Principal Investigator Submission Checklist

This checklist is designed to ensure all basic requirements have been included as part of your IRB submission. Applications/Protocols without the following will be returned without review. Reminder: As studies vary greatly in topics and methodologies, the IRB reserves the right to request additional information or clarifications as required.

Mark/Address all items

Reminder: Faculty Advisors must review and confirm the application is complete before submitting the application to the IRB for review.	
☐ **Yes** ☒ **No**	Does the research involve interaction with a vulnerable population i.e. Children, Prisoners, Pregnant Women? If yes, complete the applicable addendum to the application available at IRB website.
☒ **Yes** ☐ **No**	I have read and understand the IRB Researcher Manual for IRB Submission.
☐ **Yes** ☒ **No**	Will any of the researchers be non-UCCS personnel? If Yes, please contact the IRB (irb@uccs.edu) to discuss the role of the non-UCCS researcher.
☒ **Yes** ☐ **No**	Does the research involve employees of the PI or Co-PI as research participants; or is the PI or Co-PI recruiting students of classes they currently teach as research participants?
☒ **Yes** ☐ **No**	The correct and most up-to-date application and templates from the IRB website have been used.
☒ **Yes** ☐ **No**	Did you attach the Consent/Assent Forms using the IRB template?
☒ **Yes** ☐ **No**	All study-specific supporting documents are included with the application. Examples may include (but not limited to) final copies of surveys, questionnaires, interview questions, recruitment scripts, flyers, letters of access, etc.)
☐ **Yes** ☒ **No**	Does the study involve a local school district? If yes, please click here for a list of school district contacts to ensure all district requirements are met prior to initiating your research study.
☐ **Yes** ☒ **No**	Does the study involve international research? If yes, review the international research SOP and complete the applicable addendum to the application available at IRB website.
Reminder	All students must route applications to their Faculty Advisor for Approval and submission. Applications that contain typos and/or grammatical errors that make the application difficult to review may be returned without review.

Version: 1.18.2018

For IRB Use Only

IRB# 19-079 Date Received V2 12-20-18 Date Approved 12-21-18
CITI Verified KK 12-3-18 Reviewer & date sent to reviewer ZV 12-20-18

UNIVERSITY OF COLORADO COLORADO SPRINGS
INSTITUTIONAL REVIEW BOARD (IRB) for Human Subjects

REQUEST FOR IRB REVIEW

APPROVED

Review application deadlines and meeting dates, listed at the beginning of each semester on the IRB meeting, which is available here.

PLEASE NOTE: IRB CITI Training is required for all **personnel** including PIs and Co-PIs involved in human subjects research. Faculty Advisors must complete the training before submitting a protocol for review. **All** student requests for review must be submitted by a Faculty Advisor; via email and IRB CITI training must be complete **PRIOR TO IRB REVIEW**. If you do not provide the Completion Report Number (located at the top of the Completion Report) and the date of your most recent training, **YOUR APPLICATION MAY BE RETURNED TO YOU WITHOUT IRB REVIEW**.

Follow the instructions to complete the required IRB training.

The level of review is determined by the IRB.

Inclusion of Application Addendums:

Check ALL pertinant application addendums that are attached:

☐ Research Involving Children ☐ Research Involving International Research	☐ Research Involving Pregnant Women, Human Fetuses, and Neonates ☐ Research Involving Prisoners

Pre-Approvals:

Will you collect or work with human blood, body fluids or tissues? (IBC approval must be obtained **before** the IRB review.) Information about the IBC can be found here.

Yes ☐ (If Yes, submit a copy of the IBC approval with your application) No ☒

A. STUDY TITLE: *Discovering and Decoding Sex Education at the Collegiate Level: How Sex Education Shapes Sexual Identity and Expression*

B. PROPOSED DATE: From *December 17, 2018*

Note- Research may not start until the IRB has provided a letter of approval.

C. PRINCIPAL INVESTIGATOR:

Name: *Ally Moseley*

IRB Training Completion Number: *6940810* Most recent IRB Training Date: *December 2, 2018*

Check one: ☐ UCCS Faculty/Staff ☒ Current UCCS Student*

Department, Center, or Institute: *Sociology and Women's and Ethnic Studies, University of Colorado Colorado Springs*

Mailing Address: *1195 Magnolia St. Apt 307, CO 80907*

Phone: *334-470-7224* UCCS email address: *amoseley@uccs.edu*

D. CO-PRINCIPAL INVESTIGATOR:

(Submit additional sheets if necessary) If additional sheets are included, check the box ☐

Name: _____

IRB Training Completion Number: _____ Most recent IRB Training Date: _____

Check one: ☐ UCCS Faculty/Staff ☐ Current UCCS Student*

☐ Non-UCCS Personnel (Note: Non-UCCS personnel must be approved by the IRB). If checked, explain role of Non-UCCS personnel: _____

Department, Center, or Institute: _____

Mailing Address: _____

Phone: _____ UCCS email address: _____

E. ADDITIONAL PERSONNEL INVOLVED WITH HUMAN SUBJECTS:

(Submit additional sheets if necessary) If additional sheets are included, check the box ☐

CITI training is required for all personnel involved in the research.

