Bethune-Cookman University Institutional Review Board
Policies and Procedures for Protecting Human Subjects from Research Risks

I. Introduction

Bethune-Cookman University (B-CU) requires that all programs and grant proposals involving Human Subject Research be presented to B-CU's Institutional Review Board (IRB), unless otherwise exempt under these policies. Approval from the IRB must be obtained **prior** to initiating a Research project involving Human Subjects, regardless of whether such project is part of a class or class requirement. Failure to seek IRB approval prior to conducting Human Subject Research is a violation of federal law and B-CU policy.

II. Purpose

The purpose of this document is to assist all B-CU faculty, staff, students, and administrators, or any other parties performing Research in conjunction with B-CU in the preparation and submission of Research proposals involving Human Subjects for review by the IRB.

III. Definitions

Assurance: A document negotiated between the IRB and an Investigator (or, when filed with a federal agency, with the institution and such agency) that states that the Research will comply with all requirements regarding the protection of Human Subjects.

Benefit: A valued or desired outcome.

Clinical Investigation: Any Experiment that involves a Test Article and Human Subjects, the results of which are intended to be submitted to the Food and Drug Administration (FDA) as part of an application for research or marketing permit. [21 CFR 50.3(c)]

Experiment: Any use of a drug or chemical (including those contained in food products) other than the use of a marketed (FDA approved) drug in the course of medical practice.

Human Subject: A living individual about whom an Investigator (whether a professional or student) conducting Research obtains: (1) data through Intervention or Interaction with the individual; (2) Private Information; or (3) who participates in Research as the recipient of a Test Article or as a control. [45 CFR 46.102(f) and 21 CFR 50.3(g)]

Human Subject Research: Research that involves Human Subjects.

Individually Identifiable: Where the identity of the Human Subject is or may readily be (1) ascertained by the Investigator; or (2) associated with the information. [45 CFR 46.102(f)]

Institutional Official (IO): The IO is the university official responsible for ensuring that the IRB has the resources and support necessary to comply with federal regulations and guidelines that govern Human Subjects Research. The IO is legally authorized to represent the institution, shall sign off on all Assurances, and assumes the obligation of any Assurances B-CU files with a federal agency. The IO is the point of contact for correspondence which addresses Human Subject Research from any federal agency, including but not limited to the Office of Human Research Protections (OHRP) and the FDA. The IO shall be the President of B-CU or such designee as the President so selects.

Institutional Review Board (IRB): An administrative body that meets the definition of this term as set forth in the Department of Health and Human Services Regulations and that is established in accord with and for the purposes expressed in such regulations or that approves and conducts the periodic review of Research involving Human Subjects performed at the institution associated with the IRB or other parties using the IRB. [45 CFR 46.102(g), 21 CFR 56.102(g)]

Interaction: Communication or interpersonal contract between an Investigator and Human Subject. [45 CFR 46.102(f)]

Intervention: Physical procedures by which data are gathered and/or the manipulation of a Human Subject's environment for the purpose of research. [45 CFR 46.102(f)]

Investigator: A person (whether a professional or a student) who conducts Research.

Minimal Risk: A Risk is Minimal where 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)]

Private Information: Individually Identifiable information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and/or Individually Identifiable information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. [45 CFR 46.102(f)]

Research: A Systematic Investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute Research for the purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstrations and service programs may include Research activities. Research may also include oral histories, interviews, surveys, and participant observations. [45 CFR 46.102(d)]

Risk: the probability and magnitude of harm or discomfort, including but not limited to physical, psychological, social, or economic harm, which may arise as result of participation in Research.

Systematic Investigation: Any methodical collection of data, whether quantitative or qualitative, incorporated into a Research plan, including but not limited to surveys, tests, observations, or Experiments.

Test Article: A Test Article is a drug, device, food, or other article including a biological product used in Clinical Investigations involving Human Subjects or their specimens.

IV. Institutional Authority

The IRB operates under the authority of B-CU's Board of Trustees, who shall regularly receive information regarding IRB minutes. Research that has been reviewed and approved by the IRB may be subject to further review and disapproval by the Board of Trustees or other B-CU officials. No Research shall be approved if rejected by the IRB.

