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Final White Paper and Final Report

The Ethical Challenges of Recruiting Minor Adolescents for the National Children's Study

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Foreward

The Ethical Challenges of Recruiting Minor Adolescents for the National Children's Study – White Paper

This white paper was created through a work assignment under EPA contract number 68-D-02-069 to RTI International. The work assignment asked the contractor to review the literature to answer eight questions posed by the Ethics Working Group for the National Children's Study and to provide a recommendation based upon their review of the literature. This assignment was successfully completed August 25, 2004. This white paper is a very small portion of activities associated with exploring the ethical issues surrounding the National Children's Study and recommendations from this paper should not be interpreted as representing the views of, or endorsement from, the National Children Study planners.

A series of comments were received during the technical review of this paper and the main points of these concerns are summarized below. Please note that the white paper is presented here in its original form as delivered from the contractor and the text does not address these important comments.

- Much of the literature that seeks to increase an adolescent's authority and capacity in decision making and an increase in respect for young adults is not adequately represented or discussed in this paper.

- Although mentioned in the paper, a more systematic review of the important guidelines from the Society for Adolescent Medicine, "Guidelines for Adolescent Health Research" (Santelli, 2003) is needed.

- The discussion of passive consent by parents is unclear given the report's recommendation for active consent upon entrance to the study.

- A more careful analysis of the extant Federal regulations that impact on the potential for adolescents to consent to research should be included. This includes analysis of the definition of children and the circumstances in which parental consent may be waived [section 46.408(c)].

- Concerning minimal risk, the recommendations provided by the reports from the National Human Research Protections Advisory Committee and Institute of Medicine should be included.

- The legal authority of adolescent parents to consent for enrollment of their own children appears to be on solid ground. The report is unclear on this point and appears to suggest that grandparents provide consent for grandchildren at delivery.

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The Ethical Challenges of Recruiting Minor Adolescents for the National Children's Study

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THE ETHICAL CHALLENGES OF RECRUITING MINOR ADOLESCENTS FOR THE NATIONAL CHILDREN'S STUDY

WHITE PAPER

I. INTRODUCTION

The federal government is designing the National Children's Study (NCS), a congressionally mandated longitudinal study that will examine the effects of environmental exposures among children, from before birth until age 21. The goal of the NCS is to improve the health and well-being of children. Current plans for the NCS include the following design components:

- About 100,000 children will be enrolled in the study, which is a sample sufficiently large to study the effects of low levels of exposure to environmental agents.
- Data collection (i.e., measurements and observations) will begin as early as possible in a woman's pregnancy. Some participants will be enrolled preconception.
- Data will be collected on the participant's environment and outcomes until the subject is at least 21 years old.
- Study findings will be combined into a database whose elements can be used to assess the impact of environmental and other factors on children and families.

NCS planners have noted that including sexually active or pregnant minors in the National Children's Study may pose unique risks and benefits to the individual and to adolescents as a group. The National Institutes of Health (NIH) and other agencies require children to be appropriately included in research studies. Before deciding whether and how to recruit minors into the NCS, the NCS planners identified eight questions to be addressed. This paper responds to those questions by synthesizing literature from the medical, behavioral, research, bioethical, and legal fields.

Definitions and Assumptions

Throughout this paper we use the terms "parent" and "guardian" interchangeably to refer to the adult legally responsible for the child. The terms "minor" and "adolescent" are used interchangeably in this paper and refer to an individual who has not reached the age of 18. All but four states have 18 as the age of majority, at which point individuals attain the legal status of adults and would be considered as such for purposes of enrolling and participating in the NCS. Interestingly, the distinction between a "minor" and a "child" is meaningful for the questions NCS planners have posed because the legal definition of the former as determined by state laws

is not necessarily the same as the definition of the latter in federal research regulations (English, 1995 XE "English, 1995").

In this paper, we assume that the NCS will not require any medical treatment or intervention with respondents. This assumption is extremely important because the literature, legislation, and judicial interpretations regarding minors' ability to make their own decisions are often based on the particular treatment or intervention of interest. We assume the NCS will collect various forms of data, including:

- participant-provided information about behaviors, attitudes, and personal characteristics;
- environmental samples (such as those needed to assess air quality or lead) from the participant's residence; and
- biomedical specimens, such as venous blood and urine.

We also assume that the NCS will have test results reported back to participants. These assumptions factor into the discussion in the remainder of this paper regarding the involvement of minors in the study.

The Ethical and Legal Framework

Ethical and legal factors affect considerations about whether to recruit adolescents for the National Children's Study. The ethical and legal framework surrounding the issue is not static; it has evolved over time in response to advances in science and medicine, judicial interpretation, and societal norms. Descriptions of the evolutionary process regarding the role of minors in research inevitably describe practices that are today considered morally reprehensible: physicians inoculated preadolescent girls with syphilis, applied gonorrheal organisms into sick children's eyes, and produced scarlet fever in young children (Lederer and Grodin, 1994 XE "Lederer and Grodin, 1994"). As recently as the 1970s, at Willowbrook State School (an institution for people who were severely mentally retarded) research was conducted that deliberately infected children with the hepatitis virus. Although the Willowbrook researchers obtained parental consent for children to participate in the study (which was not common practice at the time), noted individuals, medical journals, the media, and the general public raised concerns about the adequacy of information provided regarding possible risks, whether parents should have consented to the research when no medical benefit for the child was expected, why medicine to protect children against hepatitis was not used, and whether the admissions policy expediting entry into Willowbrook for children whose parents agreed to participate acted as a coercive influence (Beecher, 1970 XE "Beecher, 1970").

Responses to the use of minors as subjects in medical research—including the troublesome Willowbrook experience—have come from governments, the court systems, medical personnel, ethicists, researchers, and the population at large. Despite the observation that the critical issues regarding minors' participation in research are ethical, not legal (Holder, 1985 XE "Holder, 1985"), existing policies and legal requirements provide the most relevant information to guide decisions regarding the recruitment of minors into the National Children's Study.

Several efforts to guide the ethical treatment of children and adolescents as research participants are notable for their import. Current practices regarding human subjects protection are generally traced to the National Research Act (P.L. 93–348), passed in 1974, which provided for the creation of Institutional Review Boards (IRBs) and established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (Field and Behrman, 2004). The National Commission's 1978 report, referred to as the **Belmont Report**, stipulates principles for ethical research involving human subjects and provides guidelines for the ethical conduct of research (National Commission, 1978). Three ethical principles are emphasized in the Belmont Report: *respect* for persons as autonomous beings, *beneficence*, or the obligation to maximize benefits and minimize harm, and *justice*, implying a fair sharing of risks and benefits to all persons.

Other reports from the National Commission responded to congressional instructions to examine research issues for vulnerable populations, namely prisoners, people with mental disabilities, fetuses, and children. One focused specifically on **research involving children** and closely examined the kind of research that was ethically appropriate with children who cannot provide informed consent. The National Commission concluded that children could be recruited into research that would not benefit them directly only when there is a "minor" increase over minimal risk (Levine, 1995).[1]

Hearings conducted by the U.S. House of Representatives and the U.S. Senate in 1996 produced testimony about (1) problems arising from children receiving medical treatments that had often been tested only in research studies with adults and (2) multiple barriers to including children in research that cause a scarcity of scientifically evaluated treatments tested on children. In response, Congress ordered the National Institutes of Health (NIH) to develop policies

[1] The National Commission's report on research involving children (1977) is not readily available. A good discussion about it is presented in Field and Behrman, 2004.

regarding the inclusion of children in research. The result is the **NIH Policy on the Inclusion of Children as Participants in Research Involving Human Subjects**, which states (NIH, 1998):

> *Children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them.*

The NIH policy requires each research protocol for studies involving human subjects to include a section on children's participation in the research, with an explanation of plans to include them or reasons to exclude them. Exclusion of children in research may be justified by the following reasons (NIH, 1998):

1. The research topic to be studied is irrelevant to children.
2. There are laws or regulations barring the inclusion of children in the research.
3. The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study would be redundant.
4. A separate, age-specific study on children is warranted and preferable.
5. Insufficient data are available in adults to judge potential risk in children.
6. Study designs are aimed at collecting additional data on preenrolled adult participants (e.g., longitudinal follow-up studies that did not include children).
7. Other special cases justified by the investigator and found acceptable to the review group and the Institute Director.

At the same time, researchers must consider the policy of NIH's Clinical Center regarding research involving children. The policy allows an IRB to approve such research *only* if the research is scientifically sound, earlier studies have been conducted on animals and adults, risks are minimized by using the safest procedures possible, the study has provisions for privacy and confidentiality, and research subjects are selected equitably (Policy and Communications Bulletin, 2002).

The **Office for Human Research Protections** (OHRP) in the U.S. Department of Health and Human Services (HHS) provides leadership on human subjects protection and oversees compliance with federal regulations for the protection of human subjects. OHRP has several functions, which include:

- establishing criteria for and approving assurances of compliance for the protection of human subjects with institutions engaged in HHS-conducted or supported research;
- providing clarification and guidance on involving humans in research;

- developing and implementing educational programs and produces resource materials; and
- promoting the development of approaches to enhance human subjects protection.

The dominant legal requirements regarding children in research are stipulated in the Code of Federal Regulations (CFR), Title 45, Part 46, Subpart A (Basic DHHS Policy for Protection of Human Subjects) and Subpart D, Additional DHHS Protections for Children Involved as Subjects in Research, which addresses the protocol and IRB processes required to protect children involved as subjects in research. Section 46.404 of the regulations describes requirements for research involving minors that can be considered as not involving "greater than minimal risk," which is a critical distinction and discussed at length later in this paper:

> *DHHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians…*

Requirements for assent by children are outlined in section 46.408:

> *…adequate provisions [must be] made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent.*
> *…the IRB shall take into account the ages, maturity, and psychological state of the children involved.*
> *…If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted…the assent of the children is not a necessary condition for proceeding with the research.*

Requirements for permission from parents or guardians are in section 46.408. If parental consent is required—which is determined by the nature of the research and the characteristics of the adolescent—the IRB must ensure that:

> *…adequate provisions are made for soliciting the permission of each child's parents or guardian…the IRB may find that the permission of one parent is sufficient for research to be conducted.*

If parental consent is not a reasonable requirement to protect the adolescents (for example, if they are neglected or abused children):

> *…[the IRB] may waive the consent requirements… provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law.*

The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

The Food and Drug Administration (FDA) has new policies to promote the inclusion of children in research, consistent with NIH's current policies. The FDA policy states (21 CFR Part 50, Subpart D):

…adequate provisions [must be] made for soliciting the assent of the children when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of providing assent, the IRB must take into account the ages, maturity, and psychological state of the children involved.
… if the subjects are capable of assenting, the IRB may still waive the assent requirement if it finds and documents that (1) the clinical investigation involves no more than minimal risk to the subjects; (2) the waiver will not adversely affect the rights and welfare of the subjects; (3) the clinical investigation could not practicably be carried out without the waiver; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.
…the permission of each child`s parents or guardian [must be] granted.

II. THE EIGHT QUESTIONS

Recognizing that including sexually active or pregnant minors in the NCS may pose unique risks and benefits, NCS planners identified eight primary questions. These eight questions are presented below.

Before beginning that discussion, we need to point out that much of the literature identified for this paper deals with adolescents in terms of research studies that involve medical procedures or decisions regarding medical treatment; relatively few were located that focus specifically on the kinds of research procedures and data collection needs the NCS will have. Because we assume the NCS will not entail medical interventions or treatment, we draw inferences from the literature as appropriate, recognizing that concerns about recruiting minors for studies with medically invasive procedures are, in terms of human subjects protection, of a much more momentous magnitude than concerns about recruiting minors for studies involving survey questions, minimal biomedical specimen collection, and environmental measures.

1. What are the unique risks and benefits of recruiting either sexually active minor adolescents (prepregnancy) or minor adolescents who are pregnant?

Legal requirements and moral responsibilities impose the need to treat minors with special consideration in research studies. Substantial amounts of literature address questions of the specific risks or benefits for adolescents when participating in research studies, although much of the literature focuses on research studies that involve medical procedures or decisions regarding medical treatment.

Risks of Recruiting

Discussions among NCS planners have raised questions about whether sexually active or pregnant minors should be recruited into the study. The issue is probably most relevant for recruiting young people whose parents or guardians do not know that they are sexually active or pregnant. Presumably, once a parent or guardian knows that a young woman is pregnant, researchers' considerations to maintain confidentiality about the pregnancy would be moot.

We have identified two types of risks associated with recruiting sexually active or pregnant minors to the NCS: risks accruing to the study and risks accruing to the individual. Both are discussed below.

The literature does not specifically address the risks of recruiting sexually active or pregnant adolescents into research studies. We can infer, however, some factors NCS planners will need to consider in this area. First, researchers will face the challenge of identifying

sexually active or pregnant adolescents. If the primary method were to invite into the study adolescents who visit medical clinics or medical personnel to obtain contraceptives, the study population would be biased because (1) some contraceptive devices are available outside of the health care system[2] and (2) a substantial portion of the sexually active adolescent population does not use contraceptives (CDC, 1998; Darroch and Singh, 1999).

Second, if researchers were to find a reasonable way to promote the study and invite sexually active adolescents to join in a style similar to that used to advertise opportunities to enroll in clinical studies, the resultant study population could be biased. Young people who would willingly and proactively disclose their sexual behaviors to researchers will undoubtedly be different from those who prefer to keep that sort of information private. Moreover, it is hard to put into advertising-type language the notion that the government is funding research and is trying to find sexually active teenagers—without inviting public ridicule and disapproval.

Third, if the NCS will require parental consent from minors before they will be allowed into the study, researchers will need to invest substantial thought and resources into methods for obtaining that consent (O'Donnell et al., 1997). Some studies, especially those involving surveys of adolescents in educational settings, rely on passive consent whereby a parent is presumed to approve of the child's involvement unless the parent specifically states otherwise. Several observers have noted, however, that passive consent is a misnomer in that it is not clear whether the parent does, in fact, agree to have the child participate or whether the parent has simply not returned a form (Santelli et al., 2003). This is not to say that passive consent is necessarily bad or noncompliant with regulatory and ethical policies; some types of studies are perceived as posing such minimal risk that IRBs would consider passive consent as appropriate.

Requiring active parental consent may, however, introduce bias into the study. Previous research has shown significant differences between groups of young people whose parents do and do not agree to their participation (Esbensen et al., 1999; Henry et al., 2002). Most often, adolescents for these studies have been recruited through schools, which may or may not be the method used in the NCS, so the extent and type of bias the NCS would incur due to active parental consent requirements is unknown. Additionally, if the NCS indicates an interest in sexually active and pregnant minors in recruitment procedures, the resultant study sample whose

[2] In a study of contraceptive use among teenage females, 44 percent use oral contraceptives, 38 percent condoms, 10 percent use injections, 4 percent use withdrawal, and 3 percent use Norplant (Darroch and Singh, 1999). Thus, more than one-third use methods that do not require a health care visit.

parents agree to their involvement will undoubtedly not be representative of the general adolescent population.