1. Name: _____

   IRB Training Completion Number: _____ Most recent IRB Training Date: _____

   Check one: ☐ UCCS Faculty/Staff ☐ Current UCCS Student*

☐ Non-UCCS Personnel (Note: Non-UCCS personnel must be approved by the IRB). If checked, explain role of Non-UCCS personnel: _____

2. Name: _____

IRB Training Completion Number: _____ Most recent IRB Training Date: _____

Check one: ☐ UCCS Faculty/Staff ☐ Current UCCS Student*

☐ Non-UCCS Personnel (Note: Non-UCCS personnel must be approved by the IRB). If checked, explain role of Non-UCCS personnel: _____

F. * FACULTY ADVISOR (REQUIRED FOR ALL STUDENTS):

Name: *Tre Wentling*

IRB Training Completion Number: *27577488* Most recent IRB Training Date: *June 20, 2018*

Department, Center, or Institute: *Women's and Ethnic Studies, University of Colorado Colorado Springs*

Phone: *719-255-8187* UCCS email address: *twentlin@uccs.edu*

G. HAVE YOU APPLIED FOR/OR RECEIVED EXTERNAL (outside of UCCS) FUNDING FOR THIS STUDY?

☐ Yes ☒ No If yes, answer 1 below:

1. STATUS OF EXTERNAL FUNDING FOR THIS STUDY:
☐ Pending/Under Review ☐ Received** ☐ Not Awarded

Is the proposal for funding attached? ☐ Yes ☐ No (Note: If the proposal for funding is not provided the, protocol may be returned as not reviewed.)

Name of Sponsor _____ and Proposal Title _____

**If received, provide the following information:

Speed type _____ or OSP Proposal Number _____

(For assistance, contact the Office of Sponsored Programs and Research Integrity at X3321 or email osp@uccs.edu)

2. Is the study supported by an NIH award?

☐ Yes ☒ No If yes, answer questions a and b below. If no, proceed to Section H.

a. Does the protocol meet **ALL** of the following criteria?

☐ Yes ☐ No If yes, procedue to question b. If no, proceed to Section H.

I. The study involves human participants.

II. The participants are prospectively assigned to an intervention.

III. The study is designed to evaluate the effect of the intervention on the participants.

IV. The study effect is evaluating a health-related biomedical or behavioral outcome.

b. Attach Form E from the NIH proposal (Note: If Form E is not provided, the protocol may be returned as not reviewed).

c. Due to qualifying as an NIH funded clinical trial, Good Clinical Practice (GCP) training is required for all PIs, Faculty Advisors, and personnel listed on the protocol. Please complete the following, including the Completion Report Number and date of most recent training. The training is available through CITI at www.citiprogram.org. Additional information can be found on the UCCS GCP webpage.

Good Clinical Practice Training *Attach additional page(s) if needed		
Name(s)	GCP CITI Completion #	GCP Training date
Example: John Doe	*1234567*	*1/1/13*

H. PLEASE ANSWER THE FOLLOWING RESEARCH SUMMARY QUESTIONS BELOW (ADDITIONAL INFORMATION AND INSTRUCTIONS REGARDING HOW TO COMPLETE THE RESEARCH SUMMARY MAY BE FOUND HERE.)

1. Purpose/Significance:

Provide a brief background and describe the major research question/s of the proposed study in language that can be understood by an individual outside your discipline:

