



**Ethical Social/Behavioral Research
with Adolescent Participants**



INTRODUCTION

Public Health research focuses on community health needs and data collection may involve children or adolescents. Adolescents are a unique population for human subject research because they are old enough to have their own opinions and needs but are still considered minors in most situations; they are not yet complete independent legal agents. There are some circumstances where local law may allow adolescents to consent for themselves. It is imperative that researchers understand who has legal authority to consent to a study under the local laws and practices of the research setting.

This guide intends to help prepare researchers who will recruit adolescents into human subject research studies for the ethical and legal issues and challenges associated with research involving this vulnerable population. Our intent is to promote thought and discussion among researchers about how to address them and to provide some practical examples.

DEFINITIONS

46 CFR 46.402:¹

Children

Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Assent

A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Permission

The agreement of parent(s) or guardian to the participation of their child or ward in research.

Parent

A child's biological or adoptive parent.

Guardian

An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

Age of Majority: The age at which an individual is legally considered to be an adult, with all attendant rights and obligations. In the United States, States have the authority to establish the age of majority.²

Adolescent (WHO): Those people who are between 10 and 19 years of age.³ In social/behavioral human subjects research, older adolescents are often separated from younger adolescents as their physical, mental, and social development differs. It is sometimes inappropriate to ask younger adolescents the same questions that you might ask older youth, especially about sexual behavior and alcohol and drug use.

Emancipation: Emancipation establishes a minor's status as an adult, even though they may not have reached the age of majority. Emancipation may occur by court order or through operation of law. For example, in the U.S., a State law may establish that a minor who is married or who has a child is an adult and no longer bound by parental authority. A State or national authority may pass laws or statutes that will allow a minor to consent for themselves for access to certain medical services, such as reproductive health.

Foster care: Foster care (also known as out-of-home care) is a temporary service provided by States for children who cannot live with their families. Children in foster care may live with relatives or with unrelated foster parents. Foster care can also refer to placement settings such as group homes, residential care facilities, emergency shelters, and supervised independent living.⁴

Mandatory Reporting Laws: Each State in the U.S. is authorized to mandate reporting of child abuse and/or neglect to State and local authorities.⁵ Internationally, the mandatory reporting laws tend to be promulgated by national governments.

Minor Consent Laws: States in the United States may permit minors to consent for themselves for health care treatment and advice without parental consent. The types of treatment and advice varies by state.² In Maryland, minors may consent to treatment or advice for pregnancy, sexually transmitted diseases, contraception, and drug/alcohol treatment, among other things.

Orphans and Vulnerable Children (OVC): USAID and PEPFAR sponsor programs to serve children living in a variety of adverse situations.⁶ (See: [Advancing Protection and Care for Children in Adversity: Implementation Plan](#))

Risk: IRBs must consider the risk of harm to participants associated with all stages of a study, from recruitment through data sharing and archiving at the end of the study. The concept of risk is broad; risks can be physical, social, economic, psychological, legal, etc. It includes social embarrassment and distress that may be caused by the study procedures. Research risk must be reasonable in relation to anticipated benefits. For studies involving children, there are limits to the level of risk permitted. The U.S. Common Rule allows the following¹:

- Research posing no more than minimal risk to participants, and requires parental/guardian permission and assent from the participants (unless waived);
- Research posing a minor increase over minimal risk; presents experiences “reasonably commensurate” with participants’ actual, expected life experiences in a variety of situations; and is likely to yield “generalizable knowledge about the subjects’ disorder or condition which is of vital importance for the understanding or amelioration of the subjects’ disorder or condition”; and
- Research posing more than minimal risk, but is justified by the anticipated direct personal benefit to study participants; and the risk is at least as favorable as existing alternative approaches.

Safeguards: mechanisms included in the research to protect the rights and welfare of study participants.⁷ Examples include mandating parent/guardian permission, and when parent/guardian permission is not reasonable, providing alternative mechanisms to help minor participants to make decisions about whether or not to join a study. It includes providing robust privacy protections when recruiting, obtaining assent, and collecting sensitive information from minor participants.

