Berkshire Community College Institutional Review Board:

Regulations and Procedures

May, 2017

These procedures are modified from a similar document from California State University, Los Angeles (www.calstatela.edu/orad/irb-regulations-procedures-and-application-guidelines) and implement regulations outlined in the 45 *Code of Federal Regulations (CFR)* 46

IRB: Regulations and Procedures

1.0 Background and General Information

1.1 Institutional Responsibility

Institutions conducting research with human subjects must assume responsibility for the protection of their rights and welfare in compliance with federal regulations. Each institution is required to document this information within a Federalwide Assurance (FWA) issued by the U.S. Department of Health and Human Services, Office of Human Research Protections (OHRP). Federalwide assurances state the requirements and procedures for human subjects protections to ensure that all research conducted within its jurisdiction complies with the *Code of Federal Regulations (CFR)* pertaining to human subjects (DHHS Policy - 45 CFR 46). These regulations require institutions to establish an Institutional Review Board (IRB) and an institutional mechanism for approval all research protocols involving the use of human subjects.

1.2 IRB Responsibility

The IRB implements a review process established within the *Code of Federal Regulations* to ensure that human subjects research complies with federal regulations, institutional policies, and ethical standards. The IRB serves to protect the rights and ensure the safety of people involved as participants in research. The IRB also provides assistance to the investigator in complying with federal and state regulations and institutional standards for human subjects research. The IRB is guided by the ethical principles as set forth in the Declaration of Helsinki (June, 1964, www.wma.net/en/30publications/10policies/b3) and *Ethical Principles and Guidelines for the Protection of Human Subjects of Research,* also known as the Belmont Report (April, 1979, www.hhs.gov/ohrp/humansubjects/guidance/belmont.html).

1.3 IRB and Institutional Authority

The IRB may approve research reviewed, or may require that modifications to the protocol be made to secure approval to conduct the research. The IRB may also deny approval of research. Decisions made by the IRB are communicated in writing to the investigator (45 *CFR* 46.109). The IRB may also suspend or terminate approval of research that is not conducted in accordance with the approved protocol, or that has been associated with unexpected serious harm to subjects (45 *CFR* 46.113). The College may suspend or terminate any human subject research of any researcher who has not met the federal requirements or institutional policies or who has failed to secure IRB review and approval. Any researcher who has not obtained IRB approval to conduct funded human subject research may not have the College
all research conducted under the aegis of the institution.

- At least five (5) members having expertise in medical, physical, psychological, social, and/or legal risks, representing a variety of disciplines covering the research reviewed, awareness of institutional regulations, and invited by the current IRB to serve staggered two-year terms;
- Diversity of members, including consideration of race, gender, cultural backgrounds and sensitivity to community attitudes;
- Some must be scientists experienced in research involving human subjects, while others must be non-scientists;
- At least one public member who is not otherwise affiliated with the College and who is not part of the immediate family of a person affiliated with the College;
- One or more alternate members may be appointed to the IRB, using the same appointment method, to serve in the absence of a particular member upon that

For review by the full IRB, a majority of the voting members of the IRB must be present, including at least one member whose primary academic background is in a non-scientific area. No action may be taken without a quorum present. In order to approve an application, it must receive a majority of members present.

1.7 IRB Member Conflict of Interest

Regulations stipulate that an IRB member may not participate in the initial or continuing review of a project in which the member has a conflicting interest, as suggested by any IRB member, except in response to information requested by the committee (45 *CFR* 46.107e).

2.0 Human Subjects Research and IRB Review

The IRB reviews research proposed to obtain information about a living individual through the use of a survey, interview, observation, or experimentation, records, samples, or other data previously collected from human subjects. All research involving human subjects must be reviewed and approved by the IRB in advance of study initiation. The IRB reviews both funded and unfunded research projects, whether they are conducted by faculty, staff, or students of the College, or by researchers not affiliated with the College but whose research involves college students, faculty, staff and/or data.

2.1 Definitions

In determining whether or not a project requires review by the IRB, the first step is to determine if the project is research, and the second step is to identify whether or not it involves human subjects. The IRB only reviews activities that involve the participation of human subjects in research. See the following sections for definitions.

2.1.1 Research. The Department of Health and Human Services (DHHS) *Code of Federal Regulations* (45 *CFR* 46 a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. As described in the Belmont Report, ...the term 'research' designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge

2.1.2 Human Subject. *about whom* an investigator (whether professional or student) conducting research obtains 1) Data through intervention or interaction; or 2) I *CFR* 46.102f).

2.1.3 Generalizable Knowledge. The IRB considers *generalizable knowledge* to include

IRB review is required when any College faculty, staff, student, any external person or institution, or anyone utilizing any College property or facility, is engaged in human subjects research.