This exploratory research project, "Discovering and Decoding Sex Education at the Collegiate Level: How Sex Education Shapes Sexual Identity and Expression," investigates the influence of high school sex education curriculum on the development of sexual identity among currently enrolled college/university students. Sex education, as a U.S. national educational priority, began at the end of the 19th century and has continued into the 21st albeit not without controversy about its value-added, curricular content, and un/intended effects. Changes in federal funding between 2006 and 2013 has both reduced the number of schools that offer formal sex education and reformed the very curriculum content of sex education. Among the public schools that received funding, much of the curriculum during this time period specifically focused on abstinence only until marriage (Hall et al., 2016). In more recent years, sex education funding has seen an increase and is changing to offer curriculum inspired by medically accurate sexual health information that provides information regarding birth control and self-health (Hall et al., 2016). Ultimately, formal sex education is unevenly implemented as the U.S. education system is organized at multiple levels of governance (e.g., state, districts, and school boards) as well as divided by private and public monies. Such fragmentation shapes implementation, content of the curriculum, and devotion of resources to formal sex education. This exploratory project will investigate these large-scale changes to formal

sex education and their impact on the development of sexuality (e.g., identity, expression and behavior).
Research shows inequities in who is exposed to formal sex education (e.g., boys vs girls, rural vs urban, etc.) as well as the content (Hall et al. 2016). Evidence also suggests that formal sex education that has "rights-based content, positive, youth-centered messages, and use of interactive, participatory learning and skill building are effective in empowering adolescents with the knowledge and tools required for healthy sexual decision-making and behaviors" (Hall et al., 2016:3-4). The internet has likely played a significant role as an outside source that informs understanding sex and sexuality (Lindberg et al. 2016). Thus, the proposed research seeks to identify differences of formal sex education, both exposure and content, in order to better understand the resulting impact(s) on the development of sexuality.

Due to the gaps in formal sex education curriculum, the following broad research questions guide this exploratory project: 1.) how did currently enrolled college/university students learn about sex during high school; 2.) what external sources did they use to educate themselves regarding sex; 3.) how did these sources combined influence the development of sexuality; and 4.) what differences emerge according to gender, geography, and years of high school attendance?

The proposed exploratory research is important as it responds to questions concerning differential exposure and content of sex education and its impact on identity, behavior, and practice. This exploratory research will identify how current college/university students learned about sexuality during high school, which may support initiatives that rely on digital technologies to provide sex education pertinent to the healthy development of sexuality. It also has the potential to inform sex education programing focused on college/university students.

Hall, Kelli Stidham et al. 2016. "The State of Sex Education in the United States." Journal of Adolescent Health. 56(6): 595-597.

2. Methodology (Answer all questions):

a. Describe, in narrative format, the research design (descriptions of methods) and list procedures to be used: *Qualitative method is most appropriate to better understand how currently enrolled college/university students learned about sexuality during their high school years. Semi-structured interviews will consist of open-ended questions that cover five-content modules (Appendix A). Interviews will invite participants to share stories regarding their experiences and exposure to sex education in both formal and informal settings; the development of gender and sexuality identities; as well as broader demographic variables. All interviewees will receive a consent form before the interview that states the project's overall aim and the list of potential risks and benefits to study participation (Appendix B). The location and time of each interview will be mutually determined by each participant and Moseley, with attention to privacy and comfort as interview questions pertain to sex education and sexuality. With interview participants consent, all interviews will be audio recorded for the purposes of transcription and analysis. Once transcribed, interviews will be uploaded into NVIVO (qualitative software) for coding and analysis.*

i. Check ALL of the different procedures planned for this study:

☐Records review	☒Audiotaping / videotaping
☐Questionnaires / surveys	☐Social or behavioral intervention
☒Interviews	☐Behavioral observation
	☐Other: _____

b. Participant Recruitment:

i. Describe from where the participant population will be drawn; include when, where, and how potential participants will be recruited: *To be eligible, participants must be 18 years and older, as well as currently enrolled as an undergraduate student at UCCS. UCCS is an ideal institution as both traditional and nontraditional aged students are active college/university campus citizens. Beginning with a convenience sample of interested students, participants will be encouraged to share the research project with other students thus relying on the snowball recruitment method. Recruitment will begin immediately after IRB approval and end once 12 interviews have been completed on or by March 1, 2019.*

ii. Estimated number of participants to be enrolled: *12*

iii. Describe how participants will be *selected* and *rationale* for the selection criteria: *Interviewees will consist of six traditional students and six nontraditional students. For the purposes of this exploratory research, traditional students include those who attended high school between 2014–2018 and nontraditional students are those who attended high school 2006-2010. More, both groups will attend to gender such that each has equal number of students identified as women, men, and nonbinary.*

iv. Will participants be placed into groups? ☐ Yes ☒ No If "Yes", please describe: _____

v. Does your research involve any of the following populations? Address all that apply:

Indicate the age of the participants you plan to use	Total Number of Participants	Number of Expected Male Participants (If applicable)	Number of Expected Female Participants (If applicable)
☐ **Neonates 30 days or less**			
☐ **Children 31 days - 18**			
☒ **Adults 18-65**	*12*		
☐ **Adults over 65**			

vi. Does the research involve any of the following populations? Check all that apply:

