

Draft Research Protocol: Comprehensive Sexuality Education Program Assessment

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UNESCO, UNFPA and UNICEF Asia-Pacific regional offices are partnering to undertake a joint assessment to review implementation of school-based comprehensive sexuality education¹ in several countries in the region.

The Population Council is providing technical assistance in the research design and can provide technical assistance on the implementation of the assessment. It is anticipated that the assessment will be conducted in 2014 at secondary school levels in select locations within identified countries.

The review will examine the status of comprehensive sexuality education implementation on the ground. It will examine whether sexuality education is included in the formal curriculum; whether the topics and content of actual sexuality education classes align with international technical standards (including whether and how gender, power and rights are addressed); whether sexuality education is mandatory and/or examinable; whether teachers who are delivering the classes have been trained and how; management support for teaching sexuality education in the school; and, communication with parents on CSE. This assessment will be designed to be administered at the school level to students, school principals and teachers.

Carrying out such an assessment of school-based comprehensive sexuality education in a country will involve a series of key decisions made in consultation with several different players, as outlined below. These steps assume there is a sexuality education program already operating on at least a small scale.

Getting started: Roles and responsibilities

UNFPA/UNESCO/UNICEF country offices:

The country offices of the UN agencies will work together and be responsible for the overall implementation of the assessment. This includes to:

- Decide on a division of labour and workplan for supporting review of CSE in the country
- Contract a national research group to undertake the below tasks
- Liaise with UN regional offices and Population Council for technical assistance to the national research group
- Engage stakeholders from ministries of education and health, UN agencies, and others to form a working group to oversee the review process. This working group

¹ Please note that topics related to sexuality education might be covered under curricula with different names (e.g. family health, adolescent health, etc.) or integrated into different subjects (e.g. some topics covered in social studies, some in biology, some in science, etc.)

would then call for an initial consultation with a broader group to ensure buy-in from all key partners

- Support the sharing of results from the assessment, and advancing the recommendations with country partners

National research groups:

- Conduct a background literature review including country-level papers and policy documents that are relevant to sexuality education in the particular country context. Sample questions to guide the background literature review are given in [Annex I](#).²
- Do a translation of survey tools (and add in any optional questions as necessary, and upon conferring with the Population Council and the regional offices)
- Decide on a sample size – under guidance from the Population Council
- Obtain ethical clearance
- Undertake training of data collectors with technical assistance from the Population Council
- Conduct the assessment – this includes a preliminary ‘simulation’ exercise to test the tools; revision of the tools as required, based on the outcomes of the simulation exercise; data collection; data analysis; and production of a final report of the results

National stakeholder committee/platform:

- Guide the national research groups in adapting tools and deciding on sample size
- Provide overall guidance on the roll-out of the review
- Ensure that the results are disseminated widely and used appropriately to influence policy and programming on comprehensive sexuality education

Study Objectives

The objectives of this review are to better understand how CSE is being implemented at school level, factors that may contribute to successful implementation of CSE, and where the gaps are as well as to examine knowledge, values and attitudes of teachers and students on topics related to sexuality education.

Countries undertaking the review process can add specific sub-objectives under these overarching objectives. The results from this review can be used for advocacy purposes to strengthen CSE, to support development of policies/guidelines on CSE, and to create more supportive

² Some of the relevant documents may be online, but some of the answers may be in unpublished material. Places to start looking for information include the websites of the Ministry of Education, Ministry of Health, UNESCO, UNFPA, UNICEF, IPPF affiliate, or websites like DHS/Macro, Population Council, Google Scholar, JSTOR, or PubMed. Web-based searches may need to be supplemented with individual correspondence with relevant persons in the country, like district health and education officials.

school environments to support CSE including through teacher training, new pedagogic techniques etc.

The geographic scope of the research will depend on financial and human resources available. While ideally the assessment would apply to an entire country or sub-region of the country, depending on funding and staff, this may not always be feasible. Once tools have been translated, study and sampling specifics decided, and ethical clearance obtained, all countries will conduct an initial 'simulation exercise' in a few schools in a convenient location. The purpose of this simulation exercise will be to test the tools in a 'real life' setting, ensure that the data collectors are prepared, help pilot logistical procedures for the larger survey, and that unforeseen 'risks' and challenges are identified and taken care of before implementation of the full study.

