

# **Bethune-Cookman University (B-CU) IRB Application Handout**

Bethune-Cookman University (B-CU) encourages research as a vital part of the academic enterprise and is committed to the ethical practice of research. It is the duty of the Institutional Review Board (IRB) to review and approve research in accordance with the Federal Policy for the Protection of Human Subjects (Common Rule) to assure compliance with the ethical principles as outlined by the Belmont Report. Any research involving human participants as subjects 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 must be reviewed by the IRB.

The IRB meets on the 3rd Friday of each month during the academic year. For full consideration complete applications should be received by the 2nd Friday of each month, during the academic year. Completed IRB applications should be submitted via email to [bcuirb@cookman.edu](mailto:bcuirb@cookman.edu). Please allow 4-6 weeks from the date of your submission for the process to complete.

## **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.

**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 contact 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.

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.

### **Actions of the IRB**

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 with 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.

### **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;

### **Instructions for Completing an Application to the Institutional Review Board of Bethune-Cookman University**

1. There is a link to the Redcap website where the application is. <http://j.mp/2xvAity>
2. Click on the link.
3. A new screen will appear, with a blank application, this is the application to determine eligibility. This application must be completed and approved by IRB
4. In the application there are a total of five sections.

#### **Section 1: Investigator Information**

Principal Investigator: the person who is responsible for conducting the research and ageing to all assurances and obligations outlined in Section 5 of the Application.

Name of Principal Investigator (PI): Please complete identifying information.

Faculty Advisor: A Student must have a Faculty Advisor for this research. This must be completed if a Student is the PI.

Please list each Co-Investigator and provide complete identifying information

#### **Section 2: Project Information**

Title: This must reflect the actual research.

Project Summary: Please do not exceed 50 words.

Number of subjects: Total number of subjects to be considered.

Project Start Date/Project End Date: Projects that exceed one year, require annual IRB Review.

NIH Certificate of Completion: A Copy of the Certificate for each Investigator must be submitted with the application.

### **Section 3: Compliance Information**

Which of the following will be used in your research? Please choose any that apply.

#### **Part 1 Human Subjects:**

Purpose of Research: Determine the reason for your research and check all that apply.

Included in Study: For definitions and additional information related to items in this list, please go to [www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html). Subparts A, B, C and D provide guidance.

#### **Part 2 Care and Use of Vertebrate Animals:**

Purpose of the use/care of animals: Determine the reason for your research and choose all that apply.

Included in Study: For definitions and additional information related to items listed below, please go to [www.grants.nih.gov/grants/olaw/olaw.htm](http://www.grants.nih.gov/grants/olaw/olaw.htm).

### **Section 4: Project Description**

#### **Personnel:**

a. List any persons who will be assisting in this research beyond the PI and Faculty Advisor; provide their level of involvement in the research for example will they be interviewing, tabulating data, etc. and their level of access to information.

**Purpose:**

- a. Describe in one or two sentences, the purpose, specific aims, or objectives of your research.
- b. What research questions are you trying to answer in this study or what hypotheses will be tested?
- c. Clearly indicate how participants and others will benefit from knowledge gained through this research.
- d. Briefly discuss how your current research has helped you frame your research focus and methodology.

Provide a list of references to support the information provided. Describe any relevant preliminary data.

**Description of Participants:**

- a. How many participants are in your research? Include the age range, gender and any special population characteristics. If you need to estimate, please give the higher number anticipated to avoid exceeding the total subjects approved.
- b. How will your participants be recruited? Describe how, when, and where your participants will be recruited. Please attach copies of any advertisement to be used. When or if advertisements are taped for broadcast, provide the final audio/video tape to the IRB. You may submit the wording of the advertisement prior to taping to preclude re-taping provided the IRB approves the final audio/video tape.
- c. How will the data be collected? For example through personal interviews, observations, surveys, etc.  
Also, what is the frequency of the collection?
- d. How will you protect the identity of your participants? Describe how you will screen for eligibility and protect the privacy interest of your participants.
- e. Will identifying information be collected such as Social Security numbers, addresses, names, or other identifying information? Yes or No

If YES, how will you protect the confidentiality of the participants and their information? Describe the steps that will be taken to abide by promises made to the participant to limit dissemination of identifiable data. Describe where data will be stored, who will have access to the data, measures taken to secure the data, and how long data will be stored.

