IRB Policy Handbook

Institutional Review Board (IRB)
irb@fullcoll.edu

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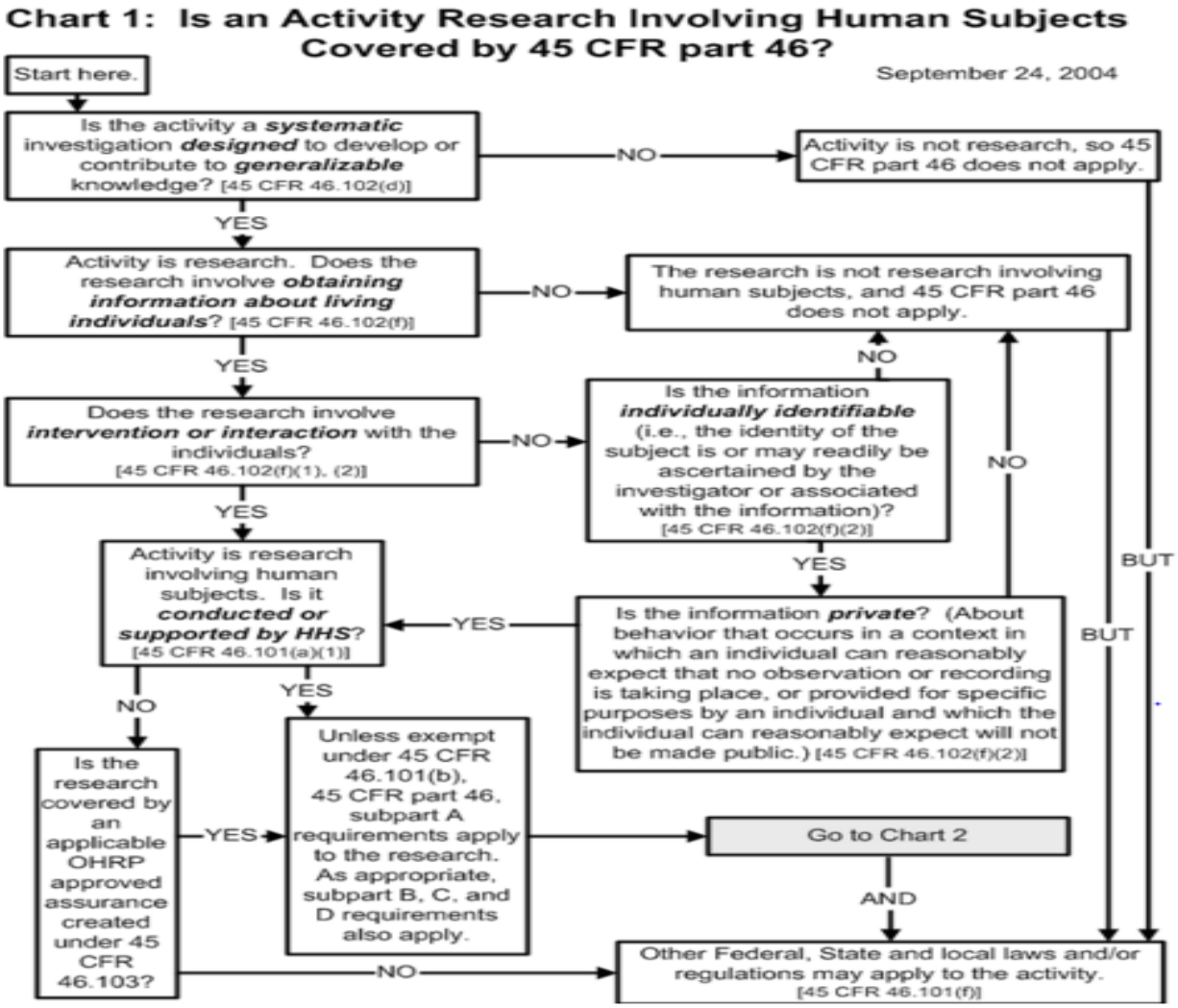
IRB Application Process

To adhere to federal and local regulations, the Fullerton College IRB has a formal application process in place to address requests for research. Applicants are requested to become acquainted with the process.

