



Position paper

Guidelines on the Inclusion and Protection of Adolescent Minors and Young Adults in Health Research: A Position Statement of the Society for Adolescent Health and Medicine

The Society for Adolescent Health and Medicine



ABSTRACT

These guidelines aim to assist researchers and research ethics committees/institutional review boards in the ethical conduct of health research with adolescents and young adults (AYA), particularly research with adolescent minors. Inclusion of AYA in research and protection from research harms are essential if, as individuals and as a group, they are to receive the benefits of research. The ethical principles of respect for persons, beneficence, and justice, the human rights concepts of best interests and emerging capacity, and the concept of appropriate inclusion collectively provide an ethical framework for evaluating the circumstances within which adolescent minors can and should be involved as research participants. Likewise, legal concepts guiding informed consent in health-care practice—age of majority, emancipation, mature minor, and minor consent—provide an important conceptual basis for informed consent with adolescents in health research. Consent processes in adolescent health research should be based on scientific understandings of AYA cognitive, psychological, and social development; the weight of current scientific evidence suggests that capacity to provide informed consent for research is present by the age of 14 years. When adolescent minors consent for themselves (i.e., autonomously or independent of parents/guardians), procedures should be in place to assess and support their desire for advice from parents and other trusted adults. Researchers should involve AYA in the codesign of research and should involve community members, parents, and AYA in the development of research priorities and questions, to ensure that research is relevant to AYA, to protect privacy and confidentiality, to facilitate the dissemination of research findings, and to promote translation of research into practice. Research with AYA should never reinforce stigma and discrimination of AYA or the groups to which they belong.

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Positions

Position 1

The inclusion of adolescents and young adults (AYA) in research is essential if they are to share in the benefits of research.

Position 2

The principles of respect for persons, beneficence, and justice and the concepts of best interests and emerging capacity provide an important framework for ethical conduct of research with AYA.

Position 3

Legal concepts that guide the informed consent process in adolescent healthcare—the age of majority, emancipation, mature minor, and minor consent—provide an important framework for informed consent to health research involving AYA.

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Position 4

Consent processes in adolescent health research should respect the evolving capacity of the adolescent for autonomous (i.e., independent) decision-making. Consent processes in adolescent health research should be based on scientific understandings of AYA cognitive, psychological, and social development. The weight of scientific evidence suggests that the capacity to provide informed consent for research is generally evident by the age of 14 years.

Position 5

Adolescent minors should be allowed to provide informed consent autonomously for research: (1) if the research is low risk (e.g., minimal risk); (2) if obtaining parental permission is impracticable and ethically unnecessary; (3) when parental permission would compromise adolescent rights to confidentiality, health-care, or prevention services; (4) when requiring parental permission could potentially compromise the safety and well-being of adolescent participants; and (5) when requiring parental permission is otherwise ethically problematic.

Position 6

Parental permission may be an important practice in protecting young adolescents from research risk.

Position 7

When parental (including guardian) permission for research is not required and adolescent minors consent autonomously, procedures should be put in place to assess and support adolescent's desires or expectations for advice from parents and other trusted adults.

Position 8

For higher-risk research, researchers and research ethics committees/institutional review boards (RECs/IRBs) should consider the potential direct benefit to the adolescent and the degree of risk (magnitude and probability of harm), the potential for adolescents as a group of persons to benefit, and the potential ethical benefits and harms from requiring or waiving parental permission.

Position 9

For research conducted in health-care settings and where adolescent minors can autonomously (i.e., independently) provide informed consent for clinical care, adolescent minors should be able to provide consent for research.

Position 10

Investigators, RECs/IRBs, and funders must be aware of and work to prevent stigma and discrimination in adolescent health research by using human rights principles such as equity, inclusion, and an antioppression framework throughout all research stages from creating research questions, designing studies, evaluating proposals, gathering and analyzing data, and disseminating and translating results.

Position 11

Researchers should involve AYA in the codesign of research priorities, research questions, piloting of procedures of a study, development of plain language statements to protect privacy and confidentiality, and in the dissemination and translation of research findings.