Protections:⁸⁻¹⁰ Child protections may be considered a subset and/or extension of child safeguarding procedures, which can infer a duty or obligation of an investigative team to protect child well-being. So, while safeguarding refers to making a study safe for children (protecting them within the study), protection is about making the world a safe place for children and refers to actions taken (or procedures built into studies) to protect children from concerns of risks and harms. So, safeguards are inherently a mechanism for protection within a study context. However, protections can also expand beyond what is happening inside of a research study (and the built-in safeguards therein). Investigators can consider the following differentiation: safeguarding is to prevent harm; child protection is to respond to harm. Because safeguarding is a mechanism for protection, it is not always clear that protections may involve further obligations or duties in research. Indeed, the expectations for each may differ according to the regulatory context in which a study is working. The base expectation is to build in safeguard protocols – which inherently protect the ways in which children participate in a study – but there is opportunity to expand on protections to support the well-being of children and adolescents holistically.

Vulnerability: The U.S. Common Rule provides that IRBs must “...be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons,” see 45 CFR 46.111(a)(3).¹¹ Children, because of their age and lack of experience, are vulnerable to the influence of others. As part of its review of non-exempt research, IRBs are required to ensure that “additional safeguards have been included in the study to protect the rights and welfare of these subjects,” see 45 CFR 46.111(b).¹¹



CONTEXT

Of community, sensitivity of topic, subpopulations, research setting

Before addressing the ethical challenges of engaging individual adolescents in research, it is important to consider the context of the research study. In social/behavioral studies, context introduces risks and other challenges that will be missed unless researchers think about them during the research planning process.

Community Engagement:

Communities, families, and adolescents vary across nationality, age, sex, gender identity, religion, ethnicity, education, social acceptance, socio-economic status, and many other factors. Researchers must identify and consider these variables when planning their recruitment and consent/assent strategies. Recruitment processes themselves may insert risk to the adolescents you are interested in.

Before initiating a study that will involve adolescents, researchers should understand how local institutions are organized and consider initiating a dialogue with the community, including community leaders, stakeholders, parents, and youth to increase the receptivity of the community to your study and its objectives.

Topic Sensitivity:

At the community level, certain topics may be culturally taboo or highly sensitive.

For different families, sensitivities may depend upon family dynamics, religion, tradition, and other factors. Even defining what “violence” is in a community, or what types of sexual activities constitute reportable abuse, will vary across communities and may or may not have legal implications. These concepts must be clearly understood if study goals will involve exploring them with adolescents. Thus, each study must adapt its procedures and materials to be appropriate to the target population.

- This also means that data collection instruments should be examined with topic sensitivity and study populations in mind as the wording of certain questions might inadvertently be offensive to some groups or persons. Discussing the wording of instruments ahead of time with community representatives might prove useful so as to anticipate and adapt to potential issues.

Population Vulnerability:

Researchers may need to adapt research recruitment and consent/assent processes to address particular subpopulations in addition to targeting questions to subgroups, for example, by age (12-14, 15-17), sex (males, females, nonbinary, transgender, and others identifying across the gender spectrum) ethnicity, etc. For adolescents who have no parent or guardian, you may need to provide a “substitute mechanism” to advise them; this should be an adult (often a social worker or other counselor), otherwise unaffiliated with the study, who can help the adolescent decide whether or not to join the study.

Subpopulation Considerations:

Who are the adolescents that you seek to include in your study? Are they particularly vulnerable, such as “street kids”, orphans without family placement, “emancipated” minors without adult guidance, females in settings where child marriage or gender-based violence is the norm, children caring for sick adults or being parented by parents suffering from mental health, children who are heads of households, or children of incarcerated parents? Are they older adolescents (15-17) or younger (10-14)? Are they married? Parents? Urban or rural? Sexually active or pre-pubescent? What is their capacity to make decisions about joining a research study? What kind of help or advice will they need? It is helpful to think through the capabilities of the adolescents in advance. Likewise, thinking through how to maximize diversity of your study sample is important in the planning stage so as to assure that the study findings are as broadly applicable as possible.

