IRB Approval
7/22/2022
IRB # 69567
Exempt

PROTOCOL TYPE

0 u
co

Which IRB

○ Medical ◉ NonMedical

Protocol Process Type

◉ Exemption
○ Expedited (Must be risk level 1)
○ Full

IMPORTANT NOTE: You will not be able to change your selections for "Which IRB" and "Protocol Process Type" after saving this section. If you select the wrong IRB or Protocol Process Type, you may need to create a new application.

See below for guidance on these options, or refer to ORI's "Getting Started" page. Please contact the Office of Research Integrity (ORI) at 859-257-9428 with any questions prior to saving your selections.

Which IRB

The **Medical IRB** reviews reviews research from the Colleges of:

- Dentistry
- Health Sciences
- Medicine
- Nursing
- Pharmacy and Health Sciences
- and Public Health.

The **Nonmedical IRB** reviews research from the Colleges of:

- Agriculture
- Arts and Sciences
- Business and Economics
- Communication and Information
- Design; Education
- Fine Arts
- Law
- and Social Work

Note: Studies that involve administration of drugs, testing safety or effectiveness of medical devices, or invasive medical procedures must be reviewed by the **Medical IRB** regardless of the college from which the application originates.

Which Protocol Process Type

Under federal regulations, the IRB can process an application to conduct research involving human subjects in one of three ways:

- by exemption certification
- by expedited review.
- by full review;

The investigator makes the preliminary determination of the type of review for which a study is eligible. Please refer to ORI's "Getting Started" page for more information about which activities are eligible for each type of review.

The revised Common Rule expanded exemption certification category 4 for certain secondary research with identifiable information or biospecimens. The regulations no longer require the information or biospecimens to be existing. For more information see the Exemption Categories Tool.

EXEMPTION CATEGORIES

0 unresolved comment(s)

LIMITATIONS: Certain research activities **cannot** be exempt because additional protection has been granted by federal regulations for vulnerable populations. The categories of research that cannot be exempt are as follows:

- Research involving the surveying or interviewing of children (exempt category 2);
- Research involving educational test or the observation of public behavior of children if the investigators participate in the activities being observed (exempt category 2);
- Research involving benign behavioral intervention with children (exempt category 3);
- Research involving prisoners (unless the research is aimed at involving a broader subject population and the involvement of the prisoner(s) is only incidental).

Please note: *The revised common rule regulations now allow for the application of all exempt categories to research involving the use of pregnant women, human fetuses, and neonates, assuming* ***all*** *the research activities fall within one or more categories of exempt research as determined by the IRB.*

Research activities are exempt from the human research protection regulations when the only involvement of human subjects falls within one or more of below categories. **Research categories 1-5 do not apply to Food and Drug Administration (FDA) regulated research.** For additional guidance, see the UK ORI Exemption Categories Tool or the Issues to be Addressed with Exempt Review document.

Check the appropriate category(ies) that apply(ies) to your research project:

☐ (1) Research, conducted in established or commonly accepted educational settings that specifically 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 instruction 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 with adults, or observation of public behavior including visual or auditory recording (with minors as long a study personnel do not interact when observing), if at least **one** of the following criteria is met:

i. 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; or
ii. 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; or
iii. 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 an IRB conducts a limited IRB review.

If retaining identifiers, complete and attach the Limited Review Form under the Additional Information section using the Additional Materials attachment button.

☑ (3) (i) 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; or
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; or
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 an IRB conducts a limited IRB review.

(ii) 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. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

If retaining identifiers, complete and attach the Limited Review Form [PDF] under the Additional Information section using the Additional Materials attachment button.

☐ (4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens that have been or will be collected for some other 'primary' or 'initial' activity, if at least one of the following criteria is met:

i. The identifiable private information or identifiable biospecimens are publicly available;
ii. Information, which may include information about biospecimens, 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, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
iv. The 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 20B(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq*.

☐ (5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including 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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

- Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

☐ (6) Taste and food quality evaluation and consumer acceptance studies:

i. If wholesome foods without additives are consumed; or
ii. If 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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exemption Category 7 and Category 8 both require "Broad consent" provisions and involve storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research (7) OR research involving the use of identifiable private information or identifiable biospecimens for secondary research use (8). These categories are not an option at the University of Kentucky at this time, as the provisions require institution-wide tracking of individuals who do not agree to secondary use of their identifiable private information or identifiable biospecimens.

☐ This protocol is approved by a Non-UK IRB. This category should be chosen only after you have contacted the ORI Reliance Team and submitted the Reliance Registration Form [PDF]. If you have not submitted the Reliance Registration Form to ORI Reliance staff, please contact us at irbreliance@uky.edu.

PROJECT INFORMATION

0 unresolved comment(s)

Title of Project: (Use the exact title listed in the grant/contract application, if applicable).
If your research investigates any aspect of COVID-19, please include "COVID19" at the beginning of your Project Title and Short Title

Speed-up or slow-down: Examining Instructor and Student Behaviors Affecting Learning Outcomes with Video Lectures

Short Title Description
Please use a few key words to easily identify your study - this text will be displayed in the Dashboard listing for your study.

Instructor Video Lectures

Anticipated Ending Date of Research Project: 8/1/2023

Maximum number of human subjects (or records/specimens reviewed) 400

After approval, will the study be open to enrollment of new subjects or new data/specimen collection? (•) Yes ( ) No

PI CONTACT INFORMATION

0 unresolved comment(s)

Principal Investigator (PI) role for E-IRB access
The PI is the individual holding primary responsibility on the research project with the following permissions on the E-IRB application:

1. Read;
2. write/edit;
3. receive communications; and
4. submit to the IRB (IR, CR, MR, Other Review*).

If research is being submitted to or supported by an extramural funding agency such as NIH, a private foundation or a pharmaceutical/manufacturing company, the PI listed on the grant application or the drug protocol must be listed as PI here.

Please fill in any blank fields with the appropriate contact information (gray shaded fields are not editable). Required fields left blank will be highlighted in pink after you click "Save".

To change home and work addresses, go to myUK and update using the Employee Self Service (ESS) portal. If name has changed, the individual with the name change will need to submit a 'Name Change Form' to the Human Resources Benefits Office for entering into SAP. The new name will need to be associated with the individual's Link Blue ID in SAP before the change is reflected in E-IRB. Contact the HR Benefits Office for additional information.

The Principal Investigator's (PI) contact information is filled in automatically based on who logged in to create the application.

If you are not the Principal Investigator, do NOT add yourself as study personnel.
To change the PI contact information on an application in Researcher edit status:

- click "Change Principal Investigator";
- search for the PI's name using the search feature;
- click "Select" by the name of the Principal Investigator, then "Save Contact Information".

  You will automatically be added as study personnel with editing permissions to continue editing the application.

Change Principal Investigator:

First Name:	Brandi	Room# & Bldg:	Lucille Little Library 310G
Last Name:	Frisby	Speed Sort#:	40506
Middle Name	N		
Department:	School of Information Scienc…	Dept Code:	8M500
PI's Employee/Student ID#:	10088710	Rank:	Professor
PI's Telephone #:	8592579470	Degree:	PhD
PI's e-mail address:	brandi.frisby@uky.edu	PI's FAX Number:	
PI is R.N.	○ Yes ◉ No	Trained:	Yes
		Date Trained	8/24/2021
		RCR Trained:	Yes

Do you, the PI, have a significant financial interest related to your responsibilities at the University of Kentucky (that requires disclosure per the UK administrative regulation 7:2)?

○ Yes ◉ No

RISK LEVEL

0 unresolved comment(s)

Indicate which of the categories listed below accurately describes this protocol

- (●) (Risk Level 1) Not greater than minimal risk
- ( ) (Risk Level 2) Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects
- ( ) (Risk Level 3) Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- ( ) (Risk Level 4) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects.

*"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

*****For Expedited and Exempt Applications, the research activities must be Risk Level 1 (no more than minimal risk to human subjects).*****

Refer to UK's guidance document on assessing the research risk for additional information.

SUBJECT DEMOGRAPHICS

0 unresolved comment(s)

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc..) 18 to 99

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations. Possible demographic sources: Census Regional Analyst Edition, Kentucky Race/Ethnic Table, Kentucky Population Data.
(Please note: The IRB will expect this information to be reported during Continuation Review for Full review applications, FDA-regulated Expedited applications, and Pre-2019 Expedited applications.):

Enter Numbers Only!

Ethnic Origin	#Male	#Female
American Indian/Alaskan Native:		
Asian:		
Black/African American:		
Hispanic/Latino:		
Native Hawaiian/Pacific Islander:		
White/Caucasian:		
Other or Unknown:		

If unknown, please explain why: We are unable to determine sex or the ethnic origin of our participants given the nature of our recruitment on CI SONA. There are no inclusion/exclusion criteria related to sex or ethnic origin.

Indicate the categories of subjects and controls to be included in the study. You may be required to complete additional forms depending on the subject categories which apply to your research. If the study does not involve direct intervention or direct interaction with subjects, (e.g., record-review research, outcomes registries), do not check populations which the research does not specifically target. For example: a large record review of a diverse population may incidentally include a prisoner or an international citizen, but you should not check those categories if the focus of the study has nothing to do with that status.

Check All That Apply (at least one item must be selected)

- ☐ Children (individuals under age 18)
- ☐ Wards of the State (Children)

ADDITIONAL INFORMATION:

Please visit the IRB Survival Handbook for more information on:

- ☐ Emancipated Minors
- ☑ Students
- ☐ College of Medicine Students
- ☐ UK Medical Center Residents or House Officers
- ☐ Impaired Consent Capacity Adults
- ☐ Pregnant Women/Neonates/Fetal Material
- ☐ Prisoners
- ☐ Non-English Speaking
- ☐ International Citizens
- ☐ Normal Volunteers
- ☐ Military Personnel and/or DoD Civilian Employees
- ☐ Patients
- ☐ Appalachian Population

- Children/Emancipated Minors
- Students as Subjects
- Prisoners
- Impaired Consent Capacity Adults

Other Resources:

- UKMC Residents or House Officers [see requirement of GME]
- Non-English Speaking [see also the E-IRB Research Description section on this same topic]
- International Citizens [DoD SOP may apply]
- Military Personnel and/or DoD Civilian Employees

Assessment of the potential recruitment of subjects with impaired consent capacity (or likelihood):

☐ Check this box if your study does NOT involve direct intervention or direct interaction with subjects (e.g., record-review research, secondary data analysis). If there is no direct intervention/interaction you will not need to answer the impaired consent capacity questions.