The IRB shall conduct its activities in accordance with the existing guidelines of the Code of Federal Regulations established by the OHRP and FDA. [45 CFR 46, 21 CFR 56]

V. Institutional Responsibilities

Before any Human Subject Research is conducted, the Investigator must apply for approval from the IRB. The IRB, after approving any Research to be performed under a grant from the Department of Health and Human Services (HHS), shall submit a written Assurance to the HHS on behalf of the Investigator confirming that the Research or Experiment will comply with the requirements of all policies governing Human Subject Research. All Assurances submitted to the HHS or other federal agency shall be signed by the Institutional Official.

Any Human Subject Research conducted (1) at B-CU; (2) by or under the direction of any employee or agent of B-CU in connection with his or her institutional responsibility; (3) by students of B-CU in connection with their institutional responsibilities; or (4) by or under the direction of any employee or agent of B-CU using any property or facility owned by B-CU or involving non-public information collected by B-CU shall be reviewed by the IRB.

VI. Governing Principles

It is the duty of the IRB to review and approve Research only if it complies with the ethical principles of the Belmont Report, attached hereto as Exhibit A. To ensure that all Research complies with the Belmont Report, Investigators shall be required to obtain informed consent forms from any Human Subjects, or their parent/guardian, involved in Research.

The IRB shall determine whether Research is approved by balancing the Risks and Benefits of the Research. So long as the Risks are reasonable in relation to the anticipated Benefits, and informed consent is obtained, the Research shall be approved. The factors that the IRB may consider when balancing the Risks and Benefits include (1) risks of injury or discomfort to the individual, including but not limited to physical, psychological and/or social risks; and (2) potential benefits to the individual, a group to which the individual belongs, and/or society.

The IRB's goal is not to review the scientific design of the Research submitted for approval, but to determine whether the Benefits of any proposed Research outweigh the Risks. However, if the IRB determines that the design of the Research is not adequate to attain the Research's purpose, the IRB may determine that no Benefit can be derived, and the Research will not be approved.

VII. Duties of Investigators

No Research, including but not limited to Interaction or Intervention with Human Subjects, may begin until the Research has been reviewed and approved by the IRB, or a determination has been made, in good faith, that the Research does not constitute Human Subjects Research or that the Research is otherwise exempt from this policy. An Investigator may submit a Research proposal to the IRB for a determination as to whether or not the Research is considered Human Subject Research or is otherwise exempt.

In the event that an Investigator fails to submit a project or study to the IRB, and the project or study qualifies as Human Subject Research, then any data or information collected for the study prior to receiving IRB approval may not be published, presented, or used. The IRB may refuse to approve Research that was started by an Investigator without seeking prior-approval from the IRB. Investigators should err on the side of caution and seek IRB review and approval for any Research that could potentially involve Human Subjects, even if such involvement is conditional or anticipated at a future date.

Investigators should attempt to forward all materials in the Research proposal to the IRB in a timely manner. It is the intention of the IRB that members have access the Research proposal materials two weeks prior to a scheduled IRB meeting so that they have the opportunity to review such materials.

VIII. Membership in the IRB

The IRB shall have a minimum of five members, including a Chairman as designated by the IO, from varying backgrounds. The members of the IRB must be qualified in their particular area of experience and expertise. Membership to the IRB should include considerations of diversity, including but not limited to race, gender and cultural background as well as sensitivity to issues within the community and safeguarding the welfare of Human Subjects. Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely or men or entirely of women, so long as no selection is made solely on the basis of gender.

The IRB should include persons familiar with the Research activities that come before the IRB for approval, but no member shall participate in the IRB's initial or continuing review for any project in which the member has a conflicting interest or is otherwise involved in the Research. In the event that the IRB regularly reviews research involving a vulnerable category of subjects, including but not limited to children, prisoners, pregnant women, or disabled persons, the IRB shall attempt to include at least one member who possesses knowledge and experience regarding these subjects.

The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are not in scientific areas. The IRB shall include at least one member who is not otherwise affiliated with B-CU, nor is an immediate family member of a person affiliated with B-CU.

The IRB may, in its sole discretion, invite individuals with competence in special areas to assist with the review of any Research project which requires expertise beyond the knowledge of the IRB, but such person may not vote on the approval of the Research. Any individual that is invited to assist with the review of a Research project must agree to keep any information such individual learns at the IRB meeting confidential, and may be required to sign a confidentiality agreement ensuring the same.

