Bluefield College Institutional Review Board

Policy and Procedure

Purpose

The primary purpose of the Institutional Review Board (IRB) for Bluefield College is to ensure that all research involving human subjects, conducted by all persons affiliated with the College, meets professional standards of ethical conduct, protects the rights and welfare of all human subjects, and meets the highest ethical standards. The efforts of the IRB are guided by the pursuit of wisdom, integrity and truth, and the common good. The IRB further promotes that all research is rooted in the Bluefield College Mission and Core Values and that the institution is committed to the recognition of the dignity of each individual.

Function

The Institutional Review Board (IRB) at Bluefield College reviews all research projects involving human subjects who are conducted by the College's faculty, staff, or students where findings are designed to develop or contribute to generalizable knowledge. The IRB's jurisdiction includes all faculty, staff, and students affiliated with the College.

The IRB is charged with the responsibility of ensuring the following:

1. All participants voluntarily participate and provide informed consent,
2. The anonymity and confidentiality of all participants is appropriately assured and,
3. No participant in the research project is subjected to undue risk.

Board Composition

The IRB is composed of five full time faculty members (one each from the College of Arts and Letters, the College of Sciences, the College of Professional Studies, School of Education, and the School of Nursing), two adjunct faculty members from the InSPIRE Program, and two external members selected based on sufficiency of professional competence, experience, and expertise. These external members will not be directly affiliated with the College or a part of the immediate family of a person affiliated with the College. The Vice President for Academic Affairs will serve as an *ex officio* member of the IRB.

Every effort will be made to ensure that the IRB is appropriately and adequately representative of the diversity of the community it serves in regard to race, gender, and culture. In addition, the IRB will exhibit sensitivity to community attitudes and promote respect for the rights and welfare of human subjects.

The IRB reserves the right to, at its discretion, invite non-voting individuals with competency in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.

Review Categories

Exempt

Projects that are traditionally exempt from an expedited or full IRB review 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.

4. 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.

5. 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.

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.

Expedited

Expedited review covers research that poses no more than minimal risk to human subjects. "Minimal risk" is defined as risk encountered in everyday life. Expedited review may be employed for minor changes in previously approved research, collection of data through noninvasive procedures routinely employed in clinical practice, collection of data from voice, video, digital or image recordings, the use of materials that have been collected solely for non-research purposes, research on individual or group characteristics or behavior, or research employing survey or interview methodologies. Expedited review may be used for these types of research regardless of the age of the subjects.

Expedited reviews are completed by the IRB Chair or designee and at least two additional IRB members. Minor modifications to the protocol may be requested by IRB members participating in the review during this process. The applicant will be notified of the IRB approval or concerns requiring additional evaluation as soon as a decision is made.

Full Review

Full IRB review includes research where the subjects can be identified and the data collected poses risks to the subjects, in terms of their financial or social standing, employment or criminal or civil liability. It also includes research that involves more than moderate exercise, research on individual or group characteristics or behavior that employs deception of the subjects or where they are placed under psychological or emotional stress, and research that poses potential physical, psychological, social, legal or other risks to the subjects.

Research targeting vulnerable populations, including minors (unless an expedited review is allowed), pregnant women and fetuses, institutionalized

populations, the mentally disabled and economically and educationally disadvantaged persons will receive a full review to insure that adequate protections are in place.

Process

Prior to initiating any interaction with research participants, investigators must present their proposed research project to the IRB and obtain a favorable recommendation. A favorable recommendation is constituted by a majority vote of the IRB's membership.

The IRB will evaluate research project proposals against the following criteria:

1. Participation is voluntary and selection is fair and without bias.
2. Informed consent is obtained and properly documented for each participant or from the legal representative of each participant.
3. Risks to participants are reasonable and necessary in relation to benefits derived from the project.
4. Risks to participants are absent or minimized (risks may be physical and/or psychological).
5. Adequate effort is made to ensure anonymity and/or confidentiality.
6. Appropriate and adequate provisions are made to monitor participants' welfare including the right to service and the right to discontinue participation.

