Revised 21 Oct 2017

COVER PAGE FOR IRB SUBMISSION

Purdue University, Institutional Review Board

Type of Submission: ☐ Human subjects determination [*complete both sides of this form*]
☐ New exemption determination [*complete both sides of this form*]
☐ New application narrative [*complete both sides of this form*]
Check here if you believe your protocol will require full board review: ☐

*Complete only #1 & 2 below **AND** PI signature at bottom of page 2*

☐ Amendments to approved protocol / IRB Protocol #:
☒ Renewal of approved protocol / IRB Protocol #:
☐ Revisions requested by IRB / IRB Protocol #:
☐ Study Closure / IRB Protocol #:

1. Project Title: **Sexual Health Education: What Students Really Want to Know**

2. Principal Investigator: **Dr. Marifran Mattson, Department Head, mmattson@purdue.edu, (765) 494-7596**
(Name, Title, Department, E-mail, Phone; ***Must sign at the bottom of page 2***)

3. Co-Investigators, Key Personnel and/or Consultants (Name, Title, Department, E-mail, Phone, for each):

4. Has the PI and all Co-Investigators, Key Personnel and Consultants completed CITI training?
☐ Yes (Proceed to 5)
☐ No (STOP here: CITI training must be completed by all prior to submission of this application)

5. This project will be conducted at the following location(s):
☐ Purdue, West Lafayette Campus ☐ Purdue, Regional Campus (Specify): _____
☐ Other (Specify, including city and state): _____

6. Check the box(es) below if your project involves any of the following (check all that apply):
☐ Minors under age 18
☐ Pregnant women
☐ Fetus/fetal tissue
☐ Prisoners or Incarcerated Individuals
☐ University students (Purdue PSY Department subject pool? Yes _____ No _____)
☐ Elderly persons
☐ Economically/educationally disadvantaged persons
☐ Mentally/emotionally/developmentally disabled persons
☐ Minority groups and/or non-English speakers

7. Indicate the anticipated maximum number of subjects to be enrolled under this protocol as justified by the hypothesis and study procedures: (Suggestion: if unsure, err on the side of a higher sample size)

8. This project involves the use of an investigational new drug (IND) or an approved drug for an unapproved use:

☐ YES ☐ NO

If YES, provide drug name, IND #, and company supplying it: _____

9. This project involves the use of an investigational medical device or an approved medical device for an unapproved use:

☐ YES ☐ NO

If YES, provide device name, IDE #, and company supplying it: _____

10. This project involves the use of radiation or radioisotopes:

☐ YES ☐ NO

11. Check the box(es) below if your project involves any of the following (check all that apply):

☐ Intervention(s) that include medical or psychological treatment
☐ Use of voice, video, digital, or image recordings
☐ Subject compensation (Please indicate the maximum payment amount to a subject: US $)
☐ VO2 max exercise
☐ More Than minimal risk, as defined by federal regulations
☐ Waiver of informed consent
☐ Waiver of documentation (signed) of informed consent
☐ Extra costs to subjects
☐ Use of blood (Total amount of blood: , over what time period? (in days):)
☐ Use of rDNA or biohazardous materials
☐ Use of human tissue or cell lines
☐ Use of other bodily fluids that could mask the presence of blood (including urine and feces)
☐ Use of protected health information (obtained from healthcare practitioners or institutions)
☐ Use of academic records

12. Does investigator or key personnel have a potential financial or other conflict of interest in this study?

☐ YES ☐ UNSURE ☐ NO

By signing below, I give my assurance that information supplied to IRB relevant to this project is complete and correct. All materials submitted for review within this submission, unless otherwise indicated, are the original work of myself or those working in collaboration with me. I agree to accept responsibility for the scientific conduct of this project. I understand that providing false information or concealing a material fact regarding this research is a criminal offence (U.S. Code, Title 18, Section 1001):

Marijean Mattson

March 7, 2019

Signature of Principal Investigator

Date Signed

CONTINUING REVIEW

Purdue University, Institutional Review Board

Federal regulations require many research studies approved by the IRB to be reviewed subsequently. Your study approval letter from IRB will indicate when your study approval expires. Should you wish to continue your research beyond that date, you will need to complete this form, along with a Cover Page for IRB Submission, which can be found at www.irb.purdue.edu (under "Application Forms"; Note that with continuing reviews, you only need to complete the first two items on that Cover Page, along with the PI's signature).