The Chairman shall nominate qualified individuals to serve as IRB members. All IRB members must receive their final appointment to the IRB from the IO. Each member of the IRB shall serve for two year terms (excluding certain initial members, as listed below, who will serve terms of 2.5 years, in order to allow for terms to be staggered. After the initial term of 2.5 years, all members shall serve terms of 2 years.) Membership in the IRB may be renewed for additional terms at the discretion of the IO.

A list of the current members is available on Exhibit B, attached hereto.

All members of the IRB must complete an orientation as designated by the IRB Chairman. A member may resign from the IRB at any time by providing written notice to the IRB Chairman or IO, as applicable. The IO may remove a member of the IRB for any reason at any time.

IX. Duties of Members

Members should attend all IRB meetings, or provide the Chairman with advance notice if they are unable to do so. Members should ensure that any and all information provided by Investigators in Research proposals to the IRB remains confidential, and return any and all documents the Members are given in order to evaluate the Research to the Chairman upon the IRB's final decision. All Members are required to report to the Chairman or IO any instances of which they are aware that involve a use or disclosure of confidential or Private Information obtained by another member via his or her position with the IRB.

X. Record Keeping

The Chairman will ensure that the IRB prepare and maintain adequate documentation of all its activities, including but not limited to copies of all Research proposals, minutes of IRB meetings, records of continuing review activities, correspondence received from Investigators, and statements of significant findings. The IRB shall also maintain and update this policy as required, and keep an updated membership list at all times.

Minutes of IRB meetings will be kept 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 requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution.

All IRB records will be retained by the IRB for at least three years. Records that pertain to Research that is approved will be retained for a minimum of three years after the completion of such Research. All IRB records will be accessible for inspection and copying for authorized representatives of the HHS, applicable federal agencies, or Investigator at reasonable times and in a reasonable manner, provided that the security of all such documents is maintained.

XI. Duties of the IRB

The IRB shall approve/disapprove any Research, and may terminate, suspend, or place restriction on any Research that comes before it, even after such Research has been approved, should such Research cause harm to Human Subjects. The IRB shall also provide training and educational information for Investigators in order to assist Investigators in obtaining approval for their Research.

Throughout the review process, the IRB shall document all decisions it makes in regards to the Research, including documentation of any findings regarding the Risks and Benefits of the proposed Research, ethical considerations, scientific merit, Private Information, and compliance with any regulations required by federal agencies. The IRB shall also monitor ongoing Research after it has been approved to ensure that it complies with the terms of its approval.

A. Types of Review

1. Exempt Research

Certain categories of Human Subjects Research are exempt from IRB approval. Such research includes:

(a) Research conducted in established or commonly accepted educational settings, involving normal educational practices, including but not limited to:

(1) Research on regular and special education instructional settings; or

(2) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(b) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior unless:

(1) information obtained is recorded in such a manner that Human Subjects can be identified, directly or through identifiers linked to the Human Subjects; and

(2) any disclosure of the Human Subjects' responses outside the Research could reasonably place such Human Subjects at risk of criminal or civil liability or be damaging to the Human Subjects' financial standing, employability, or reputation.

(c) 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 (b) above if:

(1) the Human Subjects are elected or appointed public officials or candidates for public office; or

(2) federal statue(s) require(s) without exception that the confidentiality of the Identifiable Information will be maintained throughout the Research and thereafter.

(d) 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 the Human Subjects participating in such Research cannot be identified via any information reported in the Research.

(e) 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:

(1) public benefit or service programs;

(2) procedures for obtaining benefits or services under such programs;

(3) possible changes in or alternatives to those programs or procedures; or

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

(f) Taste and food quality evaluation and consumer acceptance studies, if:

(1) wholesome foods without additives are consumed or;

(2) 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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Services of the U.S. Department of Agriculture.

Notwithstanding any exemptions contained herein, any Research (1) dealing with sensitive aspects of the behavior of a Human Subject, including but not limited to illegal conduct, drugs or alcohol use, or sexual behavior; or (2) using Human Subjects that are under-age children, mentally or physically impaired, pregnant, prison inmates, or suffering from an illness, is not exempt under this section.