Proposals to the IRB must address each of these items. The IRB may request an evaluation of additional factors unique within the context of the research being proposed.

Only after favorable action by the IRB can investigators begin to interact with research participants.

Bylaws of the
Bluefield College Institutional Review Board for the
Protection of Human Subjects

1. Name

The name of the board is the Bluefield College Institutional Review Board, hereinafter called "BC-IRB."

2. Mandate

The IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. (Department of Health and Human Services Office of Human Research Protections, *Institutional Review Board Guidebook*, 2.)

The BC-IRB is responsible for reviewing all research involving human subjects conducted at the College or by faculty, staff, and students affiliated with Bluefield College in order to ensure compliance with and fulfillment of: (1) the policies contained in the IRB document entitled "Guidelines for Researchers;" (2) the U.S. Department of Health and Human Services Office of Human Research Protections' *Institutional Review Board Guidebook* (hereafter, HHS OHRP *IRB Guidelines*); and (3) federal and state regulations related to research with human subjects.

3. Authority

The BC-IRB is empowered to:

- Review all funded and unfunded research by faculty, staff, or students that involves the use of human subjects, prior to the beginning of the research.
- Determine the type of review (exempt, expedited, or full board) the research requires.
- Disapprove, modify, or approve research protocols based upon consideration of the protection of human subjects.
- Suspend or terminate a research project.
- Require progress reports and perform such monitoring, as it deems necessary.

4. Relationship to the College

The BC-IRB is directly responsible to the BC Vice President for Academic Affairs. The Office of Academic Affairs will include within its budget the funds to provide the BC-IRB with needed clerical support, files, copying facilities, supplies, equipment and space.

5. Board Membership and Duties

a. Membership: The BC-IRB consists of five full-time faculty members, one from each of the following: the College of Arts and Letters, the College of Sciences, the School of Nursing, the College of Professional Studies, and the School of Education; two adjunct faculty members from the inSpire Program; and two external members whose selection is based on professional competence, experience and expertise. The Vice President for Academic Affairs is responsible for appointing and maintaining the BC-IRB, in consultation with the Deans of the Schools and the appropriate Department Chairs, and with the advice and consent of the BC-IRB. After the initial appointment, terms are for three years and are renewable. The Vice President for Academic Affairs is a non-voting *ex officio* member of the BC-IRB. A BC-IRB member can be removed from service by the Vice President for Academic Affairs on the recommendation of the Chair.

b. Duties of Members:

- Attend BC-IRB meetings.
- Review and evaluate all assigned studies in advance of each meeting.
- If designated by the Chair, act as a reviewer for research projects eligible for **Expedited Review.**
- Complete CITI or other approved training for research with human subjects, which will be funded by the Office of Academic Affairs.
- Become familiar with federal and state regulations, BC policies, and BC-IRB guidelines and procedures.

6. Chair/Secretary

a. Appointment of Chair: The Chair of the BC IRB must be a Dean and is appointed by the Vice President for Academic Affairs in consultation with the Academic Council. The Chair is appointed for one-year with a renewable term and on the advice and consent of the BC-IRB. The Chair can be removed by the Vice President for Academic Affairs on the recommendation of the BC-IRB.

b. Duties of Chair:

- Chairs all regular and special sessions of the BC-IRB. If the Chair is unable to attend the meeting, he or she appoints a substitute from the BC-IRB membership.
- Performs all the functions of a BC-IRB member.
- Has the authority to temporarily suspend research that is not in compliance with BC-IRB guidelines.
- Represents the BC-IRB in dealings with the College and the public when attendance of the total membership is not required.
- Participates in or designates others to participate in sessions designed to inform and educate BC faculty, staff, and students about the responsibilities and activities of the BC-IRB.
- Stays informed about the latest changes in federal and state guidelines for research with human subjects and communicates that information to other members of the BC-IRB and to the College community.
- Has the authority to authorize emergency changes to a research protocol to avoid an immediate hazard to subjects.