Position 12

Researchers should involve community members, including parents and AYA, in the creation of research priorities, research questions, efforts to protect privacy and confidentiality, and dissemination and translation of study findings.

Position 13

Compensation to AYA and community advisors should be provided in situations where adults are customarily compensated in research.

Position 14

Ethics education and consultation about the ethical involvement of AYA in research should be readily available to REC/IRB members, adolescent health researchers, parents, and community members. Educational programs should emphasize the unique ethical, legal, and developmental issues in research with AYA and the social contexts of their lives including AYA relationships with parents/guardians.

Position 15

RECs/IRBs that review adolescent health research should ensure that the REC/IRB has expertise in AYA health and development, via committee/board membership or through consultation.

Position 16

Adolescent health researchers and RECs/IRBs should implement strategies to minimize risks of technology-based research.

Position 17

National governments and other research funders should support adolescent health research including research during the early adolescent period (10–14 years) and research to clarify and define adolescent competence, judgment, and capacity to provide informed assent or consent in research.

Position 18

Nations should identify priorities for AYA research, develop coordinated research and policy agendas, and facilitate collaboration among agencies and institutions involved in adolescent health and research.

Statement of the Problem

This updated position paper reflects new research and new ethical thinking on adolescent research participation, including

adolescents' capacity to provide informed consent; parental permission and consultation; adolescent codesign of research; AYA, parent, and community consultation and engagement in research; ethics education; technology-based research; and racism, stigma, and discrimination in research. This revision updates the 1995 consensus *Guidelines for Adolescent Health Research* [1] and the 2003 The Society for Adolescent Health and Medicine (SAHM) position paper on Guidelines for Adolescent Health Research [2] which were based on U.S. federal research regulations [3]. These revised *Guidelines* are based on well-accepted ethical principles [4], international research ethics guidance [5], and human rights concepts; the Guidelines have a global focus. The revised position paper is titled *Guidelines on the Inclusion and Protection of Adolescent Minors and Young Adults in Health Research* (hereafter, the *Guidelines*). Young adults are included in this revision as their health and developmental issues often represent a continuum from adolescence, although issues of inclusion and protection in research are more complicated among adolescent minors.

SAHM believes that the ethical principles of *respect for persons*, *beneficence*, and *justice* from the Belmont Report [4]; the concepts of *best interests* and *emerging capacity* from the U.N. Convention on the Rights of the Child (CRC) [6,7]; and the concept of *appropriate inclusion* from the U.S. National Institutes of Health [8] and the Council for International Organizations of Medical Sciences (CIOMS) [5] provide an ethical framework for evaluating the circumstances within which adolescent minors can and should be involved as participants in research. Legal principles guiding informed consent for adolescent health care are helpful in guiding consent for adolescent health research.

Likewise, various national and international regulations and guidelines on research ethics address the ethical conduct of research with adolescents [3,5]. However, existing regulations and guidelines do not fully speak to the complexity of ethical research with adolescents, particularly adolescent minors. Therefore, interpretation and commentary from SAHM and other professional organizations that understand AYA health and development and research ethics are essential. Adolescent-specific ethical guidance can address the unique strengths and vulnerabilities of adolescents and advance ethical health research.

Methods

The author group for the revised guidelines included individuals with expertise in adolescent health research, AYA development, clinical care, law, and ethics. This position paper is based on a review of the scientific and ethics literature, a review of existing practice guidelines, and a consensus of opinions among the multidisciplinary group of authors. These revised guidelines were peer-reviewed and approved by the SAHM Publication Editorial Board and the SAHM Board of Directors.

There are no fixed legal or scientific definitions of the terms “adolescent,” “adolescent minor,” or “young adult.” In this position paper, “adolescents” refers generally to people 10–19 years old; “adolescent minors” refers to adolescents who are younger than 18 years (or the age of majority where they live); 18–19 year olds are adolescents but legally adults; and “AYA” generally encompasses young people aged 10–24 years [9,10].