- Adolescents vary as adults do in their individual capacities and life experience. Some youth understand more than others in their age group and others lag behind. Some youth want to make all their own decisions and others are happy deferring to their parent/guardian.
- When formulating guides, there are questions that are not “age appropriate” for children at the younger end of the age range. It’s important to calibrate the questions to the population under study.
- Depending on their level of comfort with technology, some youth may be more comfortable answering questions on a tablet or other device than responding to an interviewer.

Research Encounter Setting:

The setting of data collection is important to assessing risk. Will you ask adolescents sensitive questions in the clinic setting where service providers are trained to keep information confidential and, in some situations, the law permits adolescents to consent for themselves? Or do you plan to ask the questions in the home or educational setting where protecting privacy and confidentiality is more challenging? The recruitment and consent/assent processes and the data collection procedures must be designed to maximize protections for the study population.



ETHICAL CHALLENGES

1. ESTABLISHING TRUST:

All human subjects research is founded on trust; without it you will not be able to answer your research question and you may taint the relationship between community and researchers.

Community Dialogue

Trust requires engagement and dialogue with community, including parents and youth, to learn more about what is appropriate for that community and how to adapt study materials to that community's needs. The research may require formative work to help researchers understand community norms before approaching families and adolescents. Failure to take this step could increase the risk that families and adolescents incur social risk if they do agree to participate in the study. It also increases the risk that the community could be harmed by dissemination of study results about the community without its knowledge.

Ultimately, failure to establish trust with the community could impede the ability to conduct research with this population or reduce the reliability of collected data.

Understanding Risks and Tensions

When planning a research study involving adolescent participants, it is important to understand the tensions that lie at the forefront of conducting ethical research with adolescents:

- Most social/behavioral studies offer no direct benefit to the participants, so minimizing the risk of study participation is essential to designing an ethical study with a reasonable risk: benefit ratio.
- The community setting contributes to the element of risk to adolescent participants with respect to a breach of privacy or confidentiality. Researchers must consider social expectations about adolescent behavior, religious mandates, power hierarchies within communities and families and the like. **It is imperative for the researchers to put into place community engagement and privacy and data security protections to minimize the risk of an adverse outcome for the study participants.**

- Investigators must respect the autonomy of adolescents while also recognizing the legal authority of the parent/guardian to provide consent and their right to protect their youth's interests.
- The interests of the parent/guardian and the concerns of the adolescent may not always coincide, especially with collecting personal information about sensitive topics like sexual and reproductive health, child abuse experiences, gender-based violence, gender identity, mental health, child marriage, migration experiences or illicit drug use.
- Who has legal authority to provide consent for a study involving adolescents? In general, parents/guardians have the legal authority to consent to their children's participation in research studies. But there are exceptions in law and in practice.
 - There are some very benign studies that seek non-sensitive information from minor participants and may merit an IRB or ethics board' waiver of parental permission.
 - In some jurisdictions laws allow adolescents to consent for themselves for studies, such as those that involve reproductive health or drug abuse. These laws are driven by policy to ensure that adolescents safely get the care they need when parental/guardian permission may be an obstacle.
 - The U.S. Code allows an IRB to waive the requirement for obtaining parental permission "if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children)...," see 45 CFR 46.408(c).¹¹ However, the investigator must propose a substitute mechanism as a safeguard for the minors. Some studies have used an objective outside party like a social worker or another adult who works with adolescents; their sole role is to discuss with the adolescent whether or not the adolescent should join the study.

Minimizing Risks to Participants: Do no harm, and provide safeguards

Human subjects research projects involving children, youth, and adults, must address the risks they pose to participants and how risks will be mitigated.