Step 1	Determine whether the proposed study is research, as defined by the federal government. Please refer to Research section of this handbook to learn how the federal government defines research.
Step 2	If the study is research, then determine the type of review the study should likely receive from the IRB. To learn about the different types of reviews, please refer to Types of Review section of this handbook.
Step 3	Complete the Fullerton College Application for Approval of Human Subjects Research. A complete application packet should include all of the following and be submitted to irb@fullcoll.edu: 1. Application for Approval of Human Subjects Research 2. IRB Approval from External College/University 3. Recruitment Documents (Letter, Email, Flyer, and any other) 4. Informed Consent Form and, if applicable, Assent Form 5. Instruments (surveys, questionnaires, interview protocol, etc) 6. Evidence of Completion of Human Subjects Ethics Training in the form of a certificate from either the Collaborative Institutional Training Initiative (CITI) or the National Institutes of Health (NIH) Training.
Step 4	The IRB will review the completed application. The timeframe will depend on the type of review. • Exempt Status – The IRB chair person determines whether a research study is exempt from review. Generally, a decision is made within 30 days. • Expedited Review – The IRB chair person along with one IRB member, or two designated IRB members, review a research proposal. Generally, a decision is made within 30 days. • Full Review – The majority of the IRB Committee, including the non scientist representative, review the research proposal. Generally, a decision is made within 60 days.
Step 5	The IRB may request from the primary investigator a clarification, additional documents, and/or revisions.
Step 6	If approved, a primary investigator has one year to complete all data collection. If not approved, a primary investigator must not collect data at Fullerton College.
Step 7	If there is a need for an amendment to the original proposal or an extension to go beyond the one year approval period, a primary investigator must submit the Application for Amendment to or Extension of Previously Approved Human Subjects Research. The primary investigator must await approval from the IRB before proceeding.
Step 8	At the conclusion of the study, the primary investigator must submit to irb@fullcoll.edu a Closure Form along with a copy of the final study report.

What is Research?

Federal guidelines define research as "means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities." CFR 46.102(d)



What is a human subject?
A human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

What is minimal risk?
The federal government defines minimal risk as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

What is an IRB?

Fullerton College Institutional Review Board No. IORG0007053 has been approved by the Office for Human Research Protections (OHRP) and is valid until 8/07/2017. The Fullerton College IRB assures the government and the public that it will comply with the federal regulations for the protection of human research subjects as noted under its Federalwide Assurance (FWA).

In accordance with the Federal Regulations, an IRB—Institutional Review Board--is a diverse committee of scientists, nonscientists and community/unaffiliated members who review proposed research involving human subjects to protect their rights and welfare. The Fullerton College IRB is comprised of 11 members and X alternates and is diverse in members' backgrounds, knowledge, and experiences. To ensure diversity, the IRB includes one classified staff member, five faculty members, two administrators/managers, the director of the Office of Institutional Research, a representative knowledgeable of an at-risk student population, and an unaffiliated/community representative. Each IRB member and alternate serves a term of 2 years. The President of Fullerton College appoints all IRB members after gathering input from the appropriate constituency groups.

Research investigators and their institutions have a fundamental responsibility to safeguard the rights and welfare of people participating in research activities. All reviews of research activities involving human subjects are done by the IRB. Should an IRB member have a conflict of interest with a particular research activity and/or project, s/he will refrain from reviewing, engaging in the discussion of, and voting for it.

The purpose of the Fullerton College IRB rises above meeting the legal requirements of the federal government. The IRB also serves as a forum for the development and understanding of the ethical guidelines governing human subjects research.

The IRB reviews and has the authority to approve, require modifications or disapprove all research activities, including previously approved research that is currently undergoing new modifications. The research protocol and the informed consent document are the interface of communication for ethical research practices between the IRB and the researcher.

Types of Review

There are three different types of reviews that an IRB may undertake to review a proposed project. The type of review is based on the sensitive nature of the proposed project and level of potential risk to human subjects. A proposed project can be exempt from review or may undergo expedited or full review.

Exempt Review

Federal regulations stipulate the type of research that is exempt from IRB review. Specifically, there are six categories of research activities that may be exempt. These exempt categories are noted in the following manner in CRF §46.101(b):

(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.