Fourth, there is substantial state-by-state variation regarding the types of medical services for which an adolescent can seek help without parental consent (see Appendix). By extension, that means there would be substantial state-by-state variation regarding the types of research that adolescents can participate in without parental consent. For a national study such as the NCS, understanding and accommodating the complexity of multiple requirements will require attention and investment of resources.

A different set of risks accrues to potential participants through the kinds of questions asked and responses given. The mere action of asking or answering a question may produce adverse outcomes for the participant, either through suggesting or encouraging risk-taking behaviors or through inducing mental or emotional distress (Wender, 1994). The prospect of distress may be particularly acute if respondents are concerned that information they provide as confidential may become known to others.

Another set of risks accrues to potential participants due to the kinds of information that may be produced from tests of their biomedical specimens. Again, the literature is scant and tends to deal mostly with tests for sexually transmitted diseases, plus with some material emerging on genetic testing. The question is: Who receives test results? Minors may not want information disclosed to parents because, in principle or in practice, that would be seen as violating their privacy and telling something they may not want told. One example of the overarching issue, which is discussed more at length later in this paper, may make the point particularly salient: How should the NCS handle reports of urinalyses that may detect a previously unknown pregnancy? Should findings be sent to the adolescent, who may not be able to understand them? What if the test results produce emotional distress? If confidentiality is guaranteed to participants, how can researchers ensure that test results are given only to adolescents? If parental consent was obtained for the minor to participate in the NCS, must test results be provided to the parent?[3] How can the NCS accommodate various state laws with a range of legal requirements? What are the researcher's moral obligations in terms of providing additional information to the pregnant adolescent, encouraging her to talk with her parents, and obtaining medical care?

[3] This situation could arise for several reasons. For example, parents could point to the signed informed consent form that promises to answer any questions they may have about the study—which could include test results.

Although the NCS is being planned as a study that only collects data and does not introduce any medical experiments or medical procedures, the mere fact of asking questions may be an intervention. For example, questions that ask about how recently the minor visited a medical professional may cause that person to seek medical care. While this may be a good consequence for the health of the minor, it suggests that the initial assumption that the NCS involves no medical treatment may, in fact, not be completely accurate.

Benefits of Recruiting

The concept of beneficence in human subjects protection typically refers to the benefit that an individual will obtain as a consequence of participating in medical research studies. Thus, for example, a young leukemia patient may enroll in a clinical study investigating the use of a new medication and reasonably expect to benefit from the drug, or a runaway teenager may agree to answer survey questions and reasonably expect to have the answers used to expand food and shelter services.

Research such as the planned National Children's Study falls into a somewhat different category. The U.S. Department of Health and Human Services, the federal agency that sponsors the most amount of research involving children, allows minors to participate in research projects that have no benefit to the child as long as the proposed research project poses "no greater than minimal risk," which some say IRBs are interpreting as meaning "no risk" (e.g., Arnold et al., 1995). To determine what constitutes "minimal risk," the Code of Federal Regulations states:

> *Minimal risk means that the probability and magnitude of harm of discomfort anticipated in the proposed research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

The terminology has led to the need to interpret the letter and intent of the statement. It could be argued, for example, that some children "ordinarily encounter" hardships in their daily lives that are far more threatening than the ones other children encounter. For example, minors living in low-income communities may be more likely to be exposed to violence than minors living in upper-income communities, but it is hard to imagine that ethical researchers would choose to expose children from low-income communities to greater risks of violence and claim that doing so is appropriate because of their living circumstances. As a result, researchers have suggested that the standard should be clarified to reflect the assumption of a "relatively safe and caring home and environmental context" (Koocher and Keith-Spiegel, 1994, p. 51).

Both HHS and ethical research practitioners allow minors to participate in research that involves more than minimal risk, but only when the child stands to benefit from the research. Moreover, they say that minors may participate in research involving more than minimal risk and no benefit to the child when certain conditions are met, such as risk levels slightly higher than minimal or generalizable knowledge that can help advance science. Because the NCS is unlikely to entail research that involves more than minimal risk, these kinds of situations are not addressed in this paper.

Typically, scientific research is undertaken to advance knowledge and improve the human condition, ideals that have often been used in planning studies with no immediate benefit to participants. The relatively new awareness of and legal requirements for children's rights in research studies may have produced overprotection from IRBs and policy makers without a complementary recognition of the need for research that will benefit adolescents as a group (Arnold et al., 1995). Plans to include sexually active and pregnant young people in the NCS could help rectify the situation by highlighting the need for research to ultimately benefit this population and demonstrating appropriate ways to include them. An additional benefit to the study is to acquire knowledge about children of minors that might not otherwise be available, enabling society and health care providers to better meet the needs of both the adolescent population and their infants.

One benefit that may accrue to adolescents for being recruited into the NCS is the concept of empowerment. The Society for Adolescent Health recognizes the role of empowerment and takes it further by encouraging researchers to involve members of the study population—that is, adolescents—in formulating research priorities (Litt, 2003). A related concept is that the opportunity to participate in research can help socialize adolescents into their community as they develop a sense of responsibility, both toward themselves and others (Brock, 1994). The positive psychological benefits they may gain include feelings of competence, higher self-esteem, and lower levels of depression or anxiety.

Conclusion

What are the unique risks and benefits of recruiting either sexually active minor adolescents (prepregnancy) or minor adolescents who are pregnant?

The study and the individuals involved face minimal risks from recruiting sexually active or pregnant minors. Including minors in the study would produce substantial benefits for the NCS.

2. How are these risks and benefits influenced by the development and legal status of the minor adolescent?

Developmental Status of the Minor Adolescent

Developmentally, the stage of adolescence bridges the stages of childhood and adulthood, with much variation between individuals (Rau, 1997). Piaget's theory of developmental stages asserts that knowledge and maturity grow from lesser to more complete states—in other words, there is a continuum of maturity and no single event shifts an individual from one stage to another (Piaget and Inhelder, 1969). Determining the developmental status of a minor requires combining his or her physical, mental, and social stage and is often ascertained by assessing the adolescent's values, behaviors, and capacity for decision-making (Peterson and Leffert, 1995; Oberman, 1996).

The various stages of development from childhood through adolescence into adulthood have been divided into three broad age groups, based on the "Rule of Seven," which reflects the progression of reasoning abilities in children and adolescents and their attendant capacity to consent. As referenced in the Tennessee Supreme Court case *Cardwell v. Bechtol*, the "Rule of Seven" states that children under age 7 have no capacity to consent; children ages 7–14 do not generally have the capacity to consent, but they may in some circumstances; and children ages 14–21 have the capacity to consent, but they may not in some situations (Cardwell v. Bechtol, 1987; Belle et al, 2002).

Interestingly, the very act of maturing from birth through adolescence and adulthood involves a socialization process that could affect the recruitment of sexually active and pregnant minors into the NCS. The socialization process pressures children to respond to adult instructions or requests, so offering an adolescent the right to decline to participate in a research study could produce one of two responses: (1) acquiescence because the minor does not fully grasp the concept of free choice or (2) outright rejection because the minor welcomes a chance to rebel against perceived authority (Koocher and Keith-Spiegel, 1994).[4]

An important topic in the literature on involving adolescents in research makes careful note of the "mature minor." The concept of the mature minor has been developed through court

[4] Information from another study, although of a younger population, supports the point regarding parental influence as inferred through parental permission. In a study on the capacity of children ages 5-12 to consent to participate in psychological research, obtaining permission from parents seemed to induce additional pressure on children to agree to participate and to remain in the study (Abramovitch et al., 1991).

decisions that use the following as criteria: older adolescents (typically at least age 15), with capacity to give informed consent (as determined by their maturity, intelligence, and ability to make good decisions), to receive treatment for their benefit that does not involve high risk and is consistent with established medical opinion (Curr, n.d.). In practice, the mature minor is generally able to consent for medical care when these criteria are met. The respect accorded mature minors is obvious in discussions regarding their ability to refuse life-sustaining medical treatment (Derish and Heuvel, 2000).

From a developmental and legal perspective and for the purpose of discussion and recommendations in this report, minors can be divided into three groups:

1. Minors aged 12–14
2. Mature minors, generally those between the ages of 15 and 18; and
3. Emancipated minors (depending on state laws)

The first two groups are based on developmental factors; the last is based on legal factors. Aspects of both factors must be reviewed in determining whether adolescents should be recruited into the NCS.

Within the medical and public health systems, and even in the human services system, there has been an increasing recognition of adolescents as individuals having rights (Ruck et al., 1998; Toner and Schwartz, 2003; American Academy of Pediatrics Committee on Bioethics, 1995). The notion that minor adolescents have legal rights to autonomy and privacy has been evolving as well, as evidenced by judicial decisions, policy statements (e.g., the NIH's 1998 policy requiring appropriate inclusion of children in research), and statutes (e.g., the Health Insurance Portability and Accountability Act) (Melton, 1983; Santelli et al., 2003).[5]

For minors to be capable of giving their own informed consent to medical treatment, they must be able to "understand the nature, extent, and probable outcome of treatment. They must be able to understand the information provided and rationally make and voluntarily reach a decision" (Toner and Schwartz, 2003). Under commonly agreed upon approaches, mature minors who understand the consequences of proposed medical treatment can give legal consent.

[5] According to the HIPAA Privacy Rule, (45 CFR 164.502 g3), generally a parent or guardian of an unemancipated minor is treated as the minor's personal representative, except in three cases: when the parent consents to such independence; when the applicable state or local law allows the minor to exercise independent consent and the minor does so; and when applicable law permits a third party such as a court to grant consent on the minor's behalf and does so (FEHBP Lawyers Discussion Group, 2003).

Legal Status of the Minor Adolescent

The term "minor" refers to a person who has not attained the age of majority specified in applicable law. In research studies, minors are people "who have not attained the legal age for consent to treatments or procedures involved in research studies, under the applicable law of the jurisdiction in which the study will be conducted" (Reynolds, 2002). In the recent past, research studies with minors have often but not always required the parent's consent, depending on the particulars of the adolescent's situation and the focus of the research study.

Defining an Emancipated Minor. The legal age of majority in most states is 18 years, in Alabama and Nebraska it is 19 years, and in Pennsylvania and Mississippi it is 21 years (Belle et al., 2002; American Bar Association, 2004). Under certain conditions determined by state law, minors are given the status of "emancipated minor," enabling them to make legal decisions.

Nine of the 50 states plus the District of Columbia have no specified legal provisions that allow minors to be emancipated, other than a court order that can authorize emancipation of minors in any state. The remaining 41 states allow for emancipation through a spectrum of possible situations. Marriage is the most common method for becoming emancipated; pregnancy, parenthood, or both are legal emancipation methods in five states (New Jersey, New York, Oklahoma, Texas, and Vermont). The following are grounds for emancipation, with many states having multiple options (Belle et al., 2002; American Bar Association, 2004):

- marriage (24 states), with 2 states requiring the minor to be at least 16;
- military service or active duty (8 states), with one state requiring the minor to be at least 16;
- parent (4 states);
- pregnant (2 states);
- living away from home (4 states);
- criminal conviction as an adult (1 state);
- notarized by parent (1 state);
- emancipated in another state (1 state); or
- financially independent (1 state).

Medical Treatment Decisions. Even if not emancipated, many states allow adolescents—subject to some age restrictions—the right to consent to medical procedures such as contraceptive services, prenatal care, HIV testing and treatment, substance abuse treatment, and mental health services (see Appendix). All 50 states and the District of Columbia allow minors to consent for STD/HIV services. South Carolina gives this permission to minors age 16

and older, whereas 10 others indicate age 14 or 12. In 29 states and the District of Columbia, laws allow a minor parent to consent to medical care for his or her child.[6]

The legal ability of minors to consent to mental health services is allowed much less than for other health services, with many more restrictions and circumstances specified. Only 24 states and the District of Columbia have laws that provide guidance on mental health services. Of those with laws, two (Georgia and Utah) prohibit minors from providing consent, eight allow all minors the full ability to consent to mental health services, and another four allow them to consent under certain circumstances (e.g., a physician believes it would harm the minor's health to withhold treatment). Age restrictions are placed on minors' ability to consent for mental health services in the remaining 11 states.

Some states have laws stipulating that health care providers may use their judgment to perform medical procedures they believe necessary for the health of the minor. Additionally, states that do not give minors the right to consent to treatment often allow emergency care without parental consent if the parent is not immediately available (McCabe, 1996). Such increased freedoms for minors to consent for their own medical care have been widely discussed and debated by medical, ethical and legal specialists (DeVille, 1997; Derish and Heuvel, 2000; Harrison and Hunt, 1999; McCabe, 1996).

Patient Confidentiality. While a state may not require parental consent for an adolescent to receive a particular medical service, the health care provider is often permitted to inform parents that a minor has requested or received certain medical procedures. This is especially true for HIV testing: Iowa requires that parents be notified if their child receives a positive HIV test, and the District of Columbia requires parent notification if the minor tests positive for STD/HIV and refuses treatment. Eighteen states allow the health provider to inform a minor's parents that the patient is receiving STD/HIV services (Belle et al., 2002; American Bar Association, 2004).

Because mental health services are particularly sensitive, confidentiality in patient care is of the utmost importance. State laws vary considerably in their mandates regarding confidentiality and sometimes requirements differ for general health care and for mental health care. For example, in New Jersey parents are entitled, by statute, to have access to a minor

[6] The NCS may involve prenatal tests that could detect fetal abnormalities. If so, situations could arise regarding a minor's rights and abilities to make decisions regarding the continuation or termination of the pregnancy.

child's medical records. For mental health services, however, a minor must provide written consent before records can be disclosed to a parent. In Ohio, the physician may not inform parents of any mental health services unless the minor consents, but there is no comparable requirement that applies to general health care.

State laws vary on the degree of specificity regarding confidentiality. While a few states (such as New Jersey and Ohio) protect a minor patient's privacy, many mandate that the parent must be notified. Other states give the treating physician the option on whether to disclose treatment information to parents, thus allowing subjective judgment. For example, Oregon requires a physician to notify parents of any medical care provided to an adolescent, but California requires the physician to notify parents unless the notification would be detrimental to the minor's health.