Researchers often underestimate the risks of social/behavioral research and the potential harm that this research can cause. Researchers must provide safeguards and support as appropriate and necessary to mitigate adverse consequences.

2.PROMOTE DIVERSITY AND INCLUSION:**Historically underrepresented populations; Justice; Good Science**

Human subject research has historically underrepresented women, minority and marginalized populations.¹² In the U.S., black and brown populations have not received the same access to health care as the white population; neither have people who belong to the LGBTQIA+ community, or who engage in sex work, those who use drugs, those with disabilities, are non-English speaking or are otherwise outside the mainstream.^{12,13} Researchers must do their best to actively and intentionally broaden their participant pool.¹³ The ethical principle of Justice requires investigators to distribute the burdens and benefits of research fairly across populations, and science and health suffer when research populations are too narrow.¹² The excluded populations cannot have confidence in research outcomes if they are not included in the research studies that drive health care decisions. In order to facilitate the participation of underrepresented populations, certain aspects of research and consent may need to be modified (e.g. inclusion of community representatives or interpreters).¹³ In many cases, such modifications may demand additional expenses to the research process.¹³

Expand your research team to include involvement with individuals or representatives from underrepresented populations

Different perspectives improve human subjects research, which is why Institutional Review Boards are required to have members from different disciplines, of different genders, and include members of the community. Research teams attempting to extend the scope of a study to include a broader, more representative, population of participants will benefit from increasing diversity on the study team. Engaging trusted community members from the start can integrate a much-needed lens to each step of the research process.¹³ It is important to frame the scope of their involvement so as to avoid being tokenistic and do due diligence in leveraging their expertise and capacities in the community.

Hard to reach adolescent populations are harder to recruit and include in the study

It is true that underrepresented adolescent populations may be harder to recruit; investigators may have to think about including trusted community partners to help get the message out in different ways. In fact, in many cases these community partners are more knowledgeable than the research team and so should be relied on for key insights throughout recruitment processes.¹³ Different populations use different platforms for communications, and trusted communications from trusted sources are more likely to yield positive connections. Indeed, investigators should turn away from recruitment strategies that are easy for themselves in favor of approaches more in tune with the people whom they are to recruit.¹³ Including community members as an integral part of the research team, and more broadly the public health workforce, is more people-heavy and thereby more expensive; however, it is more ethical, cost-effective, and worthwhile for the sake of good research in the long-run.¹³

3. DO NO HARM

Conducting human subjects research itself may introduce the risk of harm to adolescents that they might not otherwise experience. For example, adolescents may engage in personal behavior without the knowledge of their parent/guardian or community that, if known, could expose them to community or parental disapproval, stigma, embarrassment, distress, or even severe responses like social ostracism or violence. If a research study facilitates disclosure of this behavior, and the adolescent's privacy and/or data are improperly protected, the researcher is responsible for the adverse consequences to the adolescent participant.

Sensitive information can take different forms: some is about personal behavior or decisions that an adolescent may make that, if known outside the study, could create problems for the adolescent; other information might be about activities that an adolescent may be a victim of, such as sexual abuse, neglect, and interpersonal or gender-based violence. Personal choices on the part of the adolescent that might deviate from community norms or family expectations need privacy protections and potential referrals for care. Uncovering the fact that an adolescent may be the victim of ongoing abuse, neglect or violence raises a different and potentially more complex set of obligations on the part of the researcher.

The researcher has a duty to identify and anticipate the consequences of collecting personal information about an adolescent and the harms associated with the disclosure of sensitive information outside the study.

How, if necessary, will the team navigate privacy considerations? What line is there to be drawn between protecting adolescent participants and respecting their autonomous decision as to whether or not to accept a referral for care?