Does this study focus on adult subjects with any conditions that present a high *likelihood* of impaired consent capacity or *fluctuations* in consent capacity? (see examples below)

○ Yes ◉ No

If Yes and you are not filing for exemption certification, go to "Form T", complete the form, and attach it using the button below.

Examples of such conditions include:

- Traumatic brain injury or acquired brain injury
- Severe depressive disorders or Bipolar disorders
- Schizophrenia or other mental disorders that involve serious cognitive disturbances
- Stroke
- Developmental disabilities
- Degenerative dementias
- CNS cancers and other cancers with possible CNS involvement
- Late stage Parkinson's Disease
- Late stage persistent substance dependence
- Ischemic heart disease
- HIV/AIDS
- COPD
- Renal insufficiency
- Diabetes
- Autoimmune or inflammatory disorders
- Chronic non-malignant pain disorders
- Drug effects
- Other acute medical crises

Attachments

INFORMED CONSENT/ASSENT PROCESS/WAIVER

2 unresolved comment(s)

For creating your informed consent attachment(s), please download the most up-to-date version listed in "All Templates" under the APPLICATION LINKS menu on the left, and edit to match your research project.

Additional Resources:

- Informed Consent/Assent Website
- Waiver of Consent vs. Waiver of Signatures
- Sample Repository/Registry/Bank Consent Template

Consent/Assent Tips:

- If you have multiple consent documents, be sure to upload each individually (not all in a combined file).
- Changes to consent documents (e.g., informed consent form, assent form, cover letter, etc...) should be reflected in a 'tracked changes' version and uploaded separately with the Document Type "Highlighted Changes".
- It is very important that only the documents you wish to have approved by the IRB are attached; DELETE OUTDATED FILES -- previously *approved* versions will still be available in Protocol History.
- Attachments that are assigned a Document Type to which an IRB approval stamp applies will be considered the version(s) to be used for enrolling subjects once IRB approval has been issued.
  Document Types that do NOT get an IRB approval stamp are:
  - "Highlighted Changes",
  - "Phone Script", and
  - "Sponsor's Sample Consent Form".

How to Get the Section Check Mark

1. You must check the box for at least one of the consent items and/or check mark one of the waivers.
2. If applicable attach each corresponding document(s) **as a PDF**.
3. If you no longer need a consent document approved (e.g., closed to enrollment), or, the consent document submitted does not need a stamp for enrolling subjects (e.g., umbrella study, or sub-study), only select "Stamped Consent Doc(s) Not Needed".
4. After making your selection(s) be sure to scroll to the bottom of this section and SAVE your work!

☐ Not applicable

Check All That Apply

- ☐ Informed Consent Form (and/or Parental Permission Form)
- ☐ Assent Form
- ☑ Cover Letter (for survey/questionnaire research)
- ☐ Phone Script
- ☐ Informed Consent/HIPAA Combined Form
- ☐ Debriefing and/or Permission to Use Data Form
- ☐ Sponsor's sample consent form for Dept. of Health and Human Services (DHHS)-approved protocol
- ☐ Stamped Consent Doc(s) Not Needed

Attachments

Attach Type	File Name
CoverLetter	LectureSpeed_ori-f10355-cover-letter-surveyquestionnaire.pdf

☐ Request for Waiver of Informed Consent Process

If you are requesting IRB approval to waive the requirement for the informed consent process, or to alter some or all of the elements of informed consent, complete, Section 1 and Section 2 below.

Note: The IRB does not approve waiver or alteration of the consent process for greater than minimal risk research, except for planned emergency/acute care research as provided under FDA regulations. Contact ORI for regulations that apply to single emergency use waiver or acute care research waiver (859-257-9428).

SECTION 1.

Check the appropriate item:

☐ I am requesting waiver of the requirement for the informed consent process.

☐ I am requesting alteration of the informed consent process.

If you checked the box for this item, describe which elements of consent will be altered and/or omitted, and justify the alteration.

SECTION 2.

Explain how each condition applies to your research.

a) The research involves no more than minimal risk to the subject.

b) The rights and welfare of subjects will not be adversely affected.

c) The research could not practicably be carried out without the requested waiver or alteration.

d) Whenever possible, the subjects or legally authorized representatives will be provided with additional pertinent information after they have participated in the study.

e) If the research involves using or accessing identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

- Private information/specimens are “identifiable” if the investigator may ascertain the identity of the subject or if identifiers are associated with the information (e.g., medical records). This could be any of the 18 HIPAA identifiers including dates of service.
- If not using identifiable private information or identifiable biospecimens, insert N/A below.

☑ Request for Waiver of Documentation of Informed Consent Process

If you are requesting IRB approval to waive the requirement for signatures on informed consent forms, **your research activities must fit into one of three regulatory options**:

1. The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., a study that involves participants who use illegal drugs).
2. The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside of the research context (e.g., a cover letter on a survey, or a phone script).
3. The participant (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk to the subject, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Select the option below that best fits your study.

*If the IRB approves a waiver of signatures, participants must still be provided oral or written information about the study. To ensure you include required elements in your consent document, use the **Cover Letter Template** as a guide. There is an English and a Spanish version.*

○ **Option 1**

Describe how your study meets these criteria:

a) The only record linking the participant and the research would be the consent document:

b) The principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves subjects who use illegal drugs).

Under this option, each participant (or legally authorized representative) must be asked whether (s)he wants to sign a consent document; if the participant agrees to sign a consent document, only an IRB approved version should be used.

◉ **Option 2**

Describe how your study meets these criteria:

a) The research presents no more than minimal risk to the participant:

The research presents no more than minimal risk. No identifying information will be collected that can tie participants' identities to their individual responses. Participants will provide data by interacting with their personal computers in a way that is analogous to their daily lives.

b) Involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script):

Students will watch a video lecture and take a survey. The cover letter will be on the computer where they will watch the video and complete the survey. We request that student participants consent electronically before participating.

○ **Option 3**

Describe how your study meets these criteria:

a) The subject (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm.

b) The research presents no more than minimal risk to the subject.

c) There is an appropriate alternative mechanism for documenting that informed consent was obtained.

STUDY PERSONNEL **0 unresolved comment(s)**

Do you have study personnel who will be assisting with the research?
After selecting 'Yes' or 'No' you must click the 'Save Study Personnel Information' button.

(•) Yes ( ) No

Manage Study Personnel

Identify other study personnel assisting in research project:

- The individual listed as PI in the 'PI Contact Information' section should NOT be added to this section.
- If the research is required for a University of Kentucky academic program, the faculty advisor is also considered study personnel and should be listed below. ***Residents and students who are PI's are encouraged to designate the faculty advisor or at least one other individual as a contact with an editor role (DP).***
- Role: DP = Editor (individual can view, navigate, and edit the application for any review phase (IR, CR/FR, MR) or 'Other Review", and submit Other Reviews on behalf of the PI.)
- Role: SP = Reader (individual can view and navigate through the currently approved application only.)

To add an individual via the below feature:

- Search for personnel;
- Click "select" by the listing for the person you want to add;
- For each person, specify responsibility in the project, whether authorized to obtain informed consent, AND denote who should receive E-IRB notifications (contact status).

NOTE: Study personnel must complete human subject protection (HSP) and Responsible Conduct of Research (RCR) training before implementing any research procedures. For information about training requirements for study personnel, visit UK's HSP FAQ page, the RCR Getting Started page, or contact ORI at 859-257-9428. If you have documentation of current HSP training other than that acquired through UK CITI, you may submit it to ORI (HSPTrainingSupport@uky.edu) for credit.

Study personnel assisting in research project:

Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI
DeVito	Allyson	Co-Investigator	DP	Y	Y	PhD	P	Y	01/31/2021	Y	N	05/19/2021	N
Frey	Terrell	Co-Investigator	DP	Y	Y	PhD	P	Y	06/29/2022	Y	N	05/19/2021	N
LeRoy	Leslie	Co-Investigator	DP	Y	N		P	Y	06/13/2022	Y	N	02/02/2022	N
Kaufmann	Renee	Co-Investigator	DP	N	Y	PhD	P	Y	04/26/2022	Y	Y	08/25/2021	N

RESEARCH DESCRIPTION

0 unresolved comment(s)

You may attach a sponsor's protocol pages in the "Additional Information" section and refer to them where necessary in the Research Description. However, each prompt that applies to your study should contain at least a summary paragraph.

****!!!PLEASE READ!!!** Known Issue: The below text boxes do not allow symbols, web addresses, or special characters (characters on a standard keyboard should be ok). If something is entered that the text boxes don't allow, user will lose unsaved information.**

Workaround(s):

- **Save your work often to avoid losing data.**
- **Use one of the attachment buttons in this section, or under the Additional Information section to include the information with your application. During the document upload process, you will be able to provide a brief description of the attachment.**

Background: Provide an introduction and background information. Describe past experimental and/or clinical findings leading to the formulation of your study. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section, however, a summary paragraph must be provided in the text box below. Provide a summary of research reported in the literature that forms the scientific background for the present study.

Pandemic pedagogy necessitated that many instructors shift their content to an online learning format. Whether the course was online synchronous, online asynchronous, or took a hybrid form, many developed online lectures delivered in either a video or audio format for students. Further, even traditional face to face courses often employ video and audio lectures to supplement or reinforce in-person learning with the integration of new technological tools, resources, and skills. In this shift, and with learner control exerted over the approaches to learning, the phenomenon of changing the speed at which one listens or watches recorded content has drawn scholarly attention. The limited research on this phenomenon points to mixed results.

Many scholars and practitioners have examined the benefits of recorded lectures for students. Students may choose to watch or listen to recorded lectures at a time that is flexible and convenient or they may choose to rewatch videos as needed to increase comprehension, for example (Dinsmore, 2019; Heijstra and Sigurðardóttir (2018). Conversely, others have discussed concerns with providing course content in recorded form. Wilson, Martin, Smilek, and Risko (2018) reported that nearly 50% of students terminate watching a video within the first 5 minutes. Heijstra and Sigurðardóttir (2018) found that viewing behavior declines over time in a course. Even when viewing the videos, students report high levels of mind wandering. The reality of watching or listening to lectures on a device also present opportunities for students to be digitally distracted which can negatively affect learning (CITES). Moreover, Traphagan, Kucsera, and Kishi (2010) reported that students justified missing class more often when webcasts were available, and that attendance declined overall.