As comparison schools, and pre-/post-surveys are beyond the scope of this implementation review, there will be no assessment of whether students' knowledge, attitudes or behaviors, may be related to school-based sexuality education.

Ethical considerations

Before undertaking any research, the team will need to have the study approved by a local Institutional Review Board (IRB) or Human Subjects Research Ethics Committee. These can be found through governments and universities. The purpose of obtaining ethical clearance is to both protect the research subjects' privacy and well-being as well as the researcher. Ethical issues need to be taken into account for all participants, but those individuals under age 18 years require special protections because of their status as minors. **Annex III** provides more information on ethical clearances and provides templates for the two most important pieces of documentation for most ethical review processes: the informed consent form and the IRB protocol.

Study Design & Methods

Basic design

The data will be cross-sectional, not longitudinal. A one-time cross-sectional data collection will be sufficient to provide a "snapshot" of current practice regarding CSE implementation in schools – i.e., is CSE being implemented at this time and how.

When assessing student knowledge and attitudes, it should be noted that this cross-sectional design cannot provide insight into the effectiveness of CSE but it can provide a single, cross-sectional "snapshot" to see what is / is not known/believed by students at the time of the survey.

Choosing a sample of schools depends on what data is available in a particular setting, the resources available, and the scope of research, and will be determined in each country. The study can aim to be representative within a limited geographical area (e.g. representative at provincial or district level).

In terms of which grade or grades to select, our general recommendation is that in each country 1 or 2 purposely selected secondary school grades be utilized. For the purposes of this study, this is likely to be grades in which the average age of students is 12 years and 15 years (ages 12 and 15 were selected as they mark the overlap from “level II” to “level III” and from “level III” to “level IV,” respectively, as defined in the International Technical Guidance on Sexuality Education).³ The application of this assessment outside of these age ranges should be reviewed with the regional UN offices.

For further details on sampling, please refer to [Annex I](#).

What to assess

In a situation assessment such as this project, there are a few main areas of interest with regard to the CSE program itself and its implementation that would ideally be assessed. The following areas are included in this assessment:

Program inputs:

- Curriculum, guides, and/or syllabi provided by the national, subnational, or school district level
- Pedagogic support e.g. guides, lesson plans and handouts for teachers
- Pre-service and in-service teacher training
- Policies, tests or assessments that can be an incentive to implement CSE

Enabling environment:

- Community engagement from parents and community leaders to teach CSE in schools (both support and opposition)
- Supportive school policies for CSE such as policies to support its' implementation, training of teachers, resources for CSE etc.
- Supportive school environment that has a zero tolerance approach to bullying and harassment and provides an environment in which sensitive topics can be taught and learned
- Open and interactive classroom environment where students are engaged in discussions and critical thinking is fostered

Implementation:

³ Ideally, more grades would be examined, but with limited resources, it was decided to focus on these ages. Level I (for 5-8 year olds) would likely be too young in these settings to have received sexuality education, and level IV (for 15-18 year olds) runs the risk of students having dropped out already.

- Teacher training both in school or outside the school
- Incorporation of CSE into the school's program or courses / curricula
- Topics covered (or not) under CSE – both in terms of what is in the curricula but also what is actually being taught in the classroom
- Timing, duration and length of classes on CSE or related to CSE
- Which grades receive CSE in school
- Who teaches CSE
- Adequate materials for delivering the curricula and use of these materials
- Pedagogic techniques to deliver CSE
- Integration of gender and rights including in curricula and in the school environment – i.e do traditional gender norms/roles get reinforced in curricula or in the CSE class

Research tools

While there are multiple ways to assess some of these issues – for example, classroom observation, content analysis of curricula, etc. – this assessment will aim to obtain insight into these topics by interviewing principals, teachers, and students, and by conducting in-depth interviews with key informants. Survey questionnaires have been developed that are specific to each group—principals, teachers, and students. The questionnaires are standardized but should be translated into the relevant local language(s) and pre-tested in a simulation exercise.

