

**Guidelines for  
Exempt Human Subjects Protocol  
Including Samples**

1. Before completing the Exempt Human Subjects Protocol Form, review the exempt categories below. On pages 2 and 3 of the form, you must choose a category that qualifies your research as exempt from human subjects review by the full IRB.

**Research Involving Minors:** Exemption categories 1, 4, 5 and 6 may be applied to research involving minors if the conditions of the exemption are met. Category 2(a) and (b) only may apply to minors involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Category 2(c) may not be applied to research involving minors. In addition, the IRB shall determine that adequate provisions are made for soliciting the assent of the minors, when in the judgment of the IRB, the minors are capable of providing assent and that adequate provisions are made for soliciting the permission of each minor's parents or guardian.

**Research Involving Pregnant Women, Fetuses, or Neonates:** Each of these exemptions may be applied to research involving pregnant women, fetuses, or neonates if the conditions of the exemption are met.

**Research Involving Prisoners:** Each of these exemption categories do not apply to research involving prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

**Exempt Categories:**

1. Research, conducted in established or commonly accepted educational settings that involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; (c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and the IRB conducts a limited IRB review.

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; (c) The information obtained is recorded by the investigator in such a

manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and the IRB conducts a limited IRB review.

[**Note:** (1) To be eligible for this exemption, the research cannot involve deception; (2) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.]

4. Research involving the collection or study of existing data sets, documents, records, or specimens, but only if these sources are publicly available **or** if the information is recorded by the investigator in such a manner that subjects cannot be identified, either directly or through identifiers linked to subjects. Alternatively, the research is exempt when information collection and analysis involves the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E; **or**, (d) research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501.

5. Research and demonstration projects conducted by a federal department or agency designed to study or evaluate public programs, procedures for obtaining benefits or services under those programs, possible changes or alternatives to those programs, or possible changes in methods or levels of payment for benefits under those programs.

6. Taste and food quality and evaluation and consumer acceptance studies, as long as safe, normal foods are being consumed, and federal guidelines regarding acceptable levels of agricultural chemical or environmental contaminants are adhered to.

2. Enter today's date

3. Log # (leave this blank)

4. Enter the title of your research project

5. Provide the projected dates of your research. Determine these dates carefully. You cannot start your project prior to the stated date. If you need to extend it beyond the stated end date, you will need to submit a Modification Request (see IRB website for the form).

6. Provide the name, department, and email address for the Principal Investigator/Project Director. This person will manage the project and serve as the primary point of contact for the IRB. If this is student research, the Principal Investigator/Project Director is the faculty member supervising the research.

7. If you are doing doctoral dissertation research, please provide the name of your advisor, their Institution's name, and email address. Any research request from an external institution must first be approved by that institution's IRB. If necessary, an IRB Authorization Agreement can be arranged to establish one IRB as the primary IRB for review and approval.

8. Provide the name, department/external institution, and email address for any Co-Principal Investigator/Project Directors. These are team members who have a significant role in the project (e.g.: participating in the design, conduct, and reporting of the research). If this is a student research project, the student is a co-PI.

9. Provide the name, department/external institution, and email address for any Sub Investigators. These are team members who are assisting in the research project (e.g.: recruiting participants or collecting study data).

10. Provide the name, organization, and email address for any External Evaluators for externally grant funded research projects.

11. List any collaborators that are part of this project: schools, community organizations, churches, etc. This includes places where you will solicit research subjects.

12. Your research may or may not be funded. If it is, please check the appropriate box. If your research is not funded, check non-funded research. If you check "Other", please provide an explanation. If your research is funded, the IRB wants to confirm that the protocol is consistent with the grant proposal. Provide the date the proposal was submitted and include a copy with the protocol form. If the proposal is not yet due, provide the date it is due and submit it as soon as it is complete.

10. Select the exempt category that you think applies to your research. Check the box that corresponds to that criterion. The IRB may determine that your research meets a different criterion or that it is NOT exempt from review.

11. Required signatures - Sign and date the protocol form and obtain signatures for all members of the research team. In addition, obtain the signature of the dean or director of your department. Digital or wet ink signatures are required for submission.

