Berkshire Community College Institutional Review Board:

Application Guidelines

April, 2017

*These procedures are modified from a similar document from California State College, Los Angeles (www.calstatela.edu/sites/default/files/groups/Research%20and%20Development/irbapplicationguidlines.pdf) and implement regulations outlined in the 45 *Code of Federal Regulations (CFR)* 46

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1.0 Introduction

Institutions receiving U.S. Department of Health and Human Services (DHHS) funds to conduct research with human participants must assume responsibility for the protection of the rights and welfare of human subjects in compliance with federal regulations. Each institution is required to document this information within a Federal wide Assurance issued by the U.S. Department of Health and Human Services Office of Human Research Protections. Federal wide 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 pertaining to human subjects (DHHS Policy - 45 *CFR* 46). These regulations require institutions to establish an Institutional Review Board (IRB) and an institutional mechanism to review for approval all research protocols involving the use of human subjects.

2.0 Review Process and Procedures

2.1 Research Requiring IRB Review

Following are examples of research requiring IRB review:

• The investigator intervenes with a living individual for research purposes (e.g., to draw/collect blood or other biological samples, dispense drugs, administer treatments, use physical sensors, test sensory acuity, collect information by survey or interview).

• The investigator manipulates an individual's environment for research purposes (controls environmental light, sound, temperature, social interactions).

• The investigator interacts with an individual for research purposes (obtains consent, conducts interviews, screens potential subjects).

• The investigator releases individually identifiable private information or obtains an individual's private information without the individual's written consent (e.g., release of subject's name to investigators for recruitment, allowing access to an individual's academic or medical record).

• The investigator obtains, receives, or possesses private information that is individually identifiable (with or without coding system) for research purposes.

• The investigator obtains, receives, or possesses individually identifiable private information for use in maintaining a statistical center for a multi-site research program.

• The investigator receives a direct award to conduct human subjects research that will be carried out by a subcontractor or collaborator.

2.2 Types of Applications

2.2.1 Application for Administrative Review. The research protocol may qualify for an administrative (exempt or expedited) review. Completion of this review process should take no less than four weeks. Administrative reviews are conducted in the order received. Protocols eligible for an administrative review should be submitted as soon as possible to receive the timeliest review.

2.2.2 Application for Full Committee Review. The full IRB meets during the semester, as needed for review of applications. The times are determined based on the availability of the members of the IRB. Research that is more than minimal risk or that involves more than minimal deception requires full committee review.

Research protocols to be reviewed during the full meeting are accessible to the IRB members approximately seven days in advance of the meeting. Therefore, protocols submitted for full committee review must be received two weeks before the scheduled full committee meeting. An intake review and a prereview will be done prior to the meeting.
Investigators are encouraged to attend the meeting at a time certain, in order to facilitate review and answer questions regarding the research. The investigator will be notified by email and hard copy memo of the review decision within one week following the meeting date.

2.3 Intake Process

The IRB Administrator will review the screening form. The IRB will reject, without further review, any application that is incomplete, and will not do a more thorough prereview of the application until all intake requirements have been met.

The IRB will not forward any application for expedited or full committee review until all prereview requirements have been met. For applications that qualify for exemption, this will be the only review process.

2.4 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 Committee. The appropriate review procedure is determined by federal regulations and applied analysis 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. Part of the process of risk/benefit analysis includes reviewing what has been done in the past and what should be done in the future in order to gain a better

understanding of the phenomenon under study. 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, 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.

2.5 Administrative Review

Research that is considered minimal risk and that meets federal criteria for an exempt or expedited review (e.g., use of existing data; some survey or interview procedures) is eligible for review through administrative procedures (45 *CFR* 46.101 & 45 *CFR* 46.110). All nonexempt research will be reviewed through IRB expedited review or by the full committee.

2.6 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, 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.

This form of research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens may qualify for a waiver. In order to qualify for a waiver, the archival or reanalyzed data sources must not reveal information that may have implications for the privacy, reputation, employability, or insurability of classes or individuals. Applications qualifying for a waiver will be filed with the IRB; no formal review will be conducted. However, applications are subject to periodic IRB audit to assure compliance. Research that does not qualify for a waiver may qualify for exemption, and can be verified through an administrative review of the standard application form (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.

2.7 Expedited Review

The IRB may review research that qualifies for an expedited review using the criteria listed below.

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. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The following types of research do not qualify for an expedited review:

(A) 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.

(B) The expedited review procedure may not be used for classified research involving human subjects.

(C) 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.

(D) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

2.8 Nonaffiliated Investigator

Investigators not affiliated with the institution who plan to conduct research that involves the use of BCC facilities, students, and/or employees must obtain a campus sponsor prior to submitting an application to the IRB. An affiliated employee (faculty or administrator) with sufficient expertise in the research area to provide limited oversight of the project may act as the campus sponsor. The campus sponsor should review the protocol prior to agreeing to serve as the campus sponsor and sign the application before it is submitted to the IRB.

2.9 Access to BCC NonPublic Information

Research that involves the use of BCC nonpublic information to identify or contact human research subjects or prospective subjects may require additional approval signatures from other College administrators, e.g., if access to student or employee records is involved.

3.0 Protocol Development

The Institutional Review Board reviews the study protocol to determine study benefit and to assess risk and risk management procedures. This guidance is for use in creating a protocol specific to the research study. The protocol is the most important section of the IRB application, as it outlines the specific procedures that will be followed during the course of the study. One of the most common reasons for delay of IRB approval is due to an incomplete protocol.