Key Informant Interview (KII) guides have also been prepared. Again, the guides are standardized but should be translated into the relevant local language(s) and pre-tested during the simulation exercise. Key informants should be determined at country level, and can include Ministry of Education officials from both national and district levels, Ministry of Health officials from both national and district levels, Ministry of Youth officials, school teachers (both those teaching CSE and those who are not), headmasters, heads of parent-teacher associations, representatives from the school management board, NGO members who are linked to delivery of school-based CSE programmes or related programming. A select number of key informants should be identified, with consideration to the amount of time that will be required to undertake the interviews and for the qualitative data analysis. Further adaptation of the KII guide may also be required to adjust the questions and the language for the different key informants and for different objectives of the interview (e.g. between the guide for Ministry officials, as compared to parent-teacher associations).

In case there are additional country-specific questions that have not been captured in the standardized questionnaires and KII guides, then countries are welcome to develop an additional module of questions. The length of the interviews will vary depending on whether all questions are relevant to the respondent, but should not exceed 30 minutes for any interviewee. After this amount of time, respondents at all levels may start to lose interest in the questionnaire, cut the interview short, or rush to finish.

Within each country, the research tools will be fully pilot-tested within a small set of schools. This exercise will allow the questions and responses to be adapted to the local context. It will also help pilot the logistical procedures in place for the larger survey.

Key indicators (outcome and process) have been developed for each domain of inquiry. For example, for the basic question, “is CSE being taught?” we would ask all respondent groups: students, teachers, and principals, questions about whether, when, and for how long. In addition to this outcome, we have developed questions that get at barriers and facilitating factors – such as resources (curricula, training, dedicated class time, etc.) that are or are not in place, or administration and teacher attitudes regarding CSE, etc. – that different respondent groups would have insight into.

Training on research tools

The research group contracted to undertake the assessment will also need to ensure that all data collectors are properly trained in how to handle/assist respondents with the devices as well as in ethical procedures and behaviors. This includes the process for obtaining informed consent from participants, importance of maintaining confidentiality, and the administration of the computerized survey.

Particular attention will also be required for those undertaking the key informant interviews. This includes ensuring that all data collectors understand the objectives of the interviews with different audiences, and being able to adapt the questions based on the responses from the participants. The data from the KII will be particularly useful in complementing the quantitative information around perspectives regarding CSE, and on opportunities and challenges with regard to its implementation.

Data collection

Ideally, and recommended by the UN partners and the Population Council, teachers and students⁴ will complete a **self-administered, custom-built computerized survey**. While this requires an upfront investment (especially purchase and programming of digital devices), it is cost-saving in the long-run as the data is electronically recorded, and it decreases time needed to collect and clean data. However, it does not guarantee more valid or more reliable data. Pop Council will provide some technical support for the computerized survey for the initial participating countries.

An alternative is to have an interviewer administer the survey, and enter the data immediately into a computer or tablet. This is less advantageous than a self-administered question in some ways, primarily in terms of the number of interviewers or time required to collect data. This is the proposed method for the administration of the principal survey as there will only be one principal per school and will enable the collection of qualitative data through probing.³

The least desirable method, which is not recommended, is to have the interviewers enter all responses on paper forms which they would then need to enter manually onto computer databases. Data cleaning is an important step before data analysis to ensure that errors in entering data are minimized. This also means additional funds for the data cleaning process.

Regardless of what method is chosen, the researchers will need to provide privacy for respondents so that they are free to give honest answers and so that their confidentiality is maintained. Local researchers will also need to be trained to facilitate key informant interviews using an interview guide, and to undertake the survey with principals.

If some settings wish to utilize participatory methods, there are several ways this might be done. For example, teachers and administrators can be involved in identifying key questions of interest and in participating in the selection of sampled schools. Participatory data collection techniques could also be employed. For example, teachers and students could develop – with assistance from the national research teams and the Council – logs that they then maintain over the course of a set period of time. Such logs (which could be submitted anonymously) could include how much time was spent on any given day on selected CSE topics, how often males versus females spoke up in class, etc.

All data collected will need to be managed and analyzed. Recommended software skills for the person responsible for this task include Microsoft Excel and a statistical analysis package like Stata, SPSS or R.