Some areas of research with adolescents produce more troublesome situations regarding confidentiality than others. The field of substance abuse treatment and research provides a good example of the potential complexities in defining confidentiality regulations for minors and parental consent procedures. It is illegal for minors to consume alcohol and use illicit drugs, but society, statutes, and health care providers generally believe that it is better for minors to receive treatment for substance abuse—and keep the treatment confidential—than to disclose the matter to parents so the minor can receive treatment. Recognizing the sensitivities associated with treating substance abuse, regulations specifically govern confidentiality for participants in such programs that receive federal funds (45 CFR 46). The reality that researchers face, however, is that confidentiality considerations may not be the same for applicable state and federal laws, raising both ethical and legal issues (Brody and Waldron, 2000).

Levels of Consent. Federal regulations governing human subjects protection segment research involving children into four categories, each of which involves a different degree of risk and prospect of benefit to the child. Each category imposes special requirements upon research procedures and IRB reviews of protocols involving children (Exhibit 1).

Exhibit 1. Categories of Research Involving Children

Category of Research	Regulatory Requirements	Examples of Research Procedures
Research does not involve greater than minimal risk.	1. Assent of children/adolescents. 2. Permission of one parent/guardian.	• surveys • venous blood draws • x-rays • educational interventions
Research involves greater than minimal risk but presents the prospect of direct benefit to the individual subjects.	1. Assent of children/adolescents. 2. Permission of one parent/guardian. 3. The risk is justified by the anticipated benefit to the subjects. 4. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.	• randomized clinical trials
Research involves greater than minimal risk and no prospect of direct benefit to individual subjects but is likely to yield generalizable knowledge about the subject's disorder or condition.	1. Assent of children/adolescents. 2. Permission of both parents/guardians. 3. The risk represents a minor increase over minimal risk. 4. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations. 5. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition that is of vital importance for the understanding or amelioration of the subjects' disorder or condition.	• bone marrow aspiration • lumbar puncture
Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.	1. Assent of children/adolescents. 2. Permission of both parents/guardians. 3. The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children. 4. The Secretary of the U.S. Department of Health and Human Services, after consultation with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) and after opportunity for public review and comment, has determined the research will be conducted in accordance with sound ethical principles.	• bone marrow aspiration • bronchoscopy (for treatment of cystic fibrosis)

Source: Santelli et al., 2003.

Risks to the Participant

Although researchers and data collectors may promise a minor that all data gathered will receive the protection of **confidentiality** and fully intend to uphold that promise, some situations may require that responses from an adolescent must be disclosed to a parent, guardian, or other adult such as a physician or health care official. Although legal considerations differ by state regarding disclosure, some examples of topics that might require violating the pledge of confidentiality and informing an adult include the following:

- the age of a sexual partner, because if the partner is over 18 and the adolescent is under 18, sex between the two might be considered rape;[7]
- reports of rape, incest, or sexual abuse;
- evidence of physical or sexual abuse; and
- HIV+ status in some states.[8]

In many instances states require parental consent for medical services. Certain services may not require parental consent, but parental notification is often required for services that would generally be confidential for adults, such as HIV/AIDS test results, contraception, and abortion (see Appendix). If the confidentiality of sensitive data were at all compromised during the NCS or adolescents feared the possibility of losing privacy, the candor and reliability of adolescents' responses would undoubtedly be inhibited.

Many minors feel particularly insecure and vulnerable to breaches of confidentiality. For example, a study in Wisconsin of females under age 18 who use Planned Parenthood services found that 59 percent would stop using these services if parental notification were required (Reddy et al., 2002). Even among the many minors who have open and honest communication with their parents, privacy may be of high utmost importance.

The Federal Certificate of Confidentiality allows researchers to keep all research data completely confidential unless the participant asks otherwise (NIH, 2003). A Certificate of Confidentiality helps researchers protect the privacy of research participants enrolled in sensitive

[7] The age of sexual consent in most states ranges from 12 to 18 years. Consensual sex with a minor may be considered rape if the partner is significantly older (by, for example, 7 years). However, prosecution generally does not occur unless the minor submits a statutory rape report (Davis and Twombly, 2000). The laws aim to protect minors from predatory, exploitative behavior, focusing on large age gaps. A recent Florida statute prohibits people aged 24 years from sexual activity with minors 17 years old.

[8] Health care practitioners in Iowa must disclose HIV+ to parents; in the District of Columbia, they must notify parents if minor who tests positive for HIV refuses treatment; in 18 states the physician may notify parents.

biomedical, behavioral, clinical, and other forms of research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant (NIH, 2003). The NIH identifies sensitive information as including

> *…information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol, drugs, or other addictive products; information pertaining to illegal conduct; information that, if released, might be damaging to an individual's financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination; information pertaining to an individual's psychological well-being or mental health; and genetic information or tissue samples.*

A different type of risk to the participant could arise from **asking questions**. Depending on several factors, simply asking a question may lead to a research participant's emotional or mental stress. The concern about conducting surveys with adolescents (i.e., studies that do not involve medical treatment or any intervention) is often associated with the awareness that asking a question may force adolescents to think through issues they may not have otherwise considered. Studies of sexual behavior, for example, may introduce concepts to young people they had previously not known about; studies with questions on drug or alcohol abuse may cause youth to become aware of substances or practices they had previously not encountered. Parents, researchers, and other adults may fear that asking questions could result in encouraging sexual activity, pregnancy, or drug use or could result in promoting other unhealthy behaviors (Rogers et al., 1994; Santelli et al., 2003).

A related risk associated with asking questions, even in anonymous surveys, may be that of potential embarrassment to the respondent. Adolescents are notoriously sensitive to questions asking about matters they consider personal, such as sexuality, drug and alcohol use, and risk-taking behaviors (Fisher, 1994).

A potential risk to the study includes **fallout from negative perceptions or findings**. If the media, local organizations, or the general community for some reason perceive the NCS as negative or as producing negative reports, it is possible that adolescent participants could experience feelings of failure, hostility, sadness, betrayal, or similar negative emotions. The negative perceptions or findings could arise from unfavorable results, such as those that may show unacceptably high pregnancy rates for adolescents from specific racial, ethnic, economic, or neighborhood groups.

The relatively new field of genetic testing is rapidly evolving and carries issues for NCS planners to consider. The prospect that biomedical specimens might be tested for **genetic information** (immediately upon collection or at some point in the future) raises the possibility that data could adversely affect study participants. If genetic information shows the adolescent has or is at risk of having gene disorders, the consequences could include stigmatization, feelings of unworthiness, "survivor guilt" among family members without the disorder, parental anxiety, and inability to interact well with peers (Wertz et al., 1994).

Risks to the Study

Informed consent is an affirmative agreement to participate in research given by a person who has the legal capacity to give consent, exercises free power of choice, and has sufficient knowledge and understanding of the nature of the proposed research, the anticipated risks, potential benefits, alternatives, and the requirements of the research as to be able to make an informed decision (Policy and Communications Bulletin, 2003). If data are collected in the home (including air samples or paint) and minors are living at home, an adult's permission to enter the home will certainly be necessary and consent from the adult will probably be needed. Even if parental consent is not required by statute or by IRBs, a minor who resides in the parent's home is bound to household rules. The NCS could face difficult situations, such as having an IRB's approval to waive parental consent but needing to accommodate a parent's right to demand information before allowing a data collector to enter the home or collect samples.

The NCS research design envisions a longitudinal study, but a cohort of sexually active or pregnant minors may have relatively high levels of attrition. Because of their age, they are likely to be mobile over the course of the study (Gregory et al., 1992), and typical tracking efforts (such as the use of reports from credit bureaus) may be irrelevant for this age group. Moreover, attrition rates may be heightened in cases of minors living outside their parents' home, including homeless and independent youth. Adolescents who have moved out of their parents' home will probably be more difficult to track because of their transient habits, causing them to move around frequently. They may also find it challenging to make (and keep) a long-term commitment to participate in the NCS study because of the many changes occurring at this point in their lives.

Although not specifically a "risk" to the study, the developmental status of minors as socially and mentally different from adults means that questions in any interviews or surveys must be worded appropriately to the age group. This means that questions posed to adults may need to be altered when asked of minors to accommodate their sensitivities, emotional

vulnerabilities, and relatively limited life experiences. Because questions cannot be asked with identical wording and will need to be altered, the amount of analytical comparability between adolescents and adults may be inhibited.

Benefits to the Participant

In general, minors are not likely to receive direct substantial benefits from participating in the National Children's Study. We have identified three areas of benefits: empowerment, knowledge about medical care, and incentives. These are discussed below.

Minors are likely to gain a sense of empowerment from being asked to participate in an important large-scale study. Adolescents frequently want to feel part of a group and part of "something important." Many adolescents develop insecurities and are uncertain about themselves and their own behaviors. Having researchers spend time with them and show interest in them may increase their feelings of self-worth, their confidence, and their self-esteem (Ruck et al., 1998). Adolescents often seek role models; research study personnel may inspire youth in a positive manner.

If they receive medical procedures associated with the NCS, such as prenatal care visits, adolescents may have an increased awareness of the medical care system and reap benefits from better health care.[9] Most adolescents are not aware of what medical care they may need regularly or how to access it, especially when the system is complex and may be intimidating. Those involved with the NCS may develop feelings of comfort with the health care system, enhance their skills at navigating the system, and learn to ask questions as needed.

We assume that the NCS will involve some form of financial incentive, if only to compensate participants for the time and costs they incur in answering questions and having medical procedures (e.g., blood draws). Adolescents without substantial amounts of disposable income may perceive any monetary incentive as of great value (Arnold et al., 1995). In addition to the small income it provides, the incentive again acts to improve the self-esteem of adolescents by putting their self-worth into monetary terms. At the same time, researchers will need to be extremely careful to ensure that the amount of the incentive is not such that it could be perceived as coercive (Moolchan and Mermelstein, 2002). Although cash is probably the strongest incentive for recruiting adolescents, nonmonetary incentives may be of value to minors.

[9] The act of providing medical care—a possible intervention—is one that NCS planners must consider for both adults and adolescents.

For example, participants may welcome access to medical assistance, support groups, or other social services.

Benefits to the Study

Children born to adolescent mothers may have developmental trajectories that can be detected and tracked only through a long-term study such as the NCS, thus filling a large knowledge gap. Characteristics of pregnant and parenting adolescents have been studied and documented (e.g., their health, age, race, socioeconomic status, and education level), very little research has focused on children born to adolescent mothers (Shearer et al., 2002; Santelli et al., 2003). The effects of adolescent pregnancies on the children they bear may be even more dramatic than the effects for the adolescent mothers. Compared to adults, adolescents may be exposed to different situations, take different risks, and in general experience different environmental, behavioral and social settings. All of these factors occurring before, during and after pregnancy contribute to the development of the adolescent's child. With a longitudinal research study, additional knowledge about children born to adolescents may be discovered.

In the past, scientists have often excluded adolescents from research because of legal and ethical uncertainties regarding the inclusion of this population (Santelli et al., 2003). While the volume of adolescent health research studies has increased dramatically in recent years, gaps in the knowledge base still exist as researchers remain cautious about including minors. During a 1996 workshop sponsored by the National Institute of Child Health and Human Development and the American Academy of Pediatrics, findings from a study of NIH-sponsored research showed that 10 to 20 percent inappropriately excluded children—leading workshop conveners to conclude that there is a need to increase children in clinical research (NIH, 1998). In response, NIH amended policy guidelines, which now state that children (individuals under age 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them (NIH, 1998). Now, many more research studies include a provision for including minors.

The potential use for the vast amount of information to be collected in the NCS, systematically gathered about sexually active and pregnant teenagers, is high. Information could be used for policy development and program planning to address matters such as the effects of environmental exposures on fetal development relative to the age of the mother. If sexually active and pregnant minors are not included in the NCS, programs and services planned in light of NCS-generated data may not be optimal for this segment of the population.

Conclusion

How are these risks and benefits influenced by the development and legal status of the minor adolescent?

Both risks and benefits to the individual and the study arise from the complexity of dealing with minors in their variety of developmental stages; some are considered "mature minors" in terms of their mental or emotional advancement, with older minors (ages 14+) exhibiting more of these qualities. The legal status of the minor influences the risks and benefits as determined by the federal regulations and NIH policy that minors must be included in research (with few exceptions) and varying state laws on consent and minor emancipation.

3. Should the NCS develop guidance that recommends blanket inclusion or exclusion of these two groups of minor adolescents?

The literature contains multiple perspectives on this topic. The following two sections discuss, respectively, factors supporting a blanket inclusion and a blanket exclusion of sexually active and pregnant minors.

Factors to Support Inclusion of Sexually Active and Pregnant Minors

Including sexually active and pregnant minors in the NCS will produce increased knowledge about the age group. The opportunity for scientific advances is substantial. The need for research to determine the outcomes of pregnancy in minors—and to have data preceding their pregnancy—spans multiple fields, including behavioral, developmental, and life cycle issues. Data gathered through the NCS can inform childhood antecedents of adult disease and prevention and health services research (NIH, 1998).

Empirical evidence regarding fetal and neonatal development, exposure, and environmental factors for children of adolescents will be extremely valuable information. Minimal research has been conducted in this area with pregnancies in minors. In seeking to understand the outcomes of adolescent pregnancies, research has focused much attention on identifying characteristics of minors who become pregnant, but has neglected to focus on outcomes for the children of these minors (Shearer et al., 2002; Santelli et al., 2003). Initial studies on children of adolescents have determined that poor outcomes such as low birth weight and infant mortality have been more related to the adolescents' poor social environment than to age or physical maturity of the minor (Santelli et al., 2003). To fully understand outcomes of the minor adolescent's fetus and infant their development must be studied over a substantial period of time.

Because the NCS involves no specific medical intervention or treatment,[10] the chance of physical, emotional, or mental harm is minimal. IRBs and federal regulations would probably place the NCS in the category of "minimal risk" research, namely that the likelihood of harm or discomfort is no more than that typically encountered "in daily life or during the performance of routine physical or psychological examinations or tests" (Policy and Communications Bulletin, 2002). It is important to note, however, that individual IRBs are likely to have their own sets of opinions and could easily require different procedures. For example, one study that enrolled HIV+ adolescents into multiple centers to observe the progression of HIV disease provided a natural experiment when 11 IRBs reviewed the common study protocol and sample consent forms (Rogers et al., 1999):

- Four of the 11 IRBs thought the research did not involve greater than minimal risk for participants, but one did; three IRBs did not indicate whether the issue of minimal risk had been discussed.
- At the 11 sites, eight researchers asked for some waiver of parental permission (five asked for all parental consent to be waived, three asked for it to be waived only for HIV+ participants).
- Two of the five that asked for all parental consent to be waived were denied, one received a waiver for participants with certain characteristics (e.g., had no contact with parents for at least six months), and one was told to consider waivers on a case-by-case basis with reviews from the principal investigator and the IRB coordinator.