3.1 Study Abstract

The IRB uses the study abstract to gain a general understanding of the scope of the research and to verify the type of review that is needed (e.g., exempt, expedited, or full committee). The abstract should provide a basic understanding of why the study is being conducted, how it will be carried out, how the results will be interpreted, and how risks will be managed. Specifically, the abstract should include a one-paragraph summary of the protocol that includes a brief description of the study purpose/objective, methods, subjects, planned analyses, potential benefits, potential risks, and risk management procedures.

3.2 Introduction/Statement of Purpose and Background

Part of the process of risk/benefit analysis includes reviewing what has been done in the past and what should be done in the future in order to gain a better understanding of the phenomenon under study. In this section, the investigator should discuss the relevant background information and literature reviewed to provide the rationale for the proposed research. The relevance of this research to and potential for contribution to the field of study should also be included. The investigator should include a justification for involving humans in the research.

3.3 Subjects

The IRB is required to evaluate whether subject selection procedures for a given research study are fair to ensure that the burdens of research participation are distributed equitably across groups of people. Therefore, information regarding the characteristics of subjects that will be involved in the proposed study is required to conduct an adequate review. In addition, the IRB must consider recruitment procedures to ensure that a broad cross-section of research subjects are included in the research and to evaluate the procedures that will be established to protect subject privacy during the recruitment phase.

3.3.1 Subject Characteristics. The investigator must define the group of subjects that is appropriate for use in the research study and must provide a description of subject characteristics (e.g., type of population, number of subjects, gender, age range, etc.). Additional information to justify inclusion of special populations in the research should be included, especially where ability to acquire informed consent may be limited.

3.3.2 Number of Subjects. The investigator must include information on how many subjects are planned for recruitment into the study. Information should be included on how the number of subjects was determined.

3.3.3 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 investigator must describe the additional safeguards that are included to protect these participants.

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 by the IRB in reviewing protocols that include vulnerable subjects.

3.3.4 Students with Documented Disabilities. When recruiting participants who have documented disabilities, 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.

3.3.5 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.

3.3.6 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 investigator 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.

3.3.7 Employees. The IRB must consider the potential for coercion or undue influence and breaches of confidentiality when employees are recruited as research subjects. The investigator must indicate 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.

3.3.8 Selection Criteria and Screening. Investigators need to describe the criteria by which subjects will be selected for study participation to determine whether subject selection practices are equitable and justified. The protocol should include rationale to support the selection criteria. In order to know that subjects will be selected appropriately, the protocol should describe how the inclusion/exclusion criteria will be assessed and by whom (include a description of the assessor's professional qualifications/credentials if relevant). The aim is to protect subject confidentiality, and for ensuring that a prospective subject has given informed consent before disclosing private information. In certain cases, investigators are interested in screening individuals before they are formally enrolled into the study to determine whether they meet the basic study selection criteria. This process can often lead to disclosure of private information prior to obtaining and documenting informed consent. Therefore, if a screening procedure will be used, information is required on how screening will take place (e.g., interview, survey, records review) and how data collected during screening will be handled if the person is found to be ineligible (e.g., used as research data or destroyed). If individuals will disclose private information, a review will be done of the procedures used to obtain consent from the person in advance of implementing screening procedures. If the protocol identifies specific inclusion and exclusion requirements to determine subject eligibility (e.g., age, physical or psychological condition), a screening checklist will be reviewed in which specific inclusion and exclusion criteria are listed and defined. The procedures used to document appropriate screening of subjects will be part of the review.

3.3.9 Recruitment Source. The investigator must include information regarding the location from which subjects will be recruited (e.g., schools, College campuses, fitness facilities, hospitals, government agencies, nonprofit organizations, places of business, places of worship). Also included should be a confirmation that permission has been obtained from the institution to conduct this protocol, in the form of a letter from an authorized official, on the organization's official letterhead.

3.3.10 Recruitment Methods. The investigator must include a description of how and by whom potential subjects will be identified and recruited. If records are accessed to identify potential subjects, the procedures used to ensure that records are only accessed by those with consent from the individual should be identified.

3.3.11 Legitimate Access to Records. Recruitment procedures in which names of individuals are released from private sources to an investigator are generally not endorsed. Recruitment procedures should allow for the individual to consent to the release of information in advance of being contacted directly by an investigator.

Established Legal/Ethical Protections:

It is not advisable to release identifiable private information from a source to an unaffiliated researcher without the permission of the potential subject, where legal and ethical guidelines prohibit the source from doing so. An example of when this may occur is when a researcher is attempting to identify prospective subjects according to specific eligibility criteria for recruitment to a study by accessing private files through a hospital or medical clinic. To obtain permission to access private and identifiable information about a prospective subject, the investigator will need to propose procedures to obtain consent from the individuals involved.

This may be in the form of a release form used by the source to document permission to release information to the investigator. The consent statement should include information about what information is requested, how it will be used, and to whom it will be given. Review and acceptance of this consent document is required in advance of its use.

No Established Legal/Ethical Protections:

• It is not recommended to release information about an individual where the individual about whom information is to be released may normally consider the information to be private, although not protected by law or the ethics of a specific profession.

• It is not advised that procedures that involve a person or organization provide information about another individual/potential subject without his or her permission for the purpose of recruitment. It is recommended that procedures that allow for an organization or an enrolled subject provide information about the study to a prospective subject (flier, postcard, or other announcement) that allows for the prospective subject to initiate contact if he or she would like additional information about the study, e.g., in "snowball" recruitment methods.

