Suffolk University
Office of Research and Sponsored Programs

INSTITUTIONAL REVIEW BOARD
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Protocol Number:

FOR IRB USE ONLY----- ☐ Meets Criteria for Exemption ☐ Does Not Meet Criteria for Exemption under category _____

HUMAN SUBJECT RESEARCH APPLICATION EXEMPTION
FROM CONTINUING REVIEW BY THE INSTITUTIONAL REVIEW BOARD

Instructions: Please complete this form with all appropriate signatures and attach a copy of the study protocol and all supporting documentation, to include verification of CITI training for key personnel for all new non-exempt human subject research. All the questions must be addressed in order to provide the Institutional Review Board with the necessary information to review your proposed research study. IRB approval **must** be obtained prior to beginning any non-exempt human subjects research. **The application should be written in layman's terms such that it can be understood by a non-scientist.**

1. GENERAL INFORMATION:	
Protocol Title: Online learning modules for introductory media large lecture course	
Date: 01/08/14	
2. PRINCIPAL INVESTIGATOR:	
Name: Nina Huntemann	**CITI Certified:** ☒ **Yes** **Date:** 08/19/13
School/Department: CAS - Communication & Journalism	
Campus Mailing Address: 41 Temple Street (410 Ridgeway Building)	**Telephone Number:** (617)573-8767
E-mail Address:nhuntemann@suffolk.edu	☒ **Faculty** ☐ **Staff** ☐
3. CO-INVESTIGATOR: If additional space is needed, please add on a separate page.	
Name:	**CITI Certified:** ☐ **Yes** **Date:**
School/Department:	
Campus Mailing Address:	**Telephone Number:** ( ) -
E-mail Address:	☐ **Faculty** ☐ **Staff** ☐ **Student**

4. RESEARCH STAFF: If additional space is needed, please add on a separate page.	
Name	**CITI Certified**
To Be Determined	☐ **Yes** **Date:**
	☐ **Yes** **Date:**
	☐ **Yes** **Date:**

5. COLLABORATORS: If you will be conducting this study in collaboration with non-Suffolk investigators or in non-Suffolk facilities, please complete the section below. If the IRB from a collaborating institution has approved their participation in this research study, attach a copy of the IRB approval letter. ☐ **N/A**

Name	**Affiliated Institution**	**IRB Approval**	**CITI Certified**
		☐ **Yes** ☐ **No** ☐ **Pending**	☐ **Yes**
		☐ **Yes** ☐ **No** ☐ **Pending**	☐ **Yes**
		☐ **Yes** ☐ **No** ☐ **Pending**	☐ **Yes**

Do the collaborating institutions hold a Federalwide Assurance (FWA)? ☐ **Yes** ☐ No
If yes, specify which institutions hold an FWA:

Does the involvement of Suffolk University include the receipt of a sub-award from a collaborating institution? ☐ **Yes** ☐ **No**

Does any part of this research involve collaboration with an **independent** (not with FWA institution or organization) investigator?
☐ **Yes** ☐ No
If yes, please identify investigator:

Is the involvement of a Suffolk University investigator limited to the evaluation of archived de-identified data? ☐ **Yes** ☒ No
If yes, check Category 4 under Section 7 and complete Sections 8, 15, 16, 18, 23, 25 and 26 only.

6. FUNDING SOURCES: If the study is funded, please provide a copy of the full grant, proposal and/or award ☒ **N/A**	
☐ External Federal-Funding	Agency:
☐ External Non-Federal Funding	Source:

7. EXEMPTION CATEGORIES: The following categories of research are exempt from continuing review by the IRB. Check all that apply

☒ **Category 1**. Research conducted in established or commonly accepted educational settings, involving normal educational practices such as:

- research on regular and special education instructional strategies, or
- research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ **Category 2**. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

- information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
- any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Note: this exemption does NOT apply to research involving children as subjects, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

☐ **Category 3.** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that otherwise would not be exempt if:

- the human subjects are elected or appointed public officials or candidates for public office; or
- federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ **Category 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.

