Columbus State Community College
Institutional Review Board

FULL HUMAN SUBJECTS PROTOCOL FORM

Log #

1 Title of Research Project:

	Name	CSCC Department or Other institution	Office Phone	E-mail
2 PI/PD*				
3 Doctoral Advisor				
4 Co-PI/PD/Student				
Co-PI/PD/Student				
5 Sub Investigator**				
Sub Investigator				
Sub Investigator				
Sub Investigator				
Sub Investigator				
Sub Investigator				

* PI/PD - Principal Investigator/Project Director
**Sub Investigator - any other personnel, not subjects, participating in the research project

6 **Evidence of training in human subjects protection:** Any PI/PD, Co-PI/PD/Student, or Sub Investigator must be trained. See the **CSCC IRB website** for instructions in online training from Collaborative Institutional Training Initiative (CITI). If you have documentation of IRB training from another resource, **please attach**.

7 **Project Funding Source** (Check all that apply)

- ☐ External Grant / Sponsor Name:
- ☐ CSCC Grant
- ☐ Non-funded Research
- ☐ Other:

8 **If grant funded, provide the following dates:**

Proposal Due: Proposal Submitted:

(IRB requires one copy of the grant proposal as soon as it is available.)

9 Projected Dates of Research

Data Collection Start Date: _____ Data Collection End Date: _____

10 Collaborators: (List any other organizations/agencies involved in the study.)

_____

11 Project Information

A. Project Activity Status:

- ☐ New Project
- ☐ Periodic Review of Continuing Project
- ☐ Revision to Previously Approved Project

B. This project involves Columbus State Community College **students**

☐ Yes ☐ No

This project involves Columbus State Community College **employees**

☐ Yes ☐ No

C. Human Subjects from the following populations will be involved in this study:

- ☐ Minors
- ☐ High School Students
- ☐ Mentally Disabled
- ☐ Prisoners
- ☐ Elderly
- ☐ None of the above

D. Total number of subjects to be studied: _____

12 Certification and Signatures:

I certify tht the protocol and method of obtaining informed consent as approved by the Columbus State Institutional Review Board will be followed during the period covered by this research project. Any future changes to the research project will be submitted to the IRB for review and approval prior to implementation.

	Signature	**Date**
PI/PD	_____	_____
Co-PI/PD/Student	_____	_____
Co-PI/PD/Student	_____	_____
Dean/Director	_____	_____

Note: *Your signature indicates you are aware this survey and/or research protocol will be submitted to the Columbus State IRB.*

PIs in Academic Affairs, Student Affairs, and Center for Workforce Development need their ***Dean's*** *signature*
All other PIs need the signature of their ***Director****.*

Certification and Signatures cont....

	Signature	Date
Sub Investigator		
Sub Investigator		
Sub Investigator		
Sub Investigator		
Sub Investigator		

Note: Approval of an IRB protocol implies that the PI/PD will carry out the research **as described** in the approved protocol. If changes are needed to any part of the research protocol, the researcher completes a **Modification Request** and submits it to the IRB.

FOR IRB USE ONLY

IRB DETERMINATION

☐ Approved ☐ Not Approved (see attached memo)

Signature: _____ **Date:** _____

PROTOCOL NARRATIVE

In a separate document, in addition to pages 1, 2, and 3 of the protocol, write a narrative that provides the information requested in items I through VIII.

See Full Protocol Guidelines http://cscc.edu/IRB/docs/FullGuidelines.pdf

Number the pages and put the project title and PI name on each page.

I. PURPOSE, RESEARCH VARIABLES, AND POPULATION

1. Purpose of study: State concisely and realistically what the study is intended to accomplish. Provide research questions, if applicable. State the benefit of this project to Columbus State Community College.

2. Background: Briefly state the background of the study, including some relevant references and identify the main questions the current study is intended to address.

3. Characteristics of the Subject Population: The following information should be provided:
    a. Age Range - What is the age range and why was it chosen?
    b. Sex - What is the sex of the subject? If there is a restriction, provide the rationale.
    c. Number - What is the estimated number of subjects?
    d. Inclusion Criteria - What are the specific inclusion criteria?
    e. Exclusion Criteria - What are the specific exclusion criteria? Clear rationale should be provided for the exclusion of any particular population group, unless the title of the study reflects the restricted population range.
    f. Vulnerable Subjects: If vulnerable subjects will be included (children, pregnant women, fetuses, prisoners, mentally disabled persons), provide justification of the need to use these subjects in research.