Factors to Support Exclusion of Sexually Active and Pregnant Minors

Planners of the NCS may want to consider public sentiment and parental concerns as reasons to exclude sexually active and pregnant minors from the NCS. Issues surrounding surveys with sensitive questions—especially those sponsored with public revenues—may cause misleading media stories or political positions that could adversely affect the study. Parents and other adults may fear that asking questions may encourage sexual activity, encourage pregnancy, or otherwise promote unhealthy behaviors (Rogers et al, 1994; Santelli et al., 2003). The risk to the NCS could be high.

A community participating in the NCS may have concerns about findings regarding its adolescents that reflect poorly on the site. Certainly no community would welcome a label designating it, for example, as being in the top 10 United States communities for rates of sexual

[10] We assume the NCS research may include surveys, interviews, blood draws, x-rays, environmental samples, and possibly educational services. None of these constitutes a medical treatment or intervention.

activity among teenagers. Any negative publicity, which would certainly be beyond the control of researchers, could adversely affect the NCS.

Relatedly, community-specific factors need to be considered in discussions about the NCS instituting a blanket practice to include sexually active and pregnant teenagers. Social values and beliefs vary across and within different regions of the country. While some communities may welcome the opportunity to participate in the NCS, others may show complete opposition because of previous negative experiences. Many communities and religious groups are protective of their youth and may perceive involvement of minors in this study as a threat to their value system, particularly when pregnant minors are involved.

Conclusion

> *Should the NCS develop guidance that recommends blanket inclusion or exclusion of these two groups of minor adolescents?*

Because of sensitivities regarding the inclusion of minors in this study, the NCS should not recommend a blanket inclusion or exclusion of pregnant or sexually active minors. Multiple factors suggest that blanket exclusion would be neither practical nor politically astute.

4. If the NCS does decide to include minors, what are the appropriate protections that NCS should require in recruiting sexually active minor adolescents or minor adolescent mothers?

Consent and Assent Procedures

Given the nature of the NCS, it will be legally and ethically imperative for researchers to obtain consent and assent from study participants. The constructs that factor into informed consent are fully developed and consist of those articulated in the Belmont Report, namely information, comprehension, and free will. The constructs that factor into obtaining a minor's assent are not as sophisticated or rigorous, nor do they need to be until children attain the capacity to make decisions as adults do (Rossi et al., 2003). Guidance from the NIH Clinical Center (which by definition focuses on clinical studies and is hence different from work to be performed under the NCS) requires (Policy and Communications Bulletin, 2002):

> *Every protocol involving children shall include a discussion of how assent will be obtained for that particular study. This may take the form of a description of how information will be verbally communicated to the child or a sample written assent document appropriate to the age and comprehension level of the children to be enrolled.*

Researchers must justify every instance when assent is not possible, such as the age, maturity, or psychological situation of the child.

One question for NCS planners is who should give consent and assent? Many combinations of consent and assent from parents and adolescents are possible, as shown in Exhibit 2 (Flagel, 2000). A strict interpretation that only parents can give consent and minors can give assent would find only two situations in Exhibit 2 where a minor could be included in research: #1 (where both the minor and the parent agree) and #2 (where the minor's assent is unknown but the parent agrees). Three situations—#3, #4, and #7—have either the minor's or the parent's wishes overruled. It is interesting to compare situations #7 and #8. In the former, a minor's preference can be overruled by a parent's ambivalence, but in the latter, a minor's preference cannot be overruled by a parent's ambivalence.

Exhibit 2. Possible Combinations of Assent and Dissent for Participation in Research

Situation	Minor		Parent or Surrogate		Proceed with Research?
	Assent	Dissent	Consent	Dissent	
1	X		X		yes
2	?	?	X		yes
3	X			X	no
4		X	X		no
5		X		X	no
6	?	?		X	no
7	X		?	?	no
8		X	?	?	no

X = a confirmation of assent, consent, or dissent

? = situations in which the individual's wishes are unclear or unknown.

Source: Flagel, 2000.

Because statutes and judicial interpretations tend to treat minors as lacking judgment and experience to make authoritative decisions, a conservative approach for the NCS would require that consent be obtained from the parent and assent obtained from the minor, unless state law or regulation suggests (or requires) otherwise.[11] For example, if a given state's law considers an

[11] This method has been used successfully in many studies, including one that evaluated an adolescent pregnancy prevention program through school-based surveys with 7th and 8th grade students (Aarons et al., 2001).

adolescent mother as an emancipated minor, the adolescent mother could provide her own consent. Even if state law or regulation would allow the minor to provide her own consent, the NCS might be well advised to also attempt to obtain parental consent. Although we found no studies in the literature to suggest otherwise, it is possible that an adolescent's consent garnered in one state may not be valid if she moves to another state with a different regulatory system.[12]

When conducting studies with minors, researchers have documented good reasons for involving participants in decisions (McCabe, 1996), so the NCS planners may want to do so, too. The principle of autonomy or self-determination applies to minors, thus strongly suggesting the need for them to be involved in decision making about recruiting their sexually active or parenting peers. Moreover, involving minors in the decision making process about whether and how to recruit them to the NCS will improve credibility and communication between researchers and adolescents, both of which are fundamental to collecting high quality data and achieving successful study outcomes.

Parental Permission and Parental Consent

In most instances of medical research, an adolescent must have parental consent to participate. In general, from a cultural and social—if not legal—standpoint a parent must have knowledge of and approve of a minor's involvement. Because of state-by-state variations in statutes and regulations regarding consent for minors and because the NCS will be of national scope, planners will need to carefully investigate, fully understand, and completely follow state-specific requirements to recruit sexually active and pregnant adolescents—or any adolescents, for that matter. Even the age at which adolescents are no longer considered as minors but become adults for purposes of obtaining medical care (and participating in research) varies: in most states, the legal age of majority is 18, but in four states the age of majority is 19 or 21. In states where adolescents have legally reached the age to give consent, NCS planners or IRBs may ask for voluntary parental permission so as to gain approval from or provide additional assurances to the community.

Generally, the literature indicates that parental permission is not needed in several types of research: (1) no-risk or minimal-risk research with older adolescents (e.g., anonymous surveys of high school juniors and seniors); (2) purely observational studies (i.e., no intervention) of public behavior (e.g., classroom activities); (3) studies of existing data; and (4)

[12] To be sure, it is hard to imagine that scientific censure, political backlash, or legal liability would result from this kind of circumstance, but the field of having adolescents consent to medical care and research is ever evolving.

research with emancipated minors that is directly applicable to their medical condition(s) (University of Rochester, 1997).

Resource Referrals for Participants

Because adolescents constitute a special class of human subjects, lists of supportive services or resources should be available and provided for participants who ask for assistance (Fisher, 1994). These might include information on prenatal care clinics, counseling services, and health education (e.g., tobacco cessation, nutrition). Additionally, since the NCS will test participants for medical conditions and their environments for exposure to hazardous materials, lists of services should also be available and provided to those who ask. Identifying services or resources that are youth-friendly and confidential would increase their appropriateness.

Confidentiality Protections

Both legal and ethical considerations lead to the conclusion that ensuring confidentiality will be essential, especially if the NCS will ask about behaviors that could be considered unacceptable or illegal (Moolchan and Mermelstein, 2002). Planners of the NCS need to carefully consider the types of protections to establish for ensuring that information is kept confidential and may want to propose protocols for doing so. In the process of developing those protocols, careful attention will need to be given to (1) state laws that do not allow confidentiality for minors in certain situations such as medical care, HIV testing, or other sensitive areas[13] and (2) the types of medical tests that will be conducted on sexually active and pregnant adolescents and recipients of test results.

Conclusion

> *If the NCS does decide to include minors, what are the appropriate protections that NCS should require in recruiting sexually active minor adolescents or minor adolescent mothers?*

If the NCS decides to include minors in the study certain protections should be required from a legal and ethical perspective. These include assent from minors (unless they are legally able to give consent), consent from parents (unless the minors are of certain classes that warrant waiving parental consent), lists of health care resources for adolescents who request such, and strict confidentiality protections.

[13] For example, in Iowa health care providers are required to report positive HIV test results to parents of minors.

5. If the NCS does decide to include minors, is parental permission a reasonable requirement in recruiting minor adolescents who are either sexually active or pregnant?

Parental Permission is Reasonable

Both the law and ethical considerations generally favor parental involvement for adolescents receiving health care or participating in research (English, 1995). If the NCS recruitment procedures focus on enrolling adolescents, regardless of whether they are sexually active or pregnant, it would seem reasonable to have parental permission as part of the consent process.[14] Several factors lead to this conclusion: the mixed history of federal statutes, policies, and IRB directives regarding the need for parental consent or permission, even for studies involving no more than minimal risk; uncertainty regarding the way that biomedical test findings will be shared and with whom; the need to take environmental samples in the home, which will undoubtedly be the parental home for many adolescents; and the need to generate community support (or at least avoid opposition) toward the NCS.

Parental Permission is Not Reasonable

Federal regulations clearly stipulate exceptions to parental permission and allow IRBs to waive the requirement under certain conditions. They specifically mention only research involving abused and neglected children, but other noted authorities have provided more situations that may be considered as those under which obtaining parental permission might not be reasonable (National Commission, quoted in English, p. 282):

1. Research to identify factors related to the incidence or treatment of certain conditions for which adolescents may receive treatment without parental consent;
2. Research with "mature minors" that involve no more than minimal risk;
3. Research to help meet needs of children whose parents have designated them as in need of supervision; and
4. Research with minors whose parents are legally or functionally incompetent.

If for some reason the NCS needed to recruit adolescents specifically because they are sexually active (as opposed to being members of the general adolescent population), any reason

[14] Given the rates of pregnancy and sexual activity in the adolescent population, a general sample of teenagers would produce some who meet the criteria of interest. According to the National Campaign to Prevent Teen Pregnancy, one-third of females in the United States will become pregnant at least one time before reaching the age of 20. CDC's Youth Risk Behavior Survey shows that 47 percent of all high school students have had sexual intercourse: 61 percent of twelfth graders, 52 percent of eleventh graders, 41 percent of tenth graders, and 34 percent of ninth graders.

to disclose the adolescent's sexual activity status to a parent would probably constitute reasonable grounds to get a waiver of parental consent or permission. The same logic would apply for adolescents who are pregnant and have not told their parents.

When an IRB waives the requirement for parental permission, federal regulations require that an alternative mechanism to protect the minor must be used. Various methods to meet this requirement include obtaining consent from the adolescent, receiving judicial approval, having a medical professional not involved in the research explain it, or appointing a professional to act as a surrogate parent.

Conclusion

> *If the NCS does decide to include minors, is parental permission a reasonable requirement in recruiting minor adolescents who are either sexually active or pregnant?*

If the NCS decides to include minors in the study, parental permission is a reasonable process that should be followed in all but a few circumstances, such as those that would damage the minor's health and wellbeing.

6. If the NCS does decide to include minors, what are the risks and benefits of requiring or waiving parental permission, especially in a study such as the NCS where most procedures are minimal risk?

Risks of Requiring Parental Permission

Before beginning a discussion of the risks of requiring parental permission, we want to distinguish between informed consent and permission. The two concepts are different: informed consent implies an opportunity for an individual to act autonomously (Brody, 2001), whereas permission implies approval to do some act. The two concepts occasionally become muddied in the literature, such as in one study that defined passive consent procedures as those where "parents of participants respond only if they do not want their child to participate" (Henry et al., 2002, p. 645). In this section, we will try to maintain the distinction.

Studies that require parental permission may result in a biased sample. For example, one study compared middle school students according to whether they returned signed permission slips allowing participation in a life skills training course, returned signed permission slips declining participation in the course, and did not return signed permission slips. Those with permission to participate had fewer school absences and less likely to be in special education when compared to those who did not return permission slips (Henry et al., 2002). Thus,

requiring parental permission may bias a sample of adolescents for the NCS, and it is possible that those less at risk may be more likely to obtain their parents' permission to participate.

The costs of obtaining parental permission can be substantial (O'Donnell et al., 1997). When considered in terms of the relatively low risk associated with information to be collected under the NCS, planners may consider the resources that would be required for parental permission to be better used elsewhere.

As noted earlier, neither regulations, policies, or guidelines provide clear direction in terms of who would receive test results from biomedical specimens collected from adolescents in the NCS. The research literature has little to say directly on the subject, so we must extrapolate from investigations into similar questions.

Some researchers have noted that expanded research opportunities have presented ethical dilemmas: When evidence of a child's or adolescent's developmental delay, pathologies, abuse, or risk-taking behaviors come to light through research studies, should the investigator share findings with the parent, refer the young person to services, or file a report with authorities? Decisions about the steps to take, if any, must weigh the validity of diagnostic tools and the researcher's obligations to the community and the adolescent (Fisher, 1994). Based on this approach, the NCS planners would need to carefully consider the types of tests to be conducted and the consequences of providing results (or not) to individuals in positions to act on adverse outcomes.

One sensitive area that may start to provide an answer to questions about biomedical test results concerns whether adolescents can obtain HIV tests without parental permission or consent. Some states have decided that the benefits gained by giving adolescents the right to consent to medical care outweighs the advantages for giving parents the right to authority over their minor children. Testing for sexually transmitted disease (STD) provides a clear case: because an STD might arise from behaviors a parent would not approve of, an adolescent may avoid getting tested and treated, which could lead to serious illness and the further spread of an infectious disease.

An examination of state regulations affecting HIV testing produces some troubling findings. States may allow minors to consent to HIV testing, but may also allow (or require) health care providers to inform parents when their children ask for HIV tests. Iowa requires that parents are notified if a minor tests positive for HIV, Colorado permits parental notification if the minor is under age 16, and North Carolina allows minors to be tested without parental consent if

the parent has refused to consent to the test or the minor has been sexually abused. The reality or the possibility that parents may be notified may have a deleterious effect on their children's willingness to have HIV tests (Jackson and Hafemeister, 2001), a finding that can reasonably be extrapolated to biomedical tests that may be conducted as part of the NCS.

Benefits of Requiring Parental Permission

Unexpectedly, a few studies have found that adolescents and parents share similar views on the role of parental consent in research. One study conducted a survey with 100 parent-child dyads (200 respondents) that presented various hypothetical research scenarios and asked opinions about granting consent. Very few differences in opinions were found, with both adolescents and parents agreeing that teenagers could consent to participate in research that involved no more than minimal risk, more teenagers perceiving the need for parental consent in telephone interviews and HIV tests, and more parents perceiving the need for parental consent for questions on sexual behavior (Sikand et al., 1997). Similarly, a study involving adolescents with asthma and their parents that presented hypothetical research scenarios found 74 percent agreement on questions such as whether to enroll in research, who would make consent decisions, the importance of the research, and the level of risk (Brody et al., 2003).