☐ **Category 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:

- public benefit or service programs;
- procedures for obtaining benefits or services under those programs;
- possible changes in or alternatives to those programs or procedures; or
- possible changes in methods or levels of payment for benefits or services under those programs.

☐ **Category 6.** Taste and food quality evaluation and consumer acceptance studies if:

- wholesome foods without additives are consumed or
- 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

8. PURPOSE AND SCOPE: Please provide a brief summary of any relevant background information, study aims and its hypothesis. Please provide a rationale for the use of human subjects in meeting your study objectives.

Background:
While the large lecture format is a staple of higher education and can be an effective method for student learning, it can limit the amount of student engagement with course material to in-class lectures and out-of-classroom reading assignments, especially if the class size is also large. Educational research has shown that students often need to employe multiple learning formats in order to best grasp course content. Integrating blended learning (or hybrid) methods with the lecture format can provide students with additional opportunities to engage with course material that cannot be offered during lecture. The idea of using blended learning in an online setting is to bring learning methods available in small or mid-size classes, such as class discussion, application-oriented assignments, and response writing, to the large lecture class. One well-established blended method is the online learning module, which is a structured but self-directed initiative that can deepen student comprehension of course material and help prepare students for knowledge assessments.

Purpose:
The purpose of this study is to assess the effectiveness of online learning modules for student learning in a large lecture format class. The hypothesis for this study: Student who complete the online learning modules will score better on course quizzes than class average score.

Participants:
All students, aged 18 or older, enrolled in CJN 255: Introduction to Media during the Spring 2014 semester will be eligible for participation. No more than 80 students will participate. The rationale for using human subjects is that the research question is only relevant to humans.

Duration: **From:** 2/1/2014 **To:** 2/1/2015

Study Site(s): Suffolk University

9. DESCRIPTION OF STUDY POPULATION

Total Number of Subjects: 80	**Age Range**: 18 and older
Characteristics of Study Population: Please check all that apply.	
☐ Elderly	☐ Children
☒ Suffolk Students/Staff	☐ Educationally-Disadvantaged Persons
☐ Non-English Speaking	☐ Economically Disadvantaged Persons
☐ Ethnic Minorities (exclusively)	☐ Pregnant Women
☐ Fetuses/Neonates	☐ Other:

10. SELECTION OF SUBJECTS: Describe the inclusion/exclusion criteria and explain rationale for such. Explain rationale for using special populations such as children, pregnant women, minorities or any vulnerable individuals and describe the additional safeguards that are in place to protect their rights and welfare. Provide rationale for concluding that the risks and benefits are fairly distributed among the population that stands to benefit from the research. If Suffolk University students are involved in research as subjects appropriate measures must be in place to ensure the age requirement for informed consent (age 18 or older) is met. If not, parental permission must be sought for their participation.

The rationale for using Suffolk students is that I am examining the effectiveness of online learning modules as supplemental material in a large lecture course at Suffolk University. As students enrolled in the course as Sophomores, Juniors or Seniors, it is unlikely that any students will be younger than 18. However, the Informed Consent Form also specifically states that students must be 18 to participate.

11. RECRUITMENT TOOLS: Please provide copies for all marked.

☐	**Flyers, Posters, Brochures**
☐	**Study Advertisement** (*e.g., radio, television, online (Facebook, craigslist, private or public websites), newspaper, student newsletters, etc.)*
☐	**Word of Mouth** *(e.g., participants referring other individuals to study)*
☒	**In Person Recruitment** *(e.g., public events, meetings, open houses, school events, etc.)*
☐	**Referrals (***e.g., psychologist refer patients to study, teachers refer students to study, etc.)*
☐	**Scripts** *(e.g., phone scripts, e-mail scripts, screening scripts, presentations, etc)*

12. RECRUITMENT PROCESS: Describe in detail how subjects will be identified, method of initial contact and rationale for such method. If the recruitment process involves the recruitment of children who are being accessed through school or places where children participate in extracurricular activities, a letter of authorization must be obtained from the school principal, district superintendent, or administrative director or CEO of all applicable sites and included with the application.