The Society for Adolescent Health and Medicine has embraced the health and health care of AYA, recognizing that the health and developmental issues of young adults often represent a continuum from adolescence [10]. The general terms in this paper, such as “adolescent health research” and “adolescent development” are not limited to strict age ranges and are intended to be inclusive of young adults.

These positions and recommendations are grouped into 8 sections: (1) ethical principles that can be used to guide adolescent health research (positions 1–3); (2) applications of ethical principles to the informed consent process (positions 4–9); (3) stigma and discrimination in research (position 10), (4) adolescent and community involvement in research (positions 11–12); (5) compensation in adolescent health research (position 13); (6) ethics education and expertise of REC/IRB members and adolescent health researchers (positions 14–15); (7) technology-based research (position 16); and (8) priorities in funding research (positions 17–18).

Positions and Recommendations

Position 1: The inclusion of AYA in research is essential if they are to share in the benefits of research

Both biomedical and behavioral research that include AYA significantly contribute to understanding and improving AYA health and well-being. Research with AYA may benefit individual young people and AYA as a group. Inclusion of adolescent minors in research should incorporate the dual goals of promoting the benefits of research and protection from potential research harms [5,11]. Exclusion of adolescent minors from research is not protection, as it denies adolescents the potential benefits of research, and raises justice concerns about adolescents not receiving their fair share of the benefits. Thus, RECs/IRBs should strive for the inclusion of adolescent minors in health research with appropriate protections.

Risks and benefits—both to individuals and to groups of adolescent minors and AYA—should be considered in evaluating proposed research. The risks and benefits of not performing the research should also be considered. Policies from the U.S. National Institutes of Health in 1998 [8] and 2017 [12] and from CIOMS [5] recognize the importance of inclusion in research; likewise, policies by the European Commission expert group on clinical trials [13] emphasize the meaningful involvement of adolescents in clinical research. Adolescent minors should not be excluded from participating in research that might benefit them as individuals or as a population solely because of age and instead should be meaningfully engaged in a manner appropriate to their age and capacity.

Position 2: The principles of respect for persons, beneficence, and justice and the concepts of best interests and emerging capacity provide an important framework for ethical conduct of research with AYA

The principles of respect for persons, beneficence, and justice in research ethics were articulated and codified in the 1979 Belmont Report [4], and applied to adolescents in the National Commission's 1977 report on Research Involving Children [14]. The concepts of emerging capacity and best interests are from

the 1989 CRC [7]. These 5 core principles provide an ethical framework for evaluating the circumstances under which adolescent minors can be involved as participants in research. The CRC augments the Belmont principles by situating research ethics within a human development framework which recognizes the critical transitions from childhood through adolescence to adulthood. The CRC articulates a specific set of human rights across multiple domains (e.g., education, health, work, political participation) and recognizes the changing roles of parents and children (including adolescents) across the early life course [7]. The CRC respects the essential role of parents in protecting their children from risks, with that essential role shifting to supporting the emerging capabilities of adolescents to make autonomous decisions that are independent of parents [6]. Ideally, parents help ensure children thrive as they mature and learn to make autonomous decisions. The Committee on the Rights of the Child comment 20 [15] addressed the specific issues of adolescence and the full realization of adolescents' rights.

Respect for persons demands that researchers balance respect for an adolescent's emerging capacity for independent decision-making with the need to continue to protect them, particularly for more vulnerable individuals. *Emerging capacity* recognizes the profound developmental changes that occur throughout childhood, adolescence and young adulthood in terms of cognitive capacity, desire for autonomy, and exposure to potential risks. *Beneficence* provides the ethical basis for conducting health-enhancing research and for maximizing benefits and minimizing risks, with the focus on the *best interests* of the child in the CRC. *Justice* demands that adolescent minors are not exploited for the benefit of others but also that adolescents should not be excluded from participation in research that may have direct or indirect benefits [16]. Justice also encompasses the concepts of health equity and the use of research, not only to generally advance adolescent health, but also to reduce health disparities and redress the harms of stigma, discrimination, and marginalization, including from systemic racism and colonialism.

