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

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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's legal protection and may jeopardize all research conducted under the aegis of the institution.

1.4 IRB Composition and Selection

The composition of the IRB, consistent with federal requirements (45 *CFR* 46.107), includes members as follows:

- 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 member's request. Due to the diversity in an individual's academic and/or professional training as well as experience, an alternate member is selected to represent an absent member using the following criteria: scientist, non-scientist, community member, or student (45 *CFR* 46.107); and
- IRB membership includes those familiar with the type of research routinely conducted primarily in the social and behavioral sciences.

Re-appointment may occur provided that the member demonstrates an interest in research ethics, knowledge of regulations and ethical standards, is able to determine the acceptability of proposed research, and has the time to devote to associated responsibilities.

1.5 IRB Member Responsibilities

1.5.1 member training. IRB members participate in an initial online training course developed by the NIH Office of Extramural Research (https://phrp.nihtraining.com/users/login.php). They also undertake continuing education by reviewing relevant materials on issues, regulations, and guidance concerning human subjects protections (45 *CFR* 46.107). In addition, IRB members are provided with copies of the *Institutional Review Board Guidebook* (www.hhs.gov/ohrp/irb/irb_guidebook.htm)*; Code of Federal Regulations* (45 *CFR* 46) (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm); and the Belmont Report, *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (www.hhs.gov//ohrp/humansubjects/guidance/belmont.htm).

1.5.2 reviewer expertise. The IRB recognizes that additional expertise may be necessary when reviewing a protocol, and may request consultation from an individual with competence in a specific area; such experts may not vote.

1.5.3 review process. For review by the full IRB, all members will receive the entire application packet, including the protocol, consent documents, recruitment materials, and other supporting documents (study instruments, letters of permission, etc.). The IRB will also receive a copy of any related grant proposal, if applicable.

1.6 Quorum and Voting Requirements (45 *CFR* 46.107 and 46.108)

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* 46.102d) has defined research as "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. A human subject is defined as "a living individual *about whom* an investigator (whether professional or student) conducting research obtains 1) Data through intervention or interaction; or 2) Identifiable private information" (45 *CFR* 46.102f).

2.1.3 Generalizable Knowledge. The IRB considers *generalizable knowledge* to include the dissemination of research findings beyond the boundaries of the institution, e.g., publication, presentation or use outside the specific instructional setting.

2.2 When is IRB Review Required?

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 not utilize the institution's 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 an applicant's 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,

the IRB must consider recruitment procedures to ensure that a broad cross-section of research subjects is included in the research and to evaluate the procedures that will be established to protect subject privacy during the recruitment phase.

There are specific federal regulations (45 *CFR* 46 Subparts B-D) that apply to conducting research with vulnerable populations. These regulations assure that the risks associated with participation are minimal or that the research is of direct benefit to the subjects. Additional safeguards for all subjects that are likely to be vulnerable to coercion or undue influence must be included in the study to protect the rights and welfare of these subjects. At BCC, these vulnerable populations include women and minorities, college students and employees (see p. 14).

3.2 Administrative Review

3.2.1 Exempt Review. The IRB may review research that qualifies for an exempt review using the criteria listed below. An investigator may not determine whether his or her own research is exempt, according to OHRP guidance memoranda.

The following types of research qualify for an exempt review (45 *CFR* 46.101):

(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 (2), 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, 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,

(iii) possible changes in or alternatives to those programs or procedures,

(iv) possible changes in methods or levels of payment for benefits or services under those programs.

3.2.2 Expedited Review. The IRB Chair may review research that qualifies for an expedited review using the criteria listed below. When conducting an expedited review, the IRB Chair has the authority to act on behalf of the IRB with the exception of disapproving the research.

The following types of research qualify for an expedited review:

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 *CFR* 46.110 and 21 *CFR* 56.110.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may NOT be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or full—utilized by the IRB.

(E) Categories one (1) and two (2) pertain to both initial and continuing IRB review.

Research Categories

(1) Collection 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.

3.4 Approval Criteria

For approval of a research protocol, the following federal requirements must be satisfied (45 *CFR* 46.111):
• Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.
• Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.
• Selection of subjects is equitable.
• Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
• The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

• 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

The Office for Human Research Protections (OHRP) states that "informed consent is one of the primary requirements underpinning research with human subjects; it reflects the basic principle of respect for persons."

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).

• In addition, the investigator must retain the signed copies of the consent document for a minimum of three years following completion of the study.

4.3 Alternative Consent Procedures (45 *CFR* 46.116 (6c))

The IRB may approve a consent procedure that does not include or changes the basic consent requirements or even waive the requirement to obtain informed consent when the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is 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.

Note: The regulations referenced do not preempt any applicable federal, state, or local laws that require additional information to be disclosed in order for informed consent to be legally effective.

4.4 Documentation of Informed Consent (45 *CFR* 46.117)

In most cases, informed consent is documented by the use of a written consent form approved by the IRB and signed by the subject.

Unless the IRB has authorized revisions to the consent procedure, the consent form must include all elements identified within the IRB-approved consent template. The IRB-approved consent form may be read to the subject in addition to allowing the potential subject an opportunity to review the consent document and ask questions before signing the consent document.

4.5 Waiving Requirement to Document Consent (45 *CFR* 46.117(c))

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 him or her to the research. The subject's wishes for documentation will dictate whether or 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 individuals (e.g., students and employees), and fetuses. Additional safeguards for all subjects that are likely to be vulnerable to coercion or undue influence must be included in the study to protect the rights and welfare of these subjects (45 *CFR* 46.111(7)(b)).

