Bluefield University Institutional Review Board

Policy and Procedure

Purpose

The primary purpose of the Institutional Review Board (IRB) for Bluefield University is to ensure that all research involving human subjects, conducted by all persons affiliated with the University, 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 University 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 University reviews all research projects involving human subjects who are conducted by the University'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 University.

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 at least five full time faculty members chosen for their expertise in research and/or quantitative/qualitative analysis, and a community member selected based on sufficiency of professional competence, experience, and expertise. The Provost 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 regarding 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.

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 in such

a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. 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 ensure 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.