Position 3: Legal concepts that guide the informed consent process in adolescent healthcare—the age of majority, emancipation, mature minor, and minor consent—provide an important framework for informed consent to health research involving AYA

Historically, children below the age of majority—the demarcation of legal adult status—had few legal rights, with little recognition of adolescence as distinct from childhood or adulthood. Beginning in the 20th century, increasing acknowledgment of adolescence as an important developmental stage led to legal rights being recognized for adolescent minors under specific circumstances [17,18].

Of relevance for adolescent health research are rights pertaining to health care for minors. Legal concepts such as the age of majority, emancipation, mature minor, and minor consent reflect historic understandings of adolescent welfare, decision-making capacities, as well as health and sociocultural realities [17]. Individual AYA who have reached the “age of majority” are considered adults and are legally able to provide consent for themselves. However, different rules apply for adolescent minors. Specifically, in the U.S. and in some other countries [17,19], the concept of

minor consent was incorporated into laws that allow adolescents without full adult status to consent for their own health care. Minor consent laws allow adolescent minors to receive health care without parental permission because they are seeking a specific service (e.g., sexually transmitted infections and HIV testing and treatment, contraception, pregnancy care, or mental health services, or substance use care) or because they have a specific status (e.g. marriage, homelessness, military service). The concept of “emancipated minors” refers to the adolescents who meet certain criteria being granted the legal status of independence from parental control for specific purposes; one of these purposes may be consent for health care. Under the mature minor doctrine, certain adolescent minors may have demonstrated a requisite degree of maturity that enables them to give informed consent [17,20–23].

Position 4: Consent processes in adolescent health research should respect the evolving capacity of the adolescent for autonomous (i.e., independent) decision-making. Consent processes in adolescent health research should be based on scientific understandings of AYA cognitive, psychological, and social development. The weight of scientific evidence suggests that the capacity to provide informed consent for research is generally evident by the age of 14 years

Adolescence comprises the developmental stage between childhood and adulthood that, among other changes, is characterized by developing cognitive and decision-making capacities. These emerging abilities directly affect adolescents' capacity to provide informed consent and to be involved independently or collectively in the research process.

Despite the common belief that the adolescent brain is immature and not capable of making decisions, decades of adolescent neurocognitive research suggest a more nuanced reality. Research suggests that adolescents do approach decisions differently than adults (e.g., less decision-making experience, more tolerance for risk, more influenced by peers, more influenced by distraction and the emotional context). However, decision-making studies of adolescents across the age range and from both high- and low-resource settings suggest that adolescents' abilities to understand research information, appreciate how it would affect them, reason and weigh risks and benefits, and make a voluntary choice are similar to healthy adult populations [24–32]. Thus, the weight of scientific evidence from these studies suggests that for adolescents with typical development, the capacity to provide informed consent is evident by the age of 14 years.

The arbitrary threshold used to define the legal age of majority (18 years in most countries today) does not adequately consider these emerging abilities. Current scientific understandings of adolescent cognitive, psychological, and social development should inform the ethical involvement and protection of adolescents in research processes. Research on cognition and capacity for informed consent suggests that even young adolescents (age 10–14 years) show significant ability to provide informed consent that is often equivalent to their parents' or other adults' abilities [25,27]. Adolescents aged 15–17 years and 18–19 years demonstrate the ability to understand research and make decisions about research participation that are similar to these abilities among parents and older adults [25,27–32].

Position 5: Adolescent minors should be allowed to provide informed consent autonomously for research: 1) if the research is low risk (e.g., minimal risk); 2) if obtaining parental permission is impracticable and ethically unnecessary; 3) when parental permission would compromise adolescent rights to confidentiality, healthcare, or prevention services; 4) when requiring parental permission could potentially compromise the safety and well-being of adolescent participants; or 5) when requiring parental permission is otherwise ethically problematic