Overall, the sentiment in the United States seems to favor parental consent for research involving adolescents. One study that had 233 IRBs complete and return surveys found that 70 percent required parental consent for all research on minors. The same study also found, however, rather substantial variability across IRBs in their interpretations of human subjects protection for minors: 51 percent would require parental consent for a survey on patient satisfaction with a sports physical, and 30 percent would waive parental consent requirements for an anonymous study to test for HIV (Mammel and Kaplan, 1995).[15]

Requiring parental permission would produce positive benefits for the NCS. First, researchers would have some degree of protection from legal concerns that could arise during the study period. Second, the study would have some degree of insulation from political pressures that could mount to curtail or abort the NCS. Third, community members—adults and minors alike—could have a degree of assurance that proper procedures are being followed and no one is being exploited.

[15] The authors note that findings may be biased because of the relatively low response rate to the survey (30 percent).

Benefits and Risks of Waiving Parental Permission

Legal provisions clearly recognize that obtaining parental consent in some circumstances is not reasonable. The National Commission suggested that parental permission may not be necessary if (1) the research is related to conditions that, under state law, minors may consent to; (2) the research involves mature minors (i.e., they can give informed consent) and it involves no more than minimal risk; and (3) research with neglected or abused children, children who are the responsibility of the courts, and children whose parents are legally or functionally incompetent (English, 1995, Santelli, 1997).

Sometimes when the reasons to waive parental consent are quite clear (e.g., homeless and runaway youth) and the research involves only minimal risk (e.g., a survey and interviews), the procedures to ensure proper human subjects protection can be substantial. In one such study, the principal investigator consulted with the Compliance Oversight Branch Division of Human Subject Protections, Office of Protection from Research Risks and NIH, then followed instructions from that office to consult with the state attorney general's office to review applicable statutes and regulations. Only then did the researcher prepare materials for IRB review. In conducting the study, participants received verbal and written informed consent materials, were recruited by street outreach workers (i.e., trusted individuals), and were offered a summary of the study's results (Rew et al., 2000).

Even authors who argue that active parental consent is appropriate for most studies of adolescents offer instances where parental consent has been appropriately waived. In one example, 14–18 year old gay and lesbian adolescents completed a survey (at a gay and lesbian community center) that asked about psychosocial stressors, anxiety, and depression. Most of these young people had not informed their parents of their sexual orientation, and the researchers concluded that parental consent would have placed the research subjects at risk. Their decision was bolstered by having a psychologist at a clinic serve as an advocate for the young people (Hoagwood et al., 1996)

Waiving parental consent requirements does not necessarily mean that adolescents are fully able to make decisions about enrolling in medical research studies. Some have suggested that if studies are to be conducted without parental consent or permission, researchers should establish a strategy to interact with community representatives and explain the study's purposes and procedures, safeguards for privacy and confidentiality, and relevance of study findings (Rogers et al., 1994). Others have suggested the possible need for adults who can act as proxies for parents to ensure that minors' interests are protected, but spare children the risk of exposing

information to their parents they would rather keep private (FEHBP Lawyers Discussion Group, 2003).

Overall, the NCS may face several risks if parental permission is waived:

- if concerns arise during the study period from parents, participants, or observers, the study team may be held legally liable;
- the NCS could be adversely affected by poor public relations; and
- if the adolescent had any adverse consequences from participation, he or she may be hesitant to turn to a parent for assistance.

Conclusion

If the NCS does decide to include minors, what are the risks and benefits of requiring or waiving parental permission, especially in a study such as the NCS where most procedures are minimal risk?

The benefits of waiving parental permission are important, but not very numerous: the NCS would save money and time, and the NCS could help adolescents understand that they are in a position to be responsible for their own decisions. The benefits of requiring parental permission are strong and include added protection for ensuring the minor's best interests are paramount, development of community support, and the practical need to make sure that parents understand their children's involvement in the NCS in case the parents' involvement is needed, too (e.g., in the event of an adverse report from a medical test).

7. If the NCS does decide to include minors, what is the capacity of the adolescent to provide effective informed consent?

"Unless there is a specific exception in the regulations, an investigator may not involve a human being as a subject in research without the legally effective informed consent of the subject or of the subject's legally authorized representative" (English, 1995, p. 279). The Code of Federal Regulations sets forth the basic elements of informed consent, which include a description of the purpose of the research, procedures involved, anticipated risks and benefits, confidentiality protections, and compensation. IRBs may add requirements; under certain circumstances, they may also delete or modify aspects of informed consent.

Cognitive Ability of Adolescents to Consent

Because informed consent is centered on the value of autonomous decision making, it is important to question whether adolescents have sufficient capacity to make such decisions. Traditionally, researchers and ethicists have said they do not and have created additional protections for them, along with other vulnerable populations (Melton, 1983). Others have

argued that an individual's capacity to make an autonomous decision can be helped or hindered by the context of the situation, meaning that different sorts of information or extra supports may need to be provided (Brody, 2001).

There are calls in the research literature for mature minors to be able to consent to participate in research. Some authors say that by age 14, "children generally ought to be recognized as independent agents who are capable of making all of their health care decisions, including the decision to participate as a research subject, without the threat of any parental veto" (Toner and Schwartz, 2003, p. 38). They point out that maturity and the ability to make good decisions do not appear the day the adolescent turns 18 because development is a gradual process (Brody and Waldron, 2000; Wendler and Shah, 2003).

Depending on the circumstances, minors may have the cognitive ability to provide informed consent. In studies investigating cognition and capacity, minors in mid- and late adolescence (aged 14 years or older) have abilities to make decisions about participation in research similar to the abilities of adults (Leikin, 1983; Santelli et al., 2003). In addition, minors at 14 years of age have been found to be as skilled as adults in understanding multiple viewpoints and considering conflicting information (Weithorn, 1983; Santelli et al., 2003).

The still-developing cognitive abilities of young people, however, affect their ability to comprehend. In terms of features embedded in informed consent procedures, adolescents have more knowledge and understanding of concrete information (e.g., the freedom to ask questions, time elements involved, and the benefits of participation) than knowledge and understanding about abstract information (e.g., scientific versus therapeutic purpose of the study and alternative treatments) (Susman et al., 1992). As they age, they develop more abilities to understand their rights in terms of declining to participate in research, to be protected from harm, and to be informed about procedures, with older adolescents (those in 10^{th} grade) showing understanding similar to that of adults (Bruzzese and Fisher, 2003).

The question about who receives results from biomedical specimen collection must be raised here in the context of the adolescent's cognitive ability. Presumably, the person who consented to the test should have the right to receive results and have some ability to control who else learns about results. Genetic information presents a particularly complex situation because of the gravity associated with learning about effects on an individual's future life. The person requesting (or in the case of the NCS, consenting to) the test may feel compelled to keep the information private or feel a moral obligation to share it with others; some recommend that adolescents of reproductive age should be able to decide about genetic testing because they have

the "negative right" of deciding not to know the results (Wertz et al., 1994). The adolescent's cognitive ability and still-developing moral sense make for a particularly challenging situation in considering genetic testing.

Cognitive Ability of Adolescent Mother to Provide Consent for her Infant

In general, society permits parents to have authority over decisions affecting their children. Parents have this right because they are the ones who most know their children and are presumed to have their children's best interests as paramount concerns.

The situation is both similar and unalike for parents who are adolescents. They presumably have their children's best interests as foremost concerns and perhaps become more responsible parents because of their decision making responsibilities. But adolescents may not have the intellectual and psychological capacity to make all decisions regarding their children's medical care, and there is some evidence that adolescents who become parents have lower cognitive abilities than their peers who are not parents. One of the few articles we located that directly addresses the issue of an adolescent's ability to make medical decisions for her child does so thoughtfully and concludes that older adolescent parents should, if they have sufficient decision making capacity for the matter being considered, be the presumptive decision maker for their child, with additional oversight functions performed by grandparents and health care personnel (DeVille, 1997).

Conclusion

If the NCS does decide to include minors, what is the capacity of the adolescent to provide effective informed consent?

The adolescent has the capacity (but perhaps not the legal authority) to provide effective informed consent when the adolescent's decision-making skills are such that he or she is considered a "mature minor." Given the type of information anticipated in the NCS, this would probably be around the age of 15 for most adolescents.

8. If the NCS does decide to include minors, what is the capacity of the adolescent's parents to provide effective informed permission?

Comprehension Regarding Informed Permission

Given the legalities and ethical considerations surrounding informed consent and the extent of information that researchers are sometimes obligated to provide potential participants, it is reasonable to ask whether those providing informed consent truly comprehend what they have agreed to. Consistently, studies have found that signers of informed consent forms have far

better understanding of specific aspects regarding the study rather than the higher-order concepts informed consent may include.

The problem continues into a participant's ability to understand medical treatment. For example, a study that asked parents about dental surgery their children were to have found that nearly one in five did not understand the procedure their children were to undergo—even after the researchers had provided informed consent and treatment information on two occasions and thought the information was sufficient (Tahir et al., 2002).

Active vs. Passive Consent

The practice of passive consent—namely, assuming that the parent agrees to have the minor participate in research unless the parent specifically states otherwise—has extensive appeal. Compared to active consent (i.e., where the parent is fully informed about the research and conscientiously agrees to have the minor participate in research), passive consent is less costly, can be completed quicker, produces higher response rates, and reduces bias in study samples. Methods sometimes used in educational settings involve active and passive permission—a letter is sent to the parent who returns a signed paper signifying permission to participate or not (active), or does not return a signed document (passive)—but "permission" is not equivalent to "informed consent" (Santelli, 1997).

Studies of adolescent risk-taking behaviors are often conducted through schools, where students are a captive audience. One study was cited previously about the possibility that requiring consent may produce bias in the resultant sample. A review of the literature found the following (Tigges, 2003):

- With passive parental consent procedures, 93 to 100 percent of eligible students participate, compared to 30 to 60 percent of eligible students with active consent procedures.
- Return rates of permission slips may drop to 6 to 25 percent when a parent's signature is required to participate.
- Extensive follow-up with parents who do not send back permission slips can raise the return rate to 55–100 percent, of whom 48 to 96 percent agree to have their children participate.

- Costs to obtain a school-based sample using active parental consent[16] range between $8 and $32 per student.
- Intensive efforts and incentives to obtain high permission rates can produce results, but at a cost. One study spent $60,000 to obtain a sample of 3,000 students in three schools serving mostly low-income, minority adolescents.

Under passive consent procedures, researchers assume that no response from parents indicates approval to participate. The assumption is questionable, however, because a parent may not have received the information, received it but forgot about it, did not understand the information, or made an active decision that was somehow obviated by the child (Santelli et al., 2003; Tigges, 2003). There are some suggestions in the literature that those who oppose passive consent for studies involving minimal risk (such as attitudinal or behavioral surveys administered in schools) are, in fact, either opposed to the notion of public health or social science research in the schools or are concerned that parents are losing ground in terms of autonomy toward their children.

Conclusion

If the NCS does decide to include minors, what is the capacity of the adolescent's parents to provide effective informed permission?

In sum, it seems that requiring active parental consent may be more onerous than is necessary for gathering information for certain parts of the NCS, such as attitudinal and behavioral survey questions. In these cases, passive consent from the parent *and* active assent or consent from the minor should be sufficient human subjects protection for most IRBs. An exception should be made for emancipated minors, who will have the ability to consent for themselves. The issue gets a bit more complicated with the collection of biomedical specimens and environmental measures—the former because it introduces invasive medical procedures (albeit ones creating only minimal risk situations), the latter because it may require data collectors to enter the parent's home, and both because it is not clear who will receive test results.

[16] Although it is not completely certain, it appears that this figure may refer to parental permission, rather than parental consent as stated in the study.

III. RECOMMENDATIONS AND NEXT STEPS

Based on the work conducted to date and answers provided to the eight questions in the previous section, several steps are possible for further addressing the ethical issues of recruiting minor adolescents—especially sexually active and pregnant adolescents—into the National Children's Study. We were asked to consider at least two possible activities, namely convening an expert panel workshop or conducting surveys of IRB directors, parents, adolescents, or other experts.

The United States government requires the inclusion of minors in research studies. Agencies such as the NIH have instituted policies requiring the inclusion of minors in research, with very specific exceptions, as follows:

- The research topic to be studied is irrelevant to children.
- There are laws or regulations barring the inclusion of children in the research.
- The knowledge being sought in the research is already available for children or will be obtained from another ongoing study and an additional study would be redundant.
- A separate, age-specific study on children is warranted and preferable.
- Insufficient data are available in adults to judge potential risk in children.
- Study designs are aimed at collecting additional data on preenrolled adult participants (e.g., longitudinal follow-up studies that did not include data on children).

As shown in this paper, the NCS does not have sufficient reason to exclude minors from the study and in fact has compelling reasons for their inclusion. Thus, we recommend that the NCS recruit minor adolescents into the study.

We conclude that the work of NCS planners and the extensive laws, regulations, policies, research findings, and discussions of ethical matters lead to one major recommendation: the National Children's Study should require parental consent and adolescent assent for all minors recruited into the study, unless state law requires otherwise or the candidate participant is an emancipated minor.

If NCS planners agree with this recommendation, then the focus of future work is to devise optimal methods for organizing the consent and assent processes.

To do so, however, will require more information about the actual nature of involvement in the NCS. The study has been a long time in the planning process, and those plans are nearing the implementation stage. One aspect that is probably nearing a conclusive decision concerns

whether sexually active and pregnant adolescents would be specifically recruited into the study because of their status or simply enroll in the study as part of a cohort of adolescents.

Some issues that will be critical to the questions about recruiting and enrolling adolescents can be addressed only after decisions are made regarding the details of the NCS. One very important issue concerns the kinds of biomedical specimens that will be collected. As discussed earlier in this paper, both the nature of the test and the kind of results it produces matter. For example, the degree of invasiveness and associated discomfort or risk can vary a great deal, depending on whether the test involves a venous puncture, urine sample, blood pressure, x-ray, mouth swab, hair sample, lung function assessment, or other methods of collecting biomedical data. It is not hard to imagine that both parents and adolescents would care about the particulars, so knowing them before proceeding to develop the consent and assent processes is important.