2. Expedited Review

The IRB may review certain types of Research under an expedited review procedure. Such Research includes:

(a) Any Research found by the IRB to involve no more than a Minimal Risk to the Human Subjects participating in such Research;

(b) Any Research that has been previously approved by the IRB within the last calendar year and which contains only minor changes; or

(c) Any other categories approved by the HHS.

Expedited review may be carried out solely by the Chairman or by any IRB members that the Chairman so designates. Research shall not be disapproved unless the Research undergoes a full review, as provided for below. All IRB members shall be notified when Research subject to expedited review comes before the IRB.

3. Full Review

All Research not falling into (1) or (2) above shall be fully reviewed by the IRB. A full review shall be carried out at a meeting of the IRB in which a majority of the IRB members, including at least one non-scientist, are present. Members may not participate in a full review by mail, but may participate by telephone. Research shall not be approved without a majority vote of the members participating in the full review. Any abstention from voting shall be recorded as a disapproval.

Any member with a conflict of interest, or whom shall participate in the Research up for review before the IRB may not participate in the meeting reviewing such Research. After presentation of all material submitted by the Investigator proposing the Research, followed by a discussion amongst the IRB members regarding the potential Risks the Research may cause to Human Subjects, the Chairman shall move for a vote to determine what category the Research should be placed in, as set forth below.

B. <u>Actions of the IRB</u>

At a review meeting, proposals will be voted upon by the IRB and categorized into one of five categories. Such categories are:

1. Approved. The Research is approved. Upon receipt of an approval letter from the IRB, the Investigator may begin the study.

2. Approved contingent upon modifications. The Investigator will be notified in writing as to the nature of the modifications required by the IRB. Once the Investigator has complied will all required modifications, and sent written notice to the IRB confirming compliance, the IRB will send the Investigator an approval letter. Upon receipt of an approval letter from the IRB, the Investigator may begin the study.

3. Deferred. This category indicates that the IRB has not completed a full review of the Research and that the IRB desires to continue reviewing and discussing the Research at an additional meeting. Research may be placed into the Deferred category more than once.

4. Tabled. This category indicates that the IRB requires additional information and/or has a serious concern regarding the proposed Research. The Chairman, or a member appointed by the Chairman, will contact the Investigator to learn more information regarding the Research. The

Chairman may, in his or her sole discretion, require the Investigator to come to a meeting of the IRB and further discuss the Research in front of the IRB members. After receiving additional information, the IRB will again review any Tabled Research and place it into a new category.

5. Disapproved. If a Research proposal is disapproved, the Investigator may make modifications to the Research and resubmit the Research for review. Research may not be disapproved unless a full review is performed by the IRB.

In order for the IRB to approve Research it must determine that:

(a) Risks to Human Subjects are minimized;

(b) The Research design is sound and has scientific merit;

(c) There is an appropriate Risk to Benefit ratio;

(d) The selection of Human Subjects to participate in the Research is equitable;

(e) Appropriate procedures are followed by the Investigator for obtaining and documenting informed consent or waiving or altering informed consent documentation or procedures in an appropriate manner;

(f) The Research plan has adequate provisions for monitoring the data collected to ensure Human Subject safety;

(g) There are adequate provisions to protect Human Subject privacy and data confidentiality; and

(h) Additional safeguards are included to protect the rights and welfare of any vulnerable persons involved in the Research.

C. Informed Consent

In order to obtain approval from the IRB, the Investigator must obtain legally effective informed consent from the Human Subject or the Human Subject's legally authorized representative, such as a parent or other legal guardian (in the case of a minor), unless the conditions for a waiver or alteration of informed consent are approved by the IRB upon review. Informed consent (or a waiver or alteration) must be obtained prior to conducting any Research. A copy of the informed consent form or procedures, or an explanation as to why the same should be waived or altered, must be submitted by the Investigator for review by the IRB.