Adolescent minors should be allowed to provide consent for many kinds of research [5,11]. In research that is low risk (e.g., poses no more than minimal risk such as confidential or anonymous survey research or a low-risk clinical trial, adolescents are generally able to provide informed consent themselves. In other cases, seeking parental permission may be impractical, such as research involving adolescents who are homeless and have little contact with their parents. For other types of research, such as research involving underage or illicit activities, requiring parental permission for research may reduce participation by adolescents for a range of reasons (e.g., adolescent concerns of confidentiality). Requiring parental permission for research about health services received under minor consent laws (where adolescents are allowed to consent for clinical care,) may compromise adolescents' subsequent access to confidential care based on their own consent. Because there are multiple reasons why parental permission might be ethically unnecessary or problematic, we suggest these 5 categories where adolescents should be allowed to consent themselves. In these cases, we recommend that researchers present the most relevant ethical rationale to the IRB/REC for their particular study.

Position 5: Parental permission may be an important practice in protecting young adolescents from research risk

Parents are primary protectors of their children and remain important in guiding AYA about research participation [6,11]. For young adolescents (under 14 years), when parents are available and capable of providing support, seeking parental permission is a helpful tool in assuring good decision-making consent and promoting adolescent safety.

However, in some instances parents are unable to guide young adolescents' decisions about research participation because of impaired capacity, overwhelming obligations, conditions such as drug use or mental illness, and other burdens [11]. Other young adolescents are recognized in practice as emancipated (e.g., living independently and supporting themselves) and may have capacity to make their own decisions about research participation. Decisions about whether to waive parental permission for research involving young adolescents should consider the reasonable availability of parents or guardians; parental capacity to make informed choices; the adolescent's capacity for informed consent; the specific risks and benefits of the research; the preferences of adolescents, parents, and their community; and the likely availability of alternative pathways for ensuring adult support.

Position 7: When parental (including guardian) permission for research is not required and adolescent minors consent autonomously, procedures should be put in place to assess and support an adolescent's desire or expectations for advice from parents and other trusted adults

Adolescents require a secure adult base as they explore the attitudes, values, and beliefs of the larger society. Parents or guardians often provide this secure base. Children and adolescents mature best when they are surrounded by supportive and loving families and communities. As not all adolescents have such a familial structure, other institutions and resources must be available to provide this support.

Parents and guardians have essential roles in fostering protection from research harms and inclusion in research among adolescents (and younger children) [11]. These roles include ensuring adolescents' welfare, supporting adolescents to make decisions about participation in health research, and in some cases, providing parental permission (a form of surrogate informed consent) for adolescent minors.

However, parental permission for adolescent research participation may sometimes be ethically problematic, impractical, or unnecessary. Adolescents and parents vary considerably in the quality of their relationships and the sharing of personal information. While most parents or guardians will make decisions in the best interest of their children, others are absent, indifferent, controlling, or abusive. Some research is about sensitive, stigmatizing, or marginalizing topics (e.g., sexual orientation) for which adolescents would risk disclosure if they involved a parent. Adolescents in these situations may need alternative support for research decisions and consent.

Moreover, relationships vary over time reflecting developmentally normal changes in desire for privacy and autonomous decision-making, the maturity of the adolescent, and emotional closeness and trust between adolescents and their parents. Adolescents differentiate between needing parental permission and parental advice [31]. Many adolescents will voluntarily seek the advice of parents, other family members, and/or other trusted adults when confronted with important life decisions including decisions to participate in health research. Researchers should seek to foster communication between adolescents and these trusted adults about research decisions. For adolescents unable or unwilling to involve parents or guardians, researchers can provide decision-making support broadly, using methods such as teach-back approaches to consent, engaging an ombudsperson for the study, asking the adolescent to consult with a trusted adult, and, in limited situations (e.g. higher risk research, very young adolescents), a capacity assessment. Adolescents should ultimately decide when and how to seek advice from adults in their lives; supporting that decision should be a responsibility of the research team.

