BEAUFORT COUNTY COMMUNITY
INSTITUTIONAL REVIEW BOARD (IRB)

The Beaufort County Community College (BCCC) Institutional Review Board met in the Conference Room of Building 9 on Thursday, August 19, 2010. Those attending were Crystal Ange – Dean of Student Services, Tim Mattimoe – Lead Instructor for Social/Behavioral Sciences, Bill Smith - Lead Instructor for Science, Dorie Richter – Director of Planning and Institutional Effectiveness, and Richard Zablocki – BCCC's service-area community representative.

Temporary Board Chair, Dorie Richter, called the meeting to order at 12 noon and welcomed everyone. Ms. Richter asked the IRB members to review the agenda for the meeting and to make any additions or modifications they wished. Tim Mattimoe made a motion to accept the agenda as presented; Richard Zablocki seconded the motion. The motion carried.

The agenda items were as follows:

I. Elect an IRB Chair for FY2010-2011.
A motion was made by Tim Mattimoe and seconded by Richard Zablocki to approve Dorie Richter as chair for FY2010-2011. With no further discussion, the motion carried.

II. Approval of the following forms

A. Modified IRB Purpose (Attachment 1)
A motion was made by Bill Smith and seconded by Richard Zablocki to modify the IRB Purpose wording so as to include other types of activities - such as research conducted in established educational settings, research involving the use of educational tests, and research with demonstration projects.

The purpose would read
"To review all federal grant proposals submitted by, or in collaboration with, the College to determine compliance with the federal guidelines specified in 45 CFR Part 46 protecting the welfare of human subjects used in research. To review any non-federal grant proposals **and/or activities** that may involve such research."

Following a brief discussion, the motion carried.

B. Modified IRB Exempt Protocol Summary Form
Dorie Richter reviewed suggested changes to the IRB Exempt Protocol Summary Form. (Attachment 2) Originally, she explained, the forms were developed by Sinclair Community College located in Dayton, Ohio. Sinclair Community College has given their official approval for other colleges to use and adapt Sinclair's IRB forms. Ms. Richter subsequently modified the Exempt Protocol Summary Form by changing the content text 'Sinclair' to 'BCCC.'

Tim Mattimoe made a motion to approve the IRB Exempt Protocol Summary Form as modified; Crystal Ange seconded the motion. With no further discussion, the motion carried.

C. Modified Informed Consent Form
Dorie Richter reviewed similar changes to the IRB Informed Consent Form, i.e. changing the text 'Sinclair' to 'BCCC.' (Attachment 2) Since the IRB Chair is elected from within each year, Ms. Richter also suggested assigning one area, or an individual not serving on the Board, as the primary point of contact for any inquiries to the Board.

The IRB members discussed this at length. Crystal Ange recommended that the President's Office serve as the primary point of contact with the Dean of Student Service's Office as a back-up. Tim Mattimoe seconded the motion. With no further discussion, the motion carried.

III. Determine if the study conducted by Crystal Ange, BCCC Dean of Student Services, is 'exempt' as set forth in 45 CRF Part 46.

Crystal Ange, BCCC Dean of Student Services, described the study she is proposing to undertake for her doctoral dissertation, the procedures planned for the data collection on the BCCC campus, the assurances of data confidentiality, the disposition of the data, and the access/publication of the study. Ms. Ange is requesting 'exempt' status as set forth in 45 CRF Part 46.101 (b)(4) to conduct the study.

Using the IRB Human Subjects Decision Charts 1, 2, and 5, (Attachment 3) the Board members determined that the study activities are exempt. Bill Smith then made a motion to approve Ms. Ange's request with a 'determination that the study is an exempt activity in compliance with 45 CFR Part 46.101 (b)(4)' allowing Ms. Ange to move forward with the study. Tim Mattimoe seconded the motion. The motion carried with four of the five IRB members approving the request; Ms. Ange abstained from the vote.

IV. Elect an IRB Chair for 2011-2012.

A motion was made by Bill Smith and seconded by Tim Mattimoe to nominate and approve Crystal Ange as chair for FY2011-2012. With no further discussion, the motion carried.

V. Other……..

Dorie Richter reviewed the Institutional Effectiveness assessment activities – procedures and processes - with the IRB members. She asked the IRB members if these activities should be considered for an 'exempt' status as set forth in 45 CRF Part 46.101 (b)(1). The Board reviewed the IRB Human Subjects Decision Charts 1, 2, and 3 (Attachment 4) and determined that the assessment activities were exempt.