- It is useful for the research team to consult with collaborators in the community, such as NGO/collaborator staff, to get their perspectives on what constitutes “harm” in the setting, assessing acceptable risk, and considering what mitigation strategies would work best in the setting. NGOs/collaborators have the advantage of often knowing the trusted gatekeepers/leadership in the community and have longer term relationships with these communities. For example, if a study is about reproductive health and plans to ask unmarried adolescent girls about sexual behavior, community norms and expectations about what that topic vary considerably. If asking about depression, will the adolescent experience any negative social stigma if identified as needing mental health care (if available)? The same concerns exist for questions about substance and alcohol abuse and sexual orientation or gender identity. And are there referral mechanisms identified if questions asked trigger unanticipated negative responses?
- When asking about violence or sexual abuse, investigators must think about the consequences if an adolescent discloses that they are, or have been, a victim or perpetrator of behaviors that are reportable to authorities in their communities. Mandatory reporting rules vary by State in the U.S. and by international and local laws in countries abroad. Investigators must comply with the mandatory reporting requirements in the setting where they are collecting data. Reporting itself may put an adolescent at risk of further violence or abuse, loss of home, ostracism, or abandonment.
 - If you ask a research question about past child abuse, not ongoing, some local laws (such as in the state of Maryland in the USA) require reporting, even if the victim is now an adult.

- Researchers must consider the consequences of asking about child abuse that could be ongoing; what protections are available for the adolescent? Will mandatory reporting help protect the youth or make life riskier? What are the legal options?
- If the abuser is also the adolescent's parent/guardian/head of household, will reporting the abuse endanger the youth? Is it possible to remove the youth from the home? What actions are you obliged, or able, to take to help the youth now that you know about this activity?
- If research requires asking about abuse, and you do not need to link the responses to other data, will collecting the data from the youth in a de-identified way be more protective of the youth? What information might you provide to all survey-takers to help them understand resources available to them?



PROVIDE SAFEGUARDS AS PROTECTIONS FOR HEALTH AND WELFARE

After identifying the potential harms associated with a research study, researchers must be creative in identifying the safeguards they may put into place to protect study participants.

- One kind of safeguard is to ensure that all risks are clearly outlined in the parent/guardian permission and assent documents so that the parent/guardian and adolescent can make an informed decision about assuming the known risk. Collecting sensitive information may be embarrassing or distressing for the adolescent. It is important to be clear about what information will or will not be shared with the parent/guardian and what access to care or other resources will be available through the study. Mandatory reporting, calling for emergency care in acute health situations, and other actions that a researcher must take should be clearly outlined in the consent/assent documents.
- The assent process includes other safeguards, if done properly. Participants have the right to withdraw consent at any time, and they have the right to skip questions that they do not want to answer. The adolescent should be reminded of these rights. This reinforcement will underscore consent as a continuous process throughout research.
- When forming a survey or interview guide, researchers should consider what it is like to be the respondent. These guides should include introductions and transitions that let participants know what's coming. For example, questions with great sensitivity should not be dropped like bombs into the conversation; there should be preparatory language to help the participant understand what questions are coming. Additional language should remind them of their options in responding to the questions and the support mechanisms in place upon responding.

- Another safeguard is to provide robust privacy protections to reduce the chance of someone who is not authorized to hear or see the private information accesses it. For example, ensuring that an adolescent is alone in a quiet place during a Zoom discussion, or conducting an interview outside the home under a tree (when appropriate) can help minimize this risk. For Zoom, safeguards including using pseudonyms and not using video in a focus group discussion. Some researchers use noise-cancelling machines when conducting an interview inside a home to minimize the chance of other family members hearing a participant's responses.
- Researchers have an obligation to anticipate the needs of adolescent participants if asking about their health and wellbeing. Studies asking about health issues should provide referral for locally available care or services. For example, for sexually active adolescents in a study on reproductive health, providing access to condoms, STD testing and birth control. For mental and behavioral health concerns, referral to mental health providers and counseling. The assent form must be explicit about whether or not the adolescent will have a choice to consent to these referrals. Research groups should also be clear ahead of time as to whether they have an obligation or capacity to ensure that these referred services are followed through with, for example, by covering the costs of such visits.
- Referrals for care may not be enough. A researcher-facilitated "warm hand-off" to caregivers is far preferable in certain situations such as those involving imminent episodes of abuse, or acute needs like mental health/suicidal ideation. Afterwards, it is important to consider in advance if the study team is obliged to include follow up procedures to see if the adolescents got the help that they needed. For longitudinal studies, what should researchers do when the abuse is perpetually reported but no help is given. What is the moral obligation of the researcher to follow up for such cases? Is it ethical to keep asking questions and not providing solutions?