Position 8: For higher-risk research, researchers and RECs/IRBs should consider the potential direct benefit to the adolescent and the degree of risk (magnitude and probability of harm), the potential for adolescents as a group of persons to benefit, and the potential ethical benefits and harms from requiring or waiving parental permission

For higher-risk studies, the balance of potential risks and benefits should be as favorable as alternatives (i.e., equipoise), for individual participants and for AYA as a group [4]. Waiver of parental permission for such research should be based on compelling ethical considerations. When an adolescent minor consents autonomously, additional protections should be considered [3,5]. Additional protections may include guidance from a trusted adult or health professional unaffiliated with the research (e.g., an ombudsperson), advice from a parent or trusted

adult selected at the discretion of the adolescent, use of teach-back or other enhanced informed consent approaches, community consultation, and/or an individual assessment of adolescent decision-making capacity.

Position 9: For research conducted in health-care settings and where adolescent minors can autonomously (i.e., independently) provide informed consent for clinical care, adolescent minors should be able to provide consent for research

Many countries, including the U.S., have laws that enable adolescent minors to receive health care based on their own consent in a variety of situations. They may be allowed to do so because they have a specific status or living situation (e.g., an emancipated minor, a minor experiencing homelessness, or a minor who has reached a specific age below the age of majority) or because they seek a particular service (e.g., screening and treatment for sexually transmitted infections, contraception, mental health services, or substance use treatment) [17]. The federal research regulations in the U.S. [3] allow for the waiver of parental permission when research is designed for conditions or a participant population for which parental permission is not a reasonable requirement. CIOMS and some countries also allow waiver of parental permission [5,33,34]. In circumstances in which adolescent minors are legally able to access health care based on their own autonomous or independent consent, they should also be able to consent to their own participation in research. An exception may be research involving highly risky procedures or research where it is difficult to quantify risk, such as a phase 1 clinical trial of a new drug. This logic is based on some of the same rationales that provide the foundations for minor consent laws. These foundations include promoting the health of individual adolescents as well as population health in the context of the evolving capacity of adolescents for independent decision-making [17]. Adolescent minors should be able to consent for lower risk studies or studies of treatments that are already used with adults and have well-characterized risks and benefits when parental permission can introduce a risk of disclosure and loss of confidentiality and, as a consequence, a potentially significant risk of harm to the adolescent minor.

Position 10: Investigators, RECs/IRBs, and funders must be aware of and work to prevent stigma and discrimination in adolescent health research by using human rights principles such as equity, inclusion, and an antioppression framework throughout all research stages from creating research questions, designing studies, evaluating proposals, gathering and analyzing data, and disseminating and translating results

Stigma and accompanying systematic discrimination of groups represent fundamental violations of human rights; they also violate the basic principles guiding research ethics, such as justice and respect for persons. Research has often reinforced stigmatization and exploitation of groups within societies and discrimination against those groups, which has taken the form of xenophobia, racism, colonialism, sexism, homophobia and transphobia, antisemitism, Islamophobia, other religious intolerance, and fascism, as well as discrimination based factors such as age, caste, gender identity, sexual orientation, incarceration,

and pregnancy; and against indigenous communities, persons with developmental and other disabilities, and other marginalized groups [35]. In research, adolescents may face stigma and discrimination simply because of their age, starting with the research questions asked and the populations recruited and extending to the interpretation of results as well as the dissemination and translation of findings. Research that reinforces stigma and discrimination and thereby harms communities can create barriers to subsequent important work between researchers and those communities. The principle of justice demands that AYA health research not exploit, selectively include, or exclude groups from research participation. Researchers should demonstrate consciousness about stigma and discrimination, awareness of racialization as a social phenomenon, appreciation of the need to end biological determinism and recognize structural determinism, and appreciation of discrimination as embedded in the fabric of our societies [35]. Research should not reinforce societal prejudice; instead, it should aim to redress such discrimination. Investigators, REC/IRB, and funders have an obligation to eschew stigma and discrimination when asking research questions, designing and implementing studies, and evaluating proposals.