Ms. Richter turned the meeting over to Richard Zablocki to temporarily chair the meeting. Mr. Zablocki called for a vote. Bill Smith made a motion to approve the 'exempt' status as set forth in 45 CRF Part 46.101 (b)(1) for the Institutional Effectiveness assessment activities. Crystal Ange seconded the motion. The motion carried with four of the five IRB members approving the request; Ms. Richter abstained from the vote. Mr. Zablocki turned the meeting back to Ms. Richter to conclude the meeting as chair.

Before adjourning, Ms. Richter briefly reviewed the "List of Basic Tasks to Establish an IRB" - Section 2 in the IRB member notebooks. She expressed some interest in items #11 and #15. (Attachment 5) Ms. Richter offered, with the consent of the IRB members, to discuss both items with Dr. McLawhorn. Any information or action needed would be reported back to the IRB members. Approval was granted by consensus of the IRB members.

Finally, Richard Zablocki noted that several sections in the IRB member notebooks had not been updated for BCCC. Ms. Richter offered to make the changes to the appropriate sections and forward copies to the IRB members.

All IRB members were thanked for their time, effort, and input. Bill Smith made a motion to adjourn the meeting, Richard Zablocki seconded the motion. With no further business or discussion, the motion carried. The meeting was adjourned at 12:45 p.m.

ATTACHMENT 1

Institutional Review Board

Purpose:

To review all federal grant proposals submitted by, or in collaboration with, the College to determine compliance with the federal guidelines specified in 45 CFR Part 46 protecting the welfare of human subjects used in research. To review any non-federal grant proposals **and/or activities** that may involve such research

	Composition:	**Appointed by:**
(1)	Lead Instructor for Science	Position
(2)	Lead Instructor for Social/Behavioral Sciences	Position
(3)	Director of Planning and Institutional Effectiveness	Position
(4)	Dean of Student Services	Position
(5)	Non-affiliate of BCCC	President

Chaired by: Elected From Within:

Reports to: Administrative Council

ATTACHMENT 2

~~Sinclair Community College~~ Beaufort County Community College
Institutional Review Board

EXEMPT PROTOCOL SUMMARY FORM

ACTIVITIES EXEMPT FROM COMMITTEE REVIEW

Research activities involving human subjects in the following categories may be exempt from review by ~~Sinclair's~~ **Beaufort County Community College's** Institutional Review Board. The principal investigator/project director**/BCCC IRB Chair [45CFR Part 690.110 (b)(2)]** is authorized to make the first determination of eligibility for exemption; however, the College bears the responsibility for concurring in that determination based on notice provided by the principal investigator to the Institutional Review Board.

*The following exemptions do **NOT** apply when (a) **deception** of subjects may be an element of the research; (b) subjects are **under the age of eighteen**; (c) the activity may **expose the subject to discomfort or harassment** beyond levels encountered in daily life; or (d) **fetuses, pregnant women, human in vitro fertilization, children, or individuals involuntarily confined or detained in penal institutions** are subjects of the activity.*

EXCEPT FOR THE ABOVE EXCLUSIONS, the federally-approved Categories of Exemption are:

1. Research conducted in established or commonly accepted educational settings involving normal educational practices, such as: (a) research on regular and special education instructional strategies; (b) 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: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and** (b) any disclosure of the human subjects' responses outside the research 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, or achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Category 2 if: (a) the human subjects are elected or appointed public officials, or candidates for public office, **or** (b) 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. 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: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) 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: (a) if wholesome foods without additives are consumed, or (b) if a food is consumed that contains a food ingredient or 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 U.S. Food and Drug Administration or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exempting an activity from review does not absolve the investigator(s) of the activity from ensuring that the welfare of subjects in the activity is protected and that methods used and information provided to gain subject consent are appropriate to the activity.