☐ Cognitively impaired	☐ Prisoners*
☐ Educationally disadvantaged individuals	☐ Placental/fetus tissue
	☐ Pregnant Women/fetuses*
	☐ Neonates (non-viable/uncertain viability)*

☐ Economically disadvantaged individuals ☐ Subjects who are supervised by or are students of the investigator ☐ Non-English speaking individuals ☐ Active duty military/Veterans	☐ Children under the age of 18* ☐ People living outside the United States* ☐ People living in Native Peoples Tribal Communities** ☒ **Research involves NONE of the populations listed**

*** If your research targets/focuses on a population with an asterisk, please complete the applicable addendum to the application. Addendums are available on the IRB website.**

**** If your research involves Native Peoples Tribal Communities, approval from the Tribal Chief will be required.**

vii. Will the following items be used to identify and/or recruit potential participants?

- Paper files (e.g., school or medical records) ☐ Yes ☒ No
- Electronic files (e.g., school or medical records) ☐ Yes ☒ No
- Other records ☐ Yes ☒ No
  If "Yes", describe: _____
- Flyers/brochures ☐ Yes ☒ No
- Web postings ☐ Yes ☒ No
  If "Yes", what companies: _____
- Advertising company ☐ Yes ☒ No
  If "Yes", what companies: _____
- Letters/Emails/Tweets ☐ Yes ☒ No
- Recruit students in your current courses ☐ Yes ☒ No
- Recruit employees supervised ☐ Yes ☒ No
- Other ☐ Yes ☒ No
  If "Yes", describe:_____

viii. List all recruitment materials used in this study. Recruitment materials must be submitted as attachments and approved by the IRB in their final form, including graphical elements, before the study can be implemented.

Document Name	Description
1:	
2:	
3:	
4:	
5:	

(**Submit additional sheets, if necessary**) If additional sheets are included, check the box ☐

ix. Describe how coercion or perceived coercion of research participants will be avoided for all research populations (i.e. provide detail regarding subjects who are students of or supervised by the investigator): *Participation is completely voluntarily, however all interviewees will receive a $15 gift card. In addition to participant reading the written consent form, Moseley will remind interviewees at the beginning of the interview and then again at*

least once during the interview that participant can end interview or request certain interview answers to be removed from the study without penalty. Compensation is guaranteed regardless if participant completes interview. These efforts aim to remove any and all perceived or actual coercion.

Coercion – When an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance. For example, if an investigator tells a student that non-participation in their study could affect their grade.

**Please note, if your research involves a vulnerable population (prisoners, children under 18, or pregnant women) your protocol may need to be reviewed at a full board meeting. Please click here for IRB meeting dates and protocol submission deadlines.*

x. How will participants be involved? Include information for each procedure that will be used: *Participants will be given a written consent form prior to the start of the interview and with consent, interviews will be audio recorded for purposes of transcription and analysis.*

c. List ALL materials used in the research that will be shared with research participants (Marketing material is addressed question H.2.c.viii above. Items must be submitted as attachments and approved by the IRB in their final form. (e.g. surveys, questionnaires, images, instructions, debriefing, etc.)

Document Name	Description
1:*UCCS IRB Consent Form*	*Consent form to gain written concent from participants*
2:*Interview guide*	*Semi-structed, interview guide*
3:	
4:	
5:	

(Submit additional sheets, if necessary) If additional sheets are included, check the box ☐

d. Does this protocol involve the use of medical equipment (i.e. X-rays, PET Scans, MRI, etc.)?

☐ Yes (If Yes, provide information in the box below.) ☒ No (If No, proceed to 2e)

Name of medical equipment used	**Describe how the equipment will be used**	**Describe any known risks/safety concerns (if unknown, mark N/A)**
1:		
2:		
3:		
4:		
5:		

(**Submit additional sheets, if necessary**) If additional sheets are included, check the box ☐

e. Will existing or archived data, documents, records, or biological specimens be used?

Existing - Data, which have been collected for purposes other than the proposed research and are on the shelf at the time of this application.

☐ Yes (If Yes, answer i. and ii.) ☒ No (If No, proceed to 2f)

i. Is the source publicly available? ☐ Yes ☐ No (If Yes, describe the source: _____)

ii. Is the information recorded in such a manner that subjects can be identified, directly or through identifying links? ☐ Yes ☐ No

f. Will you be conducting surveys (online or in person), interviews, OR tests; and/or observations of public behavior?