II. METHODS AND PROCEDURES

1. Method of Subject Selection: Describe the study's method(s) of identification and recruitment of prospective subjects. Provide a copy of any planned advertisements.

2. Study Site: State the location(s) where the study will be conducted. Include letters of approval to conduct the study from all non-CSCC sites.

3. Methods and Procedures Applied to Human Subjects: Describe in detail the study design and all procedures (sequentially) to be applied to subjects. Attach copies of any instruments to be used, such as surveys, ratings scales, or questionnaires. Explain the role of any sub-investigators named on the form and provide a resume or vita for each.

4. An informational letter or script is **required** to introduce a survey or other research instrument, provide instructions, and explain options to a research participant. For surveys conducted online, this information should be provided at the beginning of the survey. Attach this to the protocol form.

III. RISKS/BENEFITS

1. Potential Risks: identify the potential risks of the study. Specify the types and levels of risks.

2. Protection Against Risks: For all studies involving greater than minimal risk, specify the procedures for preventing or minimizing any potential risks.

3. Potential Benefits: Describe any potential non-monetary benefits of the study, both for subjects and for society in general.

4. Compensation for Participation: Describe any monetary or other forms of compensation which will be provided to subjects, and any conditions which must be fulfilled to receive compensation.

5. Alternative to Participation: Describe any alternatives to participation in the study which might be advantageous to the subject. If the subjects are to receive academic credit for research participation, describe the alternatives available to earn equivalent academic credit.

6. Information Withheld: Identify the nature of any information to be purposely withheld from subjects, and provide justification for the non-disclosure.

7. Debriefing: Describe the procedure for post-study debriefing of subjects.

IV. CONFIDENTIALITY

Describe explicitly how confidentiality of data will be maintained. If any information with subject identifiers will be released, specify the recipients. Include a statement that all data will be retained for at least three years in compliance with federal regulations. Refer to Securing Research Data on the IRB web site.

V. ATTACH A COPY OF CONSENT FORM

As a guide to developing the form, see *Essentials of Informed Consent and Sample Consent Form* (attached to this protocol format).

VI. RESEARCH PROPOSAL

IRB members may want to see this; provide a copy or attach it to an e-mail addressed to the IRB Administrator.

VII. MAILING ADDRESS

Send all documents to:

IRB Administrator
Columbus State Community College
550 E. Spring Street
Columbus, OH 43216
614/287-2440
614/287-5476 FAX
IRB Administrator

VIII. CHECKLIST: Have you...

- ☐ Completed items 1 through 12
- ☐ Signed the protocol and obtained the signatures of others named on the form
- ☐ Written a narrative for items I through VI using the *Full Protocol Guidelines*
- ☐ Numbered the pages and put the PI name and title on each page of the narrative
- ☐ Attached informational letter or script
- ☐ Attached a copy of the *Consent Form* for this project
- ☐ Provided or e-mailed a copy of your Research Proposal

ESSENTIALS OF INFORMED CONSENT

Title: Show the heading of "Informed Consent Form." You may want to add the full title of the project.

Involvement: Identify the investigator, faculty sponsor (if relevant), and any funding or sponsoring organizations. Identify CSCC as the responsible institution or as one of the responsible institutions.

Overview: Invite subjects to participate and tell them the purposes of the study. Give a brief description of the procedures to be used and the time required, providing enough detail to enable subjects to make an informed decision. It might be helpful to ask yourself what information you would need to have as a naive potential subject in order to feel that you could make such an informed decision.

Risks and Benefits: Describe any reasonable foreseeable risks or discomforts associated with the study. If there are no known risks, this should be stated. Also, give a description of the likely benefits to subjects or to others.

Compensation: Provide a statement of any compensation available to subjects, along with information on how it can be obtained.

Handling Discomfort or Injury: If appropriate, tell subjects what treatment will be available and how it can be obtained.

Confidentiality: Specify the procedure for maintaining the confidentiality of records that identify subjects.