12. Do not write below the area labeled FOR IRB USE ONLY.

13. Additional documents to be included with the completed form:

- Research project abstract, to include:
  - summary of objectives and significance of the research
  - participants and recruitment procedures
  - study site/location(s)
  - data collection and storage procedures
  - confidentiality and privacy
  - disposition of the data
  - research subject compensation or reward
  - potential risks and benefits to research subjects
- Informational letter or script and consent documents appropriate to the activity, to include:
  - what the research involves
  - introduction of the survey or other research instrument
  - what the subject will be expected to do
  - how the project will affect the subject
  - compensation or reward
  - contact information of the principal investigator
- All surveys, interview or focus group questions, and other testing instruments
- Recruitment materials (if applicable)
- For those completing doctoral dissertation research, the IRB approval letter from the external institution; see #7 above
- Letters of support from outside institutions or entities that are allowing recruitment, research, or record access at their sites (if applicable); see #11 above
- Grant proposal (if applicable); see #12 above

Writing tips for the abstract:

You are writing a scholarly document that supports a research project. The document is reviewed by the IRB chair or designee that is knowledgeable about research and the protection of human subjects.

- Write the protocol as you would any academic or professional paper.
- Proofread for grammar and typos.
- Give sufficient detail so that the IRB chair can determine if it is exempt.

- If you are supervising a student's research, read the protocol before it is submitted to the IRB.

14. Submit the protocol electronically to [irb@csc.edu](mailto:irb@csc.edu). It may be submitted as one large PDF document package or as individual attachments.

15. Upon receiving the protocol, the IRB Administrator gives the protocol a preliminary review. If the protocol does not follow the guidelines, is unsigned, or contains a number of typos and grammatical errors, it will be returned for revision. The IRB Chair will review the protocol and determine one of the following: Approved, Modification Required, Referred for Expedited Review, Referred for Full IRB Review. You will receive an IRB Action Response Letter. If the determination is anything other than approved, the letter will contain additional details.

16. If you have any questions, please contact the IRB administrator at [irb@csc.edu](mailto:irb@csc.edu).

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## Sample abstracts and informational letters/scripts

#343 Lewis-Hotopp – Exempt Abstract

### **AEP Credits Count (AEP) Program Evaluation Abstract**

Funding for AEP Credits Count (abbreviated AEP in this document) was awarded to Columbus State Community College (CSCC) to facilitate development of a, "comprehensive national model program integrating high school, college, and career readiness in STEM career pathways". CSCC's specific funding was allotted to strengthen college readiness, dual enrollment, middle school STEM experiences, professional development for high school faculty, and workforce preparation.

As part of the annual evaluation of AEP, Community Research Partners (CRP) is acting as a third party evaluator to assess the progress made thus far utilizing AEP funds and the opportunities for improvement. CRP is submitting this IRB exemption request in order to conduct interviews of AEP partners and instructors.

### **Procedure**

**Participants:** CRP intends to speak with up to 10 teachers or staff members who facilitate AEP programming. This will provide CRP with information to evaluate AEP's potential for growth and improvement and assess the grant's progress towards the program goals. All interview participants will be 18 years old or older.

**Recruitment:** Participants will be selected from a list of AEP teachers and staff members that will be compiled by CSCC staff. They will be contacted via email by CRP and informed of the voluntary nature of their participation as well as the evaluation's goals. All participants will offer their verbal consent to participate in the interview either over the phone or in person.

**Location:** All interviews will be conducted over the phone if possible. If that is not possible they may be conducted in person at a location convenient to the interviewee or via email.

**Data collection procedures:** Information will be collected using the attached interview protocol. The interviewer will take notes during the phone call but will not record the conversation. The interviewee will not be identified by name or other identifying characteristic in the final report.

**Confidentiality:** All notes will remain confidential to CRP staff integral to this evaluation project. None of the subjects will be identified in the final report.

**Disposition of data:** Notes will be stored on CRP's secured network. They will not be shared with any other entities or CSCC staff. Data will be purged from the CRP network after three years.