Students will be provided with an Informed Consent Form (ICF) describing the goals of the study and the nature of their involvement. (see Appendix A). In order to minimize coercion, students will be invited to participate in the study by a Research Assistant (RA) without the instructor/Principal Investigator in the room. The RA will explain the details of the study by going over the consent form in class, underscoring the voluntary nature of participation. After students have the opportunity to read the ICF and ask questions, students will be instructed to either sign the form (if they wish to participate) or leave it blank (if they do not) and to place it into a sealed envelope. This envelope will be collected and stored by the RA until the semester is over and grades have been submitted. At that point, the investigator will "break the blind" by opening the envelopes and determining whose data can be used for research purposes.

13. INFORMED CONSENT/ASSENT/PARENTAL PERMISSION PROCEDURES: Provide copies as separate attachments for all marked.

☒	**Written Informed Consent will be obtained**
☐	**Waiver of Documentation of Informed Consent per §46.117(c)** *(Please complete appropriate form)*
☐	**Informed Consent will be obtained via a short form written document per §46.117(b)(2)**
☐	**Waiver of some of the elements of informed consent per §46.116(d)** *(Please complete appropriate form)*
☐	**Waiver of informed consent per §46.116(d)** *(Please complete appropriate form)*

14. INFORMED CONSENT OR ASSENT AND PARENTAL PERMISSION PROCESS: Describe consent/assent and/or parental permission procedures to be followed, including the circumstances under which consent/assent and/or parental permission will be sought and obtained, the nature of information to be provided to prospective subjects, and method of documentation.

Students will be provided with an Informed Consent Form (ICF) describing the goals of the study and the nature of their involvement. (see Appendix A). In order to minimize coercion, students will be invited to participate in the study by a Research Assistant (RA) without the instructor/Principal Investigator in the room. The RA will explain the details of the study, underscoring the voluntary nature of participation. After students have the opportunity to read the ICF and ask questions, students will be instructed to either sign the form (if they wish to participate) or leave it blank (if they do not) and to place it into a sealed envelope. This envelope will be collected and stored by the RA until the semester is over and grades have been submitted. At that point, the investigator will "break the blind" by opening the envelopes and determining whose data can be used for research purposes.

15. PROTECTED HEALTH INFORMATION: If collecting protected health information (PHI), describe the PHI being collected, the purpose for which it will be used, the entity from which the PHI will be collected and whether or not the entity is a HIPAA covered entity. If not applicable, insert NA below and skip item 15.

NA

16. METHOD OF COLLECTING PROTECTED HEALTH INFORMATION AND AUTHORIZATION: *Check all that apply.*

☐ **Prospective Chart Review** ☐ **Retrospective Chart Review** ☐ **Other:**

☐ **Authorization to be obtained** ☐ **Request Authorization Waiver** *(Please complete appropriate form)*

17. RESEARCH TOOLS: *Please provide copies for all marked.*

☒	**Surveys or Questionnaires (e.g. online surveys, mailed surveys, personal or medical history)**	
☐	**Measurement Instruments (e.g. psychological tests, IQ tests, diagnostic tools)**	
☐	**Interviews ☐ In Person ☐ Phone ☐ Other:**	**Recorded: ☐ Audio ☐ Video**
☐	**Focus Groups ☐ In Person ☐ Phone ☐ Other:**	**Recorded: ☐ Audio ☐ Video**
☐	**Record Review (e.g. chart review, public school records, medical records, agency records)**	
☐	**Other:**	

18. RESEARCH PROCEDURES: Describe the study procedures that a research participant should expect during the protocol. Define the type, frequency, duration of participation (e.g., what is done and when). When applicable, describe which procedures are experimental and which are routine. Does the study involve the use of deception? ☐ Yes ☒ No
If deception is to be used, the study does not meet criteria for exemption.