The degree to which these potential subjects are vulnerable is directly related to the degree to which these individuals are capable of volunteering or providing informed consent to research participation. There are specific federal regulations (45 *CFR* 46 Subparts B - D) that apply to conducting research with vulnerable populations. These regulations assure that the risks associated with participation are minimal or that the research is of direct benefit to the subjects. Special considerations will be made in reviewing protocols that include vulnerable subjects.

5.1 Children

The *Code of Federal Regulations* (45 *CFR* 46.401 Subpart D - http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#subpartd) describes additional protections for children involved as subjects in research. A child is defined by the State of California as a person who is under the age of 18 years and is not legally emancipated (link to state law on emancipation; http://www.leginfo.ca.gov/cgi-bin/displaycode?section=fam&group=06001- 07000&file=7000-7002).

The IRB may only approve research involving children when all conditions of this subpart are satisfied as follows:

- The research does not involve more than minimal risk (i.e. does not expose the child to greater risk than encountered in daily life).

- The research involves greater than minimal risk; however, the individual subject may receive direct benefit from participating in the research.

- 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 Children in Research at School. School children can be involved in research when the data collected will be used to assess classroom instructional strategies/techniques, curriculum development, or classroom management techniques. Information should be included on what is part of the usual classroom routine and what is different from the usual routine. Discussion should include whether class time is used or if children are participating outside of structured class time (address what non-participating students will be doing while the study is conducted, including whether they will have the opportunity to receive the same benefits at another time; supervision of non-participants; and procedures used to pull out children/subjects during class time).

5.2 Pregnant Women

The *Code of Federal Regulations* (45 *CFR* 46.401 Subpart B - http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#subpartb) provides additional safeguards for research that involves fetuses, pregnant women, and human in vitro fertilization. The IRB must determine that all aspects of the research comply with this subpart, and must give special consideration to subject selection, monitoring, and oversight of informed consent, and monitoring the research as needed. Pregnant women or fetuses may be involved in research if all of the following conditions are met:

(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses.

(b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.

(c) Any risk is the least possible for achieving the objectives of the research.

(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by

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 the father's consent need not be 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 include additional procedures during the consent process to ensure that the prospective subject understands the information presented about the study. The investigator may consider including questions at the end of each section of the consent document to use in assessing participant comprehension of the consent content. This mechanism allows for the investigator to clarify the participant's understanding of specific aspects of the study as the consent process. If the individual is not legally able to consent for him/herself, the person who is legally authorized to serve as the individual's advocate and caretaker is responsible for determining whether the proposed study is appropriate.

5.4 Prisoners (45 CFR 46.401 Subpart C)

The *Code of Federal Regulations* 45 CFR 46.401 Subpart C (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#subpartc) allows the IRB

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 form. Failure to conduct research in accordance with the IRB's requirements may result in suspension or termination of approval of the research.

6.2 Faculty Supervisor's Responsibility when Supervising Student Research

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 of the student's involvement in research:

• Ensure that the student has reviewed and understands the federal regulations that govern research involving human subjects, the Belmont Report, and BCC'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.

6.3 Campus Sponsor's Responsibility when Supervising Non-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-affiliated researcher's involvement in research:

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

• Be available to the 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 campus 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 campus sponsor will verify that he or she will comply with the stated responsibilities.

6.4 Modifications and New Findings

Any revision to previously approved research involving human subjects receive IRB approval in advance of implementation, except when necessary to eliminate apparent immediate hazards to the subject (45 *CFR* 46.103 (b)(4)(iii)). A modification is defined by the IRB as a change that does not alter the overall character or purpose of the original project. The full IRB reviews proposed changes that may affect the willingness of enrolled subjects to continue participation and/or increase the risk to research subjects.

A modification request requires completion of an application form with new signatures. Within the modification request, the researcher is asked to provide a complete description of and rationale for the proposed modification and to address the effects of the modification on risks, benefits, risk reduction, and informed consent. Any new findings in the literature that may influence the study procedures, risks, or benefits must also be reported to the IRB.

Changes to the consent document to inform subjects of new findings, changes in procedures, risks and benefits to study participation must also be approved by the IRB. Minor changes that do not adversely alter the overall risk-benefit profile of the study may receive an expedited review. Procedures used to inform and document consent of previously enrolled subjects affected by the modification should be addressed.

6.5 Reporting of Adverse Events

The investigator of an IRB-approved protocol must report any serious or unanticipated events within 5 days involving risks to research subjects or others that are associated with the study procedures. Any undesirable experience associated with the research may be considered an adverse event. The event is considered serious and should be reported when the subject experiences recurring problems and/or unanticipated side effects. Failure to report an adverse event to the IRB may result in temporary or permanent suspension of the protocol approval. Research associated with unexpected serious harm to subjects may also result in temporary or permanent suspension of the protocol approval.

6.6 Continuing Review of Approved Protocols (45 *CFR* 46.109(c))

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 review is based on the degree of risk associated with participation and/or the involvement of subjects that require additional protections as defined by the Department of Health and Human Services. Protocols that are verified as exempt do not need further review so long as no changes are made to the protocol.

A continuation of approval is needed if subject recruitment and/or data collection is continuing. To apply for continuation of approval, the investigator must complete a short form including the following: a progress report, explaining briefly what the study is about, including the number of subjects intended for study; what has been accomplished since the last review, including, wherever possible, the number of subjects accrued; a summary of any significant adverse events or unexpected problems; a summary of protocol revisions approved by the IRB since the last review; research to be done during the subsequent review period; current literature that may influence the conduct of the study; an update of financial interests (if applicable); and any relevant attachments, e.g., updated survey instruments, current consent/assent forms/informational letters.