Course assignments are not considered to be research as defined within the federal regulations unless they exceed minimal risk, target special populations, include sensitive subject matter, or if the assignment results in findings that the student may want to present or publish.

Pilot or feasibility studies that meet the definition of research involving human subjects must receive IRB review and approval prior to initiation.

Research involving the collection or study of existing data, documents, or records may be reviewed by the IRB or may qualify for a waiver.

Persons not affiliated with the College requiring the use of college facilities, students, and/or employees in their research must obtain a *campus sponsor* with sufficient expertise in the research area.

The IRB will not accept without further review by the BCC IRB projects approved by other institutions.

IRB review is not required when the study is outside of the employment scope, for example when a College researcher is hired on his/her own time, does
resources, and will not reference the institution in documents or publications associated with any reported outcomes.

3.0 Review Process and Procedures

3.1 Review Requirements

The IRB will review research involving human subjects to assure that the protocol meets with federal, state, and institutional regulations.

There are three different procedures that are used to review an application: Exempt, Expedited, and Full. The appropriate review procedure is determined by federal regulations based on how human subjects are involved in the research. The type of review is based on risk associated with participation in the research, the study intervention/interaction, and how informed consent is obtained and documented. A research protocol, informed consent statement, and additional supporting documents are required for all research projects submitted for review.

The IRB reviews the study protocol to determine study benefit and to assess risk and risk management procedures. The IRB may review a summary of the literature and other background information in order to justify approval of the proposed study.

The IRB is required to evaluate whether subject selection procedures are fair to ensure that the burdens of research participation are distributed equitably across groups of people. In addition,

thereafter.

(4) Research involving the collection or study of existing data, documents, or records 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 (45 CFR 46.101).

(5) Research and demonstration projects which are conducted by or subject to the approval of the federal 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,

(1) [redacted] of data from voice, video, digital, or image recordings made for research purposes.

(2) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. *(Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45* CFR *46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)*

(3) Continuing review of research previously approved by the full IRB as follows:

(a) where:

(i) the research is permanently closed to the enrollment of new subjects;

(ii) all subjects have completed all research-related interventions; and

(iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

3.3 Full Committee Review

If the research is not eligible for an exempt or expedited review the protocol must be reviewed by the full IRB membership at its meeting.

The committee will vote on a motion to either: 1) approve the protocol as it stands, 2) request revisions to the protocol to secure final approval, 3) request that additional information be provided prior to further review by the full IRB, or 4) deny approval for the protocol.

• There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
• When some or all of the subjects are likely to be vulnerable to coercion or undue influence (such as children, prisoners, pregnant women, the cognitively impaired, or economically or educationally disadvantaged), additional safeguards have been included in the study to protect the rights and welfare of these subjects.

3.5 Funded Research

The investigator must append the narrative section of the grant proposal to his or her IRB application (45 *CFR* 46.103f). In addition, the title of the IRB application must be consistent with the grant that the protocol represents.

3.6 Review Decisions

If the research is approved, an email and hard copy memo, stating the approval date and terms of approval, will be sent to the investigator. If the research is denied, the investigator may not conduct the research. The IRB will provide the investigator with the reason for its decision. The investigator may resubmit a protocol to the IRB for review if the reasons given for disapproval can be corrected and addressed. IRB approval is valid for up to one year from the date of initial review (45 *CFR* 46.109). To initiate the appeal of an IRB decision, the investigator must submit a statement to the IRB noting areas of contention. If the issue is not resolved through the IRB, the appeal will be forwarded to the President, who serves as the Institutional Official.

4.0 Informed Consent

4.1 Consent Purpose

primary requirements underpinning research with human subjects; it reflects the basic principle

4.2 Consent Process and Procedures

The following procedures should occur during the informed consent process (45 *CFR* 46.116):

• The prospective subject is given adequate information to make an informed decision about participating in the proposed study.

• The nature and expectations of the research including risks and benefits is explained to the subject.

• The study is presented in a language that is clear and understandable.

• The subject receives answers to questions he or she may have about the study.

• The study is explained in an appropriate setting and with enough time conducive to good decision-making.

• The prospective subject comprehends the information and can make a choice about whether he or she wants to participate.

• The prospective subject understands that he or she retains the right to refuse or withdraw from the study at any time without penalty.

• The prospective subject is given copies of the approved consent form(s).

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The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. If this is the case, the investigator will ask the subject whether he or she wants to sign the document that links the subject to the research and thereby waive the requirement to obtain a signed consent form. In all other cases, not a signed consent form is needed.

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

5.0 Studies Involving Special Populations or Vulnerable Subjects

Special populations or vulnerable subjects include children, pregnant women, prisoners, and physically or cognitively challenged, economic or socially disadvantaged, subordinate

The research involves greater than minimal risk and no prospect of direct benefit to the participant; however, the results of the research will contribute to generalizable knowledge about the subject's disorder or condition.