Position 11: Researchers should involve AYA in the code-sign of research priorities, research questions, piloting of procedures of a study, and development of plain language statements to protect privacy and confidentiality, and in the dissemination and translation of research findings

The principles of respect for persons and justice demand the involvement of AYA in the design and implementation of research that will include AYA and research participants. With its history in the disability movement, AYA have adopted the phrase “nothing about us without us”. Young people provide critical perspectives and lived experiences that can directly inform research funding priorities, research questions, and methods [36]. For behavioral and public health research, their perspectives can provide critical health equity input and guard against stigma, exploitation, racism, colonialism, and other forms of discrimination. Even with medicine and device research, young people can be engaged as stakeholders bringing lived experience to the table. For example, the European Medicines Agency now includes young people on their advisory panels [13]. Thus, the benefit of including AYA in all aspects of research is both as a signal of respect for their opinions as well as a mechanism to drive the quality of research.

Position 12: Researchers should involve community members, including parents and AYA, in the creation of research priorities, research questions, efforts to protect privacy and confidentiality, and dissemination and translation of study findings

Researchers also have an obligation to work with AYA, parents and guardians, and community members to define the potential applications for research and to realize the potential benefits of research findings. AYA participation and community involvement can serve as important protections for AYA participants in research; they can enhance the quality of adolescent health research and the quality of research protections; and they can help

address health inequities by improving adolescent access to the benefits of research. Furthermore, AYA and community involvement often provide important insights into the underlying forces influencing health and strengthen efforts to create programs to improve health. For example, youth advisory boards and community advisory boards are common mechanisms for incorporating AYA and community voice into research [37–40]. While some groups are formal, in other contexts, such as in East Africa, *barazas* (informal community-wide gatherings) have been utilized for community consultation around research findings [37].

For complex health and social issues, researchers should consider more intensive community involvement, such as through public deliberation, youth-led participatory action research or community-based participatory research approaches, or human-centered design [36,39,41,42]. Research on complex AYA health and social issues should also consider the fact that young people are often members of multiple, overlapping communities [43].

Position 13: Compensation to AYA and community advisors should be provided in situations where adults are customarily compensated in research

Research includes many studies where participation is paid (certain surveys, nonclinical studies, certain intervention studies) and others where participation is not paid (school surveys, many clinical studies). Where payment to adults in research is customary, AYA research participants (including adolescent minors) should also be compensated. Researchers should recognize and compensate AYA and community advisors involved in the creation and design of research [41]. Compensation for AYA participants and advisors should be commensurate with the anticipated time and effort [44]. Compensation should not create undue influence to participate in research and should therefore be carefully determined. AYA and community members may also receive nonmonetary benefits from research (personal benefit, enhanced esteem from benefitting others, education and awareness).

Position 14: Ethics education and consultation about the ethical involvement of AYA in research should be readily available to REC/IRB members, adolescent health researchers, parents, community members, and AYA themselves. Educational programs should emphasize the unique ethical, legal, and developmental issues in research with adolescents and the social contexts of adolescent lives including AYA relationships with parents/guardians

Adolescent health researchers and RECs/IRBs ethics committees need to be knowledgeable about research ethics and sensitive to the potential risks and benefits of their activities [4,11]. Researchers in adolescent health are encouraged to provide the very best protections to their study participants and to conduct research in a scrupulously ethical way. As such, research ethics education for researchers and IRB/REC should address the unique ethical, legal and developmental status of AYA. Beyond a focus on the emerging capacity for informed consent and assent among adolescent minors and the role of parents and others in providing advice and permission, such education should also be mindful of the social contexts in which

AYA live and the social forces influencing adolescent health. This policy statement may be helpful in ethics education involving adolescent research.

Position 15: RECs/IRBs that review adolescent health research should ensure that the REC/IRB has expertise in AYA health and development, via committee/board membership or through consultation

The ethical review of study protocols is often complex—requiring current understanding of disease processes, epidemiology, prevention and treatment of multiple health conditions, as well as approaches to promoting health and well-being. Membership of RECs/IRBs must therefore be diverse and encompass multiple perspectives and understandings of health conditions that are reviewed [4,11]. RECs/IRBs that routinely review protocols related to adolescent health should have at least one member with expertise in adolescent health or development. Where an REC/IRB only occasionally reviews adolescent health protocols, they should seek consultation from a professional with expertise in adolescent health or development.