Statistical analysis

⁴ As there will only be one principal/headmaster per school we recommend that the interviewer complete the survey instrument directly with the principal and enter the data into the computer. This will enable more probing and qualitative information during the data collection process.

Descriptive analyses regarding prevalence of key indicators are relatively easily done. For example, proportion of schools that teach no, 1-5 hours, 6-10 hours, or 11 or more hours of CSE in the identified grade, or proportion of students knowing basic rights, etc. Also important to analyze are variation in these outcomes according to possible mediating factors. For example, what factors (e.g., number of teachers trained, and/or curricular resources in place) make it more likely that CSE is implemented; or, do schools with more robust CSE programs have higher proportions of students who know basic facts about HIV and know where to obtain condoms than schools with no or few CSE hours. (Note, however, that without comparison schools and pre/post data, knowledge and attitudes will not be attributable to the CSE program).

Reporting template

The Council will develop a draft reporting template that can be adapted for use by country teams and will include guidance on the basic analysis that must be included in any report.

Proposed timeline

Month	Task	Options	Notes
1	Background research		This includes policy review, background document review, literature review
1	Identify appropriate local IRB	Universities Ministry of Education	For some settings, the global research ethics map can be a useful resource: https://webapps.sph.harvard.edu/live/gremap/index_main.cfm?CFID=10286005&CFTOKEN=83604946
1	Based on budget determine scope	Initial work in one (likely urban) area, followed by more regionally or nationally-representative research Start with regionally- or nationally-representative approach	This timeline assumes limited scope for initial assessment in one location. More extensive geographic reach will take more time.
1	Reach out to DoE, other relevant authorities		
2,3,4	Use data to derive sample	World Bank Ministry of Education UNESCO Census	Depends on data available in country, level of representativeness required
2,3,4	Adapt research tools	Surveys Interview guides	Will need separate tools for students, teachers, principals. Translation may be required. For key informant interviews

2,3,4	Determine format of survey	Self-administered computerized survey	Will need to allocate time (and money) for programming computers with survey, but less time for data entry, checking and cleaning **recommended approach for student and teacher surveys as cost-effective and may minimize some biases; suggest the survey be administered by an interviewer with principals
		self-administered computerized survey using ACASI techniques (audio, computer-assisted)	Will need to allocate time (and money) for programming computers with survey, audio recording of survey content. Not recommended, unless undertaken in low-literacy settings (which is not anticipated)
		Computerized survey administered by an interviewer	Will need to allocate time (and money) for programming computers with survey, and more interviewers will need to be trained (or more time allocated for data collection) to achieve the specified sample size. Requires less time for data entry, checking and cleaning. Not recommended.
		Face-to-face individual interviews with pen and paper	Will need to allocate time for data entry, data checking and data cleaning. Not recommended.
3-4	Program data collection devices		
3-4	Submit research to local IRB		Expect this process to take a few months
3-5	Pretest questionnaires in 'simulation' exercise including data collection and analysis		Make changes as needed, for example to improve comprehension or shorten time
5,6	Train interviewers		Training on ethical guidance and obtaining informed consent. Additional brief training on

	on finalized questionnaire and KII		computer platforms, if needed
7	Approach participants to inform about study and get informed consent.		This step only happens after research has been approved.
8,9,10	Collect Data		At this time will give compensation to school if appropriate
8,9,10	Data entry		This step will be automated if using phones or computers, but otherwise will need staff to do this
11	Data cleaning		Less time for data cleaning will be needed if using phones or computers, but still important to check data for consistency
12,13	Analyze data	Using Stata, SPSS, or R	Depending on software availability and skills of analyst.
14,15	Write up findings		Following the reporting template that will be developed and shared with the team

Annex I

Sample questions to guide background literature review:

Demographic and Data questions:

- At what age do girls and boys typically initiate sex? Is it in the context of marriage or pre-marital? Is data available on same-sex relationships, including age of first sex among young men who have sex with men? Age of first marriage? Is any data available on transgender youth?
- What % of girls and boys attend secondary school? Are there important gender differences in enrollment, consistent school attendance, or school leaving?