SECTION I: STUDY INFORMATION

1. Project Title: **Sexual Health Education: What Students Really Want to Know**

2. Principal Investigator: Dr. Marifran Mattson, Department Head, mmattson@purdue.edu, (765) 494-7596

3. IRB Study Number: 1606017855

4. Current Approval Expiration Date: 03/12/2018

5. Has IRB approval already expired on this study? ☐ YES ☒ NO

   If YES, please identify study activities have been undertaken since expiration of IRB approval, checking all that apply:

   - ☐ Subjects have been recruited since expiration
   - ☐ Subjects have been enrolled since expiration
   - ☐ Data have been collected about subjects (directly or indirectly) since expiration
   - ☐ Identifiable data about subjects have been used in data analysis since expiration
   - ☐ Other activities (Please describe):

6. Has funding for this study changed since the last IRB review? ☐ YES ☒ NO

   If YES, please check all that apply:

   - ☐ It is now federally funded (Identify the Sponsor and grant/award number: _____)
   - ☐ It now has other external funding (Identify the Sponsor and grant/award number: _____)
   - ☐ It is now funded by Purdue (department, college, center, etc.)
   - ☐ I now fund it myself

7. Do any of investigators or personnel have a significant financial interest in this study that has not previously been disclosed? ☐ YES ☒ NO

8. If YES to Q7: Have you disclosed your financial interest to Purdue? ☐ YES ☐ NO

9. If NO to Q8: Disclosure by going to the online Purdue Disclosure Database, at https://webapps.ecn.purdue.edu/VPR/PDD/. Login using your career account and click on the "My Disclosures" tab, then follow directions. Click the box at right to indicate you have done so: ☐

10. Do the investigators or personnel have any other known conflict of interest for this study which have not been previously disclosed? ☐ YES ☒ NO

    If YES, please explain the conflict: _____

SECTION II: STUDY STATUS GOING FORWARD, AFTER IRB REVIEW

Check only one of the three status options below and follow the instructions:

☐ **Open to Enrollment** – Check which of the following two conditions apply:

- ☐ Enrollment of new participants or review of records/specimens continues. **Go to Section III**
- ☐ No participants have been enrolled to date. **Skip to Section IV**

☐ **Closed to Enrollment** – Check which of the following two conditions apply, **then go to Section III**

- ☐ No new participants are being enrolled but they are still receiving research-related intervention or interaction.
- ☐ No new participants are being enrolled. Participants have completed research-related interventions; but long-term follow-up procedures continue. Long-term follow-up includes:
  - Research interactions that involve no more than minimal risk to subjects, or
  - Collection of follow-up data from procedures or intervention that would be done as part of routine clinical care. Research interventions which would not be performed for clinical purposes are considered research-related interventions and are not considered follow-up.

☒ **Data Analysis Only** – If both of the following conditions are met, **skip to Section III.**

- Participants have completed research-related intervention or interaction and follow-up has been completed, **AND**
- Remaining research activities are limited to only data analysis that may require access to identifiable records and/or specimens identified directly or via code with existing code key.

SECTION III: STUDY PARTICIPANT SUMMARY

☐ Check here if the study involved existing records about or specimens from people. Provide the number of records/specimens reviewed or collected in the Participant Summary Table below.

☐ Check here if the IRB has approved a waiver of consent for the study.

Participant Summary Table		On-Site*
Since last IRB review	Total number of participants **enrolled** (include those consented for screening), or whose records/samples have been accessed:	**11 focus group participants** **53 survey participants**
	Total number of participants who **failed screening** (i.e., found ineligible to participate) after they were consented:	**2 survey participants**
	Total number of participants who **withdrew**** from the study:	**none**
Since beginning of study	Total number of participants **enrolled (include those consented for screening), or whose records/samples have been accessed:**	**57 focus group participants** **144 survey participants**
	Total number of participants who **failed screening G** (i.e., found ineligible to participate) after they were consented:	**2 survey participants**

	Total number of participants who **withdrew**** from the study:	**1 focus group participant**
	Total number of participants who have **completed** the study:	**56 focus group participants** **142 survey participants (focus group participants completed the survey)** **Grand Total 142 participants**
	Total number of participants who have **yet to complete** the study:	**0*****

* **On-Site** refers to the study site for which the study was approved by the Purdue IRB. If multi-site, only include participant summary information for site(s) over which the Purdue PI had oversight.