- Alternatively, will the study team include a person with the expertise, such as a mental health provider (e.g., counsellor, psychiatrist), to directly provide the services that may be needed?
- After-study access to care: When a new therapy is introduced to a community by a study, it is fair to ask about access to that therapy (if safe and efficacious) after the study is over? If there is a control arm that has been offered placebo, will the therapy be offered to those participants?

Limits to Safeguards:

The researcher cannot protect the adolescent from all harms. Not all needs can or will be addressed because of the scope of the research and/or the capacity and resources of the research team. It's important to manage expectations with the community and participants. Investigators must make clear that collecting information may help address needs of the community long-term but will not solve immediate participant access needs. Investigators must be clear about how the research may or may not affect the lives of the participants.



PRACTICE AND PROCEDURES

Once researchers understand some of these complexities, they need to formulate practices and procedures to facilitate conducting ethical work as a continuous process.

- The researchers who intend to work in a community that is not their home must understand the context of conducting research in that setting. Collaboration with local researchers is recommended, as well as local ethical review of the study to assure that the proposed study is appropriate for the local context.
- Understand what the law requires in each research site, and incorporate those requirements into the study documents, including recruitment materials, parental permission, and assent forms. For example, if the law requires mandatory reporting when an adolescent reports child abuse, the parent/guardian and adolescent need to know that this information cannot be kept confidential.
- Researchers should be as clear as possible about what comes first, obtaining an expression of interest about the study from the adolescent before approaching a parent/guardian, or obtaining permission from the parent to approach the adolescent to discuss the study and obtain assent.
- Parents and adolescents need to understand what the study is about and how you will use the information collected. If information disclosed by an adolescent will not be shared with the parent, that fact should be clear to both the parent and the adolescent.
- Researchers must make very clear to both parents and adolescents the circumstances under which promises to protect privacy and confidentiality will be limited, such as when an adolescent discloses suicidal ideation, reportable child abuse, or other acute health-related issues.

General parent/guardian issues

(A) Legally effective informed consent: All research participants must provide “legally effective” informed consent prior to research participation. In the case of adolescents in the US, parents or legal guardians are authorized by U.S. law to provide consent for their children to participate in research, and assent must be obtained from the adolescent participants unless waived. The U.S. Code provides some exceptions to the parental/guardian permission requirement, allowing waiver of parental permission when allowed by State statute or when it is inappropriate to require parental permission and there is a substitute mechanism provided to protect the child’s interests. 45 CFR 408(c).¹¹ Adolescents must provide assent prior to study participation, unless the study offers a therapeutic benefit, and the reviewing IRB waives this requirement. The assent must also be “informed” and be active agreement that may be withdrawn at any point; failure to decline is not “assent”.

If the study site is outside the U.S., national law applies. It is important to know what constitutes “age of majority” in the country, and when minors under that age may be treated as adults for consent purposes. Even in settings where legal frameworks are different or less protective, it is also important to apply the same standards for protection of individuals in those settings as a researcher would in a setting with comprehensive legal protections.