Questions about whether a research activity may be exempt from human subjects review can be directed to the ~~Director, Research Analytics & Reporting or to the Director, Grants Development Office~~. **Chair of the BCCC Institutional Review Board.**

Beaufort County Community College
~~**Sinclair Community College**~~

___/___/___		_____
Date Submitted	**Institutional Review Board**	**File Number**

Exempt Protocol Summary Form

Title of Research Project

Principal Investigator/Project Director	**Department**	**Phone Extension**	**Email address**
Co-investigator/Student Investigator	**Department**	**Phone Extension**	**Email address**
Co-investigator/Student Investigator	**Department**	**Phone Extension**	**Email address**

Anticipated Funding Source: _____

Projected Duration of Research: _____ **months** **Projected Starting Date:** _____

Other organizations and/or agencies, if any, involved in the study: _____

Exempt under code (see definitions on page one – check one) 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐

SUMMARY ABSTRACT: Please supply the following information below: BRIEF description of the participants, the location(s) of the project, the procedures to be used for data collection, whether data will be confidential or anonymous, disposition of the data, who will have access to the data. Attach copy of the Informed Consent Form and/or the measures (questionnaires) to be used in the project.

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:

- Any additions or changes in procedures in the protocol will be submitted to the IRB for written approval prior to these changes being implemented
- Any problems connected with the use of human subjects once the project has begun must be communicated to the IRB Chair
- The principal investigator is responsible for retaining informed consent documents for a period of three years after the project.

_____ ___/___/___ _____ ___/___/___

Principal Investigator Signature Co-Investigator/Student Signature (if appropriate)

Signature of IRB Committee Chair:			**Date:**___/___/___
IRB Chair: Check 1 box:	☐ **Approved by IRB Chair**	☐ ~~**Approved with Conditions**~~	☐ **Refer to Full Committee Review**
Comments:			

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Institutional Review Board

ELEMENTS OF INFORMED CONSENT

Researchers must obtain the signed ***informed consent*** of participants. For those less than 18 years of age, the researcher must obtain the signed informed consent of parents or legal guardian and all reasonable attempts must be made to obtain each participant's ***assent***, which is defined as the participant's agreement to participate in the study.

The informed consent must include the following in sequential order and in language which the participants can understand:

1. Statement of purpose of the study.

2. Short description of methodology and duration of participant involvement.

3. Statement of risks/benefits to the participants.

4. Statement of data confidentiality.

5. Statement regarding the right of the participant to withdraw from the study at any time without negative consequences.

6. An offer to answer any questions the participant may have.

7. Contact information of all Principal Investigators, and also contact information for ~~Sinclair's Institutional Review Board (Director of Research Analytics & Reporting, 937-512-2854).~~ **the BCCC IRB can be obtained by calling the Office of the BCCC President at 252-940-6202 or the Office of the Dean of Student Services at 252 940-6217.**

8. Line for signature of participants and/or parents or legal guardian except for questionnaire research in which return of questionnaire gives implied consent.

9. Statement that participant is 18 years of age or older unless parent or legal guardian has given consent.

In situations where participants will be **deceived**, items 1 and 2 are omitted and participants are told (on the signed form) that disclosure of the purpose and/or methodology could bias the outcome of the study. In this case, **after the study is complete,** each participant must be presented with a description of the purpose and methodology as carried out and this document must be signed by the participants "after the fact" in order to guarantee informed consent.

Beaufort County Community College
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***SAMPLE* INFORMED CONSENT**

The following suggestions are offered as guidelines. The exact language is the decision of the researcher. Keep in mind, however, that the Institutional Review Board must determine if the participants will be giving ***informed consent.*** (Note: that in the case of children, it is ***assent***).

Dear (student, parent, sir, madam, etc.):

We are conducting a study to determine _____. In this study, you (your child/ward) will be asked to _____. Your participation should take about _____ minutes.

There are no risks to you (your child/ward).

or

The only risks to you (your child/ward) include _____.

All information will be handled in a strictly confidential manner, so that no one will be able to identify you (your child/ward) when the results are recorded/reported.

Your (your child's/ward's) participation in this study is totally voluntary and you may withdraw at any time without negative consequences. If you wish to withdraw at any time during the study, simply _____.

Please feel free to contact _____ (names(s), title(s) of principal researchers) at _____ phone) if you have any questions about the study. Or, for other questions, **you may** contact ~~Sinclair's Institutional Review Board (Director of Research Analytics & Reporting, 937-512-2854).~~ **the Office of the BCCC President at 252-940-6202 or the Office of the Dean of Student Services at 252 940-6217.**

If the participant is of age (18 years old or older), use:

I understand the study described above and have been given a copy of the description as outlined above. I am 18 years of age or older and I agree to participate.