Public Behavior – Behavior generally open to view by any member of a community and/or which would not involve any special permission to observe (i.e., no reasonable expectation of privacy by those being observed), such as, at a park, in a mall, at a movie theater, etc. What occurs in a classroom would not generally be considered observation of public behavior.

☒ Yes (If Yes, answer i, ii, iii, iv, and v.) ☐ No (If No, proceed to the next section)

i. Is the information recorded in such a manner that subjects can be identified, directly or indirectly or through identifiers linked to the subject? ☐ Yes ☒ No

ii. Would the disclosure of subjects' responses outside the research place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation? ☐ Yes ☒ No (If yes, describe: _____)

iii. Is the research an observation of public behavior? ☐ Yes ☒ No
(If yes, describe the setting: _____)

iv. Will you or any researcher participate in the activities being observed? ☐ Yes ☒ No (If yes, describe how you will participate: _____)

v. Is the research conducting in person interviews? ☒ Yes ☐ No (If yes, describe the setting in which the interviews will take place: *Variable settings as site will be mutually determined by each participant and Moseley. Setting must enable both privacy and sense of safety for both participants and Moseley*)

3. Research Setting: Provide information about each research site (including sites/people/organizations providing existing data) that will be included in this research study. You may be required to obtain a letter of access/permission to access the site before IRB review may be complete. Recruiting on campus typically will not require a letter of access, but you may need to get campus approval for using campus space for research activities.

Note: *If data collection will be performed through an online website (e.g., survey monkey), please include the website as the research site, and rather than permission, indicate that the terms of service of the website allow research to be performed.*

Site #1 (If applicable)

Site/Organization Name	*University of Colorado Colorado Springs*
Site/Organization Description	*research and teaching university*
Location (* if international or on Tribal Land additional approvals may be required)	
Contact Person	*Ally Moseley*
Contact Person Email/Phone #	*719-255-8187 (Dr. Tre Wentling phone)*
Site will be used for (select all that apply):	☒ Recruitment ☒ Data collection ☒ Consenting participants ☐ Existing Data ☐ Other (describe)
If a site other than UCCS, have you received permission from this site for this research study? (If	☐ Yes ☐ No (describe status)

"Yes", attach a letter of access stating what access is being provided for to you to conduct the research as stated in your protocol. The letter should also list any restrictions (e.g., time frame, types of classes, etc.)).	

Site #2 (If applicable)

Site/Organization Name	
Site/Organization Description	
Location (* if international or on Tribal Land additional approvals may be required)	
Contact Person	
Contact Person Email/Phone #	
Site will be used for (select all that apply):	☐ Recruitment ☐ Data collection ☐ Consenting participants ☐ Existing Data ☐ Other (describe)
If a site other than UCCS, have you received permission from this site for this research study? (If "Yes", attach a letter of access stating what access is being provided for to you to conduct the research as stated in your protocol. The letter should also list any restrictions (e.g., time frame, types of classes, etc.)).	☐ Yes ☐ No (describe status)

(**Submit additional sheets, if necessary**) If additional sheets are included, check the box ☐

4. <u>Risks/Benefits</u>:

a. Describe all benefits of the research (benefits to individual participants, society, and/or science). If none, state "none" in the space provided and in the consent form: *<u>The benefits of this research are multiple. First, participants are invited to share their experiences related to a topic that is often not talked about in open and affirming ways. Participants can openly discuss what is considered taboo in a safe, nonjudgmental environment, which allows them to be reflective regarding their educational journey and identity development. Second, this exploratory research opportunistically responds to a gap in understanding how young people learn about sex and its impact on their behavior and identity especially since federally funding shifted to abstinence only until marriage curriculum. Third, research outcomes may identify specific needs of college/university students and influence university-based programmatic initiatives focused on sex education and sexuality. Finally, one direct benefit includes participant compensation, which</u>*

will be provided by the funding source, 2018-2019 LAS Student-Faculty Research/Creative Works Grant.