The IRB chair person determines whether a project is exempt and notifies the researcher of such exempt status. A chair person cannot declare under exempt review that a project is disapproved. It takes approximately 30 days for a project to get through the IRB process.

Expedited Review

Expedited review takes place when the research is found to have no more than minimal risk or when minor changes are proposed to a previously approved research project if requested within a year of the original approval. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may **not** disapprove the research. A research activity may only be disapproved during the full review process. The IRB must inform all members of research proposals approved under expedited review.

The IRB chair person may determine whether a project must go through expedited review. A chair person cannot declare under expedited review that a project is disapproved. It takes approximately 30 days for a project to get through the IRB process.

Full Review

Full review calls for the review of proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. IRB members will be sent research proposals and supporting documents via email prior to the IRB meeting in order to be well informed and prepared. While all members will be sent the relevant documents, three IRB members will be selected to lead the discussion of the research proposal. Federal regulations stipulate that in order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting. Furthermore, the nonscientist must be present to approve a research project.

Research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

The IRB chair person determines whether a project shall go through expedited review. A chair person cannot declare under exempt review that a project is disapproved. It takes approximately 60 days for a project to get through full IRB review.

Human Subjects Research Training

All IRB members, alternates, and investigators proposing to conduct research must complete a research subjects ethics training. Students enrolled in courses requiring research activities or in an independent study course should complete the human subjects research training especially designed for them. The ethics training must be completed prior to collecting data. The purpose of the training is to assist IRB members to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The ethics course will also help guide student researchers as they collect data for their respective projects. IRB members and those proposing to conduct research on campus must complete the online protection of human subjects course and pass it with a score of 80% or higher. The course can be taken from either the Collaborative Institutional Training Initiative (CITI) or from the National Institute of Health (NIH) Office of Extramural Research. The online CITI course is offered at www.citiprogram.org and can be accessed by establishing an affiliation with Fullerton College during the registration process. To access the NIH course, please visit https://phrp.nihtraining.com/users/login.php and create an account.

If choosing to take the CITI course, the following modules must be completed to be certified:

- Belmont Report and CITI Course Introduction
- History and Ethical Principles
- The Federal Regulations
- Informed Consent
- Privacy and Confidentiality
- Assessing Risk

If taking the NIH course, the following modules must be completed to be certified:

- Introduction
- History
- Codes and Regulations
- Respect for Persons
- Beneficence
- Justice
- Conclusion

Please include with your application your certificate of completion from either CITI or NIH.

Consent and Assent Requirements

Consent

Federal regulations require that investigators obtain the informed consent of the human subjects invited to participate in a research study (CFR 46.116). It is the responsibility of the investigator to keep a signed copy of the informed consent form, or assent form in the case of underage children, for each participating human subject. A copy of the informed consent form should be given to each study participant. The consent form will include or address the following:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

2. A description of any reasonably foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others which may reasonably be expected from the research;

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

7. An explanation to contact Carlos Ayon, Director, Office of Institutional Research and Planning at Fullerton College, at (714) 992-7063 for answers to pertinent questions about the research and research subjects' rights, and in the event of a research-related injury to the subject; and

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

When appropriate, one or more of the following elements of information shall be included in the consent form:

9. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

10. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

11. Any additional costs to the subject that may result from participation in the research;

12. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
13. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

14. The approximate number of subjects involved in the study.

Assent

For human subjects under the age of 18, an informed assent is required. While the participation of underage (less than 18 years of age) children in research is discouraged, if and when children are invited to participate as human subjects in a study, the investigator must acquire their assent. The IRB will take into consideration age, maturity, and the psychological state of the underage human subjects when determining if those children are capable of providing assent. As with the informed consent, it is the responsibility of the investigator to keep a signed copy of the assent form for each participating human subject.

Waiving Consent or Assent

The requirement for an informed consent form or assent form may be waived in cases when the only record linking the human subject to the study is the consent document, and if the risk of a breach of confidentiality could lead to potential harm. Informed consent may also be waived if the research presents no more than minimal risk of harm and involves no procedures for which written consent is normally required outside of the research context.