For More Information: Tell subjects how to obtain more information about the project.

Voluntary Participation: Explicitly state that the subject may refuse to participate or may withdraw for any reason without penalty. Describe the procedures for electing to participate and for declining. Include a statement regarding the disposition of data collected from subjects who later elect to withdraw.

Signature: Provide a space for signatures indicating consent. Remember to obtain a second copy for the subject to keep.

Miscellaneous: Include the following statement:

> Do not sign this form if an IRB approval stamp does not appear at the top of the page.
> Do not sign this form if the dates under the stamp have expired.

This is a SAMPLE form. The information contained in the sample is used with permission. When you create a consent for for your project, delete this box.

This space is used for the IRB approval stamp.

Delete these words prior to submitting the form.

CONSENT FORM

Consent to Participate in an Experimental Study
Title: Color Memory, Word Skill, Math Skill

Investigator
Jane E. Student, M.A.
Department of Sociology and Anthropology
105 Leavell Hall
The University of Mississippi
(662) 915-5555

Sponsor (This is needed only with student research.)
David S. Faculty, Ph.D.
Department of Sociology and Anthropology
105 Leavell Hall
The University of Mississippi
(662) 915-5555

Description
We want to know whether a person's ability to remember colors is related more to the ability to use words or the ability to do math problems. In order to answer our question, we are asking you to take three short tests. One is a color memory test. We will show you several cards that are different colors. After you look at the cards, we will mix the cards up and you will have to put them back in the order that they were in when we showed them to you. The second is a vocabulary test. We will ask you to tell us the meaning of some words. The last is a math test. We will ask you to work some math problems in your head. It will take you about 15 minutes to finish all three tests. We will explain the experiment to you and you can ask any questions you have about the experiment.

Risks and Benefits
You may feel uncomfortable because you cannot do as well on a test as you would like. We do not think that there are any other risks. A lot of people enjoy taking these tests because they seem like games or puzzles. Also, we will talk with you about our experiment, and we think you may learn about how scientists do research projects.

Costs and Payments
The test will take about 15 minutes to finish, and we will talk to you for about five more minutes. There are no other costs for helping us with this study. You will receive 30 minutes of experimental course credit for being part of this project.

Confidentiality
We will not put your name on any of your tests. The only information that will be on your test materials will be your gender (whether you are male or female) and your age. Therefore, we do not believe that you can be identified from any of your tests.

Right to Withdraw
You do not have to take part in this study. If you start the study and decide tht you do not want to finish, all you have to do is to tell Jane Student or Dr. Faculty in person, by letter, or by telephone at the Department of Sociology and Anthropology, 105 Leavell Hall, The University of Mississippi, University MS 38677, or 915-5555. Whether or not you choose to participate or to withdraw will not affect your standing with the Department of Sociology and Anthropology, or with the University, and it will not cause you to lose any benefits to which you are entitled.

INCLUDE THE FOLLOWING PARAGRAPH ONLY IF YOU ARE COLLECTING DATA FROM A HIPAA COMPLIANT ENTITY (e.g., hospitals, physicians, mental health centers)

Protected Health Information
Protected health information is any personal health information which identifies you in some way. The data collected in this study includes: (describe here). A decision to participate in this research means that you agree to the use of your health information for the study described in this form. This information will not be released beyond the purposes of conducting this study. The information collected for this study will be kept (indefinitely) or (until the study is complete) or (insert an expiration date or describe an event upon which the authorization will expire). While this study is ongoing you may not have access to the research information, but you may request it after the research is completed.

IRB Approval
This study has been reviewed by The University of Mississippi's Institutional Review Board (IRB). The IRB has determined that this study fulfills the human research subject protections obligations required by state and federal law and University policies. If you have any questions, concerns or reports regarding your rights as a participant of research, please contact the IRB at (662) 915-7482.

Statement of Consent
I have read the above information. I have bee given a copy of this form. I have had an opportunity to ask questions, and I have received answers. I consent to participate in the study.

Do not sign this form if an IRB approval stamp does not appear at the top of the page.
Do not sign this form if the dates under the stamp have expired.

Signature of Participant Date

Signature of Parent/Guardian (if minor involved) Date

Signature of Investigator Date