b. Describe all risks (e.g. physical, mental, emotional, and/or legal) to the participants. The risks must be disclosed in the consent form. Include in the response all potential risks. **All studies entail at least some risk (e.g. annoyance, frustration)**: *Participation in this study carries a limited amount of emotional, mental and legal risk. For example, some questions may cause discomfort especially if previous interactions and experiences related to sex education and sexuality includes sexual harassment and/or assault. Depending on the severity of previous experiences, whether shared or not, some participants might experience a trigger. Finally, legal risk concerns any experiences shared that follow UCCS mandatory reporting procedures such as in the cases of sexual assault, child abuse, self-harm or harm of others.*

c. Describe how the risks are reasonable in relation to anticipated benefits: *Participation risks are reasonable and limited as very few questions pertain to any activity that might inspire discomfort, distress, or sharing information that needs to be reported. One important benefit that outweighs risk is talking about sex with someone who is non-judgmental and with whom the participant has no previous relationship to. As well, such reflection regarding experiences with sex education and a formal education system may facilitate understanding their own identity more clearly.*

d. Describe safeguards (e.g., medical consultation, counseling, etc.) that will be taken to protect participants' rights, welfare, and reduce risks: *Important safeguards that will be taken to protect participants' rights, welfare, and reduce risks include reminding participants about the voluntary nature of their participation and especially that they can stop at any point without penalty. Participants will be told that Moseley is a mandatory reporter and informed on what information constitutes the legal mandate to report the information to the Title IX Coordinator/Office of Institutional Equity. Another safeguard includes selecting a location that both the interviewee and Moseley decide offer comfort, privacy, and sense of safety. Throughout the interview, Moseley will pay close attention to interviewees' verbal and nonverbal cues that suggest extreme discomfort. In those cases, Moseley will stop the interview to check-in with the participant to ask if interviewee would like a break or if interviewee prefer to end the interview. In such cases, Moseley will also encourage interviewees to contact the UCCS Mental Health Services center and provide information for direct counseling services, including an appointment (719-255-4444). For interviewees who might prefer an off-campus reference, Moseley will also provide contact information to AspenPointe Mental Health Crisis Line (719-635-7000).*

5. Informed Consent: Use the informed consent template located on the OSPRI webpage, and send your consent form as a Word document along with your IRB application.

a. Are you requesting a waiver of written documentation of informed consent? ☐ Yes ☒ No (i.e., a signature or acknowledgement of reading the consent via electronically moving to the next screen of an online survey)

If "Yes", complete the following **two** questions if you are requesting a waiver of documentation of informed consent:

1. Describe how the waiver of written documentation will not adversely affect the rights and welfare of the research participants:_____
2. Describe why the research could not be carried out without the waiver:_____

Note: *(45 CFR 46.117 (c) (1 or 2) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:*

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

b. Are you requesting an alteration of informed consent? ☐ Yes ☒ No
(i.e., no consent, consent is altered to omit certain required elements)

If "Yes", complete the following **two** questions if you are requesting an alteration or waiver of informed consent:

1. Describe how the alteration of informed consent will not adversely affect the rights and welfare of the research participants:_____

2. Describe why the research could not be carried out without the waiver:_____

Note: *With sufficient justification, the IRB may approve a consent process that does not include or alters some or all of the elements of informed consent, provided that it finds and documents specific requirements. If requesting an alteration of consent, justify such in accordance with the criteria established under 45 CFR 46.116(d)(1-4) [waiver of consent] or 45 CRF 46.117(c)(1 or 2) [waiver signature]*

c. Describe the consent process, including who will be obtaining consent? *Moseley will provide the IRB consent form to individuals at the start of every interview. Participant will be asked to agree or disagree to the audio recording of the entire interview. All signed consent forms will be stored in Wentling's filing cabinet, which is secured by a key-lock and located in Wentling's UCCS campus office.*

d. Describe the time commitment to participate: *Interviews are estimated to last between 60-90 minutes.*

e. Will research participants be offered compensation for participating in the research?
☒ Yes ☐ No

If "Yes", describe the nature of the compensation. Provide dollar value and schedule of payment (Include compensation amount in the informed consent form): *$15.00 Amazon gift card given to participant once interview concludes; this includes if participant stops interview prior to the last intended interview question (Appendix B).*

Compensation will come from the 2018-2019 LAS Student-Faculty Research/Creative Works Grant that Moseley/Wentling have been awarded.

f. For research involving minors, describe how assent will be obtained, whether parental permission will be obtained, whether permission will be obtained from one or both parents (if not both parents describe why, i.e. deceased, unknown, etc.): *Not Applicable*

g. Describe any plans to share results of the research with participants: *For interested participants, Moseley will share results that are prepared/ready for publication. Moreover, appropriate university stakeholders will receive an executive like-report with relevant information that might influence programmatic events focused on sex education for college/university students.*