Relatedly, the issue of how to share test results and with whom must be considered. There is some legal guidance to help in NCS deliberations arising from research that examined the effectiveness of methods for reducing environmental lead in homes. Parents sued the Kennedy-Krieger Institute, which conducted the study, and courts have issued rulings regarding the appropriateness of the data collection technique used to determine lead levels, the adequacy of the consent process, and the delay in reporting children's blood lead levels (Nelson, 2001). The issue for the NCS, then, is to develop ways to share test results for both biomedical and environmental measures. The following are the kinds of questions NCS planners may wish to discuss:

- Given that various medical tests will be performed, will sexually active and pregnant adolescents be asked to submit to the identical tests that adults will, or will certain tests be added, waived, or otherwise varied?
- Who will receive reports from test results—adolescents, parents, medical personnel? Or will this vary depending on the laws of each state? Or by the type of test?
- What kinds of supportive services should be required to help recipients of test results understand or interpret them? This will be especially important if adolescents receive test results.
- Should automatic referral practices be instituted for certain test results, and will this process be different for adolescents than for adults?
- If genetic material is collected, what additional matters must be addressed to ensure the practices are ethically sound for testing adolescents and disseminating results?

In thinking about next steps, we emphasize the importance of considering informed consent and informed assent as a *process*, not a set of forms (Santelli, 1997). The process needs

to ensure that participants are able to demonstrate comprehension necessary for consent and assent to be given only when they are genuinely informed. Informed consent and assent needs to be a continuous process with opportunities for dialogue between researchers and participants, with opportunities for participants to withdraw from the study. The National Commission provided recommendations to support the notion of consent as a process, including commitment from researchers to conduct ethical research, peer review, and periodic review of the conduct of studies. IRBs fulfill many of these functions, but the NCS planners may want to consider establishing a panel specifically to monitor issues and research regarding involving sexually active and pregnant adolescents in terms of both the consent and assent processes and the conduct of the study.

We believe that the most productive next steps for NCS planners at this time center on consulting with the target groups. We recommend gathering opinions and information from parents and adolescents through focus groups to provide insight into their concerns, preferences, needs, and advice for unresolved matters, such as the consent and assent processes and questions regarding biomedical tests. The focus groups could also provide very useful information about optimal ways to recruit adolescents and the kinds of issues that will be important to them. We suggest conducting focus groups with adolescents, parents, and adolescents and parents together, with representation from various geographical areas, socioeconomic classes, and racial and ethnic groups. Based on information from these focus groups, NCS planners could decide whether additional data (such as information to be gathered from surveys) would be beneficial.

We considered whether it would be prudent to gather information from IRBs and conclude that the answer is probably "not yet." Previous studies have shown the wide variation in IRB interpretations and requirements, even when IRBs across multiple sites are reviewing the same research protocol. After the NCS vanguard sites have been selected, study planners may want to consider convening IRB chairs from the vanguard sites, discuss progress to date, and ask for their guidance.

There may be other ways to gather supplementary information from parents and adolescents. For example, NCS planners may want to test whether opinions could be gathered through links on web pages frequented by adolescents; if so, perhaps consent and assent forms (and descriptions of processes) could be drafted and posted for their review. Other NCS planners may be consulting with parents; if so, perhaps additional questions could be posed for their discussions. The NCS design team has sponsored focus groups that included adolescents, and information collected during those focus groups may be reviewed in light of the question regarding the recruitment and enrollment of sexually active and pregnant teenagers.

In sum, the legacy of information from commissions, federal staff, the judicial system, researchers, IRBs, health care professionals, and ethicists has set fairly clear parameters around the recruitment of adolescents into research such as the National Children's Study. What remains is to devise appropriate, ethical, and efficient ways to develop and implement the particular forms, processes, and actions necessary for the NCS.

REFERENCES

Aarons, S., Rose, A., Walker, J., Lyles, B., Jenkins, R., and Raine, T. (2001). Enhancing Recruitment and Data Quality in a Junior High School–based Teen Pregnancy Prevention Study. *Evaluation and Program Planning*, 24, 277–285.

Abramovitch, R., Freedman, J.L., Thoden, K., and Nikolich, C. (1991). Children's Capacity to Consent to Participation in Psychological Research: Empirical Findings. *Child Development*, 62, 1100–1109.

American Academy of Pediatrics Committee on Bioethics (1995). Informed Consent, Parental Permission, and Assent in Pediatric Practice. *Pediatrics*, 95(2), 314–317.

American Bar Association, Facts About Children and the Law- Table 1. *State Laws Allowing Minors to Consent to Medical Treatment.* Retrieved June 22, 2004 from www.abanet.org/media/factbooks/cht1.html.

Arnold, L. E., et al. (1995). Ethical Issues in Biological Psychiatric Research with Children and Adolescents. *Journal of the Academy of Child and Adolescent Psychiatry*, 34(7), 929–939.

Beecher, H. K. (1970). *Research and the Individual: Human Studies*. Boston: Little, Brown and Company.

Belle, R., Boardman, S., Boutilier, C., Cap, D., et al. (2002, April 1). *Legislative Initiatives for Healthier Lives.* A Collaborative Partnership: The Health Law Institute, A Program of the Justice Resource Institute and Northeastern University School of Law. Law Office #2. Web site available at: www.bostoncoop.net/lcd/mature_minor/mature_minor.html

Brock, D. W. (1994). Ethical Issues in Exposing Children to Risks in Research." In Michael A. Grodin and Leonard H. Glantz (Eds.), *Children as Research Subjects* (pp.81–101). New York: Oxford University Press.

Brody, B. A. (2001). Making Informed Consent Meaningful. *IRB: Ethics & Human Research*, 23(5), 1–5.

Brody, J. L., and Waldron, H. B. (2000). Ethical Issues in Research on the Treatment of Adolescent Substance Abuse Disorders," *Addictive Behaviors*, 25(2), 217–228.

Brody, J. L., Scherer, D. G., Annett, R. D., and Pearson-Bish, M. (2003). Voluntary Assent in Biomedical Research with Adolescents: A Comparison of Parent and Adolescent Views. *Ethics & Behavior*, 13(1), 79–95.

Bruzzese, J. M., and Fisher,C. B. (2003). Assessing and Enhancing the Research Consent Capacity of Children and Youth. *Applied Developmental Science*, 7(1), 13–26.

Centers for Disease Control and Prevention. (1998). *Contraceptive use among women 15–44 years of age, according to age, race, Hispanic origin, and method of contraception: United States, 1982, 1988, and 1995*. Data from the National Survey of Family Growth. National Center for Health Statistics, Division of Vital Statistics.

Cardwell v. Bechtol, 724 S.W.2d 739, 745 (Tenn. 1987).

Curr, N. D. (n.d.). Special Decision Making Concerns of Minors. Albert Einstein Hospital, Yeshiva University, New York. Web site available at: http://epi.aecom.yu.edu.

Darroch, J. E., and Singh, S. (1999). *Why Is Teenage Pregnancy Declining? The Roles of Abstinence, Sexual Activity, and Contraceptive Use*. [Occasional Report, no. 1] New York: Alan Guttmacher Institute

Davis, N. S., and Twombly, J. (2000, February). *State Legislators' Handbook for Statutory Rape Issues*. American Bar Association Center on Children and Law and U.S. Department of Justice, Office of Justice Programs, Office for Victims of Crime. Website available at: http://www.ojp.usdoj.gov/ovc/publications/infores/statutoryrape/handbook/cont.html

Derish, M. T., and Heuvel, K. V. (2000). Mature Minors Should Have the Right to Refuse Life-Sustaining Medical Treatment. *Journal of Law, Medicine & Ethics*, 28, 109–124.

DeVille, K. (1997). Adolescent Parents and Medical Decision-Making. *The Journal of Medicine and Philosophy*, 22, 253–270.

English, A. (1995). Guidelines for Adolescent Health Research: Legal Perspectives. *Journal of Adolescent Health*, 17, 277–286.

Esbensen, F.-A., Miller, M. H., Taylor, T. J., He, N., and Freng, A. (1999, June) Differential Attrition Rates and Active Parental Consent. *Evaluation Review*, 23(3), 316–335.

FEHBP (Federal Employees Health Benefits Plans) Lawyers Discussion Group. (2003, April). State Law Survey for Use in Applying the Personal Representative for Minor Section of the HIPAA Privacy Rule, 45 CFR 164.502(g)(3).

Field, M. J., and Behrman, R.E. (Eds.) (2004). *Ethical Conduct of Clinical Research Involving Children*. Washington, DC: The National Academies Press.

Fisher, C. B. (1994). Reporting and Referring Research Participants: Ethical Challenges for Investigators Studying Children and Youth. *Ethics & Behavior*, 4(2), 87–95.

Flagel, D. C. (2000, September–October). Children as Research Subjects: New Guidelines for Canadian IRBs. *IRB: A Review of Human Subjects Research*, 22(5), 1–3.

Gregory, M. M., Lohr M. J., and Gilchrist, L. D. (1992, February). Methods for Tracking Pregnant and Parenting Adolescents. *Evaluation Review*, 17(1), 69–81.

Harrison, L., and Hunt, B. (1999, winter). Adolescent Involvement in the Medical Decision Making Process. *Journal of Applied Rehabilitation Counseling*, 30(4) 3–9.

Henry, K. L., Smith, E. A., and Hopkins, A. M. (2002, December). The Effect of Active Parental Consent on the Ability to Generalize the Results of an Alcohol, Tobacco, and Other Drug Prevention Trial to Rural Adolescents. *Evaluation Review*, 26(6), 645–655.

Hoagwood, K., Jensen, P. S., and Fisher, C. B. (Eds.). (1996). *Ethical Issues in Mental Health Research with Children and Adolescents*. Mahway, NJ: Lawrence Erlbaum Associates.

Holder, A. R. (1985). *Legal Issues in Pediatrics and Adolescent Medicine*. New Haven: Yale University Press.

Jackson, S., and Hafemeister, T. L. (2001). Impact of Parental Consent and Notification Policies on the Decisions of Adolescents to Be Tested for HIV. *Society for Adolescent Medicine*, 29, 81–93.

Koocher, G. P., and Keith-Spiegel, P. (1994). Scientific Issues in Psychosocial and Educational Research with Children. In M. A. Grodin and L. H. Glantz (Eds.). *Children as Research Subjects*, (pp. 47–80). New York: Oxford University Press.

Lederer, S.E., and Grodin, M.A. (1994). Historical overview: Pediatric experimentation. In In M. A. Grodin and L. H. Glantz (Eds.). *Children as Research Subjects*, (pp. 3–28). New York: Oxford University Press

Leikin, S. L. (1983). Minors' Assent or Dissent to Medical Treatment. *The Journal of Pediatrics*, 102(2) 169–76.

Levine, R. J. (1995). Adolescents as Research Subjects Without Permission of Their Parents or Guardians: Ethical Considerations. *Society for Adolescent Medicine*, 17, 287–297.

Litt, I. F. (2003). Research *Wit*h, Not *On*, Adolescents: Community-based Participatory Research. *Journal of Adolescent Health*, 33, 315-316.

Mammel, K. A., and Kaplan, D. W. (1995). Research Consent by Adolescent Minors and Institutional Review Boards. *Society for Adolescent Medicine*, 17, 323–330.

McCabe, M. A. (1996). Involving Children and Adolescents in Medical Decision Making: Developmental and Clinical Considerations. *Journal of Pediatric Psychology*, 21(4), 505–516.

Melton, G. B. (1983, January). Toward 'Personhood' for Adolescents. *American Psychologist*, 99–103.

Moolchan, E. T., and Mermelstein R. (2002). Research on Tobacco Use Among Teenagers: Ethical Challenges. *Journal of Adolescent Health*, 30, 409–417.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1977). *Report and Recommendations: Research Involving Children.* Washington, DC: U.S. Government Printing Office.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1978). *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (DHEW publication no. [OS] 78-0012). Washington, DC: US Government Printing Office.

National Human Research Protections Advisory Committee (2002). Report from NHRPAC: *Clarifying specific portion of 45 CFR 46 Subpart D that governs children's research.* Retrieved July 12, 2004 from, http://ohrp.osophs.dhhs.gov/nhrpac/documents/nhrpac16.pdf.

National Institutes of Health, *Frequently Asked Questions on Certificates of Confidentiality.* (2003, July 21). Retrieved July 24, 2004 from, http://grants.nih.gov/grants/policy/coc/faqs.htm.

National Institutes of Health (1998, March 6). NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects. Retrieved June 19, 2004 from, http://grants1.nih.gov/grants/guide/notice-files/not98-024.html

Nelson, R. M. (2001). Nontherapeutic Research, Minimal Risk, and the Kennedy Krieger Lead Abatement Study. *IRB: Ethics & Human Research*, 23(6), 7-11.

Oberman, M. (1996). Minor Rights and Wrongs. *Journal of Law, Medicine & Ethics*, 24, 124–38.

O'Donnell, L. N., Duran, R. H., San Doval, A., Breslin, M. J., Juhn, G. M., and Stueve, A. (1997). Obtaining Written Parent Permission for School-Based Health Surveys of Urban Young Adolescents. *Journal of Adolescent Health*, 21, 376–383.

Petersen, A. C., and Leffert, N. (1995, November). Developmental Issues Influencing Guidelines for Adolescent Health Research: A Review. *Journal of Adolescent Health*, 17(5), 298–305.

Piaget, J., and Inhelder, B. (1969). *The Psychology of the Child*. Basic Books, New York.

Policy and Communications Bulletin, Medical Administrative Series, The Clinical Center, National Institutes of Health (2003, March). Informed Consent.

Policy and Communications Bulletin, Medical Administrative Series, The Clinical Center, National Institutes of Health (2002). Research Involving Children and Children's Assent to Research.

Rau, J. M. B. (1997, October). The Ability of Minors to Define and Recognize Their Rights in Research. *Dissertation Abstracts International: Section B: The Sciences and Engineering*, 58(4-B), 2156.

Reddy, D. M., Fleming, R., and Swain, C. (2002). Effect of Mandatory Parental Notification on Adolescent Girls' Use of Sexual Health Care Services. *Journal of the American Medical Association,* 288, 710–714.

Rew, L., Taylor-Seehafer, M., and Thomas, N. (2000, July-September). Without Parental Consent: Conducting Research with Homeless Adolescents. *Journal of the Society of Pediatric Nurses*, 5(3), 131–138.

Reynolds, S. (2002, February). Consent of Minors to Research Activities. *The Investigator*.

Rogers, A. S., D'Angelo, L., and Futterman, D. (1994). Guidelines for Adolescent Participation in Research: Current Realities and Possible Solutions. *IRB: A Review of Human Subjects Research*, 16(4), 1–6.

Rogers, A. S., et al. (1999, January–February). A Case Study in Adolescent Participation in Clinical Research: Eleven Clinical Sites, One Common Protocol, and Eleven IRBs. *IRB: A Review of Human Subjects Research*, 6–10.

Rossi, W. C., Reynolds, W., and Nelson, R. M. (2003). Child Assent and Parental Permission in Pediatric Research. *Theoretical Medicine*, 24, 131–148.

Ruck, M. D., Keating, D. P., Abramovitch, R., and Koegl, C. J. (1998). Adolescents' And Children's Knowledge About Rights: Some Evidence For How Young People View Rights In Their Own Lives. *Journal of Adolescence,* 21, 275–289.