Regardless of the potential costs of consuming recorded lectures and the fact that students report higher satisfaction with normal speed videos, students are still using speed up features in platforms to reduce their time commitment to classes (Ritzhaupt et al., 2015). This behavior spurred researchers to delve into the outcomes associated with consuming sped up lectures revealing mixed results. Wilson, Martin, Smilek, and Risko (2018) found that when lectures were used at a speed of 1.6 to 1.7 times the normal, there were negative small effects on mind wandering, learning, and comprehension. Yang, Lin, Wen, Cheng, Yang, and An (2020) found that there were no significant deficits in attention, cognitive load, or learning when the listening speed was under 3.0 times the normal level. Listening at speeds beyond 3.0 reduced comprehension and recall performance in the immediate and at a test one week later. Yet another study found minimal costs to students when speed changes were at 2.0 times the normal or lower.

Beyond speed changes, scholars have also examined additional factors. For example, Ritzhaupt et al. (2015) studied sped up lectures with captions added, a common strategy to increase accessibility and inclusivity in recorded lectures. They found that the inclusion of captions increased cognitive overload, thereby decreasing student performance. Other scholars studied sped up lectures with rewatching capabilities (Heijstra & Sigurðardóttir, 2018). Traphagan, Kucsera, and Kishi (2010) explained that while watching a sped up lecture may decrease attendance, students who rewatched the videos were still able to perform well academically. Another instructional behavior that may help to keep students on task that has not been examined to date in this context, is student note taking behavior.

Others have focused on the content of the online lectures. For example, video vs. audio. Dinsmore (2019) found that students overwhelmingly preferred a video where the instructor face was shown and slides were included (88%) compared to only 40% who preferred a video of the screen with no instructor or the 25% who preferred the instructor presenter with no slides. The communication of the instructor is also salient, whether it is speaking rate (Simonds et al), immediacy (Simonds et al.) or organizational cues in the lecture (Titsworth).

In 2001, Titsworth conducted an experiment where students watched a video lecture, on normal speed, and were assigned to take notes or to not take notes. Those who took notes had better immediate and delayed cognitive learning outcomes and when the instructor used organizational cues. Titsworth (2004) noted that student are inefficient notetakers, typically only capturing about 40% of the content from lectures. However, we argue there is potential for students to capture notes more effectively in a situation with recorded content through slowing down the speed or rewatching or relistening to the lecture. It may be more difficult to capture

effective notes when a lecture is sped up. Taking notes while consuming a recorded lecture may be complicated and produce negative effects for other reasons as well. Flanigan and Titsworth (2020) found that students taking notes on their laptop took less notes, less visual cues, and were more digitally distracted. Intuitively, this may be the case when students are on their devices to watch or listen to a recorded lecture resulting in less notetaking which has a negative effect on learning.

Taken together, students have the autonomy to alter the speed at which they consume recorded course materials and may suffer detrimental academic outcomes as a result of that speed. However, it is possible that these negative effects can be tempered through a) positive organizational cues and b) effective note taking. This study aims to examine how to maximize learning through instructor behaviors (e.g., organizational cues) and student behaviors (e.g., notetaking) regardless of the speed at which they may consume the lectures.

Objectives: List your research objectives. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section, however, a summary paragraph must be provided in the text box below.

RQ: How does recorded lecture viewing speed affect student recall?
RQ: How can instructor organizational cues and student notetaking a) reduce student distractability and b) maintain sustained attention?
RQ: Which video condition a) alleviates cognitive load and b) improves instructor Social presence?

Study Design: Describe the study design (e.g., control and experimental groups, etc.). Indicate whether or not the subjects will be randomized for this study. Address whether deception will be involved in the study. You may reference sponsor's protocol pages and attach as an appendix in the E-IRB "Additional Information" section, however, a summary paragraph must be provided in the text box below. (Including the study design table from a sponsor's protocol is helpful to IRB members.)

Community-Based Participatory Research: If you are conducting community-based participatory research (CBPR), describe strategies for involvement of community members in the design and implementation of the study, and dissemination of results from the study.

Research Repositories: If the purpose of this submission is to establish a Research Repository (bank, registry) indicate whether the material you plan to collect would or would not be available from a commercial supplier, clinical lab, or established IRB approved research repository. Provide scientific justification for establishment of an additional repository collecting duplicate material. Describe the repository design and operating procedures. For relevant information to include, see the UK Research Biospecimen Bank Guidance or the UK Research Registry Guidance.

This study is a post-test only randomized experiment with 8 conditions. We are seeking to better understand how watching video lectures at different speed influences both comprehension and affect. Additionally, we want to know more about the role that note taking and organizational cues by the instructor impact students' experiences in conjunction with the video speed. Students will be recruited through the CI SONA research pool. From there, participants will be redirected to a survey via Qualtrics, where they will be electronically provide consent to participate. Following consent, they will be randomly assigned to watch one of eight videos:

1: Normal speed, no notetaking, no organizational cues
2: normal speed, yes notetaking, no organizational cues
3: normal speed, no notetaking, yes organizational cues
4: normal speed, yes notetaking, yes organizational cues
5: sped up video, no notetaking, no organizational cues
6: sped up video, no notetaking, yes organizational cues
7: sped up video, yes notetaking, no organizational cues
8: sped up video, yes notetaking, yes organizational cues

After watching the video, they will take a short, 10 question quiz based on the content they watched. Their credit is not determined by their performance on the quiz. Finally, after completing the quiz, students will answer several questions about their perceptions of the video, affect for the content and the instructor, cognitive load, social presence, sustained attention, and demographic information.There is no deception involved. It is not community based participatory research. A research repository will not be established.

Attachments

Back to Top

Study Population: Describe the characteristics of the subject population, such as anticipated number, age range, gender, ethnic background and health status. Identify the criteria for inclusion and exclusion. Explain the rationale for the use of special classes such as fetuses, pregnant women, children, institutionalized, adults with impaired consent capacity, prisoners, economically or educationally disadvantaged persons or others who are likely to be vulnerable.

If women or minorities are included, please address how the inclusion of women and members of minority groups and their subpopulations will help you meet your scientific objectives. Exclusion of women or minorities requires clear and compelling rationale that shows inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be excluded routinely from participation in clinical research.

Provide the following information:

- A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design;
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group;
- The proposed dates of enrollment (beginning and end);
- The proposed sample composition of subjects.

You may reference grant application/sponsor's relevant protocol pages and attach as an appendix using the below attachment button, however, a summary paragraph must be provided in the text box below.

Approximately 400 students will be recruiting who are 18 and older, of any gender, race, ethnicity, and health status. The only criteria for exclusion would be those who are not students or who are under 17. Any study enrolled in the CI SONA research pool will be eligible to participate.

Attachments

Subject Recruitment Methods & Privacy: Using active voice, describe plans for the identification and recruitment of subjects, including how the population will be identified, and how initial contact will be made with potential subjects by those having legitimate access to the subjects' identity and the subjects' information.

Describe the setting in which an individual will be interacting with an investigator or how and where members of the research team will meet potential participants. If applicable, describe proposed outreach programs for recruiting women, minorities, or disparate populations as participants in clinical research. Describe steps taken to minimize undue influence in recruiting potential participants.

Please note: Based upon both legal and ethical concerns, the UK IRB does not approve finder's fees or "cold call" procedures made by research staff unknown to the potential participant. The ORI/IRB does not control permission to any UK listserv, mass mailing list, etc. Investigators must secure prior approval for access and use from owners/managers.

For additional details, see topic "Recruitment of Subjects/Advertising" on ORI's IRB Survival Handbook web page and the PI Guide to Identification and Recruitment of Human Subjects for Research.

Subjects will be recruited using the CI SONA recruitment pool. The system will inform students of the opportunities to participate in research for 1 credit hour (~approximately 30 minutes long). Students will also be able to view other studies or the alternatives. If students agree to participate, they will follow the link to the research study where they read the cover letter and choose whether to participate in the study. Because the CI SONA system collects student names to award credit, and not the investigators, the responses will remain anonymous. The CI SONA system will award credit a the completion of the study.

Back to Top

Advertising: Specify if any advertising will be performed. If yes, please see "IRB Application Instructions - Advertisements" for instructions on attaching copies of the information to be used in flyers or advertisements. Advertisements must be reviewed and approved by the IRB prior to use. For additional details, see topic "Recruitment of Subjects/Advertising" on ORI's IRB Survival Handbook web page for the *PI Guide to Identification and Recruitment of Human Subjects for Research* [D7.0000] document [PDF]. If you will be recruiting subjects via advertising at non-UK owned or operated sites, you should include a copy of written permission from that site to place the advertisement in their facilities.

Note: Print and media advertisements that will be presented to the public also require review by UK Public Relations (PR) to ensure compliance with UK graphic standards, and equal opportunity language. See Advertising Instructions for PR contacts.

The following message will be posted on CI SONA:
You are being asked to take part in a research study to learn more about how students use and learn from recorded online lectures. You must be 18 or older to participate. This study is estimated to take less than 30 minutes. If you are completing this for research credits, you will earn 1 point for completion.

Attachments

Informed Consent Process: Using active voice, describe the consent/assent procedures to be followed, the circumstances under which consent will be sought and obtained, the timing of obtaining informed consent, whether there is any waiting period between informing the prospective subject and obtaining consent, who will seek consent., steps taken to minimize the possibility of coercion or undue influence, the method used for documenting consent, and if applicable who is authorized to provide permission or consent on behalf of the subject. Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application.

Describe provisions for obtaining consent/assent among any relevant special populations such as children (see Children in Research Policy [PDF] for guidance), prisoners (see Summary of Prisoner Regulations [PDF] for guidance), and persons with impaired decisional capacity (see Impaired Consent Capacity Policy [PDF] for guidance). Describe, if applicable, use of specific instruments or techniques to assess and confirm potential subjects' understanding of the nature of the elements of informed consent and/or a description of other written materials that will be provided to participants or legally authorized representatives. If you have a script, please prepare it using the informed consent template as a guide, and submit it on a separate page.

Informed Consent for Research Involving Emancipated Individuals
If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **when preparing the IRB application and prior to submitting the application to the IRB**. Include legal counsel's recommendations (legal counsel's recommendations may be attached in the E-IRB "Additional Information" section as a separate document, if necessary). For a complete definition of emancipated minors, see the section on *Emancipated Individuals* in the Informed Consent SOP [PDF].

Informed Consent for Research Involving Non-English Speaking Subjects
If you are recruiting non-English speaking subjects, the method by which consent is obtained should be in language in which the subject is proficient. Describe the process for obtaining informed consent from prospective subjects in their respective language (or the legally authorized representative's respective language). In order to ensure that individuals are appropriately informed about the study when English is their second-language, describe a plan for evaluating the level of English comprehension, and the threshold for providing a translation, or explain why an evaluation would not be necessary. For additional information on inclusion of non-English speaking subjects, or subjects from a foreign culture, see IRB Application Instructions for Recruiting Non-English Speaking Participants or Participants from a Foreign Culture.