- May appoint *ad hoc* committees; for example, an *ad hoc* committee to review right-to-service issues.
  - **c.** Appointment of Secretary: The BC-IRB appoints one of its members to serve as Secretary for a one-year term.
  - **d.** Duties of Secretary:
- Record minutes at all BC-IRB meetings.
- Distribute minutes to all BC-IRB members for approval and then send them to the Office of Academic Affairs.

7. Meetings

a. Date and Time: The BC-IRB meets on an as-needed basis, at least three times a semester, as determined by the Chair.

b. Agenda: The BC-IRB will discuss and act on all research protocols on the agenda, which the Chair determines and distributes to all BC-IRB members prior to the meeting.

c. Voting: A quorum, consisting of one more than one-half of BC-IRB membership, is required to conduct business. A simple majority of those voting is required for BC-IRB action. If a vote is not unanimous, a roll call vote must be taken and recorded in the formal minutes.

d. Minutes: Minutes must be recorded by the Secretary and reflect the substance of all discussions. After the minutes are approved, they are sent by the Secretary to the Office of Academic Affairs to be posted on MyBC under the Faculty Tab. Minutes are open to all faculty. Observers may comment, but may not vote at meetings.

8. BC-IRB Review Categories and Processes

a. Exempt

Projects that are traditionally exempt from an expedited or full IRB review include:

- 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.
- 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.
- 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 the preceding bulleted item in 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.

- 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.
- 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.

b. Expedited Review

The Chair and at least two additional BC-IRB members may review and approve proposals that involve no more than minimal risk to the subject(s) or involve minor changes in previously approved proposals. "Minimal risk" is defined as risk encountered in everyday life. Expedited review may be employed for collection of data through non-invasive procedures routinely employed in clinical practice; collection of data from voice, video, digital or image recordings; the use of materials that have been collected solely for non-research purposes; research on individual or group characteristics or behavior; or research employing survey or interview methodologies. Expedited review may be used for these types of research regardless of the age of the subjects.

Minor modifications to the protocol may be requested by BC-IRB members participating in the review during this process. The applicant will be notified of the BC-IRB approval or concerns requiring additional evaluation as soon as a decision is made.

c. Full Review

Full Review includes research where the subjects can be identified and the data collected poses risks to the subjects, in terms of their financial or social standing, employment or criminal or civil liability. It also includes research that involves more than moderate exercise; research on individual or group characteristics or behavior that employs deception of the subjects or in which they are placed under psychological or emotional stress; and research that poses potential physical, psychological, social, legal or other risks to the subjects.

Research targeting vulnerable populations, including minors (unless an expedited review is allowed), pregnant women and fetuses, institutionalized populations, the mentally disabled, and economically and educationally disadvantaged persons will receive a **Full Review** to insure that adequate protections are in place.

Prior to initiating any interaction with research participants, investigators must present their proposed research project to the BC-IRB for a **Full Review,** which consists of all members, or alternates, that will be attending the meeting reviewing

each protocol. In emergencies where time is a serious problem, the Chair has the authority to circulate a copy or copies of the protocol to the BC-IRB for review and conduct a telephone conference meeting at which members can hear each other simultaneously.

The BC-IRB approves or disapproves a protocol, and gives conditional approval (i.e., approval if the investigator agrees to follow the BC-IRB requirements for protecting subjects). It may also table protocols whose review requires more information.

In the review process, the BC-IRB has as its primary criteria:

- Participation is voluntarily, and selection is fair and without bias.
- Informed consent is obtained and properly documented for each participant or from the legal representative of each participant.
- Risks to participants are reasonable and necessary in relation to benefits derived from the project.
- Physical or psychological risks to participants are absent or minimized.
- Adequate effort is made to ensure anonymity and confidentiality.
- Appropriate and adequate provisions are made to monitor participants' welfare, including right-to-service and right to discontinue participation.

The BC-IRB does not concern itself with the quality of the protocol or its methodology unless more than minimal risk is involved, in which case quality and methodology are appropriately considered in assessing the risk-benefit ratio.

In deciding whether a protocol shall be approved, disapproved, tabled, or conditionally approved, the BC-IRB seeks consensus. The action taken is determined by a simple majority of those attending the meeting. A member or alternate having conflicting interest in a matter before the BC-IRB should not vote on that matter.