6. Data Monitoring:

a. Describe where the data will be stored, who will have access to the data, and measures taken to secure the data. Include procedures for maintaining participant confidentiality (for any hardcopy data, CD, tapes, specimens, etc., describe any physical safeguards that will be in place; for example, locked cabinet/office, data de-identified, encryption, approved cloud storage [Dropbox not allowed], etc.): *All data will be stored on the UCCS network, which is password-protected and only accessible by Moseley. Once audio files are transcribed, interviews will be imported in to NVIVO, which will also be password-protected and accessible only by Moseley.*

Note: *Data may be required to be protected using encryption.*

b. Describe how the privacy of the participants and the confidentiality of the data will be maintained (i.e. Participants will be assigned an ID number to protect identity): *Participants will be assigned an ID number to protect identity and transcripts will not include personally identifying information. Interviewees will also be given pseudonyms in any written materials. Moseley will remind participants that interviews are completely confidential and that all personal information and answers will be confidential.*

c. Are you accessing a database/dataset that requires a privacy or confidentiality agreement?
☐ Yes ☒ No

If "Yes", please provide a copy of the agreement. Additionally, please ensure that the data management plant aligns with any restrictions places in the agreement (i.e., destruction of data, retention, access, etc.).

d. Describe the plans for the final disposition or de-identification of data that are identifiable in any way (directly or indirectly via codes) once the study has ended. If the data will be kept indefinitely describe the format of the data and purpose of retention. If data will be destroyed, describe the timeline and method: *Audio data will be transcribed and used for textual analysis. Audio will be kept for no more than 5 years once the study is finished after which the audio files will be deleted. Transcripts will be kept indefinitely and therefore be de-identified.*

Note*: Records should be kept for 3 years after the completion of the research or after the funding has ended depending on which is longer.*

e. Name those who will identify, document, and report adverse or unanticipated events: *Ally Moseley*

Note: Adverse events must be reported to the IRB within 5 days of occurrence using the Unanticipated Event Form.

I. HAVE YOU SUBMITTED THIS STUDY TO ANY OTHER IRB? ☐ Yes ☒ No

If "Yes", describe the IRB (name and location) and action taken: _____

Submit a copy of the other IRB approval.

J. WILL YOUR RESEARCH INVOLVE PERSONALLY IDENTIFIABLE INFORMATION (PII) OR FERPA DATA?

FERPA (Family Educational Rights and Privacy Act) data include educational records of any kind that may personally identify a student, such as name, address, ID number, or another personal or indirect

identifier. In addition, a record is identifiable if it includes "other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty." For more information about FERPA please visit http://www.uccs.edu/registrar/ferpa-the-family-educational-rights-and-privacy-act.html.

☐ Yes, PII and/or FERPA data from UCCS students will be utilized.

Note: The IRB will follow campus policy relating to PII and/or FERPA data. You may contact the Office of Registrar at 719-255-3361 or email registrar@uccs.edu to determine what needs to be done. If Office of Registrar's approval is required, please forward approval letter with IRB application.

☐ Yes, PII and/or FERPA data from another organization will be utilized.

Note: If you will be requesting PII and/or FERPA data from another institution, you should follow their procedure to obtain the information.

☒ No, PII and/or FERPA data are not involved.

K. WILL YOU BE COLLECTING OR SHARING PROTECTED HEALTH INFORMATION (PHI) or HIPAA protected data?

Specify if the study involves Protected Health Information (PHI).

PHI is involved if any of the following are involved:

- *Accessing or collecting information from a medical record*
- *Adding information to the hospital or clinical record*
- *Creating or collecting information as part of health care*
- *Using information collected from the study to make health care decisions*

For more information about PHI/HIPAA please visit http://compliance.uccs.edu/?cat=85.

1. ☐ Yes, PHI is involved and is being obtained from UCCS HIPAA covered entities (which may include any work performed at/with the Lane Center clinics).

   Note: You may contact the Privacy Board at 719-255-3837 or email comply@uccs.edu to determine what needs to be done if PHI is being utilized. Note that additional training may be required. The IRB and Privacy Board work together closely to ensure timely reviews.

2. ☐ Yes, PHI data from another organization will be utilized.

   Note: If you will be requesting PII and/or HIPAA data from another institution, you should follow their procedure to obtain the information.

3. ☒ No, PHI is not involved.

L. WILL THIS STUDY INVOLVE FOOD, DRUGS, OR DEVICES?

Note: Depending on the involvement of food, drugs, or devices, it is possible that the IRB application will be directed to a third party IRB, such as COMIRB. Please note that there will be a fee associated

with the external review, if required. If this is funded research, please note that the review fees will need to be included in the budget. Please contact the IRB office for additional information.