Research Repositories
If the purpose of this submission is to establish a research repository describe the informed consent process. For guidance regarding consent issues, process approaches, and sample language see the Sample Repository/Registry/Bank Consent Template [PDF]

The study will be conducted entirely online. All subjects will be prompted to review information about the study and be asked whether or not they agree to participate in the research by clicking a box next to their choice. The initial consent form will ensure that participants understand what they will be asked to do in the study. The consent form is written in language that is clear, concise, and free of jargon. Participants will be informed that participation is voluntary and that their responses are anonymous. Participants will also be informed that if they do not wish to participate, they may discontinue the survey at any time, with alternative opportunities for credit outlined in their respective course syllabus. At the end of the consent form, participants will be asked to indicate whether or not they consent to participate in the research study by clicking the appropriate button on the electronic form ("Yes, I consent to participate" or "No, I do not consent to participate"). Because the entire study will take place online and consent will also be obtained online, a waiver for the documentation of consent has been submitted.

Back to Top

Research Procedures: Describe the research procedures that will be followed. Identify all procedures that will be carried out with each group of subjects. If applicable, differentiate between procedures that involve standard/routine procedures for care/treatment from those that will be performed specifically for this research project.

After recruitment in CI SONA, students will follow a link to Qualtrics. Once there, they will read a cover letter where they agree to participate. Next, using the Qualtrics random assignment function, students will be put into one of 8 conditions and watch an introductory video (see here: https://youtu.be/1CDnFObW8rQ) that gives directions specific to their experimental group. The study will begin with students watching a 15 minute pre-recorded lecture which will be embedded in the survey (see attached scripts for videos) to simulate online asynchronous course delivery. After the lecture has ended, they will take the survey in response to the experimental condition they were a part of.
Conditions
Condition 1: Normal speed, no notetaking, no organizational cues
2: normal speed, yes notetaking, no organizational cues
3: normal speed, no notetaking, yes organizational cues
4: normal speed, yes notetaking, yes organizational cues
5: sped up video, no notetaking, no organizational cues
6: sped up video, no notetaking, yes organizational cues
7: sped up video, yes notetaking, no organizational cues
8: sped up video, yes notetaking, yes organizational cues

Attachments

Attach Type	File Name
ResearchProcedures	A Taxonomy of Sport Spectators.docx.pdf

Data Collection: List the data or attach a list of the data to be collected about or from each subject (e.g. interview script, survey tool, data collection form for existing data).

If the research includes survey or interview procedures, the questionnaire, interview questions or assessment scales should be included in the application (use attachment button below).

The data collection instrument(s) can be submitted with your application in draft form with the understanding that the final copy will be submitted to the IRB for approval prior to use (submit final version to the IRB for review as a modification request if initial IRB approval was issued while the data collection instrument was in draft form).

Note: The IRB approval process does not include a statistical review. Investigators are strongly encouraged to develop data management and analysis plans in consult with a statistician.

Data will be collected using a Qualtrics survey including survey items and a quiz. Please see attached.

Attachments

Attach Type	File Name
DataCollection	Sped Up Lectures Survey.pdf
DataCollection	Taxonomy_Quiz.docx.pdf

Resources: Describe what resources/facilities are available to perform the research (i.e., staff, space, equipment). Such resources may include a) staffing and personnel, in terms of availability, number, expertise, and experience; b) psychological, social, or medical services, including counseling or social support services that may be required because of research participation; c) psychological, social, or medical monitoring, ancillary care, equipment needed to protect subjects; d) resources for subject communication, such as language translation services, and e) computer or other technological resources, mobile or otherwise, required or created during the conduct of the research. Please note: Some mobile apps may be considered mobile medical devices under FDA regulations (see FDA Guidance). Proximity or availability of other resources should also be taken into consideration, for example, the proximity of an emergency facility for care of subject injury, or availability of psychological support after participation.

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky, at sites that are geographically separate from UK, or at sites that do not fall under the UK IRB's authority, are subject to special procedures for coordination of research review. Additional information is required (see IRB Application Instructions - Off-Site Research web page); supportive documentation can be attached in the E-IRB "Additional Information" section. Provide a written description of the role of the non-UK site(s) or non-UK personnel who will be participating in your research. The other site may need to complete its own IRB review, or a cooperative review arrangement may need to be established. Contact the Office of Research Integrity at (859) 257-9428 if you have questions about the participation of non-UK sites/personnel.

If the University of Kentucky is the lead site in a multi-site study, or the UK investigator is the lead investigator, describe the plan for managing the reporting of unanticipated problems, noncompliance and submission of protocol modifications and interim results from the non-UK sites.

UK resources will include the use of CI SONA for recruitment, a Qualtrics account for data collection, and SPSS software downloads from UK for data analysis.

Potential Risks: Describe any potential risks subjects may encounter while in the study, e.g., physical, psychological, social, legal or other, and assess their likelihood and seriousness. Where appropriate, describe alternative treatments or procedures that might be advantageous to the subjects.

Students are not expected to encounter any risks. The study is voluntary.

Back to Top

Safety Precautions: Describe the procedures for protecting against or minimizing any potential risks, *including risks of breach of confidentiality or invasion of privacy*. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events, or unanticipated problems involving subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects. If vulnerable populations other than adults with impaired consent capacity are to be recruited, describe additional safeguards for protecting the subjects' rights and welfare.

Students will complete the research from their own devices in a location of their choosing ensuring privacy and anonymity. No identifying information will be collected. Data will be stored electronically in Qualtrics and maintained for a minimum of 6 years. The data will be included in submissions for publication/conferences; however no individual or identifying data will be included. The following statement will be included on the cover letter:

"Please be aware, while we make every effort to safeguard your data once received from the online survey company, given the nature of online surveys, as with anything involving the Internet, we can never guarantee the confidentiality of the data while still on the survey company's servers, or while en route to either them or us."

Benefit vs. Risk: Describe potential benefits to the subject(s); include potential benefits to society and/or general knowledge to be

gained. Describe why the risks to subjects are reasonable in relation to the anticipated benefit(s) to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. If you are using vulnerable subjects (e.g., impaired consent capacity, pregnant women, etc…), justify their inclusion by describing the potential benefits of the research in comparison to the subjects' vulnerability and the risks to them. For information about inclusion of certain vulnerable populations, see the IRB/ORI Standard Operating Procedure for Protection of Vulnerable Subjects [C3.0100] [PDF].

The data is expected to be used to improve online content delivery in college courses and to improve student learning. While students will not individually benefit, there are no anticipated risks.

Available Alternative Treatment(s): Describe alternative treatments and/or procedures that might be available to subjects who choose not to participate in the study which offer the subject equal or greater advantages. If applicable, this should include a discussion of the current standard of care treatment(s).

Students may choose another study in CI SONA or the alternative.

Back to Top

Research Materials, Records and Privacy: Identify the sources of research material obtained from living human subjects. Indicate what information (specimens, records, data, genetic information, etc.) will be recorded and whether use will be made of existing specimens, records or data. Explain why this information is needed to conduct the study.

Return of Research Results or Incidental Findings (if applicable):
If research has the potential to identify individual results or discover incidental findings that could affect the health of a subject, describe plans to assess, manage, and if applicable disclose findings with individual subjects or provide justification for not disclosing. For IRB expectations, refer to the UK IRB "Frequently Asked Questions (FAQs) on the Return of Research Results or Incidental Research Findings" [PDF].

All research materials will be collected using Qualtrics and will be used to answer the research questions. There will be no way to pair answers provided to specific participants.

Confidentiality: Specify where the data and/or specimens will be stored and how the researcher will ensure the privacy and confidentiality of both. Please address the following items or indicate if the following has been addressed in a HIPAA or Limited Review form:

- physical security measures (e.g., locked facility, limited access);
- data security (e.g., password-protection, data encryption);
- who will have access to the data/specimens and identifiers;
- safeguards to protect identifiable research information (e.g., coding, links, certificate of confidentiality);
- procedures employed when sharing material or data, (e.g., honest broker if applicable, written agreement with recipient not to re-identify, measures to ensure that subject identifiers are not shared with recipients).
- management after the study

Describe whether data/specimens will be maintained indefinitely or destroyed. If maintained, specify whether identifiers will be removed from the maintained information/material. If identifiers will not be removed, provide justification for retaining them. If the data/specimens will be destroyed, describe how and when the data/specimens will be destroyed. For multi-site studies, the PI consults the study sponsor regarding retention requirements, but must maintain records for a minimum of six years after study closure. Also, specify who will access the identified data/specimens, and why they need access. If applicable, describe what measures will be taken to ensure that subject identifiers are not given to the investigator. If applicable, describe procedures for sharing data/specimens with entities not affiliated with UK (If the research is non-sponsored you need a data use agreement to share data/specimens [Transfer Agreements]).

HIPAA/FERPA Minimal Access Standards: The IRB expects researchers to access the minimal amount of identifiers to conduct the study and comply with applicable HIPAA and Family Educational Rights and Privacy Act (FERPA) requirements. If data are going to be collected, transmitted, and/or stored electronically, for appropriate procedures please refer to the guidance document "Confidentiality and Data Security Guidelines for Electronic Data" [PDF].

Cloud storage: For storage of data on cloud services other than UK OneDrive, please verify security settings are sufficient and in accordance with respective departmental, UK Corporate Compliance, and/or UK Information Technology requirements.

Creation of digital data application/program: If a research protocol involves the creation and/or use of a computer program or application, mobile or otherwise, please specify whether the program/application is being developed by a commercial software developer or the research team and provide any relevant information regarding the security and encryption standards used, how data is stored and/or transmitted to the research team, what information about the subjects the program/application will collect, etc. For relevant information to include, see Considerations for Protocol Design Concerning Digital Data [PDF]. The IRB may require software programs created or used for research purposes be examined by a consultant with appropriate Internet technology expertise to ensure subject privacy and data are appropriately protected.

Management after study: Describe how the collected data/specimens will be managed after the end of the study. Specify whether identifiers will be removed from the maintained information/material. If identifiers will not be removed, provide

justification for retaining them and specify what steps will be taken to secure the data/specimens (e.g., maintaining a coded list of identifiers separate from the data/specimens).

If the data/specimens will be destroyed, describe how, when, and why this will be done. Note that destruction of primary data may violate NIH and NSF retention and sharing requirements, journal publication guidance, and University Data-Retention policies. Additionally, primary data may be necessary for other purposes (to validate reproducibility, for data sharing, or for evidence in various investigations). PIs should carefully consider whether the destruction of data is justified.