3.3.12 Recruitment Announcements. Advertising a research study for the purpose of recruiting participants is part of the informed consent process. Printed or electronic media intended for use in subject recruitment are reviewed to ensure that the procedures proposed for informing potential subjects are not coercive and do not state or imply an outcome or other benefit beyond what is outlined in the consent documents and the protocol. Recruitment advertisements, such as fliers, postcards, brochures, newspaper advertisements, press releases, postings on the internet or email, and postings on subject pool boards, are reviewed for the accuracy and presentation of information prospective subjects need to determine their eligibility and interest. This includes: the review of content, language, and design. Information should not be misleading to subjects; as such, the use of words that appear neutral as opposed to sensational is encouraged. Attention should be paid to the use of appropriate graphics, font size, and format/design, and to accurate spelling and punctuation. The following information should be included in recruitment materials:

1. name and address of the principal investigator and/or research facility;
2. concise description of the purpose of the research;
3. eligibility criteria for subject participation;
4. time or other commitment required of the subjects;
5. location of the research and person to contact for further information; and
6. the following statement should appear at the bottom: 'THIS PROJECT HAS BEEN REVIEWED BY THE BCC INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH. ADDITIONAL CONCERNS AND COMPLAINTS, OR QUESTIONS REGARDING YOUR RIGHTS AS A RESEARCH PARTICIPANT, SHOULD BE DIRECTED TO THE PRESIDENT'S OFFICE (413-236-1003)."

Reference to incentives offered may include that subjects will be paid, but should not emphasize the payment or the amount to be paid.

3.3.13 Potential Problems. Address any potential problems involving subject identification, recruitment, or data collection that may negatively affect your ability to conduct this study.

3.4 Research Design and Methods

The investigator must provide the research design to be utilized to weigh the potential benefits of the study as compared to the potential risks. The protocol must include adequate information about the research design to make an informed judgment that the design will result in meaningful and valid data. The investigator must describe the research design, the scientific rationale underlying the proposed research, and the statistical basis for the structure of the investigation. This should include the specific aims of the research hypotheses to be tested, the questions to answer, and the type of data to be gathered and tested.

Note that the IRB guidelines from the federal government state, "The value of research depends upon the integrity of the study results. One of the ethical justifications for research involving human subjects is the social value of advancing scientific understanding and promoting human welfare by improving health care. However, if a research study is so methodologically flawed that little or no reliable information will result, it is unethical to put subjects at risk or even to inconvenience them through participation in such a study."

If it is determined that the experimental design or statistical methods are inappropriate, the investigator will be asked to make revisions so that review of the protocol may continue.

3.4.1 Subject Involvement. The investigator must describe the tasks that subjects will be asked to complete during the course of a study. The protocol should describe what subjects will do during their involvement and the amount of time that participation in each aspect of the study will take. The protocol should also discuss investigational, experimental, or special procedures that will involve the subject (medical devices, electrical equipment, etc.).

3.4.2 Research Instruments. The investigator must submit all research instruments such as surveys, interview or focus group guides, or questionnaires planned for use in data collection. The investigator may submit draft versions of study instruments for review; however, a review will be done of the final instruments prior to approving the use of those instruments for data collection.

3.4.3 Deception or Incomplete Disclosure. Deception involves not fully informing subjects of the real purpose of the study or providing false information about the study to subjects. This may be appropriate and justifiable in some circumstances, particularly in social and behavioral research. If the protocol involves deception, the investigator must provide a complete description of how deception will be used. The investigator must provide adequate justification for the inclusion of deception and possible alternatives to the use of deception. The protocol should include procedures to debrief subjects following participation. The debriefing statement should be presented both orally and in writing and include a description of the deception involved and an explanation about the true purpose of the research. In addition, this statement should inform subjects of their right to withdraw their data from the study if they feel upset or uncomfortable with the deception involved, and still receive any incentives offered to

participants. Applications involving more than minimal deception will be reviewed by the full committee.

3.4.4 Study Location. The review of the protocol will assess the appropriateness of the location and the setting where subjects will participate in the research. The protocol should address any special considerations associated with recruitment or data collection at the location (e.g., identifying potential subjects, obtaining voluntary participation, confidentiality/anonymity of data, and privacy concerns). If the research is supported by federal funds and persons not affiliated with the institution will conduct the study, it is necessary for the investigator to document that the facility has an assurance with OHRP and that a local IRB has reviewed the study for conduct at the performance site.

3.4.5 Special Procedures: Exercise Testing. The investigator must provide a description of any investigational, experimental, or special procedures that will involve the subject (medical devices, electrical equipment, etc.).

If participants will be exposed to exercise or exercise-related testing, the investigator must describe these activities. Only those qualified to conduct such testing will be permitted to do so, and shall adhere to all recognized guidelines for such testing. Risks associated with various types of tests or using various types of equipment should be discussed in the protocol.

3.4.6 Potential Benefits. The protocol must demonstrate that conducting the proposed study will result in a benefit either to science/society or to the individual participant. Therefore, the investigator must provide a clear description of the anticipated benefits that will be derived from the study.