When a member or alternate is barred from voting because of a conflicting interest, he or she should not be counted in determining the number of votes needed for a majority, even when he or she has been counted already to determine a quorum. Such members should be absent from the room during the deliberation and vote except for the purpose of providing information requested by the BC-IRB.

Each BC-IRB member has one vote. Voting should proceed openly, after an opportunity for full discussion and debate has been afforded.

Individuals whose protocols have been reviewed shall be notified of the BC-IRB decision in writing.

The BC-IRB retains all pertinent documents of protocols, which are stored on the Academic Drive by the Office of Academic Affairs.

The BC-IRB, upon the request of an investigator or on its own initiative, may reconsider any protocol and reverse its own determination or that of a subcommittee. An investigator

may re-submit a protocol for re-review once it has been modified in such a way as to remove the BC-IRB's objections. There is no mechanism for appeal by investigators beyond the IRB.

If adverse consequences or unanticipated side effects are encountered in the course of the study, or if new information becomes available that could change the perception of a favorable risk/benefit ratio, the principal investigator is responsible for informing the Board **promptly**. The BC-IRB will make the final determination regarding protocol changes required due to adverse event reports.

Research that has been reviewed and approved by an BC-IRB may be subject to further review and disapproval by officials of the College. Those officials may not, however, approve research if it has been disapproved by the IRB. (HHS OHRP *IRB Guidelines,* 3) Approved research is subject to continuing IRB review and must be re-evaluated at least annually.(HHS OHRP, *IRB Guidelines*, 3)

9. Human Protections Officer (HPO)

a. Appointment of the Human Protections Officer: The Vice President for Academic Affairs appoints a person within the BC college community who is not a member of the BC-IRB to serve as a Human Protections Officer.
b. Duties of Human Protections Officer:

- Serves as the point-of-contact for human subjects who no longer want to participate in a research project and communicates the information to the BC-IRB.
- Serves as point-of-contact for human subjects who have right-to-service issues, and communicates the information to the Chair of the BC-IRB, who appoints an *ad hoc* committee to address the right-to-service issue within 24 hours.

10. Changes to the Guidelines and Bylaws

Changes to the guidelines that are mandated by the federal government will be made immediately.

Changes to BC-IRB regulations and changes to the BC-IRB bylaws must be adopted by a majority of the Board and approved by the Vice President for Academic Affairs. Prior to final approval, the Vice President for Academic Affairs will inform the BC community of the proposed changes and comment will be invited.

As changes to rules, regulations, or operating procedures become necessary, they will be posted on MyBC under the Faculty Tab. They are also available in the *Faculty Handbook* and via electronic copy or hard copy from the Office of Academic Affairs.

Bluefield College Instructional Review Board

Application for Proposed Student Research

_____ an undergraduate student(s) at Bluefield College and a major in _____ present to the College's Institutional Review Board a proposal to engage in scholarly research involving human subjects and request approval for the initiation of this research as presented this _____ day of _____, 20____.

I (We) understand that the proposal is evaluated against the College's IRB policy and the collective criteria associated with the ethical execution of scholarly research including but not limited to:

Voluntary participation
Confidentiality/Anonymity
Informed consent
Right to service

Research Project Title:

Principle Investigator(s):

Brief Description (250 words or less):

Principle Investigator Information

Name: _____

BC email: _____

Phone Number: _____

Local Address: _____

Co-investigator(s) Information

Name: _____

BC email: _____

Phone Number: _____

Local Address: _____

CITI Training

Principle Investigator: YES ____ NO ____

Waived Date: _____

Co-Investigator: YES ____ NO ____

Waived Date: _____

Co-Investigator: YES ____ NO ____

Waived Date: _____

Is this research funded (in part or in total) by an entity external to the College?