_____
Signature of Participant Date

If the participant is not of age, use:

I understand the study described above and have been given a copy of the description as outlined above. I agree to allow my child/ward to participate with his/her assent when possible.

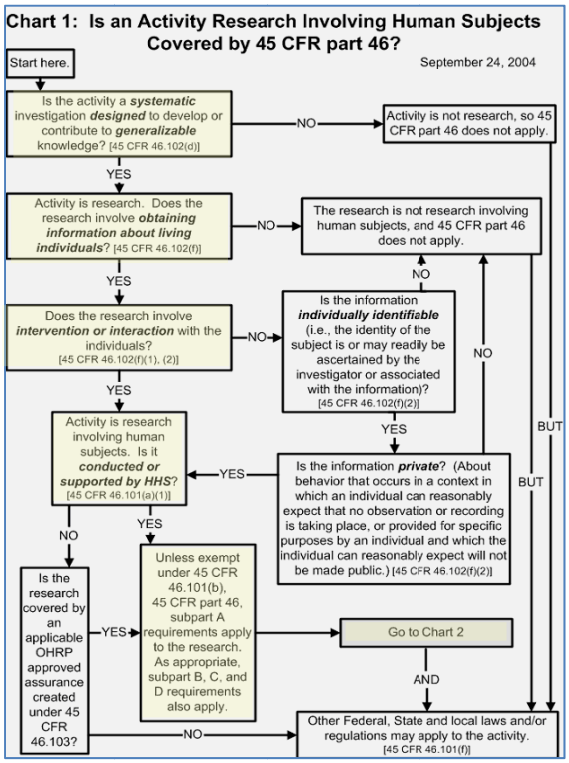
_____
Signature of Parent/Guardian Date

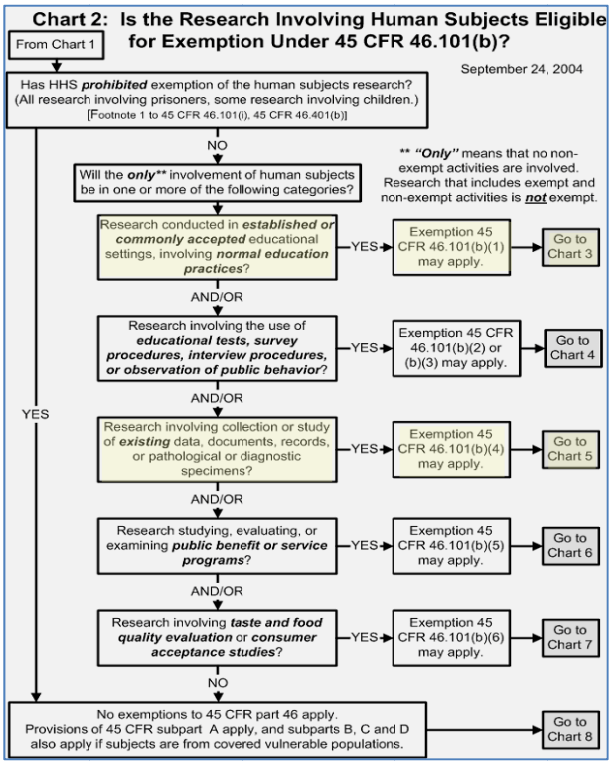
ASSENT format:

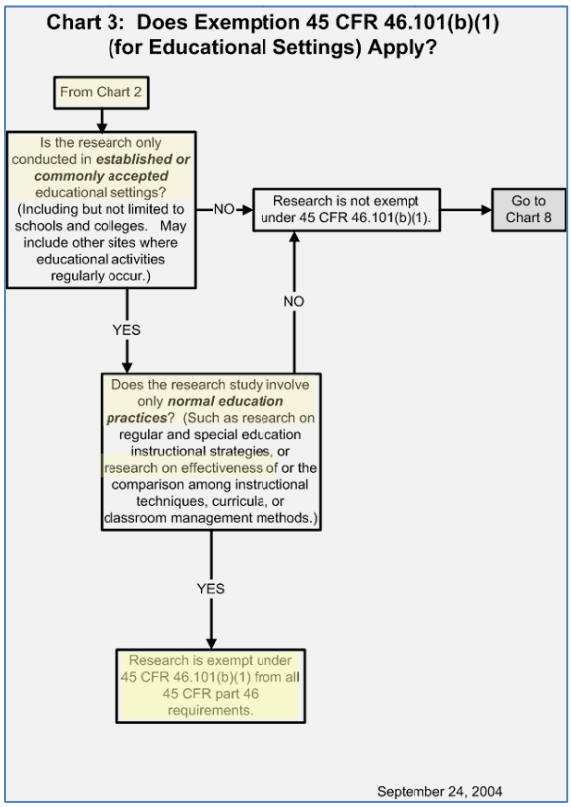
I understand what I must do in this study and I want to take part in the study.