Policy questions

- Are there policies and guidelines that refer to sexuality education in the country? If yes, which policies/guidelines and how do they reference sexuality education? Does it vary at the national and sub-national levels? What ministries (health, education, youth, etc.) are involved?

School and out-of-school structural questions

- Are there important structural aspects of the education system to be aware of? For example, if there are parallel education systems – public, private, and religious – what proportion of young people attend these different types of schools and how does that vary by class, by gender, and geographic setting? Is sexuality education required in public schools? Or in all schools?
- Are there NGOs that provide sexuality education in the schools? After school?
- Are referrals to health services provided in the school? Or are there school clinics or counseling available to students?

Curricula and teaching questions

- What national or sub-national frameworks, standards, syllabi, curricula, teacher guides/handbooks or books/teaching materials exist on sexuality education? What levels are targeted through said teaching/learning materials?
- In what grades is sexuality education taught? What is its duration (how much class time is allocated) at each grade level?
- Under what subject areas is sexuality education taught? (e.g. is it in a health class? Across subject areas such as social studies, science and language arts? Stand alone?)
- What topics are covered in curricula related to sexuality education up to the selected grades? (this section to be completed in collaboration with curricula developers from MOE through key informant interviews)
- Are boys and girls taught separately and/or using a different version of the curriculum?

- Are teachers trained to implement the program? During pre-service training? In service training? If so, how and for how many hours?
- Is sexuality education a testable subject? If so, when and what is tested?

For curriculum/content analysis, we suggest that countries use the surveys prepared for teachers, indicating whether these topic areas are already included in the curriculum. This could be a useful comparison with what teachers report is included in the content of the curriculum, or what is actually delivered in the classroom.

NOTE: In addition to using the teacher survey as a guide, tools to draw from to conduct such a content analysis include the UNESCO SERAT tool and the UNFPA/UNESCO 10-country ESA curriculum review. These are available from the UN regional offices.

Some particular areas to look for include:

- Is the information provided accurate and comprehensive (versus abstinence only)?
- Does it explicitly address issues of gender norms and power in sexual relationships? (both as stand-alone topics and underlying other content areas)
- Are lessons and activities age-appropriate and gender-inclusive?
- Are teaching approaches participatory, interactive and learner-centered?
- Does it build skills such as negotiation, condom use, and decision-making skills?
- Does it foster critical thinking?

Annex II

Sampling: Comprehensive Sexuality Education

The national research groups, with technical assistance from the Population Council and other relevant national actors, will be responsible for the sampling.

What data to use

Choosing a sample of schools depends on what data is available in a particular setting, the resources available, and the scope of research, and will be determined in each country. We recommend that the study aim to be representative within a limited geographical area (e.g. representative at provincial or district level). Such a study will need a recent listing of schools in the selected geographic unit/s, including detailed information like the number of students and grade levels within each school.

Other data are needed for the team to assess where in the country relevant outcomes (such as knowledge of HIV or reproductive health) are at high, medium or low levels. This will help the team determine where the study will take place. Examples of sources for such data include Demographic and Health Survey data, the World Bank, and the Ministry of Education.

In terms of which grade or grades to select, our general recommendation is that in each country a 1-2 purposely selected secondary school grades be utilized. For the purposes of this study, we suggest this be the grades that have the average age of students to be 12 years and 15 years (reflecting the upper ages of Level II and Level III, and lower ages of Level III and Level IV, in the International Technical Guidance on Sexuality Education).

What sampling technique to use

After we have the list of schools that will comprise our population we can use systematic or stratified random sampling to produce a list of schools for the study. Systematic sampling basically entails choosing every n^{th} unit – e.g. clinic client, house, or, in this case, school. Stratified sampling entails dividing the “population” of schools (or students) into different, unique, categories/strata – e.g., upper and lower secondary schools in public, private, and religious school systems – and then randomly or systematically selecting X number of schools from each category/strata. The Council will work with the national research groups to choose which technique or combination of techniques is most appropriate given the available data, setting and resources.

How many schools to include?