If applicable, provide the following additional elements:

How is data being linked to subjects' identifying information?  
How are unique identifiers being generated?  
How and when will the link be used?  
Who have access to the linked data?  
How long will the linked data be stored?  
Will the link ever be destroyed so that the data or the samples will become de-identified?

f. Will you use any inducements to participants such as gifts, money, etc.? Yes or No

If YES, please provide specific details as to what the inducement is, who will receive the inducement, and, are there any stipulations for receiving the inducement such as completion of a survey, interview, test, etc.?

g. Give justification for the limits that you've set on your participant population and indicate how these limits might generally affect the results of your research.

### **Methodology (Procedures):**

A. Give the specifics of what you will be doing in this research, including:

- Specific methodology that you will use to gather your data;
- Kinds of questions you will ask; and,
- Any particular behaviors that you will be observing and recording.

There may be multiple methodologies utilized during your research depending on the components to your project. Please provide answers to each area listed (a-c) for each component.

B. Please attach a copy of any survey and/or interview instruments that you will use.

C. Please attach a copy of each advertisement you will use regarding the research.

### **Research Involving Minors:**

- What information will you give to parents/guardians and how will it be provided?
- If this research will take place in a school, describe how you will attain the permission of school officials/teachers and parents. Attach your school official and parental consent letters and child assent letter (or processes for children too young to read). Indicate whether your research will take place during the regular school day.  
If student/school records are to be used, include a list of specific data to be obtained from the school and not whether it is identifiable at the student level, in accordance with Family Education Right and Privacy Act (FERPA)/Protection of Pupil Rights Amendment (PPRA). For more information about FERPA visit <http://www2.ed.gov/policy/gen/guid/fpcos/ferpa/index.html>.

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**Deception:**

- a. What is the deception and how will the participants be debriefed?
- b. What is your rationale for using deception?

**Medical Procedures:**

a. What medical procedures will be used and what safeguards will be provided? Please describe why it is necessary to use certain medical procedures in this research. If medical records are being used, include a list of specific data to be obtained. Health Insurance Portability and Accountability Act (HIPAA) regulations will apply if the data provider is a HIPAA covered entity which B-CU is. HIPAA documentation may be required. For more information please visit <http://privacyruleandresearch.nih.gov/>.

Risk: List the risks, discomforts, hazards or inconveniences to the participants as well as describing risks to others who are not participants.

- a. Is there greater than minimal risk of physical, mental, or any other discomfort to your participants?
- b. What are the specific risks and what steps will you take to minimize those risks?
- c. Justify the risks by describing specific benefits that may result from this research, at both the participant and societal levels. DO NOT SIMPLY STATE THAT NO RISKS EXIST. (The researcher is responsible for carefully considering how participants might react, even to surveys, and the researcher must adequately address both real and anticipated risks and potential reactions.)

5. Once the files are attached and all of the sections are filled out, you can click on the submit button.
6. A new screen will appear, stating that the application was completed.
7. There is a place in the middle of the screen to fill in your email for an email notification of completion to be sent. Towards the bottom of the screen is a return code. This code can be used to return to the application if revisions need to be made. This code and the application website should never be shared.

**If for any reason, you have to save the application and return later\*\***

1. At the bottom of the application there is a save and return button. Click on the Save and return button, a return code will appear.
2. This return code should be written down because it will be used to get back into the application to continue it.
3. When it is time to return, simply click on the original link sent by IRB. A blank application will appear.
4. On the top right corner, it says, "returned", click on that and enter the return code that was provided earlier.
5. Once, the code is submitted the filled out application that was started will appear.
6. Continue the application as before and submit when finished.