The investigator is responsible for retaining signed consent and assent documents and IRB research records for at least six years after study closure, as outlined in the Study Closure SOP [PDF]. If the research falls under the authority of the FDA or other regulatory agencies, or a study sponsor is involved, additional requirements may apply.

Back to Top

Participant anonymity will be protected, as there will be no direct or identifying information relative to each participant within the survey. Upon the completion of data collection, the data will first be stored in the electronic survey engine (Qualtrics). Second, the data from the survey will be downloaded in aggregate form from the survey website and stored on a password-protected computer property of the primary investigator. After the data has been collected, it may be deleted from the online database. Only the primary investigators, Brandi Frisby, T. Kody Frey, Leslie LeRoy, and Allyson DeVito, will have access to the data. The data, records, and materials will be maintained electronically for a minimum of six years following study closure.

Back to Top

Payment: Describe the incentives (e.g., inducements) being offered to subjects for their time during participation in the research study. If monetary compensation is offered, indicate how much the subjects will be paid and describe the terms and schedule of payment. (It is IRB policy that provision should be made for providing partial payment to subjects who withdraw before the completion of the research. Monetary payments should be prorated or paid in full.)

Participants will earn 1 research credit. There are no other forms of reward or compensation.

Costs to Subjects: Describe any costs for care associated with research (including a breakdown of standard of care procedures versus research procedures), costs of test drugs or devices, and research procedure costs that are the subject's responsibility as a consequence of participating in the research. Describe any offer for reimbursement of costs by the sponsor for research related injury care.

N/A

Data and Safety Monitoring: The IRB requires review and approval of data and safety monitoring plans for greater than minimal risk research, or NIH-funded clinical investigations.

If you are conducting greater than minimal risk research, or your clinical investigation is NIH-funded, describe your Data and Safety Monitoring Plan (DSMP). Click here for additional guidance on developing a Data and Safety Monitoring Plan.

If this is a *non-sponsored investigator-initiated* protocol considered greater than minimal risk research, *and* if you are planning on using a Data and Safety Monitoring Board (DSMB) as part of your DSMP, click here for additional guidance for information to include with your IRB application.

This study is not greater than minimal risk.

Back to Top

Subject Complaints: Describe procedures (other than information provided in consent document) for handling subject complaints or requests for information about the research. The procedures should offer a safe, confidential, and reliable channel for current, prospective, or past research subjects (or their designated representative) permitting them to discuss problems, concerns and questions, or obtain information.

If at any time participants have questions during the study, they are provided with contact information for the primary researcher. If participants have complaints, suggestions, or questions about their rights as a research volunteer, they are instructed to contact the staff in the University of Kentucky Office of Research Integrity at 859-257-9428 or toll-free at 1-866-400-9428.

Are you recruiting or expect to enroll **Non-English Speaking Subjects or Subjects from a Foreign Culture**? (does not include short form use for incidentally encountered non-English subjects)

○ Yes ◉ No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Recruitment and Consent:

Describe how information about the study will be communicated to potential subjects appropriate for their culture, and if necessary, how new information about the research may be relayed to subjects during the study.
When recruiting Non-English-speaking subjects, provide a consent document in the subject's primary language. After saving this section, attach both the English and translated consent documents in the "Informed Consent" section.

Cultural and Language Consultants:

The PI is required to identify someone to serve as the cultural consultant to the IRB.

- This person should be familiar with the culture of the subject population and/or be able to verify that translated documents are the equivalent of the English version of documents submitted.
- The consultant should not be involved with the study or have any interest in its IRB approval.
- Please include the name, address, telephone number, and email of the person who will act as the cultural consultant for your study.

For more details, see the IRB Application Instructions on Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture.

Local Requirements:

If you will conduct research at an international location, identify and describe:

- relevant local regulations
- data privacy regulations
- applicable laws
- ethics review requirements for human subject protection

Please provide links or sources where possible. If the project has been or will be reviewed by a local ethics review board, attach a copy in the "Additional Information/Materials" section. You may also consult the current edition of the International Compilation of Human Research Standards

Does your study involve **HIV/AIDS research and/or screening for other reportable diseases (e.g., Hepatitis C, etc…)**?

○ Yes ◉ No

HIV/AIDS Research

If you have questions about what constitutes a reportable disease and/or condition in the state of Kentucky, see ORI's summary sheet: "Reporting Requirements for Diseases and Conditions in Kentucky" [PDF].

HIV/AIDS Research: There are additional IRB requirements for designing and implementing the research and for obtaining informed consent. Describe additional safeguards to minimize risk to subjects in the space provided below.

For additional information, visit the online IRB Survival Handbook to download a copy of the "Medical IRB's requirements for Protection of Human Subjects in Research Involving HIV Testing" [D65.0000] [PDF], and visit the Office for Human Research Protections web site for statements on AIDS research, or contact the Office of Research Integrity at 859-257-9428.

PI-Sponsored FDA-Regulated Research

Is this an investigator-initiated study that:

Back to Top

1) involves testing a Nonsignificant Risk (NSR) Device, or
2) is being conducted under an investigator-held Investigational New Drug (IND) or Investigational Device Exemption (IDE)?

○ Yes ◉ No

PI-Sponsored FDA-Regulated Research

If the answer above is yes, then the investigator assumes the regulatory responsibilities of both the investigator and sponsor. The Office of Research Integrity provides a summary list of sponsor IND regulatory requirements for drug trials [PDF], IDE regulatory requirements for SR device trials [PDF], and abbreviated regulatory requirements for NSR device trials [PDF]. For detailed descriptions see FDA Responsibilities for Device Study Sponsors or FDA Responsibilities for IND Drug Study Sponsor-Investigators.

- Describe the experience/knowledge/training (if any) of the investigator serving as a sponsor (e.g., previously held an IND/IDE); and
- Indicate if any sponsor obligations have been transferred to a commercial sponsor, contract research organization (CRO), contract monitor, or other entity (provide details or attach FDA 1571).

IRB policy requires mandatory training for all investigators who are also FDA-regulated sponsors (see Sponsor-Investigator FAQs). A sponsor-investigator must complete the applicable Office of Research Integrity web based training, (drug or device) before final IRB approval is granted.

Has the sponsor-investigator completed the mandatory PI-sponsor training prior to this submission?

○ Yes ○ No

If the sponsor-investigator has completed equivalent sponsor-investigator training, submit documentation of the content for the IRB's consideration.

Attachments

HIPAA

0 unresolved comment(s)

Is HIPAA applicable? ○ Yes ◉ No

(Visit ORI's Health Insurance Portability and Accountability Act (HIPAA) web page to determine if your research falls under the HIPAA Privacy Regulation.)

If yes, check below all that apply and attach the applicable document(s):

- ☐ HIPAA De-identification Certification Form
- ☐ HIPAA Waiver of Authorization

Attachments

STUDY DRUG INFORMATION

0 unresolved comment(s)

The term drug may include:

- FDA approved drugs,
- unapproved use of approved drugs,
- investigational drugs or biologics,
- other compounds or products intended to affect structure or function of the body, and/or
- complementary and alternative medicine products such as dietary supplements, substances generally recognized as safe (GRAS) when used to diagnose, cure mitigate, treat or prevent disease, or clinical studies of e-cigarettes examining a potential therapeutic purpose.

Does this protocol involve a drug including an FDA approved drug; unapproved use of an FDA approved drug; and/or an investigational drug?

○ Yes ◉ No

If yes, complete the questions below. Additional study drug guidance.

LIST EACH DRUG INVOLVED IN STUDY IN THE SPACE BELOW

Drug Name:

Note: Inpatient studies are required by Hospital Policy to utilize the Investigational Drug Service (IDS). Use of IDS is highly recommended, but optional for outpatient studies. Outpatient studies not using IDS services are subject to periodic inspection by the IDS for compliance with drug accountability good clinical practices.

Indicate where study drug(s) will be housed and managed:

☐ Investigational Drug Service (IDS) UK Hospital

Other Location:

Is the study being conducted under a valid Investigational New Drug (IND) application?

○ Yes ○ No

If Yes, list IND #(s) and complete the following:

IND Submitted/Held by:

Sponsor: ☐		Held By:	
Investigator: ☐		Held By:	
Other: ☐		Held By:	

☐ Checkmark if the study is being conducted under FDA's Expanded Access Program (e.g., Treatment IND) or if this is an Individual Patient Expanded Access IND (FDA Form 3926).

FDA's Expanded Access Program Information for Individual Patient Expanded Access INDs, and attach the following:

- FDA Form 3926;
- FDA expanded access approval or correspondence;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the Expanded Access SOP.

Complete and attach the required Study Drug Form.

Attachments

STUDY DEVICE INFORMATION

0 unresolved comment(s)

A DEVICE may be a:

- component, part, accessory;
- assay, reagent, or in-vitro diagnostic device;
- software, digital health, or mobile medical app;
- other instrument if intended to affect the structure or function of the body, diagnose, cure, mitigate, treat or prevent disease; or
- a homemade device developed by an investigator or other non-commercial entity and not approved for marketing by FDA.

For additional information, helpful resources, and definitions, see ORI's Use of Any Device Being Tested in Research web page.

Does this protocol involve testing (collecting safety or efficacy data) of a medical device including an FDA approved device, unapproved use of an approved device, humanitarian use device, and/or an investigational device?

○ Yes ◉ No

[Note: If a marketed device(s) is only being used to elicit or measure a physiologic response or clinical outcome, AND, NO data will be collected on or about the device itself, you may answer “no” above, save and exit this section, (Examples: a chemo drug study uses an MRI to measure tumor growth but does NOT assess how effective the MRI is at making the measurement; an exercise study uses a heart monitor to measure athletic performance but no safety or efficacy information will be collected about the device itself, nor will the data collected be used for comparative purposes against any other similar device).]

If you answered yes above, please complete the following questions.

LIST EACH DEVICE BEING TESTED IN STUDY IN THE SPACE BELOW

Device Name:

Is the study being conducted under a valid Investigational Device Exemption (IDE), Humanitarian Device Exemption (HDE) or Compassionate Use?

○ Yes ○ No

If Yes, complete the following:
IDE or HDE #(s)

IDE/HDE Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

☐ Check if this is a Treatment IDE or Compassionate Use under the Food and Drug Administration (FDA) Expanded Access program.

For Individual or Small Group Expanded Access, see FDA's Early Expanded Access Program Information, and attach the following:

- FDA expanded access approval or sponsor’s authorization;
- An independent assessment from an uninvolved physician, if available;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the Medical Device SOP.