** If any participants **withdrew** from the study since the last IRB review, please state the reason(s) for withdrawal(s) if known:

Participant changed mind and did not want to participate in focus group. Participant was thanked and dismissed.

*** Note that for federally-funded studies, the sponsors will request a breakdown of participants by sex/gender, ethnicity, and racial category. You would, therefore, be wise to have that information ready for reports to funders.

SECTION IV: STUDY EVENTS

11. Since the last IRB approval, did any unanticipated problems involving risks to subjects or others, adverse events, protocol deviations, subject complaints or noncompliance occur that required prompted reporting to the IRB? ☐ YES ☒ NO

    If YES, please provide a summary of these events either in the space provided or as an attachment, and the date(s) these events were reported to the IRB:

12. Since the last IRB approval, did any protocol-related adverse events, protocol deviations or subject complaints occur that did not require prompt reporting to the IRB? ☐ YES ☒ NO

    If YES, please provide a summary of these events either in the space provided or as an attachment:

13. Is there a data safety monitoring plan for this study? ☒ YES ☐ NO

14. Did this study have a data safety monitoring board? ☐ YES ☒ NO

    If YES, please provide the most recent monitoring report if it has not already been provided to the IRB.

15. Have changes to risks to subjects presented by this study been identified (whether by type, frequency, duration and/or severity) since the last IRB approval? ☐ YES ☒ NO

If YES, please explain:

16. Have there been any external reviews of this study (i.e., by a study sponsor, federal agency, regulatory body, or other IRB) since the last IRB review? ☐ YES ☒ NO

If YES, please identify when the review was conducted, by whom, and a summary of any findings:

SECTION V: RECENT FINDINGS RELEVANT TO THIS STUDY

17. Summarize the recent literature that has been published or presented by the investigator or others relevant to this study since the last IRB approval. Include in the summary if there has been a demonstrated significant impact on the well-being of subjects:

Preliminary results of this study were chosen for an oral presentation at the The Society for the Scientific Study of Sexuality annual conference.Three final themes emerged from the data. First, adolescents live in an openly sexual active culture, where school is a key environment in which they discuss their sexuality and sexual experiences. Within this culture, abstinence is not highly regarded and this is in direct contrast with the expectations of teachers and parents. Next, although teens are open about their sexual activity with their peers, students often experience an awkwardness that discourages them from talking freely to adults, especially parents, about sex. In result, participants believe sexual education belongs in schools because it ensures they receive reliable, judgement-free information they may not receive elsewhere. Lastly, students agreed it was unrealistic to solely teach AOUM education. Students want information that mirrors their actual behaviors and believe schools have a responsibility to teach information that is useful to their lives. For students, this rationale justifies providing education on safer sex practices so teens can protect themselves from STDs and unplanned pregnancies. Conclusion: In the debate to teach AUOM or CSE, the sexual experiences of adolescents makes the answer clear, teens need and desire CSE education because it reflects their actual behaviors. Although this may be difficult for teachers and school administrators to accept, students are relying on schools to provide information they can use to make healthy sexual decisions. Without it, students will continue to be at an increased risk for poor sexual health outcomes.

18. Has the risk/benefit ratio of this study been altered since the inception of the study? ☐ YES ☒ NO

If YES, please explain:

SECTION VI: DOCUMENTS TO UPLOAD FOR CONTINUING REVIEW

Please check the appropriate boxes below as they apply to this study and (1) upload the checked files (2) along with this form, with (3) the Cover Page for IRB Submission (which can be found at www.irb.purdue.edu (under "Application Forms"):

Consent/Assent and Recruitment Documents (for studies checked as "Open to Enrollment"):

- ☐ Assent form; number of assents forms attached:
- ☐ Consent form; number of consents forms attached:
- ☐ Parent permission form; number of permission forms attached:
- ☐ Study information sheet; number of information sheets attached: _____
- ☐ Recruitment materials (please list):

Other Study-Specific Documents (for studies checked as "Open to Enrollment", if applicable):

- ☐ HIPAA Authorization
- ☐ IRB approval(s)from other institution(s), if Purdue has not deferred IRB review [please list name(s) of other institution(s)]: _____
- ☐ For studies conducted with collaborating institutions, provide a copy of the collaborative institution's current IRB approval, or indicate that IRB oversight has been deferred to Purdue.
- ☐ DSMB report, if the study includes a DSMB, submit the most recent DSMB report
- ☐ Multi-center trial reports, if there are any available