Position 16: Adolescent health researchers and RECs/IRBs should implement strategies to minimize risks of technology-based research

Advances in technology present both opportunities and risks in adolescent health research. This area of research is evolving rapidly as the technology itself evolves. As such, it is difficult to enumerate all potential risks and benefits. Technology itself creates new risks for AYA such as cyberbullying and sexting and changes the context for adolescent health research.

Youth live in a digital world and adults need to understand that world. RECs/IRBs and researchers need to be knowledgeable about technology and the risks and benefits of technology-based research. Technology-based studies need to be considered based on their ethical merits.

Technology provides an unparalleled opportunity to reach AYA who have not previously been included in research, and to involve adolescents as collaborators in research. Digital communication provides a mechanism for reaching AYA who are stigmatized and hard to reach. Technology also provides a way for adolescents themselves to participate in data collection and analysis and provides marginalized and hidden youth with a voice. Research using big data, including the use of electronic medical records, offers many different potential benefits, especially in terms of scale.

Technology-based research can create new risks to identifiability and confidentiality and investigators must ensure that appropriate protections are in place to minimize these risks. The ability to merge and link large amounts of data from different sources, the expanded use of electronic health records for research, and the use of artificial intelligence and machine learning present new threats to confidentiality through potential identification of adolescents. The risk of harms associated with identification and loss of confidentiality are evolving rapidly and must be considered in the design and conduct of research. We will need to continue to build capacity among researchers and REC/IRB members about the ethics of technology-based research.

Position 17: National governments and other research funders should support adolescent health research including research during the early adolescent period (10–14 years) and research to clarify and define adolescent competence, judgment, and capacity to provide informed assent or consent in research

With best practices in research with adolescents focused on appropriate inclusion, there is a need for additional adolescent-specific data to inform safeguards [11]. For example, measures of adolescent research decision-making capacity are currently adapted from adult measures, but adults with waning capacity have different cognitive errors than adolescents with developing capacity. Much adolescent morbidity reflects psychosocial contexts. While the health burden from mental health disorders, substance use, and sexual health conditions increases with age across adolescence, there is also the need for research on younger adolescents. Research that risks identifying younger adolescents at risk of harm may benefit from research that explores what additional responses may be required that would be advanced by being designed and tested in younger adolescents.

Position 18: Nations should identify priorities for AYA research, develop coordinated research and policy agendas, and facilitate collaboration among agencies and institutions involved in adolescent health and research

For example, many health behaviors that influence health, such as substance use or sexual behaviors, have their roots in early adolescence, reinforcing the need for appropriate inclusion of young adolescents in research, yet young adolescents are commonly excluded from research. Because of the importance of adolescent experiences and behaviors in the development of lifetime morbidity and mortality, there is a need to invest in adolescent health research within national and international research and policy agendas [45]. Nations should develop nationally relevant research priorities based on the health status of their adolescent citizens and should coordinate research agendas among key sectors (such as health, education, welfare, employment, and transport) within the nation that can be supported by collaboration with international agencies, researchers, and funders.

Summary

Research is essential to improve the health of AYA. Ethical research with AYA must address both inclusion in research and protection from research risk and must recognize emerging adolescent capacity for autonomous consent. Such research will be facilitated by participation of AYA in all aspects of research and by engaging parents and communities in this agenda. AYA health research should be informed by the same ethical principles, human rights concepts, and legal concepts that guide both health research and health practices beyond research. This position paper draws on knowledge of adolescent cognitive, social and emotional development that frames adolescents as capable yet less experienced decision makers who benefit from participation in research. We recognize the protective role of parents, family members, and trusted adults to provide guidance for adolescent minors around participating in research, adolescents desires for such guidance, and adolescent's emerging capacity to autonomously consent to without parent permission. In this context, the position paper also draws on legal and ethical frameworks that have allowed

adolescent minors to consent themselves in specific situations involving both healthcare and research. This position paper calls for Research Ethics Committees and Institutional Review Boards to ensure they have appropriate professional expertise in AYA health and development in reviewing health research about these populations. It also sets expectations for national governments to identify research priorities and fund AYA research.

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