Policy for Research Undertaken as Part of Coursework

The IRB distinguishes between research conducted in a classroom as part of the learning experience ("Student Research") from research conducted to add to generalizable knowledge or a professional body of knowledge (clinical research, thesis, or dissertation work). The purpose of this policy is to clarify when student research must be reviewed by the IRB, or if it is deemed as "Student Research," who is responsible for reviewing that research.

Research Required as Part of Coursework

The Fullerton College IRB is guided by 45 CFR 46 (Common Rule) in its definition of research as being a "systematic investigation designed to develop or contribute to generalizable knowledge." Research conducted by students as a part of classroom assignments does not usually fall under the federal regulation of research because it is not intended to or likely to lead to generalizable results. Rather, the activities are resources of teaching which facilitate learning of concepts and the opportunity to practice various procedures, including research methods (interviewing, observation and survey techniques, as well as data analysis). In such cases, the classroom project does not require Fullerton College IRB submission and approval. Such class research projects may be conducted under the supervision of the faculty member without submitting a protocol to the IRB.

The class project must meet the definition of classroom research/student research. This is defined as a project which: is a normal part of the student's coursework; is supervised by a faculty member; has as its primary purpose the development of the student's research skills; does not present more than minimal risk to participants or to the student investigator; does not include any persons as research subjects under the age of 18; does not include any persons as research subjects who are classified as part of a vulnerable populations according to federal regulations; is not "genuine research" that is expected to result in publication or some other form of public dissemination. Dissemination means the distribution of findings and includes, but is not limited to, masters and doctoral theses/dissertations, presentation at a scientific meeting or conference, submission to or publication (paper or electronic) in a scientific journal, and posting on the Internet. Such student research projects must meet all the criteria for an expedited review as defined in this handbook.

Please note that even if the intent is to not produce generalizable knowledge, if a special population or sensitive topic area is part of the project, the student's project cannot qualify for general approval and, therefore, does require Fullerton College IRB approval. Categories of sensitive information include information: Relating to sexual attitudes, preferences or practices; 2) Relating to use of alcohol, drugs or other addictive products; 3) Pertaining to illegal conduct; 4) That if released could reasonable damage an individual's financial standing, employability, or reputation within the community; 5) That would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination; 6) Pertaining to an individual's psychological well-being or mental health; 7) Genetic Information. Categories of special subject population: 1) Minors (under eighteen years of age). 2) Fetuses or products of labor and delivery; 3) Pregnant women (in studies that may influence maternal health); 4) Prisoners; e) Individuals with a diminished capacity to give informed consent.

Faculty teaching research methods and overseeing student research projects are expected to understand the philosophy, ethics and practice of protecting human subjects in research; to adhere to these principles during the conduct and supervision of classroom research projects; and to teach these

practices and principles to students. Faculty will be responsible for ensuring that all student research projects are conducted in accordance with federal regulations and principles regarding protection of human subjects in research. Faculty will recommend that student researchers take the human subjects ethics student course available via the Collaborative Institutional Training Initiative (CITI) or the National Institutes of Health (NIH) Training.

Faculty who will be Co-Principal Investigators on class research projects, along with the student researchers, must successfully complete either the CITI training or the NIH training on human subjects. The CITI training can be found at www.citiprogram.org while the NIH Computer-Based Training module may be found at the following address: http://phrp.nihtraining.com/users/login.php.

Independent Studies

Research conducted as part of the coursework differs from research conducted as part of an independent project, such as honors projects, and independent study projects, in which interactions with human subjects or access to private information DO fall under the jurisdiction of the IRB. This type of student research could potentially be generalizable. The IRB application for these student research projects must include responsibility by a faculty member who will be named as the Co-Principal Investigator of the project.

Thesis or Dissertation Research

Thesis and dissertation projects involving human subjects are considered research as defined by 45 CFR 46 and require review by the FC-IRB.

If the faculty member has concerns or doubts, he/she should consult with the Office of Human Subjects Research.

Tips for Faculty

All teaching assignments involving human subjects must respect the rights and welfare of all individuals involved. The following suggestions for faculty members provide guidance concerning class projects:

1. Consider the nature and intent of the activity. If the course assignment involves systematic data collection and if any intent of the activity is to develop or contribute to generalizable knowledge - - an indication of which is intent to publish the data -- then the student classroom project is probably research and needs to be individually reviewed and approved by the IRB.