**Access to data:** Only CRP staff will have access to the raw data from the interviews (notes). The anonymized final report will be made available to CSCC as part of the evaluation.  
#343 Lewis-Hotopp – Information Letter/Script

### **AEP Credits Count Survey script**

“Hello, my name is <INSERT NAME> and I’m a researcher with Community Research Partners, a local non-profit research and evaluation center. As you know, we’re working with Columbus State Community College to evaluate the AEP Credits Count program. As a (staff member/instructor/partner) working with AEP, you have unique knowledge about this program that we’re hoping to incorporate into our evaluation report. I’ll be taking notes during this conversation for record-keeping purposes but you will not be personally identified in the evaluation report; all of your responses will remain confidential. Please note that your participation in this conversation is voluntary and you may end the interview at any time. Answering these questions will serve as your consent to participate in this research project. Do you have any questions before I begin?”

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#298 Bertsch – Exempt Abstract

## **An Interview-Based Study of Students’ Experiences in Facilitated Online Dual Credit English Courses**

Principal Investigator/Project Director:  
Deborah Bertsch  
Prof. English, CSCC

Co-Principal Investigator:  
Kimberly Garee  
English Teacher,  
Northridge HS

Co-Principal Investigator:  
Carol Lukich  
English Teacher,  
Canal Winchester HS

### **I. PURPOSE, RESEARCH VARIABLES, AND POPULATION**

#### **Purpose**

We propose to investigate Dual Credit students’ experiences in “facilitated” online writing courses (i.e., online composition courses developed and overseen by a college Instructor of Record and facilitated in high-school classrooms by high-school instructors) in order to understand the factors that contribute to and/or impede such students’ success as college-level writers and learners.

The project could benefit Columbus State by providing a theory base for future Dual Credit composition course development and delivery.

#### **Background**

In Autumn 2015, the Columbus State English Department began offering “facilitated” Dual Credit Composition courses. In such courses, a CSCC English faculty member serves as the Instructor of Record, and a high-school teacher serves as the facilitator of the online course content. The college offered ten sections of facilitated online ENGL 1100 Dual Credit courses in Autumn 2015, and the three of us served as the Instructor of Record or High School Facilitator for three of those sections.

Given the newness of the facilitated model, as well as the recent surge in overall Dual Credit offerings at the college, we’re interested in studying students’ perceptions of their learning experiences in their facilitated Dual Credit ENGL 1100 course. We’re also interested in studying students’ perceptions of how well the course prepared them for subsequent college-level writing tasks. (list of questions)

We propose to investigate these questions via two sets of interviews with former Dual Credit students: one set of interviews in Spring 2016 (while the students are still in high school), and another set of interviews in Autumn 2016 (when some of the students will have matriculated to college, and some will have enrolled in subsequent Dual Credit courses).

#### **Characteristics of the Subject Population**

Our subject population will consist of students who completed facilitated English 1100 Dual Credit courses at Canal Winchester High School or Northridge High School during Autumn semester 2015.

## **II. METHODS AND PROCEDURES**

### **Method of Subject Selection**

As soon as the project receives IRB approval, we will email recruitment letters to all prospective subjects to invite them to participate in the study.

### **Study Site**

There will be two data-collection sites: Carol Lukich's classroom at Canal Winchester High School, and Kim Garee's classroom at Northridge High School. Both schools currently serve as sites where CSCC ENGL 1100 facilitated courses are offered.

### **Methods and Procedures Applied to Human Subjects**

We will employ interview-based methods of data collection. Specifically, we will ask subjects to participate in two sixty-minute interviews as described below.

1. Individual Interviews – Spring 2016. The PI's will conduct individual in-person interviews with each participant. We'll tape and transcribe these interviews.

2. Follow-up Individual Interviews – Autumn 2016. Towards the end of Autumn 2016, the PI's will conduct individual phone or in-person interviews with participants to learn about their academic writing experiences during Autumn 2016. We'll tape and transcribe these interviews.

Our main purpose in conducting the follow-up interviews will be a.) to gather information about participants' writing experiences in college (if participants are enrolled in college in Autumn 2016) or in other Dual Credit courses (if participants are still in high school in Autumn 2016); and b.) to follow up on any patterns that emerge from our analysis of the spring interview transcripts.