Does the intended use of any research device being tested (not clinically observed) in this study meet the regulatory definition of Significant Risk (SR) device?

- Yes. Device(s) as used in this study presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.
- No. All devices, as used in this study do not present a potential for serious risk to the health, safety, or welfare of subjects/participants.

Complete and attach the required Study Device Form.

Attachments

RESEARCH SITES

0 unresolved comment(s)

To complete this section, ensure the responses are accurate then click "SAVE".

A) Check all the applicable sites listed below at which the research will be conducted. If none apply, you do not need to check any boxes.

UK Sites

- [x] UK Classroom(s)/Lab(s)
- [ ] UK Clinics in Lexington
- [ ] UK Clinics outside of Lexington
- [ ] UK Healthcare Good Samaritan Hospital
- [ ] UK Hospital

Schools/Education Institutions

- [ ] Fayette Co. School Systems *
- [ ] Other State/Regional School Systems
- [ ] Institutions of Higher Education (other than UK)

***Fayette Co. School systems, as well as other non-UK sites, have additional requirements that must be addressed. See ORI's IRB Application Instructions - Off-site Research web page for details.**

Other Medical Facilities

- [ ] Bluegrass Regional Mental Health Retardation Board
- [ ] Cardinal Hill Hospital
- [ ] Eastern State Hospital
- [ ] Norton Healthcare
- [ ] Nursing Homes
- [ ] Shriner's Children's Hospital
- [ ] Veterans Affairs Medical Center
- [ ] Other Hospitals and Med. Centers

- [ ] Correctional Facilities
- [ ] Home Health Agencies
- [ ] International Sites

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky, at sites that are geographically separate from UK, or at sites that do not fall under the UK IRB's authority, are subject to special procedures for coordination of research review. Additional information is required (see IRB Application Instructions - Off-Site Research web page), including:

- A letter of support and local context is required from non-UK sites. See *Letters of Support and Local Context* on the IRB Application Instructions - Off-Site Research web page for more information.
- Supportive documentation, including letters of support, can be attached below.
- NOTE: If the non-UK sites or non-UK personnel are engaged in the research, there are additional federal and university requirements which need to be completed for their participation. For instance, the other site(s) may need to complete their own IRB review, or a cooperative review arrangement may need to be established with non-UK

sites.
- Questions about the participation of non-UK sites/personnel should be discussed with the ORI staff at (859) 257-9428.

List all other non-UK owned/operated locations where the research will be conducted:

Qualtrics

Attachments

B) Is this a multi-site study for which **you are the lead investigator or UK is the lead site**? ○ Yes ◉ No

If **YES**, you must describe the plan for the management of reporting unanticipated problems, noncompliance, and submission of protocol modifications and interim results from the non-UK sites in the E-IRB "Research Description" section under *Resources*.

If the non-UK sites or non-UK personnel are *engaged* in the research, there are additional federal and university requirements which need to be completed for their participation, such as the establishment of a cooperative IRB review agreement with the non-UK site. Questions about the participation of non-UK sites/personnel should be discussed with the ORI staff at (859) 257-9428.

RESEARCH ATTRIBUTES

0 unresolved comment(s)

Indicate the items below that apply to your research. Depending on the items applicable to your research, you may be required to complete additional forms or meet additional requirements. Contact the ORI (859-257-9428) if you have questions about additional requirements.

☐ Not applicable

Check All That Apply

	For additional requirements and information:
☐ Academic Degree/Required Research	• Cancer Research (MCC PRMC) • Certificate of Confidentiality (look up "Confidentiality/Privacy...") • CCTS (Center for Clinical and Translational Science) • Clinical Research (look up "What is the definition of....) • Clinical Trial • Collection of Biological Specimens for Banking (look up "Specimen/Tissue Collection...") • Collection of Biological Specimens (look up "Specimen/Tissue Collection...") • Community-Based Participatory Research (look up "Community-Engaged...") • Data & Safety Monitoring Board (DSMB) *For Medical IRB: Service Request Form for CCTS DSMB • Data & Safety Monitoring Plan • Deception* *For deception research, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process" • Emergency Use (Single Patient) [attach Emergency Use Checklist] (PDF) • Genetic Research (look up "Specimen/Tissue Collection...") • Gene Transfer • HIV/AIDS Research (look up "Reportable Diseases/Conditions") • Screening for Reportable Diseases [E2.0000] (PDF) • International Research (look up "International & Non-English Speaking") • NIH Genomic Data Sharing (GDS) Policy (PDF) • Planned Emergency Research Involving Waiver of Informed Consent* *For Planned Emergency Research Involving Waiver of Informed Consent, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process" • Use of radioactive material, ionizing radiation or x-rays for research
☐ Aging Research	
☐ Alcohol Abuse Research	
☐ Cancer Research	
☐ Certificate of Confidentiality	
☐ CCTS-Center for Clinical & Translational Science	
☐ Clinical Research	
☐ Clinical Trial	
☐ Clinical Trial Multicenter(excluding NIH Cooperative Groups)	
☐ Clinical Trial NIH cooperative groups (i.e., SWOG, RTOG)	
☐ Clinical Trial Placebo Controlled Trial	
☐ Clinical Trial UK Only	
☐ Collection of Biological Specimens	
☐ Collection of Biological Specimens for Banking	
☐ Community-Based Participatory Research	
☐ Data & Safety Monitoring Board	
☐ Data & Safety Monitoring Plan	
☐ Deception	
☐ Drug/Substance Abuse Research	
☐ Educational/Student Records (e.g., GPA, test scores)	
☐ Emergency Use (Single Patient)	
☐ Genetic Research	
☐ Gene Transfer	
☐ GWAS (Genome-Wide Association Study) or NIH-funded study generating large scale genomic data	
☐ International Research	
☐ Internet Research	
☐ Planned Emergency Research Involving Waiver of Informed Consent	
☐ Pluripotent Stem Cell Research	
☐ Recombinant DNA	
☑ Survey Research	
☐ Transplants	
☐ Use of radioactive material, ionizing radiation, or x-rays [Radiation Safety Committee review required]	
☐ Vaccine Trials	

FUNDING/SUPPORT

0 unresolved comment(s)

If the research is being submitted to, supported by, or conducted in cooperation with an external or internal agency or funding program, indicate below all the categories that apply.

☑ Not applicable

Check All That Apply

- ☐ Grant application pending
- ☐ (HHS) Dept. of Health & Human Services
  - ☐ (NIH) National Institutes of Health
  - ☐ (CDC) Centers for Disease Control & Prevention
  - ☐ (HRSA) Health Resources and Services Administration
  - ☐ (SAMHSA) Substance Abuse and Mental Health Services Administration
- ☐ (DoJ) Department of Justice or Bureau of Prisons
- ☐ (DoE) Department of Energy
- ☐ (EPA) Environmental Protection Agency
- ☐ Federal Agencies Other Than Those Listed Here
- ☐ Industry (Other than Pharmaceutical Companies)
- ☐ Internal Grant Program w/ proposal
- ☐ Internal Grant Program w/o proposal
- ☐ National Science Foundation
- ☐ Other Institutions of Higher Education
- ☐ Pharmaceutical Company
- ☐ Private Foundation/Association
- ☐ U.S. Department of Education
- ☐ State

Other:

Click applicable listing(s) for additional requirements and information:

- (HHS) Dept. of Health & Human Services
- (NIH) National Institutes of Health
- (CDC) Centers for Disease Control & Prevention
- (HRSA) Health Resources & Services Administration
- (SAMHSA) Substance Abuse & Mental Health Services Administration
- Industry (Other than Pharmaceutical Companies) [IRB Fee Info]
- National Science Foundation
- (DoEd) U.S. Department of Education
- (DoJ) Department of Justice or Bureau of Prisons
- (DoE) Department of Energy Summary and Department of Energy Identifiable Information Compliance Checklist
- (EPA) Environmental Protection Agency

Specify the funding source and/or cooperating organization(s) (e.g., National Cancer Institute, Ford Foundation, Eli Lilly & Company, South Western Oncology Group, Bureau of Prisons, etc.):

Add Related Grants

If applicable, please search for and select the OSPA Account number or Electronic Internal Approval Form (eIAF) # (notif #) associated with this IRB application using the "Add Related Grants" button.
If required by your funding agency, upload your grant using the "Grant/Contract Attachments" button.

Add Related Grants

Grant/Contract Attachments

The research involves use of Department of Defense (DoD) funding, military personnel, DoD facilities, or other DoD resources. (See DoD SOP and DoD Summary for details)

○ Yes ◉ No

Using the “attachments” button (below), attach applicable materials addressing the specific processes described in the DoD SOP.

DOD SOP Attachments

Additional Certification: (If your project is federally funded, your funding agency may request an Assurance/ Certification/Declaration of Exemption form.) Check the following if needed:

☐ Protection of Human Subjects Assurance/Certification/Declaration of Exemption (Formerly Optional Form – 310)

OTHER REVIEW COMMITTEES

0 unresolved comment(s)

If you check any of the below committees, additional materials may be required with your application submission.

Does your research fall under the purview of any of the other review committees listed below? [*If yes, check all that apply and attach applicable materials using the attachment button at the bottom of your screen.*]

○ Yes ◉ No

☐ Institutional Biosafety Committee
☐ Radiation Safety Committee
☐ Radioactive Drug Research Committee
☐ Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)
☐ Graduate Medical Education Committee (GME)
☐ Office of Medical Education (OME)

Additional Information

- Institutional Biosafety Committee (IBC)--Attach required IBC materials
- Radiation Safety Committee (RSC)-- For applicability, see instructions
- Radioactive Drug Research Committee (RDRC)--information
- Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)**--Attach MCC PRMC materials, if any, per instructions
- See requirement of Office of Medical Education (OME)
- See requirement of Graduate Medical Education Committee (GME)

Attachments

**** If your study involves cancer research, be sure to select "Cancer Research" in the "Research Attributes" section.** ORI will send your research protocol to the Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC). The MCC PRMC is responsible for determining whether the study meets the National Cancer Institute (NCI) definition of a clinical trial and for issuing documentation to you (the investigator) which confirms either that PRMC approval has been obtained or that PRMC review is not required. Your IRB application will be processed and reviewed independently from the PRMC review.

ADDITIONAL INFORMATION/MATERIALS

0 unresolved comment(s)

Do you want specific information inserted into your approval letter? ○ Yes ◉ No

Approval Letter Details:

If you wish to have specific language included in your approval letter (e.g., serial #, internal tracking identifier, etc…), type that language in the box below exactly as it should appear in the letter. The text you enter will automatically appear at the top of all approval letters, identical to how you typed it, until you update it. Don't include instructions or questions to ORI staff as those will appear in your approval letter. **If these details need to be changed for any reason, you are responsible for updating the content of this field.**

Protocol/Product Attachments - For each item checked, please attach the corresponding material.