The number of schools (or students) to include in the study will depend on the magnitude and variation in the outcome(s) of interest within the relevant population, and the numbers needed to achieve adequate statistical power. Schools should be sampled proportionally based on student enrollment. In deriving the numbers needed the team will need to keep in mind that sub-group analyses will require larger numbers. Examples of sub-groups we may want to consider are students in different grades, males/females, and married students (these groups will vary by context).

What are the inclusion and exclusion criteria for the study?

We will need to set criteria for who is included in or excluded from the study. There is one criterion for inclusion in all countries – that the survey is administered only to students in 1-2 secondary school grades where students are an average age of 12 years and/or 15 years (these ages mark the end of Level II and Level III, and lower ages of Level III and Level IV, in the International Technical Guidance on Sexuality Education). There is also one exclusion criterion in all countries: out-of-school sexuality education classes are not included in this assessment which is designed for in-school programmes. Optional criteria can be determined by countries; these can include criteria related to private and/or public school settings; including only teachers who are actually implementing sexuality education, etc.

Recruitment of participants

Once we have determined the inclusion/exclusion criteria, we will need to develop a plan for recruiting the participants. For most school-based studies the first step will be discussing the research with the national or regional authorities, such as the Ministry of Education. It is usually most effective if an outside group separate from the program implementers carries out the research and makes these contacts, so there is no coercion to participate or pressure to give inaccurate/biased responses. Once these authorities have approved the research, the principals of the schools will be the next point of contact. The principal can inform teachers of the research, who can then be invited to participate themselves and extend information to students about participating. Formal ethical considerations are detailed below. In some settings, school districts require parental approval for any data collection from students, which may require utilization of MoE or district forms separate from those you will need for informed consent for ethical/IRB reasons.

Within each school, half of all classrooms receiving any CSE in the target grades should be randomly selected and all students in these classrooms interviewed (further details available in the sampling memo). All CSE teachers in the target grades should be interviewed.

Annex III

Ethical procedures guidance

The purpose of ethical procedures is to protect the research subjects' privacy and well-being. Following ethical procedures also protects the researcher, and is in most settings legally required.

Institutional Review Boards

Before undertaking any research, the team will need to have the research approved by a local Institutional Review Board (IRB). These can be found through governments and universities. Each IRB will have its own procedures, requisite forms and deadlines but the Council will provide sample forms that cover the usual requirements. Ethical review can take several months, so time should be built in to ensure research is not delayed by lack of approval.

A detailed study description and all surveys and ethical review forms need to be submitted to the IRB, usually 4-8 weeks before the IRB meets to discuss the research studies. Most IRBs meet several times per year on dates that are pre-announced. It is sometimes the case that an IRB will not approve a proposal upon the first submission, so the research team should build in the time for two IRB cycles before planning to go into the field for data collection.

It may be that approval is also required from MOE or MOH officials, in addition to the IRB. Even if it is not required, it may still be wise to discuss the study and invite review/comment as a courtesy and an investment in building buy-in for the study. This can increase the likelihood that study findings are more readily heard.

Ethics and Informed consent

Ethical issues need to be taken into account for all participants, but those individuals under age 18 years require special protections because of their status as minors. In the case of minors, "assent" instead of "consent" is requested. Consent may only be given by individuals who have reached the legal age of consent (in the U.S. this is typically 18 years old). Assent is the agreement of someone not able to give legal consent to participate in the activity. Every participant will need to sign an informed consent (or assent) form that indicates that they understand the purpose of the research and can withdraw from participating at any time. These forms will be tailored for each category of participant: policymakers, principals, teachers, students, and students' parents or guardians. Student participants who are under age 18 years will also need to have a form signed by their parent or guardian that grants permission for the student to participate in the study. In special cases you may have "emancipated minors" (individuals under age 18 years of age who do not reside with a guardian) who may not require parental consent. They require a different consent form than do non-emancipated minors. The template provided below can be tailored to each context and type of participant. All information must be delivered in language that is clear and understandable to the specific population and age group being addressed. This will entail translating any forms into a language/s that the respondent(s) can understand.

This template guides you through the procedures for two of the most important pieces of documentation required for most ethical review processes: the **informed consent form** and the **IRB protocol**.