Santelli, J. (1997). Human Subjects Protection and Parental Permission in Adolescent Health Research. *Journal of Adolescent Health,* 21, 384–387.

Santelli, J. S., Rogers, A. S., Rosenfeld, W. D., DuRant R. H., Dubler, R., Morreale, M. English, A., Lyss, S., Wimberly, Y., and Schissel, A. (2003). Guidelines for Adolescent Health Research (A position paper of the Society for Adolescent Medicine). *Journal of Adolescent Health,* 33(5), 396–409.

Shearer, D. L., Mulvihill, B. A., Klerman, L. V., Wallander, J. L., Hovinga, M. E., and Redden, D. T. (2002). Association of Early Childbearing and Low Cognitive Ability. *Perspectives on Sexual and Reproductive Health,* 34, 236–243.

Sikand, A., Schubiner, H., and Simpson, P. M. (1997, June). Parent and Adolescent Perceived Need for Parental Consent Involving Research with Minors. *Archives of Pediatric and Adolescent Medicine,* 151, 603–607.

Susman, E. J., Dorn, L. D., and Fletcher, J. C. (1992). Participation in Biomedical Research: The Consent Process as Viewed by Children, Adolescents, Young Adults, and Physicians. *Journal of Pediatrics,* 121, 547–552.

Tahir, M. A., Mohamed, Mason, C., and Hind, V. (2002, August 24). Informed Consent: Optimism versus Reality. *British Dental Journal*, 193(4), 221–224.

Tigges, B. B. (2003, 3rd quarter). Parental Consent and Adolescent Risk Behavior Research. *Journal of Nursing Scholarship*, 283–289.

Toner, K., and Schwartz, R. (2003, fall). Why a Teenager over Age 14 Should Be Able to Consent, Rather than Merely Assent, to Participation as a Human Subject of Research. *American Journal of Bioethics*, 3(4), 38–40.

University of Rochester (1997). Consent Issues in Research Involving Minors, Research Subjects Review Board. Retrieved from http://www.urmc.rochester.edu/rsrb/pdf/minor.pdf.

Weithorn, L. A. (1983). Children's Capacities to Decide About Participation in Research. *IRB: A Review of Human Subjects Research*, 5(2), 1–5.

Wender, E. H. (1994). Assessment of Risk to Children. In M. A. Grodin and L. H. Glantz (Eds.), *Children as Research Subjects* (pp.181–192). New York: Oxford University Press.

Wendler, D., and Shah, S. (2003). Should Children Decide Whether They are Enrolled in Nonbeneficial Research? *The American Journal of Bioethics*, 3(4), 1–7.

Wertz, D. C., Fanos, J. H., and Reilly, P. R. (1994, September 21). Genetic Testing for Children and Adolescents: Who Decides? *Journal of the American Medical Association*, 272(11), 875–881.

EPA/600/R-05/027

APPENDIX

STATE LAWS REGARDING CONSENT BY MINORS

Appendix

State Laws Regarding Consent by Minors

State, Legal Age of Majority[6,9]	Methods for Minors to Obtain Legal Emancipation[6]	Can Minor Consent to:					
		Medical Care for Own Child?[8]	Mental Health Services?[1,6,9]	Prenatal Services?[1,6,9]	Contraceptive Services?[1,6,9]	STD/HIV Tests and Services?[1,6,9]	General Medical Health[6,9]
Alabama, 19	court petition	yes	yes	yes	no law	≥12; health care provider may notify parents	if ≥14 and a high school graduate, married, pregnant, or a parent; otherwise for emergency care only
Alaska, 18	court petition, marriage	yes	no law	yes	yes	yes	if minor is a parent or living on own and managing own financial affairs; minor may consent after MD counseling if parent/guardian is unable or unwilling to consent
Arizona, 18	court petition, marriage	no law	no law	no law	no law	yes	yes, but not surgical care
Arkansas, 18	court petition	yes	no law	yes, excludes abortion services	yes	yes; health care provider may notify parents	if minor is able to understand the nature and consequences of proposed medical or surgical treatment
California, 18	court petition, marriage, military service	no law	≥ 12, with conditions; parents must be notified unless MD feels it would be detrimental	yes, excludes abortion services	yes	≥ 12; HIV test results may be disclosed to specified individuals	if ≥15, living on own, and managing own financial affairs
Colorado, 18	court petition, married, living away from	yes	≥ 15; MD may advise parents	yes	if married, parent, or pregnant, or referred by	yes	no law

State Laws Regarding Consent by Minors (continued)

State, Legal Age of Majority[6,9]	Methods for Minors to Obtain Legal Emancipation[6]	Can Minor Consent to:					
		Medical Care for Own Child?[8]	Mental Health Services?[1,6,9]	Prenatal Services?[1,6,9]	Contraceptive Services?[1,6,9]	STD/HIV Tests and Services?[1,6,9]	General Medical Health[6,9]
	home				professionals		

(continued)

Connecticut, 18	court petition	yes	yes, with MD approval; must notify parents after 6 visits unless seriously detrimental to child	no law	no law	yes, but only if MD believes obtaining parental consent would deny treatment or if minor requests they not be informed	no law
Delaware, 18	court petition	yes	no law	≥ 12; health care provider may notify parents; excludes abortion services	≥ 12; health care provider may notify parents.	≥ 12; health care provider may notify parents.	yes, if a parent or married, or for emergency care
District of Columbia, 18	court petition	yes	yes	yes	yes, excludes sterilization	yes, notice to parents/guardians regarding AIDS or STD testing permitted if minor refuses treatment	no law
Florida, 18	court petition	yes	yes	yes, includes surgical care	if married, parent, pregnant, or provider believes minor would suffer health hazards	yes	yes, for emergency care only

State Laws Regarding Consent by Minors (continued)

State, Legal Age of Majority[6,9]	Methods for Minors to Obtain Legal Emancipation[6]	Can Minor Consent to:					
		Medical Care for Own Child?[8]	Mental Health Services?[1,6,9]	Prenatal Services?[1,6,9]	Contraceptive Services?[1,6,9]	STD/HIV Tests and Services?[1,6,9]	General Medical Health[6,9]
Georgia, 18	court petition, marriage	yes	no, written parental consent required for treatment	yes, excludes abortion services	yes	yes, health care provider may notify parent, guardian, or spouse	no law

(continued)

Hawaii, 18	court petition, marriage	no law	no law	≥14, health care provider may notify parents; excludes abortion services and surgical care	≥14, health care provider may notify parents; excludes abortion services and surgical care	≥14, health care provider may notify parents	no law
Idaho, 18	court petition, marriage	yes	yes	yes	yes	≥14	minor of ordinary intelligence and awareness may consent to medical services
Illinois, 18	court petition	yes	≥ 12; information about treatment may not be disclosed unless minor consents	if a parent or is referred by a doctor, clergy, or Planned Parenthood clinic	if a parent or is referred by a doctor, clergy, or Planned Parenthood clinic	≥ 12; information about treatment may not be disclosed except with minor's consent	yes, if a parent, married, or pregnant, if minor is victim of sexual assault, or for emergency care
Indiana, 18	court petition	no law	no law	no law	no law	yes	yes, if emancipated, married, divorced, in the military, authorized by statute, or ≥14 and living on own; parent or guardian may be informed of treatment and may consent to the disclosure of health care records

State Laws Regarding Consent by Minors (continued)

State, Legal Age of Majority[6,9]	Methods for Minors to Obtain Legal Emancipation[6]	Can Minor Consent to:					
		Medical Care for Own Child?[8]	Mental Health Services?[1,6,9]	Prenatal Services?[1,6,9]	Contraceptive Services?[1,6,9]	STD/HIV Tests and Services?[1,6,9]	General Medical Health[6,9]
Iowa, 18	court petition, marriage, criminal conviction as an adult	no law	no law	no law	no law	yes, parental notification required for positive HIV test	no law, test results made available to the minor and their legal guardian
Kansas, 18	court petition, marriage if ≥16	yes	no law	if parent is not available	no law	yes, the health care provider may notify parent, guardian, or spouse	yes, for emergency care, or 16 or older and if parent or guardian is not immediately available

(continued)

Kentucky, 18	court petition	yes	≥16 to outpatient care	yes, health care provider may notify parents; excludes abortion services	yes, health care provider may notify parents	yes, health care provider may notify parents	yes, if married, divorced, or a parent; health care provider may render treatment if delay caused by obtaining consent would harm minor's health
Louisiana, 18	court petition, notarized by parent, marriage if ≥ 16	yes	no law	no law	no law	yes, health care provider may notify parents	health care provider may notify parents
Maine, 18	court petition	no law	no law	no law	if a parent, married, or provider believes minor will suffer if services withheld	yes, the health care provider may notify parents	no, but minor may consent to forensic exam after sexual assault

State Laws Regarding Consent by Minors (continued)

State, Legal Age of Majority[6,9]	Methods for Minors to Obtain Legal Emancipation[6]	Can Minor Consent to:					
		Medical Care for Own Child?[8]	Mental Health Services?[1,6,9]	Prenatal Services?[1,6,9]	Contraceptive Services?[1,6,9]	STD/HIV Tests and Services?[1,6,9]	General Medical Health[6,9]
Maryland, 18	court petition, marriage [7]	yes	if provider believes minor's life or health would be affected adversely by delaying treatment to obtain consent	yes, the health care provider may notify parents	yes, the health care provider may notify parents	yes, the health care provider may notify parents	yes, if a parent or if married; health care provider may notify parents; yes, for emergency treatment, treatment of injuries from sexual assault, or initial exam after admission to a detention center
Massachusetts, 18	court petition	yes	no law	yes, excludes abortion services	yes	yes	yes, if married, parent, or pregnant
Michigan, 18	court petition, marriage, service in armed forces	yes	≥14 hospitalization for mental health; may not be disclosed to parent without a compelling need	yes, the health care provider may notify parents	yes	yes, the health care provider may notify parents	no law

(continued)

Minnesota, 18	court petition, marriage, living on own	yes	no law	yes, health care provider may notify parents	yes, health care provider may notify parents	yes, the health care provider may notify parents	yes, if a parent or if married; health care provider may notify parents; minor may consent to Hepatitis B vaccination
Mississippi, 21	court petition, 18 for medical consent, marriage	yes	no law	yes, includes surgical care	if minor is a parent, married, or referred by a doctor, clergy, family planning clinic, college, or agency[3]	yes	yes, for emergency care only

State Laws Regarding Consent by Minors (continued)

State, Legal Age of Majority[6,9]	Methods for Minors to Obtain Legal Emancipation[6]	Can Minor Consent to:					
		Medical Care for Own Child?[8]	Mental Health Services?[1,6,9]	Prenatal Services?[1,6,9]	Contraceptive Services?[1,6,9]	STD/HIV Tests and Services?[1,6,9]	General Medical Health[6,9]
Missouri, 18	court petition, marriage	yes	no law	yes, health care provider may notify parents; excludes abortion services; Includes surgical care	no law	yes, the health care provider may notify parents; includes surgical care	yes, if a parent or if married; or for emergency care
Montana, 18	court petition	yes	no law	yes, health care provider may notify parents	yes, health care provider may notify parents	yes, health care provider may notify parents; includes surgical care	yes, for emergency care, or if a parent, married, or pregnant; the health care provider may notify parents
Nebraska, 19	court petition, marriage	no law	no law	no law	no law	yes	no law
Nevada, 18	court petition	yes	no law	no law	no law	yes	yes, if a parent or married/divorced and has been on own ≥14 months; minor must be able to understand the nature and consequences of medical or surgical treatment proposed; if minor is a parent, or provider believes minor will suffer probably health hazard if services withheld; in emergencies if parent not available
New Hampshire, 18	court petition, if emancipated in another state	no law	yes, in a state facility; treatment info may be disclosed	no law	no law	≥14; the health care provider may notify parents	yes, for emergency care only

(continued)

State Laws Regarding Consent by Minors (continued)

State, Legal Age of Majority[6,9]	Methods for Minors to Obtain Legal Emancipation[6]	Can Minor Consent to:					
		Medical Care for Own Child?[8]	Mental Health Services?[1,6,9]	Prenatal Services?[1,6,9]	Contraceptive Services?[1,6,9]	STD/HIV Tests and Services?[1,6,9]	General Medical Health[6,9]
New Jersey, 18	court petition, marriage, military service, pregnancy/ children, not financially dependent	yes	≥ 14; disclosure to a parent permitted only with the minor's written consent	yes, health care provider may notify parents; includes surgical care	no law	yes, the health care provider may notify parents; includes surgical care	yes, if a parent, married, or pregnant; the health care provider may notify parents; yes, in case of sexual assault, but MD must notify parents; parents are statutorily entitled to have access to minor's medical records
New Mexico, 18	court petition, if 16 marriage, if 16 active military duty	no law	≥14	yes, limited to pregnancy testing and diagnosis	no law	yes	no law

(continued)

New York, 18	court petition, parent, marriage	yes	yes, ≥16 for psychotropic medication in certain circumstances; physician must notify parent about psychotropic medication	yes	no law	yes	yes, for emergency care only
North Carolina, 18	court petition, marriage	no law	yes	yes, excludes abortion services	no law	yes	if parent or guardian is not immediately available
North Dakota, 18	court petition	no law	no law	no law	no law	≥14	yes, for emergency care only

State Laws Regarding Consent by Minors (continued)

State, Legal Age of Majority[6,9]	Methods for Minors to Obtain Legal Emancipation[6]	Can Minor Consent to:					
		Medical Care for Own Child?[8]	Mental Health Services?[1,6,9]	Prenatal Services?[1,6,9]	Contraceptive Services?[1,6,9]	STD/HIV Tests and Services?[1,6,9]	General Medical Health[6,9]
Ohio, 18	court petition	no law	≥14 for limited services; MD may not inform parents unless minor consents	no law	no law	yes	no law
Oklahoma, 18	court petition, military, married, parent, living on own	yes	no law	yes, the health care provider may notify parents	if minor has ever been pregnant; the health care provider may notify parents	yes, the health care provider may notify parents	if a parent, married, pregnant, or if for emergency care; the health care provider may notify parents
Oregon, 18	court petition	no law	≥14; parents should be involved	no law	≥15; health care provider may notify parents	yes	≥15; the health care provider shall notify parents; parent may delegate authority to consent on behalf of minor for up to 6 months

(continued)