The procedures for this study are routine in that students will attend lectures, read course material, complete study guides, and take quizzes. These tasks will be familiar to most students enrolled at Suffolk or at any institute of higher education because these tasks reflect the standard educational practices of college-level learning. As part of these routine tasks, students will have four opportunities to complete four online learning modules, one for each course quiz. The modules will not be graded individually nor factored into a students overall course grade. Each learning module will be available for approximately three weeks prior to each accompanying quiz.
The experimental procedures of this study involve the comparison of students' quiz scores between those who use the online learning modules and those students who do not use the online learning modules. The online learning modules used in this study are made available to students via Blackboard. Student participation is voluntary. They may chose to complete an online module, start an online module but not complete it, or not attempt an online module at all. The quiz grades of students who provided informed consent will be compared to the average quiz scores for the entire class, and thus the individual quiz scores for non-participating students are not included in the analysis.

The Blackboard learning management system tracks student progress and completion of online learning modules, including data such as time it took the student to complete the modules, percentage of the modules completed and (if relevant) the student's score for the module. Since the modules created for this course will not be graded, scoring is not relevant nor will it be tracked.

Each of the four online learning modules will take between 60 minutes to two hours to complete. Student will be asked to do one or more of the following for each module: read articles, visit websites to collect data, watch videos and listen to audio files, review Power Point slides, complete true/false and multiple choice questions about the reading and in-class lecture material, write brief responses to open-ended questions about the reading and in-class lecture material, and contribute to an online closed (enrolled students only) discussion boards about topics relevant to readings and in-class lecture material. These tasks are routine and will be familiar to most students enrolled at Suffolk or at any institute of higher education because these tasks reflect the standard educational practices of college-level learning.

19. COMPENSATION METHOD: If participants will not be compensated check this box ☒ N/A; skip to section 20.

Amount/value of total compensation?	Type: ☐Gift Card; ☐ Cash; ☐ Raffle; ☐Other:

If students are participating in research will they receive course credit? ☐ Yes ☐ No
If yes, describe criteria for awarding credit, i.e. amount of credit awarded and alternatives for receiving equivalent credit in lieu of participating in a study as a research subject.

Is compensation pro-rated? ☐ Yes ☐ No; If yes, how:

20. RISKS/DISCOMFORTS: Describe any known or potential risks and/or discomforts (physical, psychological, social, legal or other) and assess their likelihood, seriousness and potential reversibility. Describe procedures for protecting against these risks and assess their likely effectiveness. Describe any alternative procedures that may be available to subjects including the choice not to participate.

There are no known risks to this project. The alternative is to not participate in the research.

21. BENEFITS: Describe any potential benefits to the individual subjects and/or to society in general that may be expected from the research. Describe the importance of knowledge that may reasonably be expected to result from the study. If no direct benefits are anticipated, please state so.

There are no known benefits to participating in this study exclusive to the participants. Students who complete the online modules but do not provided informed consent may expereince the same educational benefits as students who complete the online modules and have provided consent.

22. RISK/BENEFIT ANALYSIS: Discuss why risks are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

As there are no known risks and there is some potential benefit to learning the efficacy of blended learning practices, the risk/benefit ratio seems reasonable.

23. RESEARCH DATA

Will personally identifiable or protected health information be recorded? ☒ Yes ☐ No
If so, please check all that apply:

☒ Names (First and Last)	☐ Date of Birth	☐ Telephone/Fax Number
☐ Email Address	☐ Social Security Number	☒ Student ID
☐ Street address, city, five digit zip code, county	☐ Internet IP Address	☒ Other: Quiz grades

Will you be sharing any research data with anyone outside of Suffolk? ☒ Yes ☐ No

If yes, with whom and for what purpose? I will present statistics from the entire group of research participants. For example, I will look at the mean scores of the class. The general results of the study may be shared with faculty and administrators at Suffolk University. I may present them at an academic conference. I might publish them in an academic journal. However, these results will not contain any identifiable information. Only averages and totals for groups of participants will be included. I will not share the personal data of any one individual.