## **III. RISKS/ BENEFITS**

### **Potential Risks/ Protection against Risks**

The risks associated with this study will most likely be minimal. Participants may feel discomfort in sharing information about their course experiences, especially if those experiences include perceived negative elements. To protect against such risks, participants will be told that they do not have to answer any questions that make them feel uncomfortable and that their names will be changed in any publication of the data.

### **Potential Benefits**

The potential benefits for participants will be the self-understanding inherent in sharing and reflecting on personal experiences. Additionally, subjects may learn about qualitative research methods as they participate in the interviews. For the larger academic community, the study may contribute to greater knowledge about how students learn in Dual Credit writing classes.

### **Compensation for Participation**

There will be no compensation for the subjects.

### **Alternatives to Participation**

There are no alternatives that will be advantageous to the subjects.

### **Information Withheld**

There will be no information purposely withheld from the subjects.

### **Debriefing**

We will invite participants to discuss the overall findings of the study with the PI's, if the participants are interested. During those discussions, we will share our conclusions and invite the participants to clarify/correct/add to those conclusions.

## **IV. CONFIDENTIALITY**

Each participant will be assigned a pseudonym, and Deborah Bertsch will maintain a paper copy of the pseudonym key in her office (4100 Nestor Hall, CSCC). Examples of pseudonyms: "Student 1," "Student 2." Any publication or conference presentation resulting from this research will include pseudonyms only. All

documents used for this research (consent forms, transcripts, etc.) will be stored in a locked drawer in the office of Deborah Bertsch and/or in the classroom of Kim Garee or Carol Lukich. All data will be retained for at least three years in compliance with federal regulations. After that time, all data will be destroyed through shredding.

#298 Bertsch – Information Letter/Script

Dear (Former ENGL 1100 student),

We're writing to invite you to participate in a research study to help us learn more about Dual Credit students' experiences in ENGL 1100. Because you took ENGL 1100 as a Dual Credit student last autumn, you're eligible to participate in our study. Below are some details about what your participation would involve:

### **What you'll do**

Participation in the study will take about two hours of your time between April and December 2016. We'll ask you to do two things:

1. Participate in an individual interview with us in April 2016 in Ms. Garee's or Ms. Lukich's classroom. During that time, we'll ask you questions about your experiences in ENGL 1100. For instance, we'll ask you what your expectations were for the course, and how the course did or did not meet those expectations. We'll tape-record the conversation.
2. Participate in a phone or in-person interview with us in December 2016. During that interview, we'll ask you about your writing experiences in college (if you're in college in the fall), or about your writing experiences in other Dual Credit courses (if you're still in high school). Once again, we'll tape-record the conversation.

### **How the project will affect you**

Many students enjoy talking about their own experiences with writing and learning to write. Thus, in discussing and reflecting on your writing history and your perceptions of ENGL 1100, you may benefit by learning more about yourself and about your writing processes, strengths, and weaknesses. Additionally, we will talk with you about our research project, and you may learn more about how research is done in the field of humanities. During our interviews, it's possible that you may feel uncomfortable answering questions about your personal experiences with writing or with your ENGL 1100 course. However, you do not have to answer any questions you do not wish to answer.

### **Other details about your participation**

There is no cost or payment for being a part of this project. When we share the results of our study through publication or speaking engagements, we will change your name to a pseudonym. You do not have to take part in this study. If you start the study and later decide that you do not want to continue, all you have to do is contact us at one of the addresses/ phone numbers below to let us know. If you withdraw from the study, any information already collected about you will be discarded. Your decision to participate or withdraw will in no way affect your standing at CSCC or at your high school, and it will not cause you to lose any benefits to which you are entitled.

### **For more information**

If you have any concerns or questions about our study, you can contact one or more of us in person or by email or phone at the addresses/numbers listed at the end of this letter. Additionally, if you have any question, concerns, or reports regarding your rights as a participant in a research project, you may contact the CSCC Institutional Review Board at (xxx) xxx-xxxx.

### **If you want to participate**

If you decide to participate in our study, please call, email, or write to any one of us at the numbers/ addresses listed below as soon as possible, but no later than March 30. Once we hear from you, we'll send you an "Informed Consent Form" to sign and return, and we'll call you to set up dates for our interviews.

We look forward to the possibility of engaging in research with you!