- ☐ Detailed protocol
- ☐ Dept. of Health & Human Services (DHHS) approved protocol (such as NIH sponsored Cooperative Group Clinical Trial)
- ☐ Drug Documentation (e.g., Investigator Brochure; approved labeling; publication; FDA correspondence, etc.)
- ☐ Device Documentation (e.g., Manufacturer information; patient information packet; approved labeling; FDA correspondence, etc.)
- ☐ Other Documents

Protocol/Product Attachments

NOTE: Instructions for Dept. of Health & Human Services (DHHS)-approved protocol]

If you have password protected documents, that feature should be disabled prior to uploading to ensure access for IRB review.

Additional Materials:

If you have other materials you would like to include in your application for the IRB's consideration, please attach using the Attachments button below.

To view the materials currently attached to your application, click "All Attachments" on the left menu bar.

Attachments

Attach Type	File Name
AdditionInfoConsiderations	69567 ORI Screening Comments - Consent Cover Letter.pdf

SIGNATURES (ASSURANCES)

0 unresolved comment(s)

All IRB applications require additional assurances by a Department Chairperson or equivalent (DA), and when applicable, a Faculty Advisor or equivalent (FA). This signifies the acceptance of certain responsibilities and that the science is meritorious and deserving of conduct in humans. The person assigned as DA *should not* also be listed in the Study Personnel section, and the individual assigned as FA *should* be listed in the Study Personnel section.

For a list of responsibilities reflected by signing the Assurance Statement, refer to "What does the Department Chairperson's Assurance Statement on the IRB application mean?"

Required Signatures:

First Name	Last Name	Role	Department	Date Signed	
Donald	Helme	Department Authorization	Communication	06/30/2022 01:51 PM	View/Sign
Brandi	Frisby	Principal Investigator	School of Information Science	06/30/2022 12:51 PM	View/Sign

Department Authorization

☑ This is to certify that I have reviewed this research protocol and that I attest to the scientific validity and importance of this study; to the qualifications of the investigator(s) to conduct the project and their time available for the project; that facilities, equipment, and personnel are adequate to conduct the research; and that continued guidance will be provided as appropriate. When the principal investigator assumes a sponsor function, the investigator has been notified of the additional regulatory requirements of the sponsor and by signing the principal investigator Assurance Statement, confirms he/she can comply with them.

*If the Principal Investigator is also the Chairperson of the department, the Vice Chairperson or equivalent should complete the "Department Authorization".

**IF APPLICABLE FOR RELIANCE: I attest that the principal investigator has been notified of the regulatory requirements of both the Reviewing and Relying IRBs, according to the information provided in the E-IRB application. The attached Reliance Assurance Statement, signed by the principal investigator, confirms that he/she can comply with both sets of IRB requirements.

Principal Investigator's Assurance Statement

I understand the University of Kentucky's policies concerning research involving human subjects and I agree:

1. To comply with all IRB policies, decisions, conditions, and requirements;
2. To accept responsibility for the scientific and ethical conduct of this research study;
3. To obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent/assent form;
4. To report to the IRB in accord with IRB/IBC policy, any adverse event(s) and/or unanticipated problem(s) involving risks to subjects;
5. To complete, on request by the IRB for Full and Expedited studies, the Continuation/Final Review Forms;
6. To notify the Office of Sponsored Projects Administration (OSPA) and/or the IRB (when applicable) of the development of any financial interest not already disclosed;
7. Each individual listed as study personnel in this application has received the mandatory human research protections education (e.g., CITI);
8. Each individual listed as study personnel in this application possesses the necessary experience for conducting research activities in the role described for this research study.
9. To recognize and accept additional regulatory responsibilities if serving as both a sponsor and investigator for FDA regulated research.

☑ Furthermore, by checking this box, I also attest that:

- I have appropriate facilities and resources for conducting the study;
- I am aware of and take full responsibility for the accuracy of all materials submitted to the IRB for review;
- If applying for an exemption, I also certify that the only involvement of human subjects in this research study will be in the categories specified in the Protocol Type: Exemption Categories section.
- If applying for an Abbreviated Application (AA) to rely on an external IRB, I understand that certain items above (1, 3, 4, 7-8) may not apply, or may be altered due to external institutional/IRB policies. I document my agreement with the Principal Investigator Reliance Assurance Statement by digitally signing this application.

*You will be able to "sign" your assurance after you have sent your application for signatures (use Submission section). Please notify the personnel required for signing your IRB application after sending for signatures. Once all signatures have been recorded, you will need to return to this section to submit your application to ORI.

SUBMISSION INFORMATION

0 unresolved comment(s)

Each Section/Subsection in the menu on the left must have a checkmark beside it (except this Submission section) indicating the Section/Subsection has been completed. Otherwise your submission for IRB review and approval cannot be sent to the Office of Research Integrity/IRB.

If applicable, remember to update the Approval Letter Details text box under the Additional Information section

If your materials require review at a convened IRB meeting which you will be asked to attend, it will be scheduled on the next available agenda and you will receive a message to notify you of the date.

If you are making a change to an attachment, you need to delete the attachment, upload a highlighted version that contains the changes (use Document Type of "Highlighted Changes"), and a version that contains the changes without any highlights (use the appropriate Document Type for the item(s)). Do **not** delete approved attachments that are still in use.

Your protocol has been submitted.

	Document Type	File Loaded	Document Description	File Size	Modified By	Mod Date
	Stamped Consent Form	LectureSpeed_ori-f10355-cover-letter-surveyquestionnaire.pdf		0.112	rcvaug2	7/22/2022 1:20:05 PM
	ApprovalLetter	ApprovalLetter.pdf		0.100	rcvaug2	7/22/2022 1:20:05 PM
	CoverLetter	LectureSpeed_ori-f10355-cover-letter-surveyquestionnaire.pdf	Cover Letter	0.112	tkfr222	7/11/2022 9:36:49 AM
	ResearchProcedures	A Taxonomy of Sport Spectators.docx.pdf	Script	0.104	tkfr222	7/11/2022 9:17:40 AM
	AdditionInfoConsiderations	69567 ORI Screening Comments - Consent Cover Letter.pdf	ORI Screening Comments - Consent Cover Letter	0.095	DEH223	7/8/2022 11:49:56 AM
	DataCollection	Taxonomy_Quiz.docx.pdf	Quiz	0.066	bnfr223	6/27/2022 2:11:09 PM
	DataCollection	Sped Up Lectures Survey.pdf	survey	0.225	bnfr223	6/27/2022 2:10:59 PM

Protocol Changes

Protocol Number: 69567

Informed Consent RequestWaiverInformedConsent changed by tkfr222 on 7/11/2022 8:51:06 AM

~~Y~~N

Informed Consent WaiveIC changed by tkfr222 on 7/11/2022 8:51:06 AM

~~Y~~N

Informed Consent WaiveICInfoAfterStudy changed by tkfr222 on 7/11/2022 8:51:06 AM

~~Additional information will be available to students upon request.~~

Informed Consent WaiveICMinRisk changed by tkfr222 on 7/11/2022 8:51:06 AM

~~There is no more than minimal risk. Students will watch a video lecture and take a survey.~~

Informed Consent WaiveICPracticably changed by tkfr222 on 7/11/2022 8:51:06 AM

~~Students will watch a video lecture and take a survey.~~

Informed Consent WaiveICPrivateInformationSpecimens changed by tkfr222 on 7/11/2022 8:51:06 AM

~~No private or identifiable information will be collected.~~

Informed Consent WaiveICRights changed by tkfr222 on 7/11/2022 8:51:06 AM

~~The rights and welfare will not be adversely affected. Students will watch a video lecture and take a survey.~~

Informed Consent WaiverDocICOption2Justifya changed by tkfr222 on 7/11/2022 8:51:06 AM

The research presents no more than minimal risk. No identifying information will be collected that can tie participants' identities to their individual responses. Participants will provide data by interacting with their personal computers in a way that is analogous to their daily lives.

Informed Consent WaiverDocICOption2Justifyb changed by tkfr222 on 7/11/2022 8:51:06 AM

Students will watch a video lecture and take a survey. The cover letter will be on the computer where they will watch the video and complete the survey. We request that student participants consent electronically before participating.

PI Contact Information Degree changed by tkfr222 on 7/11/2022 8:45:52 AM

PhD

PI Contact Information Rank changed by tkfr222 on 7/11/2022 8:45:52 AM

Professor

Research Description Confidentiality changed by tkfr222 on 7/11/2022 9:13:55 AM

~~The data collected~~Participant anonymity will be protected, as there will be ~~ano~~nymous and confidential. No IP addresses will be collected and no identifying information will direct or identifying information relative to each participant within the survey. Upon the completion of data collection, the data will first be stored in the electronic survey engine (Qualtrics). Second, the data from the survey will be downloaded in aggregate form from the survey website and stored on a password-protected computer property of the primary investigator. After the data has been collected~~. Only the research team will have access to the data which will be stored in password protected UK owned computers~~, it may be deleted from the online database. Only the primary investigators, Brandi Frisby, T. Kody Frey, Leslie LeRoy, and Allyson DeVito, will have access to the data. The data, records, and materials will be maintained electronically for a minimum of six years following study closure.

Research Description InformedConsentProcess changed by tkfr222 on 7/11/2022 9:20:59 AM

The~~re will be no informed consent process. Students will read a cover letter and choose "I Agree to P~~ study will be conducted entirely online. All subjects will be prompted to review information about the study and be asked whether or not they agree to participate in the research by clicking a box next to their choice. The initial consent form will ensure that participants understand what they will be asked to do in the study. The consent form is written in language that is clear, concise, and free of jargon. Participants will be informed that participation is voluntary and that their responses are anonymous. Participants will also be informed that if they do not wish to participate~~", to continue to the study. Conversely, students may choose "~~hey may discontinue the survey at any time, with alternative opportunities for credit outlined in their respective course syllabus. At the end of the consent form, participants will be asked to indicate whether or not they consent to participate in the research study by clicking the appropriate button on the electronic form ("Yes, I consent to participate" or "No, I ~~D~~do ~~N~~not ~~Agree~~consent to ~~P~~participate~~" and will be exited from the study~~"). Because the entire study will take place online and consent will also be obtained online, a waiver for the documentation of consent has been submitted.