The informed consent document must include:

1. A clear statement that the study involves Research;

2. An explanation of the purposes of the Research;

3. The expected duration of the Human Subject's participation in the Research;

4. A complete description of the procedures to be followed, including an explanation of the standard treatment that the Human Subject would receive if not involved in the Research (if applicable) and how this treatment is different from that performed in the Research;

5. A description of the reasonably foreseeable Risks or discomforts that the Human Subject may experience during the Research;

6. A description of any Benefits to the Human Subject or to others that may reasonably be expected from the Research;

7. A disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the Human Subject;

8. A statement describing the extent to which confidentiality of records identifying the Human Subject and privacy will be maintained, including a statement as to what information will or will not be included in the Human Subject's medical record (if applicable);

9. For Research involving more than a Minimal Risk, an explanation as to whether any compensation is available and an explanation as to whether any medical treatments are available if injury occurs and, if so, what such treatments consist of and where additional information on such treatments may be obtained;

10. An explanation of whom to contact for (a) answers to pertinent questions about the Research, (b) injuries related to the Research, and/or (c) complaints or concerns about the Research;

11. An explanation of whom to contact at the IRB (as an alternative to the person listed in 10 above) in order to obtain any of the information listed in 10 above;

12. A statement that participation is voluntary, that refusal to participate at any point during the Research will not result in a loss of benefits that the Human Subject is otherwise entitled to receive, and that the Human Subject may discontinue participation at any time;

13. For Research regulated by the FDA, that the FDA has the right to inspect the Research materials at any time; and

14. Any of the additional elements, if applicable:

(a) A statement that the particular Research may involve Risks to the Human Subject (or fetus, should the Human Subject be pregnant) which are currently unforeseeable;

(b) Anticipated circumstances under which the Human Subject's participation may be terminated without regard to the Human Subject's consent;

(c) Any additional costs to the Human Subject that may result from participation in the Research;

(d) The consequences of a Human's Subject's decision to withdraw from the Research and procedures for orderly termination of participation by the Human Subject;

(e) A statement that significant new findings developed during the Research which may relate to the Human Subject's willingness to continue participation in the Research will be provided to the Human Subject;

(f) The approximate number of Human Subjects involved in the Research; or

(g) Any additional information that the IRB requires to be placed on the informed consent form.

No informed consent may include any exculpatory language by which the Human Subject or his/her legally authorized representative is made to waive or appear to waive any of the Human Subject's legal rights, or which releases or appears to release the Investigator, the IRB, B-CU or any of their respective agents or employees from liability for negligence.

Informed consent may be documented by a written consent form approved by the IRB, or obtained orally by following a written script approved by the IRB. Such script must be read to the Human Subject in the presence of a witness that can verify and document that the script was appropriately followed. The Investigator is responsible for collecting and maintaining all written informed consent forms, or documentation of oral confirmation of informed consent as verified by the witness. In the event that informed consent is obtained from a person that does not speak English, such consent shall be translated into a language in which the Human Subject is fluent.

Informed consent may be waived by the IRB where (1) the only record linking the Human Subject and the Research would be the informed consent documentation and the main Risk involved in the Research consists of a breach of confidentiality of the informed consent document. In such a case, the Human Subject will be asked whether he/she wants documentation linking him/her with the Research and the Human Subject's wishes will govern; or (2) the Research presents no more than a Minimal Risk of harm to the Human Subject and involves no procedures for which consent is normally required outside of the Research context. In situations where the IRB waives informed consent, the IRB may still require that the Investigator provide the Human Subjects participating in the Research with written information regarding the Research.

XII. Research Applications

A complete research application shall include:

A. A complete resource development checklist, as provided for by the grants office;

B. Professional qualifications of the Principal Investigator;

C. A cover letter;

D. A summary of the Human Subject Research project, written in language understandable by the IRB;

E. A copy of the informed consent form, procedures for obtaining oral informed consent, or an

explanation as to why informed consent should be waived or altered;

F. Copies of any advertisements or brochures used by the Investigator to recruit Human Subjects;

G. Copies of any survey instruments or data collection forms to be used as part of the Research;

H. Documentation showing the principal Investigator or others who are directly involved in the Human Subjects Research have received training in Research methods and the protection of Human Subjects; and

I. Any other materials that may assist the IRB when determining whether to approve the Research.

XIII. After Approval

Once the IRB has approved the Research, it is the duty of the principal Investigator of such Research to train and supervise the ethical conduct of all persons performing such Research to ensure that all Human Subjects are protected throughout the Research. The principal Investigator must also ensure that any changes in the design of the Research, which were not submitted in the original approval, are presented to the IRB. The principal Investigator must also collect any and all required forms, including but not limited to HIPPA authorization and informed consents, required to complete the Research.