The research, while otherwise not approvable, presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

5.1.1 Involving

any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part.

(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

(g) For children as defined in Sec. 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part.

(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy.

(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

(j) Individuals engaged in the research will have no part in determining the viability of a neonate.

5.3 Cognitively Impaired (45 CFR 46.111(b))

When recruiting participants who are cognitively impaired, the investigator must evaluate whether the potential subject is capable of making an informed choice to participate in the research. The process used by the investigator to determine participant autonomy must be described in the protocol. If the individual is deemed competent to make an informed choice, it may be necessary to

to review and approve research that includes prisoners when the following conditions are met: The study does not place the subject at more than minimal risk and the investigation pertains to possible causes, effects, and processes of incarceration and of criminal behavior, or the investigation pertains to prisons as institutional structures or of prisoners as incarcerated individuals, or the investigation pertains to conditions that affect prisoners as a class of people (e.g., research on disease that is more prevalent in prisoners than other groups; research on social and psychological problems of prisoners such as alcoholism, drug addiction, and sexual assaults), or the study has the likelihood of improving the health or well-being of the prisoner.

5.5 Women and Minorities

Federal guidelines require that NIH-funded studies incorporate a research design that is sufficient to elicit information about individuals of both sexes/genders and diverse racial and ethnic groups in order to examine differential effects of research procedures on such groups. For more information on this topic, please go to: http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

5.6 College Students

The IRB tries to estimate the degree of situational coercion and assist investigators in reducing the pressure that a student may experience when recruited to participate in research. The IRB encourages investigators to follow recruitment procedures intended to create the opportunity for students to participate in research while reducing the possibility of unintended coercion. If research participation is a course requirement, offer an equitable alternative to participation in a study as a method of obtaining course credit (e.g., summarize a journal article, attend a research lecture, assist with data collection). The protocol needs to identify how voluntary participation will be ensured if the subjects under study are recruited by their professor. Recruitment procedures should allow for students to participate in the study without jeopardizing their grades or their relationship with their professor or the College.

5.7 Employees

The IRB must consider the potential for coercion or undue influence and breaches of confidentiality when employees are recruited as research subjects. Information should be included on how voluntary participation will be ensured if the subjects under study are recruited by their employer. Recruitment procedures should allow for employees to participate in the study without jeopardizing their job status, their pay, or their relationship with their supervisors.

6.0 Conducting Research after IRB Approval

6.1 Investigator Responsibility

Protecting the rights and welfare of the research subject is a shared responsibility of the IRB and the investigator. Ultimately, the investigator is responsible for the conduct of the study. This includes the application and monitoring of ethical practices, compliance with state/federal regulations and institutional practices, and supervision/training of research staff. Individuals

conducting research under the auspices of the institution are required to comply with all federal, state, and institutional regulations and policies for the protection of human research subjects. Investigators will document their understanding of their responsibilities by signing the application
result in suspension or termination of approval of the research.

6.2 Faculty Supervisor

Student-initiated research involving human subjects, whether dissertation, thesis, or other research projects, must be supervised by an authorized faculty or staff member to ensure compliance with procedures and regulations relating to the protection of human subjects. The supervising member is responsible for the following aspects
research:

• Ensure that the student has reviewed and understands the federal regulations that govern research involving human subjects, the Belmont Report, and s Procedures prior to developing a study that involves human subjects.

• Meet with the student investigator to monitor the study progress.

• Be available to the student investigator to supervise and address problems should they arise.

• Oversee the prompt reporting of any unanticipated problems or significant or untoward adverse effects within five working days of occurrence.

• Arrange for an alternate faculty or staff sponsor to assume these duties when unavailable (vacation or sabbatical).

• Monitor the research activity to ensure that the protocol approved by the IRB is followed.

By signing the application form, the faculty supervisor will verify that he or she will comply with the stated responsibilities.

-affiliated Research

Non-affiliated research involving human subjects must be supervised by an authorized BCC employee member or administrator to ensure compliance with procedures and regulations relating to the protection of human subjects. The BCC sponsor is responsible for the following aspect of the non-

• Ensure that the researcher has reviewed and understands the federal regulations that govern research involving human subjects, the Belmont Report, and P2.024 446.47 Tm0 0 g0 G[0.25 0.26 0.2

• Oversee the prompt reporting of any unanticipated problems or significant or untoward adverse effects within five working days of occurrence.

• Arrange for an alternate campus sponsor to assume these duties when unavailable (vacation or

Research projects must be reviewed at least annually. The initial IRB approval expires one year following its award, unless otherwise stipulated by the IRB. Determination for more frequent