2. IRB approval cannot be made retroactive. If there is any likelihood that the results of the project might later be used for research that does lend to generalizable knowledge (for example, a presentation to a group other than the class), IRB approval must be sought prior to conducting the research. IRB approval cannot be granted retroactively.

3. Minimize risks whenever possible. Faculty members should help students understand that they are obligated to minimize risks for human subjects with whom they interact during the completion of their assignments. Depending on the circumstances, faculty members may find some of the following suggestions for students helpful:

a) Have students take either the CITI course or the NIH online training on human subject protection before collecting information from others.

b) Encourage the use of anonymous data collection so that data are not linked to specific individuals.

c) Have information identifying individuals kept separately from the information collected from those individuals.

d) Collect project data at the end of the course, or within a short time afterward, and request all copies in the student's possession be destroyed.

e) Ask for help! Ask the Office of Human Subject Research Protection for guidance when you are unsure of what review process is needed for a student classroom project. Their contact information may be found at http://irb.fullcoll.edu or you can call Carlos Ayon, Chair of the IRB 714-992- 7064.

Institutional Review Board (IRB)
Application for Approval of Human Subjects Research

Please select the type of review* you are requesting:

☐ Exempt (minimal risk) ☐ Expedited (moderate risk) ☐ Full Review (high risk)

**For a description of each category, please refer to the IRB handbook at irb.fullcoll.edu. Please allow 30 days for processing Exempt and Expedited requests, and 60 days for processing Full Review requests.*

A complete application packet should include all of the following and be submitted to irb@fullcoll.edu:

1. Application for Approval of Human Subjects Research
2. IRB Approval from External College/University
3. Recruitment Documents (Letter, Email, Flyer, and any other)
4. Informed Consent Form and, if applicable, Assent Form
5. Instruments (surveys, questionnaires, interview protocol, etc)
6. Evidence of Completion of Human Subjects Ethics Training in the form of a certificate from either the Collaborative Institutional Training Initiative (CITI) or the National Institutes of Health (NIH) Training.
7. Résumé/Curriculum Vitae (CV) of Principle Investigators

Part I: Principal Investigator (PI) Information

PI's Name: _____

Email Address: _____

Mailing Address: _____

Title of Research Project: _____

Please select the reason behind your study.

☐ Fullerton College Student Project ☐ Personal Academic Interest

☐ Master's Thesis ☐ Grant Requirement

☐ Dissertation ☐ Other (please specify): _____

If conducting a student project, thesis or dissertation, please complete the following:

Name of Advisor: _____

College/University: _____

Department/Course: _____

Degree of Study: _____

Proposed Start Date: _____ Proposed Completion Date: _____

IRB approval does not commit the IRB to provide access to human subjects. It is the PI's responsibility to secure a Fullerton College sponsor to assist with any human subjects recruitment.

Fullerton College Contact: _____

Department: _____ Email Address: _____

DO NOT COLLECT DATA PRIOR TO RECEIVING IRB APPROVAL

For IRB internal purposes.	IRB #:

IRB Contact:		Date Logged in:	
Date Approved:		Date Expired:	

Part II: Purpose and Methodology

1. Please describe the purpose of the study.

2. Describe the methodology of the study (or attached a document describing the methodology). Please be specific and include: 1) the anticipated sample size
2) the age of the targeted group
3) if a specific ethnic group, institutionalized or protected group will be targeted
4) if deception will be used
5) if audio or videotapes will be used in the study
6) how you will get consent and, if needed, assent

3. Please check all the populations you wish to study at Fullerton College:

☐ Administrators ☐ Faculty ☐ Staff ☐ Students ☐ Other:

4. Please check that the consent form includes all of the following, as required by federal law (CFR 46.116):

☐ 1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

☐ 2. A description of any reasonably foreseeable risks or discomforts to the subject;

☐ 3. A description of any benefits to the subject or to others which may reasonably be expected from the research;

☐ 4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

☐ 5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

☐ 6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

☐ 7. An explanation to contact Carlos Ayon, Director, Office of Institutional Research and Planning at Fullerton College, at (714) 992-7063 for answers to pertinent questions about the research and research subjects' rights, and in the event of a research-related injury to the subject; and

☐ 8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

When appropriate, one or more of the following elements of information shall be included in the consent form:

☐ 9. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

☐ 10. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

☐ 11. Any additional costs to the subject that may result from participation in the research;

☐ 12. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

☐ 13. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

☐ 14. The approximate number of subjects involved in the study.

