Human Subjects Review Policy

Introduction

To safeguard the rights and welfare of persons participating as subjects in any research or sponsored project involving Claflin University is considered an institutional obligation. In accordance with Title 45, Part 46 of the Code of Federal Regulations, all research involving human subjects, regardless of funding source or status of investigator (i.e., faculty, student, or staff) is required to receive review and approval prior to initiation of the activity, and at least annually thereafter for the duration of the activity, unless the activity is determined to be exempt from further review. Approval will be based upon the determination that the rights and welfare of the subjects will be adequately protected, that potential benefits outweigh any hazards, and that, when required, the informed consent of subjects or their legally authorized representative will be obtained.

The Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human subjects in research studies conducted under the auspices of Claflin University (CU). The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction. The IRB independently approves or disapproves a research protocol based on whether or not human subjects are adequately protected. The IRB reports to the Executive Assistant for Government Relations and Research.

The Federal regulations require that IRBs give special consideration to protecting the welfare of particularly vulnerable subjects, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. For research to which the DHHS regulations are applicable, the DHHS regulations set forth specific provisions on research involving fetuses, pregnant women, and human in vitro fertilization [45 CFR 46 Subpart B]; prisoners [45 CFR 46 Subpart C]; and children [45 CFR 46 Subpart D]. In general, these special regulations allow IRBs to approve research that is of minimal risk or that will benefit the subjects directly. Investigations involving these subjects that present significantly greater than minimal risk without direct benefit to them must be reviewed and approved by the Secretary of Health and Human Services, in consultation with appropriate experts.

CU requires that anyone who engages in scholarly research involving human subjects, either on- or off-campus go through the IRB for a Human Subjects Review. This includes, but is not limited to all CU faculty and staff, CU students who conduct independent research, researchers who are not affiliated with CU, but are conducting primary research with subjects on campus, and anyone analyzing unpublished data collected at the university.

Policy on Protection of Human Subjects

- All researchers conducting original research are responsible for protecting their subjects from the risk of unreasonable harm.
- The principal investigator/project director has initial responsibility for determining whether such a risk exists. A faculty member is responsible for supervising research undertaken by students in the context of his/her courses or departmental/program curriculum.
- If there is any doubt about risks, the principal investigator should contact the IRB.
- The principal investigator/project director should refer to and follow the guidelines of the relevant professional organizations and, where appropriate, those of governmental funding and regulatory agencies. Faculty members supervising student research have a responsibility for introducing the students to CU's guidelines.
- Investigators shall respect the privacy of their subjects. Investigators shall protect confidential information given them, advising subjects in advance of any limits upon their ability to ensure that the information will remain confidential.
- Subjects, including students who are participating in classroom experiments or faculty scholarship, shall not be induced to participate by means or in circumstances that might affect their ability to decide freely. When course credit is offered for participation in research, some other mechanism to "earn" that credit must also be made available to those students who choose not to participate as human subjects.
- All subjects will be made aware that they are free to withdraw from participation in the research at any time. This shall be clearly stated as part of the informed consent statement.
- Teachers who assign or supervise research conducted by students are responsible for ensuring that these students are qualified to adequately safeguard the well-being of the subjects.
- Subjects of human research are generally provided the opportunity of access to the benefits of that research at its conclusion.
- An investigator shall disclose to a subject, upon request, the source of support for the research.

Before undertaking the research activities, the PI should take the following measures.

- The principal investigator/project director should have on a file, a certificate from the IRB showing that he/she has completed the Human Subjects Review process.
- Subjects should be made fully aware of any risks.
- The principal investigator/project director shall explain to subjects, prior to their participation, the objectives of the research, the procedures to be followed, and the risks and potential benefits. In general this explanation should also be offered in writing.
- Investigators/directors shall not use individuals as subjects unless satisfied that the subjects, or others legally responsible for the subject's well-being, freely consent to participation with a full understanding of the consequences. An "informed consent" form should be completed and filed. Written consent is required even

for anonymous questionnaires.

The Principal Investigator/Project Director shall submit two copies of the Human Subjects Review Form to the Chair of the IRB for review at least thirty (30) days prior to submission to an Agency if it is to be submitted for proposal review or at least 30 days prior to beginning research.

Approval of a human subject research proposal is good for one year, unless the project has acceptable but potential risk, in which case approval is given for a six-month period. If the project will continue beyond the approval period, Principal Investigators/Project Directors are required to resubmit documents for review prior to the expiration date of the initial approval. These documents should include a status report of the project to date including:

- The number of subjects accrued;
- A summary of adverse events and any unanticipated problems involving risks to subjects or others and withdrawal of subjects from the research or complaints about the research since the last review;
- A summary of any relevant amendments or modifications to the research since the last review;
- Any other relevant information, especially information about risks associated with the research; and
- A copy of the current informed consent document and any newly proposed consent document.

In the initial approval letter, principal investigators/project directors are asked to promptly report any unanticipated problems or adverse effects of the research to the IRB.

Appeals: In the event that an application is denied because the IRB feels the risks outweigh the benefits of the research, and the investigator/director disagrees with the committee's disapproval decision, the researcher may appeal the decision by re-submitting the same application form and: 1) a letter of appeal presenting the researcher's arguments for approval; and 2) any other pertinent information in support of the appeal. The letter should be mailed with enclosures to Executive Assistant for Government Relations and Research. Applications submitted for appeal will be considered by the full board at the next scheduled meeting date. The final decision of the IRB will be stated in writing to the investigator/director. If the proposal is not approved, the research cannot be conducted. The researcher may at any point submit a revised proposal, which will be reviewed as a new application.

University Records: CU keeps records of all original human subjects research on the Review Form, along with copies of any research documents (informed consent forms, questionnaires, interview scripts, stress protocols, behavioral manipulation protocols, drug protocols, non-FDA device protocols, debriefing forms, etc.), and a copy of any

publication resulting from the research. This information is stored by the Sponsored Programs Office.

References:
Institutional Review Board Guidebook, Chapter VI, Special Classes of Subjects.

http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-031.html

http://www.orsp.umesp.maine.edu/HumanSubjects.htm

http://www.access.gpo.gov/nara/cfr/waisidx_99/45cfr46_99.html

http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm

CITI Training Program:

https://about.citiprogram.org/en/series/human-subjects-research-hsr/

https://about.citiprogram.org/wp-content/uploads/2017/10/Final-Rule-Material-Changes-to-Exempt-Determination-Process.pdf.