(B) Transparency, with discretion: Studies with adolescents may introduce tensions between personal privacy and autonomy and the right of parents to protect their children; involving minors in research must anticipate this potential conflict. Investigators must mitigate this risk by being as transparent with parents/caregivers as possible, unless transparency could put the child at risk. The collection of data about certain topics, like domestic violence and child abuse, could be tricky if it’s possible that a parent or family member may be victimizing the adolescent. The investigator must prepare for the consequences that will follow disclosure by the adolescent of reportable events or other information that reveals ongoing risk to the child. Mandatory reporting is just that – mandatory. And it’s important to understand researcher obligations and the legal exceptions that might exist in different settings when conducting research. Sometimes collecting sensitive data anonymously is more protective of the adolescent than collecting data with a link to the individual. In any event, studies that collect information about potentially reportable topics must include in the consent form the fact that the researcher will follow the law and report such information.

- (C)** How do you obtain parental permission for a study that may elicit information from an adolescent that a parent may not know about? For example, how should you ask parents to give permission to ask their children about sexual behavior, contraception, substance abuse, child abuse, violence, and/or suicidal ideation? How much information is enough, and what constitutes “omission of disclosure” that could threaten the “informed” aspect of the parental permission? Sometimes researchers may use more generic descriptions of sensitive topics when presenting the study to parents in order to protect the privacy of the potential adolescent participants. The risk depends upon community norms, but the driving principle must be the protection of adolescents and youth. For example, if the study involves asking adolescents about their personal sexual behaviors and they may be exposed to social stigma if they are unmarried and sexually active, the assent process should make clear to the adolescent what questions will be asked. On the other hand, specificity may be problematic for the parents. Instead, the researcher might use more general topic descriptions to inform parents that the study seeks to understand the reproductive health needs of young adults, and will cover topics like family planning, contraception, and reproductive health. The information must be “sufficient” enough for agreement to constitute “legally effective informed consent,” but might not disclose the specifics of the questions themselves.

Tips for Obtaining Parental/Guardian Consent:

- i.** Questions about sexual behavior, contraception, abortion = “sexual and reproductive health”; including language like “we will not tell you anything that your child tells us”; “we will not tell your parents/guardian anything you tell us”.
- ii.** Questions about violence not subject to mandatory reporting = “We will ask your child about incidents of physical harm”; “We will not tell your parent/guardian...”.
- iii.** Questions about reportable child abuse = “If your child tells us about physical harm or sexual abuse by an adult, we must report that information to the local authorities”; “We will not tell your parent/guardian, but we must report that information to local authorities such as [insert local authority...]”.
- iv.** Questions about mental health: “We will talk to your child about their thoughts and feelings; we will not tell you about anything they tell us”; “We will not be telling your parents about anything you talk about here. However, there are some exceptions (e.g., extreme distress relating to suicidal ideation, perhaps)”.

Adolescent Participation

- (A) Transparency:** Make clear what the study will and will not do FOR or TO the adolescent.
- (B) Manage expectations** (If about nutrition, will the study provide food? If about violence, what will study do or not do for the adolescent?).
- (C) Voluntariness:** It is critical that the adolescents retain their autonomy during the consent process and during data collection. Assent is a continuous process throughout the research. It is the researcher's obligation to ensure that the adolescents understand that they may decline to participate, and if they do decide to join the study, they may skip any questions they want to and may stop participating at any time.
- (D) Privacy protections:** Adolescents will not join your study if they do not trust that you will protect them. If they join, but do not feel safe, they will not provide you with accurate data. Before you finalize study materials and recruitment/consent processes, you should consider involving youth to make sure they are appropriate for your population, and by engaging them early you may be able to double-check your proposed processes through them to ensure appropriateness.