Will the research data be coded? ☒ Yes ☐ No ☐ NA
If yes, will a link between code and person's identifiable information be retained? ☒ Yes ☐ No
If yes, for how long? The code will be destroyed once all data analysis is completed.

24. PRIVACY AND CONFIDENTIALITY: Describe procedures for protecting privacy and maintaining confidentiality including procedures for collection, storage and future use of data. Describe whether codes will substitute names and/or identifiable records, who will have access to study data, whether database will be password-protected or encrypted for online data collection. Describe how long written records, tapes, or recordings will be maintained and in what manner they will be kept or destroyed (the retention period for IRB records not containing protected health information is a minimum of three years; the retention period for protected health information is six years).

I will do my best to protect participants' privacy during this study. Participants will be asked to sign their name on the consent and place it in a sealed envelope. The sealed envelope will be stored in a locked filing cabinet in the Principal Investigators (PI) office and will not be opened until the class is complete and grades have been submitted.

Once the envelopes are opened, the PI will assign all students who are participating in the research a code number, which will be used to identify data. The list of names and code numbers will be stored in a locked filing cabinet in the PI's office. The students' quiz grades and online module data will be entered into a spreadsheet on a password-protected computer in a locked office and identified by code number only. No personal, individual data will be released to any of the other faculty, staff or administrators of Suffolk University

Consistent with the guidelines that govern social science research, the data obtained in this study will be destroyed 3 years after the completion of the study.

25. FINANCIAL CONFLICTS OF INTEREST DISCLOSURE

☒ The investigator and key study team personnel have no financial or other conflicts of interest related to this study.

☐ The investigator or other key study team personnel have conflicts of interest or potential conflicts of interest related to this study. (*Identify specifically who on the study team has a conflict of interest. Identify the precise nature of the conflict(s) of interest to include financial conflicts of interest or other and how these conflicts will be eliminated or managed.* ***Conflicts of interest must be disclosed to participants during the informed consent process).***

☐ This project includes an investigator or key personnel from another institution who will comply with his or her own institution's COI policies.

☐ This project involves an investigator or key personnel from another institution who will comply with Suffolk University COI policies (completed Suffolk University COI disclosure form attached).

26. *PRINCIPAL INVESTIGATOR'S CERTIFICATION (E-SIGNATURE)

I certify that the information contained in this application is true. I understand that IRB approval of this application must be received prior to beginning any subject recruitment. I also understand that the IRB must be notified in writing of any modifications made to the study subsequent to approval of this application. I acknowledge and accept my responsibility for protecting the rights and welfare of human research participants as discussed in the Common Rule (45 CFR 46) and Belmont Report. I certify that I will comply with all applicable regulations and directions of the Institutional Review Board, which may include:

1. Conducting this research study as approved by the IRB.
2. Submitting any changes to the protocol to the IRB for review and approval prior to implementation.
3. Monitoring and supervising research staff in the conduct of the research.
4. Maintaining accurate, current and complete records of all study materials including all IRB correspondence.
5. Complying with all state and federal laws as well as Suffolk University's institutional policies regarding the conduct of research with human subjects.
6. Promptly reporting adverse and unanticipated events related to the study to the IRB.

*E-SIGNATURES ARE ***REQUIRED PRIOR TO SUBMISSION*** from the following:

Department Chair or Dean
Principle Investigator
Co-Investigator(s) (if applicable)
Faculty Advisor (for students only if different from PI)

Please contact the Office of Research and Sponsored Programs if you need assistance with setting up an account on www.irbnet.org.