_____YES
_____ NO

[If YES, describe the source and type of funding]

Conflict of Interest Pertaining to Investigators

Bluefield College recognizes the importance of and promotes and encourages faculty and/or student research. The Bluefield College Institutional Review Board (BC-IRB) recognizes that as a result of research conflicts of interest may occur when an individual is in a position to make a decision in the conduct of his or her research, teaching or outreach activities that may result in personal, family or financial gain. The BC-IRB emphasizes that adherence to the highest levels or integrity by faculty, staff, students, and other personnel in all actions are required to avoid any conflict of interest.

Regulations protecting human research subjects are based on the ethical principles described in the Belmont Report. Transparency and full disclosure are indicators of the Principle of Respect for Persons. Individuals must be treated as autonomous agents and demands that subjects enter into the research voluntarily and with adequate information.

If an investigator on the study team has an actual, potential, or perceived conflict of interest, this information must be disclosed. A research conflict of interest occurs when the design, conduct or reporting of research could be directed or affected by gained interest of the investigator. An investigator refers to any member of the study

The Principal Investigator has the responsibility to inform the entire study team and all research subjects of any conflicts of interest related to a research study.

Conflict of Interest Committee (COIC)

In the event that an investigator indicates on a BC-IRB submission that a conflict of interest may exist, more information may be required.

For more information refer to the *Code of Federal Regulations §46.109(b)* An IRB shall require that information given to subjects as part of informed consent is in accordance with *§46.116*. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights

My signature indicates all disclosure of conflict(s).

No: _____ **Yes_____**

If yes, please disclose conflict below:

_____

_____

_____

_____

Signature _____ **Date** _____

Dates of the Study (Proposed assuming IRB approval)

Start Date: _____

Completion Date: _____

Study Site(s)

Describe the location(s) at which this study will take place.

Has written and appropriate permission been obtained for all sites not a part of the BC campus? [If NO, provide an explanation]

_____ YES _____ NO

Proposed Subjects/Participants

Briefly describe the subjects participating in this study. Include the anticipated number of subjects, their age, sex, and ethnicity distributions.

Subject Vulnerability

Do any subjects have limited decision making autonomy, communication problems, or belong to a group considered vulnerable?

_____ YES _____ NO

If you indicated "YES" to the Subject Vulnerability question, place an X next to the applicable category in the table below.

Prisoners	☐	Minor Children	☐
Pregnant Women	☐	Terminally Ill	☐
Cognitive Impairment	☐	Other	☐
Emotional Impairment	☐		
Communication Impairment	☐		

If any categories are marked above, justify your rationale for including these subjects.

Risk/Benefit Ratio

Briefly make the case that this research will produce greater benefits to the subjects and/or to science than the risk involved in conducting this research.

Study Design and Method

Briefly describe the purpose of this study.

Briefly elaborate on the anticipated goals for this study as well as justification or significance.

Describe the steps in the study including the how long the subjects are involved, treatments employed, archived records searched, assessment instruments used, etc.

Sensitive Information

Is sensitive information being collected from any or all of the subjects (i.e., illegal activity, sexual orientation or history, etc.)?

____ YES ____ NO

If YES, briefly describe the information, how it will be recorded, and the procedures that ensure confidentiality and/or anonymity.

Subject Compensation

Will subjects receive any payment, gifts, incentives, etc. for their participation?

____ YES ____ NO

Briefly describe the type of incentive, the amount, and the eligibility for receipt.

Subject Recruitment

Briefly describe how subjects will be recruited for participation in the study.

Subject Coercion

Briefly describe the potential for subjects to perceive coercion to participate or to act or respond in a specific manner. (i.e., are subjects students of the primary investigator, is participation mandatory for class grade, etc.).

Informed Consent

Describe in detail the process by which subjects are provided the opportunity of informed consent.

It is the opinion of the undersigned that this proposal, faithfully executed, will abide by all prevailing ethical standards appropriate for consideration and consistent with all College policies addressing research involving human subjects, and approves the initiation of this study as presented.

Student(s):

_____ Date: _____
(**Principle Investigator**)

_____ Date: _____

_____ Date: _____

Review Board Members:

_____ Date: _____
(Chair)

_____ Date: _____

_____ Date: _____

_____ Date: _____

_____ Date: _____

_____ Date: _____