Typical features of an **informed consent form** include the following sections:

The title of the research project

The names of the researchers involved in the project

The purpose of the research

A description of the research process with information such as what types of questions will be asked, and how long the interview should take.

Compensation or benefits to participation: whether the respondent will receive money or other incentive when participating

Whether and how participants will be compensated for their time will need to be determined. Local ethical review boards may be able to provide guidance on how this is typically handled locally. School-based studies in some settings have provided a donation to the school rather than to individual participants. Research teams must take care that the value of the compensation provided is not so large as to be potentially coercive (i.e., to compel subjects to participate when they otherwise would not without the incentive). If there will be compensation, the study should determine when it will be provided, for example after enrollment, or after responding to all the research questions.

Risks and how to deal with them: Any costs, risks or discomforts to the respondent that may occur as part of the research will need to be anticipated. (These should obviously be minimized or eliminated if possible.) As part of the ethical review, the team will need to outline potential risks to subjects, and how any risks will be dealt with. Examples of risks include psychological distress or other harms. Provisions for dealing with such risks include having referrals available for counseling services should any need arise.

Confidentiality: How the respondent's confidentiality will be protected should be carefully laid out. Common examples include not collecting any individual identifying information, conducting interviews in a private setting, keeping electronic records encrypted on computers, and keeping paper records in locked cabinets, and rigorous training of data collectors regarding ethical procedures and behaviors.

Voluntariness: Information about the voluntary nature of participation should be made clear, including that the participant has the right to withdraw from the research at any point in time, even after the study or the interview has commenced.

Documentation: Documentation of consent should be obtained, along with one copy of the signed consent form for the subject to retain. This is usually a signature (or mark if the person cannot write) on a consent (or assent) form acknowledging that the respondent understands the information delivered in the preceding sections. It also includes contact

information for relevant members of the research team that the respondent can keep in case s/he has questions.

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IRB protocol template

The IRB protocol is the form that is submitted to an IRB or Human Subjects Research Board. This must be submitted and approved before research begins. Gaining approval can take several months so adequate time must be allotted if research must begin at a particular time (for example during a certain period in the school year).

Components of a typical IRB protocol:

- Title Page
- Summary of Proposed Research
- Background
- Goals and Objectives
- Overview table
- Detailed Description of Data Collection Activities
 - Subject Population
 - Research Protocol
 - Risk and Benefit
 - Confidentiality
 - Compensation
 - Informed Consent Process
- Data Management
- Informed Consent/Assent Documents
- Study Instruments (Questionnaires, focus group guides, etc.)
- Ethical Training Certificates of all investigators named in the protocol
- Additional information: Funding sources for research

These sections should be repeated in the protocol for each data gathering activity

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Title Page

Project title: "<add project title>"

Principal Investigator: <Name>
<Address>
"<Phone number>"
"<Email address>"

Project location: "<enter location where research will be conducted>"

Proposed project dates: "<enter start and end dates>"

Study Coordinator and any other relevant co-investigators: <Name>
"<Phone Number>"
"<Email address>"

Submitted to the IRB on "<date submitted to the IRB>"

"<Principal Investigator's name>"

Date

Summary of proposed research

Include a summary of the research (up to 1 page). This should include: overall goals of the project, procedures to be carried out, brief statement of the risks and benefits to the research participant

DRAFT

Background

Briefly describe the background of this research, including reference to the published literature. Describe the work of others and of the Principal Investigator, citing the published literature. Indicate the relevance of the proposed investigation to present knowledge and describe the hypotheses to be tested.

Study Goals/Objectives

Include the study goals and objectives here

Expected duration of the study overall

Expected sample size in each category of participant (student, teacher, principal, policymaker)

DRAFT

Overview Table: The following table should be filled out in its entirety. This helps the IRB see a snapshot of the research and should help investigators make sure all required components (consent forms, instruments) have been included in the annexes. **Note: activities listed are just examples and do not include all possible study activities.**