Tips for Obtaining Assent

- i.** Be clear about the sequence of events in obtaining parental consent and youth assent; which comes first? Will the parent and the adolescent be together? In some cases, it may be more appropriate to obtain an indication of interest from the adolescent, and then approach the parent. In others, the reverse order may be more appropriate.
- ii.** Are there any characteristics of the adolescent population that would suggest a cognitive capacity deficit that may hamper the assent process, requiring creative solutions such as video or a graphic presentation?
- iii.** Think through the complexities of the setting of assent, in-person and virtual. In general, assent should be obtained individually rather than in a group setting, and with privacy protections to ensure that the discussion is not overheard. It may be appropriate to provide information about a study to a group of adolescents, for example in a school setting, but each student should have the opportunity to consider participation in a way that protects their autonomy and privacy.

iv. “Private” information is that which a person expects will not be shared or made public. Adolescents may disclose personal information to researchers that they will not disclose to their parents or guardians. For example, information about personal sexual behavior and reproductive health needs may not be known to family members and must be kept private to protect the adolescent. The adolescent needs to know that the researcher will not make individual, identifiable responses known to anyone outside the study. Discuss the privacy protections you will employ, such as ensuring that you will be in a private space, using a white noise machine if appropriate, collecting data on mobile devices with adequate data security protections, and not recording personal identifiers. **It is also important to make clear to both the parent and the adolescent in the consent and assent forms what information the adolescent discloses will or will not be shared with the parent/guardian or others in the community.**

There is some information that cannot be kept private because of legal requirements or ethical concerns. Disclosures of child abuse or neglect must be disclosed in most U.S. jurisdictions, and in many countries. Disclosures about acute mental health distress, especially suicidal ideation, or imminent danger requires action on the part of investigators to refer the adolescent for care, preferably via a “warm hand-off” rather than providing a list of resources. To ensure that trust is built and maintained in these situations it is all the more important to be transparent about information disclosures at the beginning of and throughout data collection.



CASE CONSIDERATIONS

- Questionnaires including Adverse Childhood Experiences (ACEs) modules: The ACEs tool is important for learning about child sexual abuse, other abuse, neglect, and violence. It also includes questions related to mental health. Investigators must be prepared to address local reporting requirements and referrals to care.
- Adolescents in Sex Work: Adolescents may be involved in sex work and may or may not be viewed as “emancipated” in the local site. Investigators should be sensitive to how reporting may affect housing and other care issues, if for example the adolescent is living with family who may be responsible for the adolescent’s sex work.
- Orphans and Vulnerable Children: Children around the world have lost parents to HIV and other illness and may be placed in homes. Studies that investigate their health and welfare needs must take into consideration the potential impact on housing and work with local authorities to re-house the adolescents if needed.
- Reproductive Health: Adolescents have variable access to reproductive health care, depending upon local laws and practices. Studies on access and effectiveness of health interventions must ensure privacy and confidentiality. Unmarried adolescents involved in sexual activity (which may or may not be voluntary), and married adolescents who seek contraception or other reproductive health care in contravention of spousal or family expectations are particularly vulnerable.
- Children in Therapeutic Studies with Potential Benefit: Adolescents vary in their ability and willingness to engage in the assent process for studies with potential therapeutic benefit. For example, Phase 2/3 oncological drug trials may involve multiple visits and difficult side effects; some adolescents will not want to deal with the details of these studies and may want their parents to make decisions for them. Others will be very involved in the details of each study. Investigators need to be sensitive to the individual response of each participant.

- Children in No Benefit Studies with More than Minimal Risk: Some studies pose risk to adolescents and do not offer a potential direct personal benefit. For example, challenge studies for children with allergies or asthma often involve causing a reaction when testing a potential new treatment. Consent from both parents is generally required for studies like this. Investigators must be aware of the parental consent requirements in each study site.
- Children Responding to Anonymous Instruments (Surveys/Questionnaires): Anonymity does not automatically exculpate the investigator from responsibility to adolescent respondents. In some situations, anonymous responses make it possible to collect data that otherwise may not be possible to collect because of unwanted consequences for the respondent, such as triggering mandatory reporting if questions elicit information about child abuse. In another situations, such as using the PHQ-9 and inquiring about suicidal ideation, the protection of anonymity may not serve the respondent as much as the investigator. Identifying adolescents at risk of self-harm puts a responsibility on the investigator to put into place alert notifications so that the investigator can activate assistance for the adolescent with responses indicating acute distress.



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