    - that refusal to participate will involve no penalty or loss of benefits, and
    - the subject may discontinue participation at any time without penalty.

- Explain whom to contact (provide mailing address, e-mail, and phone number) for answers to pertinent questions about the research and research subject's rights.
    - Student Researcher (if applicable)
    - Principal investigator/Faculty
    - Chair, Human Subjects Research Committee
    - AU Wellness Center (if applicable)

- Do not include exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or appears to release the research investigator, the sponsor, the institution or its agents from liability for negligence.

- Use error-free and grammatically correct language that is understandable to the subject and/or or the representative.

Sample Consent Form

Survey of Undergraduate Students

You are invited to be in a research study of characteristics of undergraduate students enrolled in introductory anthropology classes. You were selected as a possible participant because you are 18 years of age or older and enrolled in an anthropology class at Alfred University. We ask that you read this form before agreeing to be in this study.

This study is being conducted by Alfred Alfredson, Ph.D., and Jane Student., Alfred University, Alfred, NY 14802.

Background Information

The current study will investigate attitudes and behaviors associated with anthropology.

Procedures

If you agree to participate in this study, we ask that you fill out the following questionnaires in full and be forthright in your answers. On the pages that follow, you will find surveys of attitudes and behavior patterns, as well as a demographics questionnaire. Completion of this study is estimated to take approximately 15-20 minutes.

Risks and Benefits of Being in the Study

While unlikely, it is possible that you may feel discomfort while considering some of the survey items that deal with potentially troubling situations. You are free to discontinue your participation at any time during the study simply by exiting the survey. In the unlikely event that this survey causes mild distress, the researchers suggest that you consult with the Alfred University Wellness Center (607-871-2300) or another mental health service provider in your immediate vicinity. Participation in this study may provide you with some additional knowledge about research related to anthropology and your participation will hopefully add to this knowledge base.

Confidentiality

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a participant. Research records will be kept in a locked file; only the researcher will have access to the records. Records will be kept for at least three years after completion of the study, after which records may be destroyed at the discretion of the researcher.

Voluntary Nature of the Study

Your decision whether or not to participate will not affect your current or future relations with Alfred University. If you decide to participate you are free to withdraw at any time without penalty.

Contacts and Questions

The researcher conducting this study is Alfred Alfredson. If you have questions about your participation in this study that you would like to ask before participating, please exit this survey and contact the researcher electronically at alfredson@alfred.edu.

If you have any questions now, or later, related to the integrity of the research, (the rights of research subjects or research-related injuries, where applicable), you are encouraged to contact Dr. Danielle Gagne, Chair of the Alfred University Human Subjects Research Committee, at (607) 871-2213 or electronically at HSRC@alfred.edu.

Statement of Consent

I have read the above information. I consent to participate in the study.

_____ _____

Signature Date

_____

Printed Name

HUMAN SUBJECT RESEARCH COMMITTEE -- PROPOSAL COVER SHEET

Project Title	_____	
Project Status	☐ New Research ☐ Modification to existing research ☐ Extension request for existing research (no changes)	
School/College	☐ College of Business ☐ School of Art & Design ☐ NYS College of Ceramics	☐ School of Graduate & Continuing Studies ☐ Inamori School of Engineering ☐ College of Liberal Arts & Sciences
Purpose of Research	☐ Institutional (Student Affairs, CDC, etc.) ☐ Faculty Research ☐ Dissertation Research ☐ Master's Research	☐ Independent Study (graduate) ☐ Independent Study (undergraduate) ☐ University Honors ☐ Class project
Type of Research	☐ Archival ☐ Experiment ☐ Survey ☐ Hybrid ☐ Other (describe _____)	
Subject Population	☐ Children and/or Adolescents (aged 0-18) ☐ Adults (aged 18+)	

Is this research in collaboration with another academic Institution? ☐ No ☐ Yes
Is this research in collaboration with an outside agency, company, or other? ☐ No ☐ Yes
If "yes," name: _____

Principle Investigator:	_____ Name, dept
Local Contact Information:	Address: _____ e-mail:
Faculty Sponsor (if student PI)	_____ Name, dept
Local Contact Information:	Address: _____ e-mail: