Baton Rouge Community College
Institutional Review Board (IRB)
Manual of Procedures

Pursuant to

BRCC Policy Number 6-002 (Effective August 31, 2018)

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I. Introduction

Baton Rouge Community College (BRCC) values quality research and data integrity as central to the student learning process and overall organizational effectiveness.

All research at BRCC must comply with Protection of Human Subjects as prescribed by the U.S. Department of Health and Human Services (45 CFR 46). All research involving human subjects must be reviewed by the College's Institutional Review Board (IRB) or its designee. In some cases, this may also include executive leadership of the College.

Written administrative procedures contained in BRCC's IRB *Manual of Procedures* must be followed to ensure that College faculty, staff, and students who may be affected by the research can be certain that it is sound and does not violate local regulations, College operating procedures, or federal regulations concerning protection of human participants.

The IRB must be composed of the following individuals:

- A representative from the Office of Institutional Effectiveness and Strategic Initiatives (who also serves as Chairperson)
- Dean of Business, Social Science, and History
- Dean of Liberal Arts
- Dean of Innovative Learning and Academic Support
- Dean of Libraries and Learning Resources
- Dean of Nursing and Allied Health
- Dean of Students
- Dean of Technical Education

II. Purpose, Definitions, Principles, and Procedure Review

Purpose

Pursuit of scholarly work and research will often involve the use of human subjects for data collection and analysis. The primary purpose of the Institutional Review Board (IRB) is to protect the welfare of human subjects in research activities. The IRB has in its purview the review of applications to perform Human Subjects Research to ensure that the rights and welfare of human participants in such research are protected; that risks have been considered and minimized; that the potential for benefit has been identified and maximized; that all human subjects only volunteer to participate in research after being provided with legally effective informed consent; and that any research is conducted in an ethical manner and in compliance with established standards and/or regulations.

The IRB or its designee is authorized to review, approve, require modifications in, or deny approval to research activities conducted by or through the College using human subjects. The federal guidelines defining an IRB's purview regarding Human Subjects Research are outlined in Code of Federal Regulations, Title 45: Public Welfare, Department of Health and Human Services, Part 46: Protection of Human Subjects (commonly known and cited in what follows as "45 CFR 46"). More detailed regulatory information regarding an IRB's purview can be found online at http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html.

Those who wish to perform research at BRCC should follow this rule of thumb when considering whether their work constitutes research requiring IRB review: if the study involves interactions with living individuals or use of individuals' identifiable private information, with the intention making the results of this study publicly available, IRB approval must be sought. This stipulation includes research that the IRB or its designee may deem upon review to qualify for "Exempt'" status (although "Exempt" research does not require subsequent IRB oversight; see sections on "Exempt" research below for more information).

Any employee of BRCC who wishes to gather student or institutional information or data *for purposes of institutional effectiveness or required reporting to external agencies* (such as for needs of program assessment, accreditation, or grant/funding applications) is not required to seek IRB approval, *providing that their access to the information to be collected is protected under federal or state regulations*, such as FERPA (Family Education Rights and Privacy Act).

Definitions

The following definitions regarding Human Subjects Research are stipulated in 45 CFR 46.102.

Research means "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." This will include any study the results of which are to be presented publicly, such as in published form (e.g. books, journals, internet sites, doctoral dissertations, master's degree theses) or in public speaking settings (e.g. academic conferences, lectures, campus presentations).

Human subject refers to “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information” pertaining to individuals.

Intervention refers to “both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.”

Interaction includes “communication or interpersonal contact between investigator and subject.”

Principles

The following principles apply to all research (including student projects) involving human subjects at BRCC, to ensure that adequate safeguards are provided:

1. Subjects’ legal rights will be respected; their rights to privacy, dignity, and comfort will also be considered in approving proposed research.

2. Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

3. Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research subject.

4. Adequate provisions should be made for recruiting a subject population that is representative of the population base in terms of gender and minority representation, unless it is scientifically justified to do otherwise.

5. Research involving human subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions and faculty members for undergraduate research projects.

6. Participation of a human subject in research must be voluntary and the right to withdraw at any time must be provided. Information provided to gain subject consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.

7. Those seeking to conduct such research may not solicit subject participation or begin data collection until they have obtained IRB authorization.

8. The IRB does not assume the role of evaluating the soundness of the proposed research study, the merits of the research design, or the potential contribution of the research to the given field. Rather, the IRB’s scope is to evaluate each project’s compliance with ethical standards in regard to issues such as informed consent, confidentiality, and any risk to the participants.

Procedure Review

The IRB *Manual of Procedures* is to be given full review at least every three (3) years, or upon the passage of applicable federal and state law.

III. Procedures

A. Submission, Review, and Approval of Applications to Perform Human Subjects Research
All Applications to Perform Human Subjects Research and accompanying materials should be submitted to the IRB Chair. The Principal Investigator (PI) must submit one (1) paper original with signatures and one (1) electronic version of the "Application for Human Subjects Research" to the IRB Chair at least thirty (30) days in advance of the project start date or any other relevant deadline in order to provide time for review and processing. The PI should keep in mind that no research may begin until the application is approved. If the researcher anticipates that Full Board Review will be required for the project, it is recommended that the proposal be submitted with significantly more than 30 days' lead time, in order to allow time for the meeting to be scheduled, for revisions to the application suggested by the IRB Chair, and so forth.

The IRB or designee may take one of the following three actions in regard to a submitted application: Approved, Tabled, or Not Approved. The IRB Chair shall notify investigators in writing of the decision to approve or deny approval to the proposed research activity, or of modifications required to secure IRB approval of the research activity. If approval is not granted, written notification from the IRB Chair will include a statement of the reasons for its decision. If the project is not approved, the PI may revise and resubmit the application for another review. All approvals of applications are subject to review of the Vice Chancellor of Academic and Student Affairs (or equivalent officer).

"Tabled" action indicates that the application was not sufficiently complete for the IRB or its designee to reach a final decision. In this case, the PI is notified by the IRB Chair, and the additional information or modifications necessary for completion of the application and IRB review is requested.

The IRB Chair or designee shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

B. Types of Review
There are three categories of review in the IRB's review procedures: Exempt, Expedited, and Full Board Review. These three categories are inclusive of applications for Cooperative Research to be conducted in partnership with other institutions. In the conduct of Cooperative Research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of appropriate officials, the College may enter into a joint review arrangement with another institution, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

When an Application to Perform Human Subjects Research is submitted to the IRB Chair, the IRB Chair or designee will perform an initial review of the application to determine if the project is eligible for Exempt status, Expedited review or, if significant risk is inherent in the study, refer the application for Full Board Review. The PI or other associated researchers cannot make this determination, although, on the application the PI should indicate which of these three categories appears most fitting for the proposal.

Exempt Status

Some applications submitted to the IRB may fall under "Exempt" status. In this case, although the application is still required, the ensuing research does not need to be monitored by the IRB.

Exempt types of research (as stipulated in 45 CFR 46) include:

(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) of this section, if: (i) the Human Subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the Investigator or Project Director in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Some types of Human Subjects Research projects that may qualify for the Exempt designation include data gathered from anonymous surveys that elicit non-sensitive information from the participants; passive, non-invasive observations of individuals' behavior in a public place such as a park or shopping mall; or research regarding teaching techniques and methods based on one's own classroom

experiences. Projects will not be given Exempt status if they include any degree of deception, involve more than minimal risk to participants, involve sensitive information, or include protected classes or vulnerable populations.

Expedited Review

Pursuant to the terms of "Expedited Review Categories (1998)" published by the Office of Human Research Protections (OHRP), certain types of research qualify for an Expedited review. These are activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed under the OHRP's categories of research that may be reviewed by the IRB through an Expedited review. The IRB also may use the Expedited procedure to review minor changes in previously approved research (i.e. Continuing Review) during the period (of one year or less) for which approval is authorized.

The IRB Chair or designee does the initial screening. The IRB Chair or designee may review an application under Expedited status, or they can recommend it for Full Board Review. In reviewing the application, the IRB Chair or designee may not deny approval to the research. In this instance, action must be tabled pending further information, or else deferred to Full Board Review. Research may be denied approval only after review in accordance with the Full Board Review procedure.

When a review of an application under expedited status is complete, the IRB Chair will inform the PI of the outcome. Any disagreement between the PI and the IRB Chair or Designee must be resolved by the IRB. The IRB Chair will follow a method for keeping all members apprised of research proposals which have been approved under the Expedited review.

Items (1)-(9) list the categories of research that may be reviewed by the IRB Chair or designee through an Expedited review. However, the activities listed should not be deemed to be of minimal risk simply because they are included on this list.

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

> (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
>
> (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

> (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
>
> (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from federal regulations for the protection of Human Subjects. This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) 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 eligible for Exempt status, as described in Section B above. Item (7) refers here only to research not meeting conditions of eligibility for Exempt status.)

(8) Continuing review of research previously approved by the convened IRB as follows:

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 where no subjects have been enrolled and no additional risks have been identified; or where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Traditional (Full Board) Review

Proposals for research involving more than minimal risk will be recommended by the IRB Chair or designee for Full Board Review. *Traditional (Full Board) Review may also be administered for all proposals from individuals not belonging to the BRCC community, including professors and students belonging to other institutions.*

IRB approval for applications requiring Full Board Review can only occur in an in-person meeting, at which all members or at least a majority of members of the IRB are present. Approval will require a majority vote of those members present at the meeting.

C. Criteria for IRB Approval of Research

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized:

(i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and

(ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) 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. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, and appropriately documented when documentation is required. (See this manual's procedures for Informed Consent, below, to determine whether the project requires Informed Consent to be documented.)

(5) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(6) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(7) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

(8) Assurances of acceptable debriefing, if appropriate. It is the responsibility of the PI to give each subject an explanation to questions ensuing from participation in the research project following its conclusion. It is strongly recommended that this occur immediately following participation for each subject, but if such information could adversely affect subsequent data collection in the same study according to the judgment of the IRB, the full explanation may be delayed for a reasonable period of time. There is an exception to this delay: In those cases in which it is unavoidable to mislead the subjects and/or in which it is possible that the experimental treatment may result in emotional stress for the subjects, it is mandatory that they receive a full debriefing immediately following participation.

Federal regulation stipulates that research covered by this policy is also subject to review by executive leadership of the College. For example, the Chancellor maintains the right to deny approval to research that has been approved by the IRB. However, no official may approve research that has not been approved by an IRB.

D. IRB Record

The IRB Chair shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requesting changes to or for not approving Applications for Human Subjects Research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members and their academic and/or professional credentials, as described in 45 CFR 46.103(b).

(6) Written procedures for the IRB as described in 45 CFR 46.103(b)(4-5).

(7) Statements of significant new findings provided to subjects that may impact a subject's willingness to participate, as required by 45 CFR 46.116(b)(5).

(8) Results of research activities, where appropriate (as furnished by the PI of approved applications).

Notwithstanding other federal or state requirements regarding the maintenance of research records (such as those for research funded by federal agencies), IRB records described in items (1)–(8) shall be retained by the IRB Chair for at least 3 years, and records relating to Human Subjects Research that is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the College at reasonable times and in a reasonable manner.

E. Suspension or Termination of IRB Approval of Research

The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the *Manual of Procedures* or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator and appropriate institutional officials.

F. Training for Prospective Researchers

All PI's wishing to engage in Human Subjects Research must complete an accepted Human Subjects Research Training course prior to submitting application to the IRB. Demonstration of a current credential (such as a printout of a course completion certificate) should be included with the PI's application materials.

One such acceptable course is the Protecting Human Research Participants (PHRP) course available at https://phrptraining.com/#!/. The company CITI (https://about.citiprogram.org/en/homepage/) also offers such a service. Successful completion of a Human Subjects Research training course will allow the user to download and print a certificate of the credential.