Research Description ResearchProcedures changed by tkfr222 on 7/11/2022 9:27:42 AM

After recruitment in CI SONA, students will follow a link to Qualtrics. Once there, they will read a cover letter where they agree to participate. Next, using the Qualtrics random assignment function, students will be put into one o~~-~~f 8 conditions and watch an introductory video (see here: https://youtu.be/1CDnFObW8rQ) that gives directions specific to their experimental group. The study will begin with students watching a 15 minute pre-recorded lecture which will be embedded in the survey (see attached scripts for videos) to simulate online asynchronous course delivery. After the lecture has ended, they will take the survey in response to the experimental condition they were a part of. ¶
Conditions ¶
Condition 1: Normal speed, no notetaking, no organizational cues ¶
2: normal speed, yes notetaking, no organizational cues ¶
3: normal speed, no notetaking, yes organizational cues ¶
4: normal speed, yes notetaking, yes organizational cues ¶
5: sped up video, no notetaking, no organizational cues ¶
6: sped up video, no notetaking, yes organizational cues ¶
7: sped up video, yes notetaking, no organizational cues ¶
8: sped up video, yes notetaking, yes organizational cues

Research Description SafetyPrecautions changed by tkfr222 on 7/11/2022 9:15:52 AM

Students will complete the research from their own devices in a location of their choosing ensuring privacy and ~~confidential~~anonymity. No identifying information will be collected. Data will be stored electronically in Qualtrics and maintained for a minimum of 6 years. The data will be included in submissions for publication/conferences; however no individual or identifying data will be included. The following statement will be included on the cover letter: ¶
~~"While the researchers~~ ¶
"Please be aware, wh~~ill t~~e we make every effort to ~~protect your information once it is~~safeguard your data once received from the ~~data gathering/~~online survey ~~¶~~
company, given the nature of online surveys, as with ~~ever~~anything ~~else on~~involving the Internet, we can~~not~~ never guarantee the confidentiality of the ~~¶~~
data while ~~it remains in the company's servers or is in route to either them or us. Depending on the company's Terms of Service and ¶ Privacy policies, it is also possible that the raw data collected for research purposes may be used for reporting or marketing once the ¶ research has concluded~~still on the survey company's servers, or while en route to either them or us."

Research Description StudyDesign changed by tkfr222 on 7/11/2022 9:27:42 AM

This study is a post-test only randomized experiment with 8 conditions.¶
We are seeking to better understand how watching video lectures at different speed influences both comprehension and affect. Additionally, we want to know more about the role that note taking and organizational cues by the instructor impact students' experiences in conjunction with the video speed. Students will be recruited through the CI SONA research pool. From there, participants will be redirected to a survey via Qualtrics, where they will be electronically provide consent to participate. Following consent, they will be randomly assigned to watch one of eight videos: ¶
¶
1: Normal speed, no notetaking, no organizational cues ¶
2: normal speed, yes notetaking, no organizational cues ¶
3: normal speed, no notetaking, yes organizational cues ¶
4: normal speed, yes notetaking, yes organizational cues ¶
5: sped up video, no notetaking, no organizational cues ¶
6: sped up video, no notetaking, yes organizational cues ¶
7: sped up video, yes notetaking, no organizational cues ¶
8: sped up video, yes notetaking, yes organizational cues ¶
¶
After watching the video, they will take a short, 10 question quiz based on the content they watched. Their credit is not determined by their performance on the quiz. Finally, after completing the quiz, students will answer several questions about their perceptions of the video, affect for the content and the instructor, cognitive load, social presence, sustained attention, and demographic information.There is no deception involved. It is not community based participatory research. A research repository will not be established.

Research Description SubjectRecruitmentMethods changed by tkfr222 on 7/11/2022 9:27:42 AM

Subjects will be recruited using the CI SONA recruitment pool. The system will inform students of the opportunities to participate in research for 1 credit hour (~approximately 30 minutes long). Students will also be able to view other studies or the alternatives. If students agree to participate, they will follow the link to the research study where they read the cover letter and choose whether to participate in the study. Because the CI SONA system collects student names to award credit, and not the investigators, the responses will remain ~~confidential~~anonymous. The CI SONA system will award credit a the completion of the study.

Study Personnel Changes:

No Changes

There are no recorded changes to study personnel.

Protocol Type Comment by Terrell Frey - PI to PI on 7/11/2022 8:53:57 AM

Thank you, Daniel!

Protocol Type Comment by Daniel Ehrlich - ORI to PI on 7/8/2022 11:53:55 AM

Select "All Comments" from the left-hand sidebar to see all of the pre-review screening comments from ORI staff.

PLEASE NOTE: The IRB has not yet seen your application.
- The feedback provided at this time is a result of the initial screening process, conducted by ORI staff, to make sure the application is ready for IRB review.
- Once you address the screening requests and the application appears to be ready, it will be forwarded to the IRB for review.
- The IRB may request additional revisions and/or clarification at that time.
** If you have any questions regarding these comments, please do not hesitate to contact me by email at daniel.ehrlich@uky.edu or by phone at 859.257.1639.

PI Contact Information Comment by Terrell Frey - PI to PI on 7/11/2022 8:46:03 AM

Completed - thank you.

PI Contact Information Comment by Daniel Ehrlich - ORI to PI on 7/8/2022 11:06:03 AM

Please complete the rank and degree fields.

Research Description Comment by Daniel Ehrlich - ORI to IRB/PI on 7/15/2022 4:15:42 PM

Subject Recruitment Methods & Privacy:
You write that "Because the CI SONA system collects student names to award credit, and not the investigators, the responses will remain confidential". Since no identifying information will be associated with survey responses, you should indicate that responses will be anonymous rather than confidential.

Research Description Comment by Daniel Ehrlich - ORI to IRB/PI on 7/15/2022 4:10:22 PM

Study Design:
Please discuss the experiment and its conditions in more detail here.

Research Description Comment by Terrell Frey - PI to PI on 7/11/2022 9:33:53 AM

Study Design: Thank you for the comment. Additional details were provided about the study, including the electronic consent process, the randomization into 1 of 8 video conditions, the use of the same video throughout each condition, and the nature of the questions asked to participants after they watch the video.

Research Description Comment by Terrell Frey - PI to PI on 7/11/2022 9:31:15 AM

Subject Recruitment Methods & Privacy: This language was updated. Thank you!

Research Description Comment by Terrell Frey - PI to PI on 7/11/2022 9:30:55 AM

Informed Consent Process: Detailed information was added about the informed consent process. The section describes how consent

will be obtained electronically before participants advance any further into the survey.

Research Description Comment by Terrell Frey - PI to PI on 7/11/2022 9:29:39 AM

Research Procedures: The script was reuploaded as PDF file. We have confirmed it opens properly when downloaded.

Research Description Comment by Terrell Frey - PI to PI on 7/11/2022 9:29:02 AM

Safety Precautions: Thank you for this feedback! This section was updated to remain consistent with the cover letter.

Research Description Comment by Terrell Frey - PI to PI on 7/11/2022 9:28:32 AM

Confidentiality:

The protocol was updated to better reflect the anonymity of the survey. A statement was also added to reflect the intention to retain the information for the 6-year minimum period.

Research Description Comment by Daniel Ehrlich - ORI to PI on 7/8/2022 11:53:03 AM

Confidentiality:
1. Instead of stating that the data collected will be both anonymous and confidential, you should only state that it is anonymous. Confidentiality presupposes that participant's data are linked to their identity somehow.
2. Please confirm that you will retain research data and IRB-related materials and records for a minimum of 6 years after the IRB-approval period.

Research Description Comment by Daniel Ehrlich - ORI to PI on 7/8/2022 11:47:31 AM

Safety Precautions: Please seem my notes on your consent document, uploaded as a separate attachment to this protocol (select All Attachments from the left-hand sidebar and select the ORI Screening Comments file), regarding the data privacy language you quote here.

Research Description Comment by Daniel Ehrlich - ORI to PI on 7/8/2022 11:27:15 AM

Research Procedures:
I am unable to open the video script document. Attempts to open it lead to an error message indicating "unreadable content". Please remove and replace this document, verifying that the file still works after you upload it.

Research Description Comment by Daniel Ehrlich - ORI to PI on 7/8/2022 11:23:38 AM

Informed Consent Process:
You state that "There will be no informed consent process". However reading the cover letter and indicating agreement to participate is a consent process: participants are given information in the cover letter they need to make an informed decision and are asked to give their informed consent (via survey question) before participating.

Informed Consent Comment by Daniel Ehrlich - ORI to IRB/PI on 7/15/2022 4:09:36 PM

Consent Cover Letter:
I have made comments directly on the PDF of your consent document. You can find this under “All Attachments” in the left sidebar. The file will have the phrase Screening Comments in the name/description. If you have problems viewing those comments please contact me directly at daniel.ehrlich@uky.edu or 859-257-1639.

Informed Consent Comment by Daniel Ehrlich - ORI to IRB/PI on 7/15/2022 4:08:31 PM

Informed Consent / Waiver of Informed Consent Process
1. For survey research, the IRB is not likely to approve your request for a waiver of the full informed consent process. In order for them to approve this waiver you would have to demonstrate that, per section 2c, "the research could not practicably be carried out without the requested waiver". Recommended that you uncheck the box to request this waiver.
- NOTE: The second waiver request (for Waiver of Documentation of Informed Consent) *is* appropriate, since this is only asking for the requirement for a written signature to be waived. Consent should still be obtained, however, in some other manner (e.g., indicating consent on in the online survey).
2. • In your Waiver of Documentation of Informed Consent request, under Option 2, part (a), please provide a brief explanation of why participating in your study poses no more than minimal risk to subjects. For instance, indicate if any of the following are the case: study is anonymous (no identifying information is collected); study does not ask about sensitive topics; if accidentally disclosed (e.g. data is hacked/stolen), responses could not put subject at risk of criminal or civil liability, harm to professional or personal reputation, etc

Informed Consent Comment by Terrell Frey - PI to PI on 7/11/2022 9:07:22 AM

Consent Cover Letter: Thank you for the recommendations on the PDF file. The required changes have been made to the cover letter to align with the request of documentation of informed consent.

Informed Consent Comment by Terrell Frey - PI to PI on 7/11/2022 8:53:34 AM

Thank you for your comments, Daniel. First, the box for the waiver of informed consent has been unchecked. We are only requesting a waiver of documentation of consent, as we expect students to consent electronically. Second, we have updated responses to questions 2a and 2b. Specifically, we have noted that the study presents minimal risk because students' responses will not be tied to their identities and they will be interacting with the survey in a manner that is not different from what they might do in their daily lives. Further, we added a statement requesting that we obtain consent from students electronically.