3.4.7 Risks. When recruiting participants for research, information about the types of risks associated with study participation must be presented to each prospective subject. Even if the level of risk is minimal, the protocol should never document that there is "no risk." The OHRP has provided the following descriptions of risks that may be associated with research participation. Physical harm is often associated with research involving medical procedures; however, it can also be related to research testing aspects of physical fitness or public health concerns. Minor pain and discomfort, as well as drug side effects or injury resulting from an invasive procedure, should be considered when evaluating exposure to physical harm. The physical risk may be minor and transient; however, some procedures may result in adverse events that may be considered serious and possibly permanent. Psychological harm may occur when subjects are asked to disclose or think about personal feelings and/or behaviors or are involved in an experiment that involves a manipulation of the environment or deception. The subject may experience changes in awareness, thought processes, and emotion as a result. Social or economic harm is associated with research where sensitive information about the subject (e.g., alcohol and other drug abuse, mental illness, illegal activities, etc.) is obtained. A breach in the confidentiality or anonymity of this information may lead to the individual being labeled in a way that could affect their reputation, insurance eligibility, or employment.

3.4.7.1 Management of Risk. The investigator must document the precautions, safeguards, and alternatives incorporated into the research activity to reduce or limit the severity, duration, and likelihood of harm. If the study activities place the subject at greater than minimal

risk for injury, the investigator should describe what the potential subject will be told during the consent process and describe whether and who will cover treatment for any injury associated with the study. If there is a risk of psychological discomfort in a questionnaire, interview, or focus group setting, the investigator should indicate that subjects will be informed that they may refrain from answering any question that makes them uncomfortable. The investigator should also indicate, if appropriate, that a resource or referral sheet will be provided to all participants.

The investigator must describe the procedures used to maintain anonymity or confidentiality during data collection, e.g., collecting completed questionnaires using a box at the front or back or the room or a sealed envelope. For anonymous questionnaires, investigators should indicate that subjects will be reminded not to place their name or other identifier on the questionnaire. For mailed questionnaires, investigators should state that subjects will be reminded not to place their name or other identifier on the envelope. It is also advisable for the investigator to place their own name and address on the return address portion of the envelope. For focus groups, the investigator should state that subjects will be reminded not to share information with others outside the group.

With the exception of focus groups and other group activities, if audio or video recording is taking place, the investigator should indicate that subjects will have the opportunity to destroy the tape if they withdraw from the study.

3.4.7.2 Assessment of Risk. The investigator must include information provided by the investigator to assess whether the risks and inconveniences associated with the research are reasonable in relation to the anticipated benefits to the subjects and in relation to the knowledge that may reasonably be expected to result from this research. In evaluating risks and benefits, the review of the protocol will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of interventions subjects would receive even if not participating in research). The possible long range effects of applying knowledge gained in the research will not be considered (for example, the possible effects of the research on public policy).

3.4.8 Confidentiality Procedures. To maintain confidentiality of research data, the investigator should protect information obtained from the subject to avoid unintentional access by others. A federal Certificate of Confidentiality may be issued to protect sensitive data from being subpoenaed by a court of law.
A determination may be made that documentation of informed consent be waived if this process increases the risk of a breach of confidentiality (see section 4.4). Subjects should be provided with information about the procedures used to protect confidentiality.

Guidelines for developing procedures to address confidentiality include:

• Limit the personal information recorded to that which is essential to the research.

• Store personally identifiable data securely and limit access to the principal investigator and authorized staff (data, consent/assent forms, code lists, and audio/video recordings should be kept in separate, secure locations, and identifiable information should be kept on campus).

• Code data as early in the research as possible and dispose of the code linking the data to individual subjects when data have been processed.

• Refrain from disclosing personally identifiable data to anyone other than the research team without the written consent of the subjects or their legal representative (exceptions may be made in case of emergency need for intervention or as required by regulatory agencies).

• Implement more elaborate measures to protect confidentiality if the data are considered to be sensitive (e.g., sexual preference or practices, use of alcohol or other drugs, illegal conduct, psychological or mental health records, etc.) and place the subject at legal risk.,. In some cases, it may be appropriate to apply for a federal Certificate of Confidentiality (see section – below).

3.4.8.1 Anonymity and Confidentiality. Anonymity means that the identity of the subject is never recorded or associated with the data collected. Maintaining confidentiality involves recording but concealing the subject's identity or codes linked to the individual's identity. The investigator should describe the procedures used to maintain either anonymous or confidential data. If the subject's identity will be recorded or a code will be created that is linked to the subject's identity, the investigator should include the rationale for doing so. If it is necessary to track information over time, consideration must be given to using a coding strategy that is not linked to the subject's identity if at all possible.

3.4.8.2 Reportable Disclosures. State law and mandated reporting requirements may limit the extent to which the investigator is able to protect the subject's confidentiality. If through interview or measurement, the subject is likely to disclose illegal or dangerous behavior (e.g., if the subject reports any kind of abuse or serious harm to self or others), the investigator must disclose whether and to whom information will be reported. The investigator should include a description of the limits to confidentiality within the consent document.

3.4.8.3 Coding Data for Tracking Purposes. In survey research, an investigator may wish to code data to track respondents. The investigator may wish to re-contact nonrespondents or publish information about non-respondents to describe the study sample. These tactics are appropriate as long as individuals are informed at the beginning of the study during the informed consent process. If coding will be used for tracking purposes, the investigator must describe the coding scheme used to track respondents and nonrespondents. If the individual's identity is linked to the code, the investigator must describe how this information will be used once data collection is complete.

3.4.8.4 Image and Voice Recording. If the study involves the use of the audio or video recordings, the investigator must describe where the subject's image or voice will be presented and to whom. The investigator must indicate whether any identifiers will be present on the recordings. The subject should be informed within the consent document about how images may be used. If the investigator would like permission to present the recorded image for purposes other than the specific research for which the subject is consenting (e.g., for educational purposes), an addendum to the consent is used to obtain this authorization.