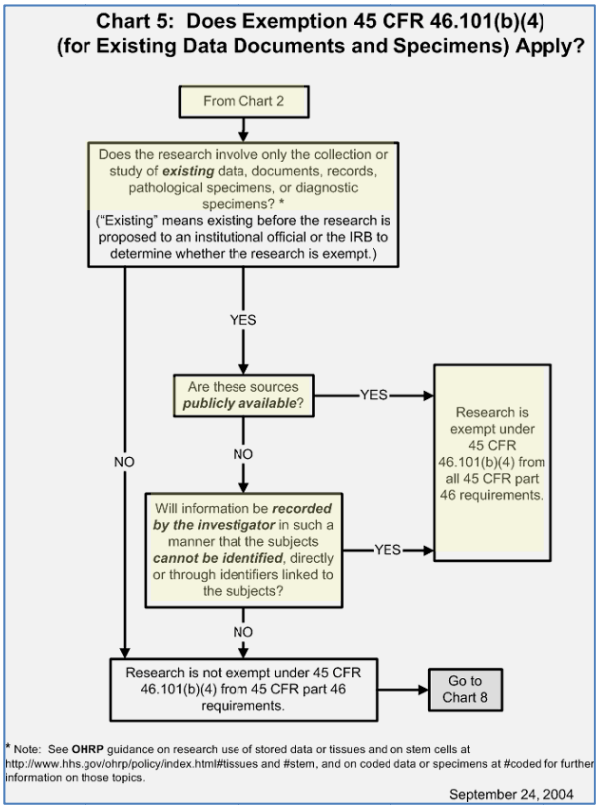
_____
Signature of Child/Ward Date

ATTACHMENT 3









ATTACHMENT 4

List of Basic Tasks to Establish IRB

1. Read Federal Regulations 45 CRF 46 http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
2. Study DHHS Office of Human Subjects Protections web site
   http://www.hhs.gov/ohrp/
3. Read IRB Guidebook
   http://www.hhs.gov/ohrp/irb/irb_guidebook.htm
4. Look at OHSP Decision Charts
   http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm
5. Read National Science Foundation requirement
   http://www.nsf.gov/bfa/dias/policy/docs/45cfr690.pdf
6. Sinclair Community College website
   http://www.sinclair.edu/departments/grants/pub/compliance/SinclairTraining.ppt
7. Research predominantly undergraduate institutions; especially benchmark with area universities
8. Create Charter/Operating Procedures
9. Create new or adapt review form(s)
10. Seek and receive permission from originators of documents before using them (EXCEPTION: you already have approval to use Sinclair Community College's documents)
11. Consult with college General Counsel and obtain approval of forms
12. Constitute IRB committee with correct representation
13. Register IRB with DHHS Office of Human Research Protection
    http://www.hhs.gov/ohrp/
14. Register Federal Wide Assurance form with DHHS Office of Human Research Protection
    http://www.hhs.gov/ohrp/
15. Determine if you need to modify existing Conflict of Interest policy, forms, and process
16. Review training materials
    DHHS Office of Human Research Protection
    http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp
    National Institutes of Health
    http://www.nihtraining.com/ohsrsite/IRBCBT/intro.html
    National Cancer Institute
    http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp
    Sinclair Community College website
    http://www.sinclair.edu/departments/grants/compliance/index.cfm
    University of North Carolina Charlotte
    http://www.research.uncc.edu/tutorial/index3.cfm
17. Create new or adapt existing training
18. Initiate IRB committee member training and obtain training verification
19. Set up record keeping system
20. Inform college employees of new IRB committee and their responsibilities