1. Does the study collect safety and or efficacy data about a device (i.e., contraption, contrivance, lab test, in vitro reagent, mechanical test, computer software, or computer algorithm)?
   ☐ Yes ☒ No

   a. If yes, will data from the study be submitted to FDA? ☐ Yes ☐ No

2. Are subjects given any drug or over-the-counter medication, food, dietary supplement, or biologic agent as part of the study? ☐ Yes ☒ No

   b. If yes, are subjects given a food or dietary supplement? ☐ Yes ☐ No

   c. If yes, is the purpose of the study to examine the impact of the food or dietary supplement on a disease or condition? ☐ Yes ☐ No

M. CERTIFICATIONS/ASSURANCES:

1. **CONFLICTS OF INTEREST SHALL BE CONSIDERED TO INCLUDE:**
   - Stock (holdings or options) in a sponsoring organization
   - Director, advisor, or consultant to the sponsoring organization
   - Other vested interests such as the inventor and/or patent holder of the drug, procedure, technique, device, or software being tested
   - Overseeing a family member or students in class which you teach

Does the PI, Co-PI or Faculty Advisor have an actual, potential or perceived conflict of interest as included above and/or defined in the University of Colorado Conflict of Interest Policies?

☐ **Yes** ☒ **No**

Is there a COI Management Plan filed with the COI committee? ☐ **Yes** ☒ **No**

If "Yes", please attach a copy to the application.

If "No", please describe the conflict and how you will manage the conflict: _____

2. **INVESTIGATOR'S CONTINUING RESPONSIBILITY TO IRB:**
   Once the study has been approved, it is the Principal Investigator's (PI) responsibility to:
   - Ensure additional personnel take the CITI training and understand their responsibility when working with human participants.
   - Report all changes in research activity related to the study by submitting a Report of Change to the IRB.
   - Provide the IRB all study and consent form amendments and revisions. IRB must approve these changes **prior** to their implementation. All changes to advertisements recruiting study participants must also receive **prior** approval by the IRB.
   - Promptly report any injury, adverse event, or detrimental incident experienced by a research participant that is or may be related to the research procedures.
   - Renew study with the IRB at least ten business days ***prior to study expiration***. All studies requiring continuing review must be reviewed at least annually. Some studies will have the continuing review more frequently as determined in the initial review and approval. Retro-active approval for lapsed studies is not allowed. If the study approval lapses, you may be required to destroy any data collected or work completed during the lapsed time period.

- Inform the IRB if there is a newly identified Conflict of Interest or perceived Conflict of Interest.
- Notify the IRB (irb@uccs.edu) when the study is complete.

Failure to comply with these federally mandated responsibilities may result in suspension or termination of the study.

INVESTIGATOR ACKNOWLEDGMENT:

- I have listed all potential Conflicts of Interest.
- I have read the definitions of Misconduct in Research.
- I have read the Training requirements for IRB review.
- I have read the Investigator's Continuing Responsibilities to the IRB.
- I understand the definitions of Scientific Misconduct and Conflicts of Interest and my continuing responsibilities to the IRB.
- I understand submitting this application to the IRB does not constitute IRB approval, and that I will not proceed with my research (including recruitment initiation and obtaining participant informed consent) until I receive an approval letter from the IRB.
- By submitting this Request for Review to irb@uccs.edu I attest to my agreement to conduct this research study in such a manner that acts of misconduct in research and conflicts of interest will not be committed and I will comply with the continuing responsibilities to the UCCS IRB.
- I will conduct my study in compliance with the UCCS IRB Standard Operation Procedures.

***FACULTY ADVISOR ACKNOWLEDGMENT:**

By submitting this Request for Review to irb@uccs.edu, I acknowledge that the information contained in the study is accurate to the best of my knowledge. I verify that I am the faculty advisor for the Principal Investigator for this study and that I shall be responsible for the oversight of the conduct of the research and adherence to all applicable University policies and procedures.

***SUBMISSION PROCEDURES:**

- UCCS Graduate and Undergraduate students must have their faculty advisor submit the application via the faculty advisors email address.

By submitting this form, As Principal Investigator, I hereby certify that to the best of my knowledge, the information furnished above is true and complete, and that I have read and understand the Investigator Acknowledgement section. I understand that if found to be otherwise, it is sufficient cause for refusal or dismissal. I authorize representatives of the University of Colorado Colorado Springs to make any and all appropriate inquiries regarding the information listed in this supplement. I hereby release you or others from any liability or damage that may result from furnishing the information requested.

Submit Requests for Review as a PDF to irb@uccs.edu. Please submit other documents when possible as Word documents.