3.4.8.5 Record Storage and Access. In an effort to further protect subject privacy, the investigator must provide information on where and for how long research records will be stored,

and who will have access to the study data (hard copy or electronic files) once data have been collected and filed. The procedures used to dispense of research records and samples/specimens upon completion of the research activity must be described. Data, consent/assent forms, code lists, and audio/video recordings should be kept in separate, secure locations, and identifiable information should be kept on campus. Records must be maintained for a minimum of three years following completion of the study. If recordings are made solely for the purpose of facilitating transcription, they may be destroyed immediately following transcription or at a time less than three years.

If the researcher is a BCC student, the faculty adviser is responsible for the maintenance of these records. If the faculty adviser leaves the institution within this three-year period, forwarding information should be sent and updated with the BCC IRB.

3.4.8.6 Release of Test Results. Data collected for research purposes may also be relevant to the participant's physician or other professional. In some cases, it may also be appropriate to disclose test results to the participant. This may depend on the investigator's training in accurately interpreting the results of a test that has been used for research purposes and the implications of imparting this information to the subject (e.g., access to healthcare or mental health counseling services). The protocol should address the collection of data that may also have clinical relevance and describe whether this information will be disclosed to the participant and/or to a clinical professional determined by the participant. In most cases, the investigator will not be sufficiently trained to make a diagnosis, but the investigator may, and in some cases should, disclose that some test results may be indicative of a certain outcome, and that the subject may wish to pursue further with a physician or other professional. In situations where neither of the above disclosures is appropriate, or where the results are anonymous, the investigator should provide a list of resources/referrals to all subjects.

3.4.8.7 Certificate of Confidentiality. If the research includes disclosure of potentially sensitive or illegal information, additional measures to protect the participant's privacy and confidentiality may be needed. A federal Certificate of Confidentiality provides additional protection for the subject in that the data would be protected from subpoena by a court of law. To initiate the process to obtain a Certificate of Confidentiality for this study, contact Olga Boikess, National Institute of Mental Health, 6001 Executive Boulevard, Room 8102, MSC 9653, Bethesda, MD 20892-9653, Phone: 301-443-3877, Fax: 301-443-2578, Email: oboikess@mail.nih.gov . Upon receipt of the Certificate, forward a copy to the IRB. For more information, visit the NIH Office of Extramural Research website at http://grants1.nih.gov/grants/policy/coc/.

3.4.9 Compensation and Incentives. To assist in subject recruitment, an incentive may be offered. The incentive should be reasonable compared to the burden or inconvenience incurred by study participants. It is important that the incentive be awarded for participation in the study rather than for completing a specific task. The purpose of the incentive is to encourage participation. By awarding the incentive only when a task is completed, it may create an undue influence that does not allow for the participant to discontinue if uncomfortable. The amount and type of incentive should not coerce or unduly influence the prospective subject into participating. The incentive is not contingent on study completion. Potential participants should understand what incentives will be offered before agreeing to participate in the study, and the

terms of the incentive should be described within the consent form. Incentives may also be described on recruitment materials, but should not be sensationalized or exaggerated.

The investigator should consider the use of a prorated incentive payment system. This allows for the subject to be paid as the study progresses and does not create the perception of a penalty for discontinuing participation. In some cases, the incentive structure involves graduated payments over the course of the study to encourage continuation without creating an undue influence for participation. An acceptable approach may involve procedures to pay the incentive in one payment at the end of the study when there is a direct benefit to the subject and a complete data set (all sessions, all interviews, all surveys) must be acquired in order to draw any conclusions. The review will include an assessment of the payment schedule to confirm that the incentive schedule does not appear coercive or unduly influence the subject's decision to participate.

If a lottery incentive will be used, the informed consent should include an estimated timeline for when the information about the drawing will occur, how the person will be notified, how many prizes will be offered, and the chances for winning one of the prizes (e.g., You have a one in five chance of winning).

The review of the protocol will consider the value of the incentive in order to determine its appropriateness and to minimize the potential for coercion. The potential coerciveness of an incentive may vary with the subjects studied, e.g., a small incentive such as a meal may be inconsequential for an employee or student, but coercive for someone in another situation where food is potentially scarce. This also applies to the award of extra credit to students, especially where a student may be earning a borderline grade.

If a monetary incentive will be offered, the investigator must consider how subjects will be paid – through cash, check/money order, or other type of redeemable coupon. The investigator must consider potential breaches in confidentiality if the payment is provided in a form other than cash. This is especially true for investigators using grant funds to pay subjects.

3.4.10 Investigator Experience. The review of the protocol will consider the investigator's experience in the area of research to be undertaken to ensure that the research will be carried out appropriately. The investigator should provide a brief summary of the investigator's relevant research experience/training.

3.4.11 Injuries to Subjects. If the study has a risk of injury, the protocol should describe what will happen if a subject is injured during the course of your study.

3.4.12 Conflict of Interest. If a financial interest is reported, the review of the protocol will assess the investigator's objectivity in communicating risks; selecting subjects; promoting informed consent; and gathering, analyzing, and reporting data. The review will include an assessment of whether the investigator, his/her spouse, dependent child, or any person affiliated with the project has **any** financial interest, financial relationship, governance, or administrative affiliation with any entity that is providing funds for or which has rights to intellectual property resulting from this study.