G. Informed Consent

Informed consent is designed to inform research subjects about the purpose, risks, potential benefits and alternatives to the research that allows one to make a decision about whether or not to participate based on one's own goals and values. The exchange of this information should occur at enrollment and throughout the study.

Informed Consent shall be sought, obtained, and documented (where appropriate) for participants in Human Subjects Research. A sample Informed Consent form adaptable for use can be obtained from the IRB Chair or downloaded from the web site of the Office of Institutional Effectiveness and Research.

45 CFR 46 stipulates the following regarding informed consent in Human Subjects Research:

Basic Elements of Informed Consent

In seeking informed consent the following information shall be provided to each subject:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental (i.e. procedures whose outcome is unknown, such as the testing of a new teaching pedagogy, or evaluation of a new clinical treatment);
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

<u>Additional Elements of Informed Consent</u>
When appropriate, one or more of the following shall also be provided to each subject:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- The approximate number of subjects involved in the study.

Furthermore, extra safeguards are required when obtaining informed consent from minors and low-reading comprehension or non-reading adults. Researchers wishing to engage subjects from these populations in their research must follow additional guidelines for obtaining informed consent. These guidelines are listed on BRCC's sample Informed Consent form. Refer to the section of this form entitled: Guidelines for Informed Consent (Assent) for Minors and Low Reading Comprehension Adults Participating in Human Subjects Research. Children under the age of 18 cannot participate in Human

Subjects Research without parent's consent. Low-reading comprehension adults must be read a description of the project and the conditions to which they consent.

Exceptions to the Above Rules

The exceptions to the above requirement for obtaining informed consent fall under two main scenarios:

(1) The IRB or IRB Chair may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

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: public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs; and the research could not practicably be carried out without the waiver or alteration.

(2) The IRB or IRB Chair may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided it has been documented that:

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

H. Minimal Risk

Minimal risk is defined to be "that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." (45 CFR 46.102(i)) When considering whether a project will pose a threshold of risk beyond minimal risk, prospective researchers should consider whether the proposed interaction with Human Subjects will involve a greater chance of harm or discomfort than activities of everyday life or routine examinations. For instance, taking cheek swabs for the gathering of cell specimens is within the minimal risk threshold, whereas, administering a new medication in a clinical trial poses a risk of side effects and clearly exceeds minimal risk. Likewise, measuring a participant's heart rate after a five-minute walk may meet minimal risk (because walking falls within everyday physical activity), but to require a participant of average physical fitness to complete a high-intensity workout will most likely exceed minimal risk.

I. Continuing Review

The IRB Chair, or designee may conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. For research projects lasting more than one year, the PI should submit a Continuing Review Form at least thirty (30) days in advance of the one-year expiration or anniversary of the original approval. In the event that significant changes to the original project description are to be reported in the Continuing Review, the PI is advised to submit the Continuing Review Form significantly earlier, in order to allow for extra time the IRB may require for review.

The Continuing Review Form is to be submitted to the IRB Chair. The PI will be notified in a timely fashion of the action taken (e.g., Approved, Tabled, etc.).

When a Continuing Review request is submitted, the IRB Chair or designee shall consider the following: changes to the research, project deviations and violations since the last scheduled review, adverse event reports, reports of unanticipated problems involving risks to subjects and, if available, data safety monitoring reports, and compliance of the PI.

Pursuant to OHRP guidelines, the IRB approval period may be held constant from year to year throughout the life of each project. When continuing review occurs annually and the IRB performs continuing review within thirty (30) days before the IRB approval period expires, the IRB may retain the yearly anniversary date as the date by which the continuing review must be approved. However, if the PI has failed to provide continuing review information to the IRB Chair, or if approval has not been granted by the continuing review date (deadline) originally specified by the IRB, the research must stop, unless the IRB Chair determines and documents that it is in the best interests of individual subjects to continue participating in the research interventions or interactions. In all other instances, after the expiration of original IRB approval, the project or protocol will be considered closed and enrollment of new subjects cannot occur, nor can any data collected be used for research purposes.