Data Gathering Activities					
	Survey (students)	Survey (teachers)	Survey (principals)	Focus groups	In-depth Interviews
Study population	Male and female secondary students in selected schools	CSE teachers in selected schools	Principals of selected schools	Teachers	Policymakers
Sample size					
Location of activity	Classroom	Office	Office	TBD	TBD
Timing	Project Month X	Project Month X	Project Month X	Project Months X	Project Month X
Method	Questionnaire	Questionnaire	Questionnaire	Focus group led by researcher	Interview led by researcher
Informed Consent document (Appendix #)	Parental permission form, Annex # and adolescent assent form, Annex #	Individual consent form, Annex #	Individual consent form, Annex #	Individual consent form, Annex #	Individual consent form, Annex #
Study Instrument (Appendix #)	Student survey, Annex #	Teacher survey, Annex #	Principal survey, Annex #	FG guide, Annex #	IDI guide, Annex #

The following sections should be repeated for every data gathering activity:

- a. Subject Population
- b. Research protocol
- c. Risk and Benefit
- d. Confidentiality
- e. Compensation
- f. Informed Consent Process

Data Gathering Activity 1:

"<insert data collection activity here (e.g., baseline survey of adolescents)>"

a. Subject Population

- Description of study population, including number and ages of participants.
- Include inclusion/exclusion criteria; provide explanation for inclusion of vulnerable groups
- Recruitment procedures. For example, announcements made in classrooms
- How subjects will be informed of the opportunity to participate and the procedure for their informing the researchers that they wish to participate

b. Research Protocol

- Procedures and methods
- Locations/facilities (where specifically will interviews be conducted?)
- Estimated period of time to complete the study

c. Risks and Benefits to Subjects

- Risks may include physical, psychological, social, economic or legal risks. A discussion of risks should also include risks associated with loss of privacy and/or breach of confidentiality. How these risks will be minimized and procedures for dealing with them if they do arise should be included.
- Benefits include direct benefits to the subject. If no direct benefits are expected, you may include benefits to society from research findings. Compensation for participation is not a benefit.

d. Confidentiality

- Discuss the steps the researchers will take to protect the confidentiality of subjects, such as de-identification of records, storage of materials in locked cabinets and password-protected folders, etc.
- State how long records will be kept and when and how they will be destroyed.
- Also include confidentiality in terms of presentation of data/study findings in papers and at conferences.

e. Compensation

- Discuss whether the subject will be paid for his/her participation. Compensation could include cash, small gifts or travel expenses. Explicitly state what the

participant will receive and when that payment will be made (e.g., after enrollment). Compensation should not be withheld if the participant decides to drop out or skip parts of the study.

f. Informed Consent Process

- When during the research process will consent be sought?
- Who will discuss consent with the participant and explain the study?
- Where will the consent process take place?
- How will confidentiality be maintained during the consent process?
- Will the participant read the consent form to him or herself, or listen to the researcher read the form?
- Will there be written consent?
- When will parental permission occur (if applicable) and/or teacher and/or school permission?
- Will there be a witness to the informed consent? (optional)

NOTE: For studies involving children (under 18), parental permission should be sought prior to asking the child to assent to participate. The child should be notified that she/he is free to decline participation even if his/her parent agrees.

If your study includes emancipated minors, please explain why these subjects are considered emancipated and why seeking parental permission is not appropriate.

If seeking parental permission is not possible given the study design/ population, please explain the circumstances in the protocol and request a waiver of parental permission.

Data Collection Activity 2:

"<insert data collection activity here (e.g., baseline survey of adolescents)>"

Repeat sections A-F above for as many study activities as proposed. Delete if unnecessary.

Data Management

Briefly describe how data collected in the study will be managed including where materials will be stored, when materials will be destroyed, etc.

Annexes:

Informed Consent Documents

Insure that two sets of telephone contact numbers are provided in all ICs for study participants so they can: 1) contact appropriate authorities regarding research or injuries; and 2) contact appropriate authorities regarding subject's rights, preferably contact information of the local IRB or health ministry.

Study Instruments

All instruments to be used in the proposed research must be submitted to the IRB. For example, these may include:

- Questionnaires
- Focus group guides
- In-depth interview guides

Note: If multiple versions of a questionnaire will be used (i.e., for students, teachers, and principals), please include all versions. Please indicate skip patterns when applicable. When certain subjects will not be asked certain questions, please specify that.