If the investigator has disclosed a financial interest in the research, the consent form should describe the financial interest as well as how the interest has been managed to avoid the possibility of a conflict in the conduct of the research.

3.4.13 Internet Research. Research conducted in the virtual world of the internet is subject to the same IRB review process and human subjects protections as research conducted in the physical world. The main concerns of the IRB for protecting subjects involved in research on the internet are informed consent, protection of privacy, and confidentiality or anonymity.

Survey Research

Similar guidelines to obtaining consent for exempt research apply in anonymous internet survey research. The investigator must clarify whether participant's information will be anonymous (no identifiers, including online pseudonyms) or confidential. If confidential, the investigator must indicate whether any information linked to the individual's identity (in the physical or virtual world) will be used. An explanation must be included on any added risks associated with privacy violations and strategies developed to reduce the risk of privacy loss or breach of anonymity or confidentiality.

Confidentiality and privacy are of particular importance for internet research, given that information may be stored and accessed for indefinite periods of time. The investigator must assure that data collected will only be accessible to the investigator. If the research requires data to be collected via the internet, efforts to enhance participant privacy and reduce risks associated with a breach to anonymity or confidentiality of subject data must be considered. Within the protocol, investigators must describe the following procedures as they pertain to data collection and submission utilizing the internet.

Privacy/Access. Procedures planned to protect participant identity when entering and submitting data via the internet. For example, will the subject have a username and/or password to gain access to the study site? If so, the investigator must develop instructions for the participant to use when creating a username or password that enhances protection of privacy (e.g., not using own name, not sharing password, etc.). Will data be transmitted in encrypted format? In an anonymous survey, will a name-blind survey URL be assigned to each individual survey to guarantee privacy?

Confidentiality of Data. Procedures to advise a participant on how to prevent another computer user from gaining access to his/her data. This concern focuses on accessing a computer for data entry that is shared with others (e.g., form autocomplete feature, Password Saving feature). The investigator should caution participants to finish the survey in one sitting and to shut down the computer after the assessment is completed.

Secure Data Storage. Procedures that do not include the participant's name or identifiers within the database. The investigator must develop a coding scheme to protect subject privacy and confidentiality of data. This should include a description of how/whether data will be backed up and kept in a secure location, how long they will be stored, and who will have access to the data collected.

Investigators should describe systems in place to prevent unauthorized persons (hackers) from accessing the database. For highly sensitive topics, it is recommended that the subject have the option of printing out a blank copy of the survey and mailing it back to the investigator.

Observational Research

For internet observational research, it is recommended that the following procedures be followed to obtain consent:

• Prior to initiating observation or data collection from a particular site, the investigator should contact the domain host, webmaster, or equivalent to provide a description of the study and request that information about the study be presented to the community. Should the host agree, study information is presented to the community for discussion. If the community indicates agreement to the host, the researcher is notified of permission to access the site.

• New users that join once the research has begun must be informed of the research in the first welcome message from the domain host, webmaster, or equivalent.

• The user/prospective subject should have an opportunity to refuse participation in the observational research study.

Deception in observational research, where the investigator identity is concealed or falsified on the internet, will be reviewed on a case-by-case basis.

Investigators conducting observational research studies on the internet must consider the perception that its members have regarding the privacy and confidentiality of the information that they disclose. The investigator must also abide by rules that govern the online community regarding disclosure of information outside the realm of the group. The investigator must consider the degree to which publication of information disclosed on the website could place subjects at risk. Given the search capabilities of the internet, even direct, anonymous quotes from subjects could be linked back to the subject with a verbatim search of that direct quote. Investigators must include assurances in the protocol that all possible precautions have been taken to ensure subject privacy and confidentiality.

4.0 Informed Consent Process and Procedures

The OHRP *IRB Guidebook* states the following: "Informed consent is one of the primary ethical requirements underpinning research with human subjects; it reflects the basic principle of **respect for persons**. It is too often forgotten that informed consent is an ongoing process, not a piece of paper or a discrete moment in time. Informed consent assures that prospective human subjects will understand the nature of the research and can knowledgeably and **voluntarily** decide whether or not to participate. This assurance protects both the subject, whose **autonomy** is respected, and the investigator, who otherwise faces legal hazards. The 'proxy consent' of someone other than the subject is not the same as the subject's own consent, although it may be an acceptable substitute when a subject is unable to give informed consent." (http://ohrp.osophs.dhhs.gov/irb/irb_chapter3.htm#e2).

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 and/or the parent or guardian is given copies of the approved consent/assent form(s).

4.1 Informed Consent Process

The investigator is responsible for ensuring that the consent process is followed. The IRB-approved consent form (based on the BCC template) must be signed before any research activity begins. Approval for the study will be withdrawn if informed consent is not obtained properly.

The process used to present the study to potential subjects will be reviewed. The study should be presented in a language that is clear and understandable to ensure full disclosure of the research and assess the potential subject's understanding of the research (i.e., purpose of the study; what participation entails; risks; risk reduction, including confidentiality/anonymity, storage and disposition of data; benefits; investigator's and, where appropriate, adviser's or campus sponsor's contact information for questions, etc.).

Consideration will be given to how and where the research will be introduced to the subject to assess whether the timing and setting of the informed consent process is conducive to objective decision-making. During the consent process, the investigator must ensure that everything is done to enhance the prospective subjects' comprehension of the information and their ability to make a choice. The review will include the procedures that may be used to inform all research subjects of any new information that might affect their willingness to continue participating in the research. If the study involves a longitudinal design, a review will be done of the description of the mechanism whereby consent can be renegotiated, as needed, and subjects can be reminded periodically of the terms of their participation in the research.