The following procedures pertain to both initial and Continuing Review:

1. The IRB Chair or designee shall have authority to determine which studies need verification from sources other than the PI that no material changes have occurred since previous IRB review.

2. PI's shall be informed at the time of project approval (both initial and Continuing) that changes in approved research may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to subjects.

3. PI's shall be informed at the time of project approval (both initial and Continuing) that any serious or on-going problems are to be reported promptly to the IRB.

4. Serious or continuing noncompliance by the PI or their associates, or any suspension or termination of activities, is to be reported promptly to the IRB Chair or designee so that appropriate remedial action can be taken, including, but not limited to, appropriate reporting to the granting agency.

J. Adverse Event Reporting Guidance

Any adverse event in a study involving Human Subjects is a potentially important occurrence because it

may reflect additional risks to subjects. Included in the IRB's purview is the monitoring of adverse reactions and unexpected events (21 CFR 56.108 and 45 CFR 46.103).

In the event of adverse events involving Human Subjects Research, the PI must promptly notify the IRB Chair (within 48 hours of the event's occurrence or of when the event was reported to the PI).

Per federal regulations, all adverse events will be reported to the Vice Chancellor of Academic and Student Affairs (or equivalent officer) as well as to the OHRP.

K. Close Out of Study Form

The study is closed when data collection and analysis are completed within the scope of the IRB approved protocol. Upon completion of the Human Subjects Research, the PI should submit a Close Out of Study form to the IRB Chair.

If the PI or any other member of the BRCC community seek to do further analysis, or to use and apply the data in ways that deviate from the original purpose stated on the Human Subjects Research application and reviewed by the IRB, the investigator or project director must submit a new application to the IRB.

L. Applications from Researchers Outside of the BRCC Community

Occasionally, the College is approached by outside researchers who wish to perform research on the College's students, faculty, staff, or services. Researchers who wish to perform work of this nature at BRCC are held to the same standards governing Human Subjects Research as those outlined above for the College. Applications from outside researchers must furnish the following materials in addition to the standard application:

(1) Documentation of approval to perform Human Subjects Research from the home institution; both the approval and the IRB application should be included (ex. If the researcher's home institution is Louisiana State University, then the researcher must include documentation of approval to perform the research from that institution's IRB and a copy of the researcher's application to that IRB).

In addition, *all proposals submitted to the IRB from doctoral students and students of lower rank must include the following materials in their application*:

(2) A timeline for the research to be performed, which specifically states when the research will begin, and when it will be terminated.

(3) A formal letter written on behalf of the student, composed on letterhead, by the student's major director, confirming the scope and plan for the research to be conducted, and which indicates the timeline of the research program, anticipated completion/publication date for the work, the start date of human subjects interactions involved with the proposed research, and *the major director's approval of these items as they pertain to human subjects at BRCC*.

These application materials should be submitted to the IRB Chair at BRCC, in both paper and electronic form.

Any approval of proposals to conduct research by outside researchers carries the following stipulations. As soon as the research (as described in the IRB application) is completed, the PI will either destroy all personal copies of research material, or will turn this material over to the appropriate BRCC authority. In addition, the primary researcher may not share the research material with others without IRB approval. Any new research to be performed beyond the scope of the originally approved application will require the researcher to submit a new IRB application.

IV. References and Further Reading

References

Bossier Parish Community College

Department of Health and Human Services, Office for Human Research Protections

Kirkwood Community College

Louisiana State University

Maricopa County Community College District

National Institute of Health

Tarrant County Community College District

Further Reading

Department of Health and Human Services, Office for Human Research Protections: http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

Department of Health and Human Services,
Office of Research Integrity: http://ori.hhs.gov/human-subject-research-0

Institutional Review Board of Louisiana State University:
http://www.lsu.edu/research/resources_for_faculty/research_compliance/institutional_review/IRB.php

National Institute of Health, Protecting Human Research Participants Training Module:
https://phrp.nihtraining.com/index.php

National Institute of Health, Research Involving Human Subjects: https://humansubjects.nih.gov

The Belmont Report: http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html