Part III. Confidentiality and Minimizing Risk

5. Please describe how you will address confidentiality issues. Specifically, indicate how you will protect the privacy of participants, store and safeguard data, and the actions you will take if confidentiality is broken by law .

6. If there are any potential risks, describe precautions you will take to minimize any risk to participants.

Part IV. Benefits of the Study

7. Please describe the potential benefits of this study.

Part V. PI Assurance and Signature

As the PI, I attest that all of the information on this form is accurate, and that every effort has been made to provide the reviewers with complete information related to the nature and procedures to be followed in the research project. Additional forms will be immediately filed with the IRB to report any change in subject(s), selection process, change of PI, adverse incidents, and final completion date of project. I also attest to abide by all government regulations that apply to this study. Upon completing the research study, I agree to submit a copy to the Fullerton College IRB along with the required study Closure Form.

PI Signature Date

Institutional Review Board (IRB)
Application for Amendment to or Extension of Previously Approved Human Subjects Research

This form is to be used when a study previously approved by the Fullerton College IRB will need to be amended or will need an extension to go beyond the IRB approval date. If modifications are being requested, the IRB will need to review all amended documents and/or methodology to assess the potential effects on human subjects. If an extension is being requested, the IRB will need to review the reasons and assess the potential effects on human subjects.

Principal Investigator (PI) Information:

PI's Name: _____

Email Address: _____

Mailing Address: _____

Title of Research Project: _____

IRB#: _____

1. Please check the type of modification you are requesting.

☐ Amendment ☐ Extension

2. If applicable, please indicate which documents related to this research study will need to be modified as a result of this proposed amendment or extension request. Please attach the amended documents and submit along with this form to irb@fullcoll.edu.

☐ Recruitment documents ☐ Informed Consent Form ☐ Informed Consent Form

3. Please describe the proposed amendment and reason behind it. Or, please explain the reason for the extension.

4. Please explain how the modification will affect human subjects, including those who have already participated in the research study.

As the PI, I attest that all of the information on this form is accurate, and that every effort has been made to provide the Fullerton College IRB with complete information related to the nature and procedures to be followed in the research project. Additional forms will be immediately filed with the IRB to report any change in subject(s), selection process, change of PI, adverse incidents, and final completion date of project. I also attest to abide by all government regulations that apply to this study. Upon completing the research study, I agree to submit a copy to the Fullerton College IRB along with the required closure form.

PI Signature Date

Institutional Review Board (IRB)
Human Subjects Research
Closure Form

The Fullerton IRB requires that every principal investigator submit a closure form upon completion of IRB approved human subjects research. This applies to research studies that received exempt status, or were approved under expedited or full review. A study is considered complete once all aspects of data collection, analysis, and final report activities have concluded. Please submit this completed form along with a copy of the final study to irb@fullcoll.edu.

Principal Investigator (PI) Information:

PI's Name: _____

Email Address: _____

Mailing Address: _____

Title of Research Project: _____

IRB#: _____

Approval Date: _____

Research Project Summary

A. Human Subjects Summary

1. Total number of human subjects who expressed interest in participating in the study: _____
2. Total number of human subjects who participated in the study: _____
3. Total number of human subjects for whom personal identifying information was collected: _____

B. Unanticipated Consequences or Adverse Events

4. Were there any unanticipated consequences or adverse events?

☐ Yes ☐ No

4a. If yes, please describe the unanticipated consequences or adverse events.

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5. Please describe the benefits of your study. Please include a copy of your final report with this form.

PI Assurance

As the PI, I attest that all of the information on this form is accurate, and that every effort has been made to provide the Fullerton College IRB with complete information related to the nature and procedures to be followed in the research project. I also attest to having abided by all government regulations that apply to this study. I assure Fullerton College that all data collection activities, contact with human subjects, and use of personal identifying information have been completed. I have attached the final copy of the research study report.

PI Signature Date