If persons who are cognitively impaired will be recruited for this study, a review will be done of the information about the process used to ensure that the prospective subject understands the information presented about the study.

4.2 Informed Consent Procedures

It is important to include a description of the person who will make initial contact with the potential subject to demonstrate that this individual is knowledgeable about the study, can present the information to lay people, and will promote voluntary participation. The procedures should also include qualifications of the individual(s) who will present the study to potential subjects, as well as the qualifications and training of the person who will be asked to inform potential subjects of the study, answer questions the subject may have about the study, and document this process through a signed consent form. In addition, the procedures should identify who will verify that the consent form is signed. The procedures should identify the process that will be utilized to retain the signed copies of the consent document in your records for a minimum of three years following completion of the study.

If non-English speaking persons will be recruited, the investigator will provide a description of the qualifications of the person who will conduct the translated consent process. If verbal, the investigator will provide an English version of the consent document before the translated version is approved. After the English version has been approved, the investigator will be required to forward a copy of the translated document and a back translation into English, done by someone other than the original translator, so that the accuracy and thoroughness of the translation can be assessed.

4.3 Waiver of Consent Requirement

If waiver of consent, alteration of consent content, or waiver of consent documentation is requested, a review will be done of the justification to support the request.

As per 45 *CFR* 46.116 (c), the requirement to obtain informed consent or approve a consent procedure that alters some of the consent content may be waived if it is found and documented that:

a. The research is designed to evaluate a public benefit or service program and the research could not be carried out without the waiver or alteration or
b. The research involves no more than minimal risk to the subject;
c. The research could not be carried out without the waiver or alteration and
d. When appropriate, the subjects are provided with additional information after participation.

4.4 Waiver of Documentation of Consent

The requirements to document voluntary participation via a signed consent form may be waived if 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 (45 *CFR* 46.117 (c)).

The requirements to document voluntary participation via a signed consent form may be waived if 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. In this case, the investigator will ask the subject whether he or she wants to sign the document that links him or her to the research, and the subject's wishes for documentation will dictate whether or not a signed consent form is needed.

If documentation of consent is waived, an informational cover letter or information provided verbally using an approved script be provided to each subject will be required.

4.5 Consent Document

The investigator should provide the consent document(s) for use in obtaining and documenting consent from study participants. Consent forms must adequately describe the study using language appropriate for the target audience and utilize an appropriate font size. If relevant, the investigator will be asked to translate consent documents into the subject's primary language after the English version of the consent form has received IRB approval.

The IRB-approved consent form may be read to the subject or to the subject's legally authorized representative in addition to allowing the potential subject an opportunity to review the consent document and ask questions before signing the consent document.

5.0 Consent Form Development

5.1 Structure of a Consent Form

The following points must be followed to ensure that the subject understands the nature and purpose of the research in which they are being asked to participate (see consent template):

• The consent should be written in 6th to 8th grade reading level, avoiding technical jargon.

• The consent document should be written in the second person (using the "you" pronoun for the prospective subject).

• Legible font size is used based on population targeted (11 or 12 point).

• Double spacing should be used between paragraphs.

Although the desired outcome is a thorough understanding of the various elements of the consent form, investigators should not insert any statement asserting that the prospective subject has understood what he or she has read or heard. One can only be certain that the prospective subject has read or heard the content and has been afforded the opportunity to ask and have answered all his or her questions.

5.2 Components of a Consent Form

The following information must be included in an informed consent document (45 *CFR* 46.116 (a,b)):

• A statement that the subject is being asked to participate in a research study.

• The name of all investigators involved in the study. The department and institution with which the investigator is affiliated (e.g., faculty member at BCC, graduate student at BCC, teacher at <name> school, social worker at <name> agency, etc.). If the investigator is a student, the name of the person supervising the research should be included.

• An explanation of what the study is designed to determine or assess, using language that is clear to the target audience.

• The number of subjects being recruited for this study and the eligibility criteria used to identify prospective participants.

• The procedures that the subject will be asked to follow. The investigator must clarify whether participation and/or the participant's information will be anonymous (no identifiers) or confidential and whether audio or video taping will take place.

• The location where the research will be conducted and the expected duration of the subject's participation. The investigator must be specific regarding the amount of time study participation will require of the subjects.

• A description of any risks or discomforts the subjects might encounter as a result of participation. Even if the level of risk is minimal, the investigator should never state that there is "no risk."

• The provisions made to address these risks or discomforts. If there is a risk of psychological discomfort in a questionnaire, interview, or focus group setting, the investigator should indicate that subjects may refrain from answering any question that makes them uncomfortable. The protocol must describe the procedures used to maintain anonymity or confidentiality during data collection, e.g., collecting completed questionnaires using a box at the front or back or the room or a sealed envelope). For anonymous questionnaires, the investigator should include a reminder not to place their name or other identifier on the questionnaire. For mailed questionnaires, a reminder not to place their name or other identifier should be included on the envelope. For focus groups, a reminder not to share information with others outside the group should also be included.

• A statement to describe potential benefits to science and society that may result from this research. This statement must include a description of any benefits the subjects can expect as a result of participating in the study.

• A statement to describe how confidentiality of records identifying the subject or anonymous records will be maintained (include the procedures for using and storing data and who will have access to the data, as well as how the results will be reported).

• If an incentive is offered to participants, a description of what is being offered and what is required of the subject to obtain the incentive. If the subject is offered a payment, a statement must be included on the amount, formula for proration should the subject or investigator choose to discontinue participation, and when payment will occur.

• Any procedures that are experimental.

• When applicable, a statement informing subjects of appropriate alternative procedures or courses of treatment that might be available or advantageous to them.

• Contact information for study personnel (including the faculty adviser or campus sponsor, if appropriate, and the IRB, should the subject have questions or concerns about participation in the research. The following statement should appear at the bottom of the consent form: "THIS PROJECT HAS BEEN REVIEWED BY THE BCC INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH. ADDITIONAL CONCERNS AND COMPLAINTS, OR QUESTIONS REGARDING YOUR RIGHTS AS A RESEARCH PARTICIPANT, SHOULD BE DIRECTED TO THE OFFICE OF THE PRESIDENT (413-236-1003)."

• A statement that the subject's participation in the study is voluntary. The investigator must explain that if the subject decides to participate, he or she can withdraw consent and stop participation at any time without penalty or loss of benefits allowed. With the exception of focus groups and other group activities, if recording is taking place, a statement should be included that subjects will have the opportunity to destroy the tape if they withdraw from the study.

• Unless a waiver of documentation of consent has been granted, a signature and date line for the participant to complete.

5.3 Disclosing a Financial Interest to Subjects

The investigator has an ethical responsibility to disclose a possible conflict of interest to potential research subjects as part of the consent process. If the investigator reports a financial interest with the study sponsor and the conflict can be managed, it is expected that the consent form will adequately inform subjects of the relationship as well as procedures used to minimize the effect the relationship may have on the study (http://aspe.hhs.gov/sp/coi/refs.htm).

5.4 Short Form Written Consent (46.117(b)(2))

The regulations also allow for consent to be documented by signing a "short form" that states only that the required elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When this method is used, approval is required of the written consent statement that will be presented orally to the prospective subject. In addition, a witness to the oral presentation is required. Following the oral presentation, the prospective

subject/legal representative will sign the "short form" if he or she decides to participate in the research. The witness verifies the consent process by also signing the "short form" and the consent statement that is presented orally to the subject. A copy of the consent statement is then given to the subject or the representative, in addition to a copy of the signed "short form."

5.5 Consent Translation

DHHS regulations (45 *CFR* 46.116) require that informed consent be obtained in language understandable to the subject (or the subject's legally authorized representative). Non-English speaking subjects must be presented with, and sign a consent form, that is written in their primary language. The investigator must include in the application a language-appropriate translated consent document for review and approval prior to recruiting subjects. It is recommended that the investigator secure approval of the English consent document prior to translating the consent form. It is not required that a certified translator perform the document translation. However, it is required that the investigator provide a "back translation" to English, done by someone other than the original translator. Translation of a document to Spanish using the back-translation method involves translation of the English document to a Spanish version. The Spanish version of the document is then converted back to English by another bilingual individual. The original English version is then compared to the English version of the Spanish-translated document for accuracy. If the two documents are comparable, the translation would be considered adequate. It is expected that the back translation will not be a verbatim rendition of the original English version.

5.6 Special Considerations

• For research involving cognitive impaired participants, 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 should 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 occurs.

• For research involving the internet, the consent form should explain added risks associated with privacy violations and strategies developed to reduce the risk of privacy loss or breach of confidentiality.

• For exercise research, the consent form should explain risks associated with exercise or exercise-related testing or using various types of equipment.

• For studies involving deception or incomplete disclosure, information about the details of the study hypothesis or research question to subjects may be abbreviated or withheld during the consent process. However, subjects should be provided with enough general information about the study or experiment to understand and make an informed decision about whether or not they want to complete the study tasks or expose themselves to potential risks involved in study participation. Subjects should be debriefed about the true nature and purpose of the study after their participation has ended.

• For research with a risk of injury, the consent form should explain what will happen if a subject is injured during the course of your study.

5.7 Debriefing Statement

The debriefing statement should be presented both orally and in writing. Debriefing procedures should include a written statement that will be summarized and then given to subjects to take home to read in more detail if they choose. Along with a description of the deception involved and an explanation about the true purpose of the research, include a statement to inform subjects of their right to withdraw their data from the study and still receive any incentive or payment (e.g., cash or course credit) if they feel upset or uncomfortable with the deception involved. Alternatively, in an anonymous study, you may refrain from collecting materials until after the debriefing; anyone upset or uncomfortable with the deception involved may elect not to submit the materials. Resource or referral information should also be provided to the subject should participation in the study raise personal concerns that he or she would like to discuss with a clinical professional.

5.8 Consent Form Templates

An informed consent form and exempt informational letter are provided here to assist investigators in developing documents specific to their studies. These templates should be edited and revised to meet the requirements of the particular research.

Statements that are in bold type need not be in bold type in your consent document.

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.

6.2 Faculty Advisor'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 member to ensure compliance

with procedures and regulations relating to the protection of human subjects. The supervising faculty member is responsible for the following aspect 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 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 adviser 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 faculty member or administrator to ensure compliance with procedures and regulations relating to the protection of human subjects. The campus 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. Minor changes that do not adversely alter the overall risk-benefit profile of the study may receive an expedited review. The full committee 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. 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 unexpected events experienced by a research subject 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, unanticipated side effects, and/or death. Failure to report an adverse event to the IRB may 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. Research that was initially reviewed by the full committee will receive continuing review by the full committee unless identified as not exceeding a minimal level of risk at the time of its initial review.

The continuation of approval request should include 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.