Pennsylvania, 21	court petition	yes	≥ 14; MD must notify parents if the minor ≤ 18	yes	no law	yes	a high school graduate, married, pregnant, or a parent; health care provide may decide if withholding such treatment until consent is obtained would increase the risk to the minor's life or health
Rhode Island, 18	court petition	yes	no law	no law	no law	yes	≥16, married, or parent
South Carolina, 18	court petition, if married may consent to health care	yes	no law	≥16; <16 when health care provider believes services are necessary	≥16; <16 when health care provider believes services are necessary	≥16; <16 when health care provider believes services are necessary	≥16 (excluding operations); <16 when health care provider believes services are necessary

State Laws Regarding Consent by Minors (continued)

State, Legal Age of Majority[6,9]	Methods for Minors to Obtain Legal Emancipation[6]	Can Minor Consent to:					
		Medical Care for Own Child?[8]	Mental Health Services?[1,6,9]	Prenatal Services?[1,6,9]	Contraceptive Services?[1,6,9]	STD/HIV Tests and Services?[1,6,9]	General Medical Health[6,9]
South Dakota, 18	court petition, military	no law	no law	no law	no law	yes	yes, for emergency care only (not elective abortion, sterilization or birth control)
Tennessee, 18	court petition	no law	yes	yes	if married, pregnant, or referred by clergy/ counselor	yes	no
Texas, 18	court petition, military, marriage, parent, living on own	no law	yes	yes, health care provider may notify parents; excludes abortion services; includes surgical care	yes[5]	yes, the health care provider may notify parents, includes surgical care	no law
Utah, 18	court petition	yes	no law	yes	yes, health care provider notifies parents whenever possible; includes surgical care	yes	no

(continued)

Vermont, 18	court petition, pregnant, married, active military duty	no law	no law	yes	no law	≥12	no law
Virginia, 18	court petition	yes	yes	yes	yes, excludes sterilization	yes, health care provider may notify parents	no, but a court may authorize treatment without parent or guardian consent
Washington, 18	court petition, marriage to an adult	no law	≥13	yes	yes[2]	≥14; includes surgical care	no law

State Laws Regarding Consent by Minors (continued)

State, Legal Age of Majority[6,9]	Methods for Minors to Obtain Legal Emancipation[6]	Can Minor Consent to:					
		Medical Care for Own Child?[8]	Mental Health Services?[1,6,9]	Prenatal Services?[1,6,9]	Contraceptive Services?[1,6,9]	STD/HIV Tests and Services?[1,6,9]	General Medical Health[6,9]
West Virginia, 18	court petition	no law	no law	no law	no law	yes	no law
Wisconsin, 18	court petition ,marriage	no law	no, if parents are responsible for payments[4]	no law	no law	yes	no law
Wyoming, 18	court petition, marriage, military	no law	no law	no law	yes	yes	yes

Notes

1 American Bar Association. *Facts About Children and the Law – Table 1. State Laws Allowing Minors to Consent to Medical Treatment,* 2004 April.
2 Washington Administrative Code (WAC 388-15-240) Available at: http://search.mrsc.org/nxt/gateway.dll?f=templates&fn=legpage.htm$vid=rcwwac:leg
3 Mississippi State Legislature. http://198.187.128.12/mississippi/lpext.dll?f=templates&fn=fs-main.htm&2.0
4 Wisconsin State Legislature. http://folio.legis.state.wi.us
5 Texas State Legislature. http://www.capitol.state.tx.us/cgi-bin/cqcgi
6 FEHBP Lawyers Discussion Group, 2003 April.
7 Maryland General Assembly, Rule 10-710. Available at: http://198.187.128.12/maryland/lpext.dll?f=templates&fn=fs-main.htm&2.0
8 Boonstra, Nash. 2000.
9 Belle R, S Boardman, C Boutilier, D Cap, et al., 2002.

Final Report for:

White Paper

The Ethical Challenges of Recruiting Minor Adolescents for the National Children's Study

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Forward

The Ethical Challenges of Recruiting Minor Adolescents for the National Children's Study – White Paper

This white paper was created through a work assignment under EPA contract number 68-D-02-069 to RTI International. The work assignment asked the contractor to review the literature to answer eight questions posed by the Ethics Working Group for the National Children's Study and to provide a recommendation based upon their review of the literature. This assignment was successfully completed August 25, 2004. This white paper is a very small portion of activities associated with exploring the ethical issues surrounding the National Children's Study and recommendations from this paper should not be interpreted as representing the views of, or endorsement from, the National Children Study planners.

A series of comments were received during the technical review of this paper and the main points of these concerns are summarized below. Please note that the white paper is presented here in its original form as delivered from the contractor and the text does not address these important comments.

- Much of the literature that seeks to increase an adolescent's authority and capacity in decision making and an increase in respect for young adults is not adequately represented or discussed in this paper.

- Although mentioned in the paper, a more systematic review of the important guidelines from the Society for Adolescent Medicine, "Guidelines for Adolescent Health Research" (Santelli, 2003) is needed.

- The discussion of passive consent by parents is unclear given the report's recommendation for active consent upon entrance to the study.

- A more careful analysis of the extant Federal regulations that impact on the potential for adolescents to consent to research should be included. This includes analysis of the definition of children and the circumstances in which parental consent may be waived [section 46.408(c)].

- Concerning minimal risk, the recommendations provided by the reports from the National Human Research Protections Advisory Committee and Institute of Medicine should be included.

- The legal authority of adolescent parents to consent for enrollment of their own children appears to be on solid ground. The report is unclear on this point and appears to suggest that grandparents provide consent for grandchildren at delivery.

Contract No. 68-D-02-069 **August 25, 2004**

Deliverable: Final Report

The Ethical Challenges of Recruiting Minor Adolescents for the National Children's Study

Work Assignment Number: 02-07

RTI Project No. 08601.001.007

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CONTENTS

EXECUTIVE SUMMARY

The federal government is designing the National Children's Study (NCS), a congressionally mandated longitudinal study that will examine the effects of environmental exposures among children, from before birth until age 21. The goal of the NCS is to improve the health and well-being of children. NCS planners have noted that including sexually active or pregnant minors in the National Children's Study may pose unique risks and benefits to the individual and to adolescents as a group. Before deciding whether and how to recruit minors into the NCS, the NCS planners identified eight questions to be addressed. The final white paper submitted as part of this work assignment responds to eight questions by synthesizing literature from the medical, behavioral, research, bioethical, and legal fields.

What are the unique risks and benefits of recruiting either sexually active minor adolescents (pre-pregnancy) or minor adolescents who are pregnant? The study and the individuals involved face minimal risks from recruiting sexually active or pregnant minors. Including minors in the study would produce substantial benefits for the NCS.

How are these risks and benefits influenced by the development and legal status of the minor adolescent? Both risks and benefits to the individual and the study arise from the complexity of dealing with minors in their variety of developmental stages; some, especially older ones, are considered "mature minors." The legal status of the minor influences the risks and benefits as determined by federal regulations and NIH policy that minors must be included in research (with few exceptions) and varying state laws on consent and minor emancipation.

Should the NCS develop guidance that recommends blanket inclusion or exclusion of these two groups of minor adolescents? Because of sensitivities regarding the inclusion of minors in this study, the NCS should not recommend a blanket inclusion or exclusion of pregnant or sexually active minors. Multiple factors suggest that blanket exclusion would be neither practical nor politically astute.

If the NCS does decide to include minors, what are the appropriate protections that NCS should require in recruiting sexually active minor adolescents or minor adolescent mothers? If the NCS includes minors certain protections should be required, including assent from minors (unless they are legally able to give consent), consent from parents (unless the minors are of certain classes that warrant waiving parental consent), lists of health care resources for adolescents who request such, and strict confidentiality protections.

If the NCS does decide to include minors, is parental permission a reasonable requirement in recruiting minor adolescents who are either sexually active or pregnant? Parental permission is a reasonable process that should be followed in all but a few circumstances, such as those that would damage the minor's health and wellbeing.

If the NCS does decide to include minors, what are the risks and benefits of requiring or waiving parental permission, especially in a study such as the NCS where most procedures are minimal risk? The benefits of waiving parental permission are important, but not very numerous. The benefits of requiring parental permission are strong and include added protection for ensuring the minor's best interests are paramount, development of community support, and the practical need to make sure that parents understand their children's involvement in the NCS in case the parents' involvement is needed, too.

If the NCS does decide to include minors, what is the capacity of the adolescent to provide effective informed consent? The adolescent has the capacity (but perhaps not the legal authority) to provide effective informed consent when the adolescent's decision-making skills are such that he or she is considered a "mature minor." Given the type of information anticipated in the NCS, this would probably be around the age of 15 for most adolescents.

If the NCS does decide to include minors, what is the capacity of the adolescent's parents to provide effective informed permission? It seems that requiring active parental consent may be more onerous than is necessary for gathering information for certain parts of the NCS, such as attitudinal and behavioral survey questions. In these cases, passive consent from the parent *and* active assent or consent from the minor should be sufficient human subjects protection for most IRBs.

We recommend that the NCS recruit minor adolescents into the study. We conclude that the work of NCS planners and the extensive laws, regulations, policies, research findings, and discussions of ethical matters lead to one major recommendation: the National Children's Study should require parental consent and adolescent assent for all minors recruited into the study, unless state law requires otherwise or the candidate participant is an emancipated minor.

The most productive next steps for NCS planners at this time center on consulting with the target groups. We recommend gathering opinions and information from parents and adolescents through focus groups to provide insight into their concerns, preferences, needs, and advice for unresolved matters, such as the consent and assent processes and questions regarding biomedical tests.

SEARCH CRITERIA USED FOR LITERATURE SEARCH

To conduct the literature search, we identified both key words and author names, based on information provided in the Work Assignment and previous efforts from planners of the National Children's Study. Electronic searches were conducted, as described later in this report. Promising books, articles, abstracts, and unpublished materials were obtained and reviewed, which led to repeated iterations with additional key words and author names. Any item that was relevant to the white paper was obtained and reviewed; references in those items were also examined for potential additions to candidate literature. Material published within the past 25 years was emphasized, although seminal pieces from earlier periods were also obtained and included.

The following key words and synonyms were used as search criteria for the white paper. The main headers of each group below are followed by synonymous terms. To ensure a wide search, all terms were included in the searches with "or" used to link the synonymous terms. All nine categories were searched using "and" to ensure specificity of results.

Key Words	**Synonyms**	
Adolescent	teenager youth	Minor adolescence
Sexually active	sexual behavior sexual intercourse pregnant or pregnancy adolescent pregnancy	pregnant women expectant parents parents or parenthood
Maturity	capacity for decision making physical maturity	emotional immaturity emotional maturity
Legal system	laws policy public policy jurisprudence	statutes legal decisions legal status guideline adherence
Values	beliefs societal consensus religion ethics	research ethics experimental ethics public opinion

Key Words	Synonyms	
Consent	parental permission parental consent informed consent	parental notification third-party consent
Study Participants	experiment volunteers experimental subjects	research subjects
Research study	research survey medical research study participant scientific study commercial exploitation contracts	research design research data collection experimental design methodology
Consent for sexually transmitted diseases	disclosure testing for	treatment of prevention of

The names listed below were used as search criteria to identify pertinent references or reports authored by these key individuals. The list of names is comprised of authors of key reports, participants in the NCS Ethics Working Group, and individuals active in the Society of Adolescent Medicine.

Norma J. Allred
Arturo Brito
Diane R. Burkom
Nancy Bethune
Sarah Carr
Donna Chen
Ellen Wright Clayton
Krista Crider
Peggy Davies
Diane Dennis-Flagler
Nancy Dubler
Robert DuRant
Abigail English
Michael Firestone
Celia Fisher
Joel Frader
Janet Gans
Gail Geller
Kate-Louise Gottfried
Jeffrey Kahn

Sheryl Lyss
Madlyn Morreale
Laurie Moyer-Mileur
John Murray
Vardit Ravitsky
Audrey Smith Rodgers
Walter Rosenfeld
John Santelli
Anna Schissel
Richard Sharp
Gary Sigman
Tomas Silber
Jennifer Singh
Marjorie Speers
Elizabeth J. Thomson
Diane Wagener
David Wendler
Yolanda Wimberly
Tineka Yowe-Conley

SEARCH ENGINES USED FOR LITERATURE SEARCH

The following search engines were used to conduct electronic searches of the key words and names listed above. All key words were searched using the resources listed in the first three categories below: general information resources, legal information resource, and grey literature resources. All author names were searched using the resources listed under general information resources and grey literature resources.

Key Words

General information resources:

- PubMed
- PsycINFO
- Sociological Abstracts
- National Library of Medicine Bibliography: Ethical Issues in Research Involving Human Participants

Legal information resource:

- Lexis (the legal part of LexisNexis)

Grey literature resources:

- Dissertation Abstracts
- NTIS (National Technical Information Service)
- Conference Papers Index
- GPO (Government Printing Office) Monthly Catalog
- New York Academy of Medicine's Grey Literature Report
- GreyNet
- Google

Author Names

General information resources:

- Web of Science (Science Citation Index Expanded and Social Sciences Citation Index)
- PubMed

Grey literature resources:

- Dissertation Abstracts
- NTIS (National Technical Information Service)
- Conference Papers Index
- GPO (Government Printing Office) Monthly Catalog
- Google

BIBLIOGRAPHY OF ALL RELEVANT LITERATURE

Aarons, S., Rose, A., Walker, J., Lyles, B., Jenkins, R., and Raine, T. (2001). Enhancing Recruitment and Data Quality in a Junior High School–Based Teen Pregnancy Prevention Study. *Evaluation and Program Planning*, 24, 277–285.

Abbing, H.D.C.R. (1996 September). Adolescent Sexuality and Public Policy: A Human Rights Response. *Politics and the Life Sciences,* 15(2), 314-6.

Abramovitch, R., Freedman, J. L., Thoden, K., and Nikolich, C. (1991). Children's Capacity to Consent to Participation in Psychological Research: Empirical Findings. *Child Development*, 62, 1100–1109.

Albert Einstein Hospital. (2003). *Enrollment of Minors in Research: Principles and Guidelines*. Website available at: www.aecom.yu.edu/home/CCI/enrollment_of_minors_in_research.htm

Albisa, C. (1996 September). Adolescent Access to Contraception: A Rights-Based Approach. *Politics and the Life Sciences*, 15(2), 283-284.

American Academy of Pediatrics Committee on Bioethics (1995). Informed Consent, Parental Permission, and Assent in Pediatric Practice. *Pediatrics*, 95(2), 314–317.

American Bar Association, Facts about Children and the Law-Table 1. *State Laws Allowing Minors to Consent to Medical Treatment.* Retrieved June 22, 2004 from www.abanet.org/media/factbooks/cht1.html.

American Medical Association. (1996). *Confidential Care for Minors. Report of the Council on Ethical and Judicial Affairs.* Chicago: American Medical Association.

Anda, R. F., Felitti V.J., Chapman, D. P., Croft, J. B., Williamson, D. F., Santelli, J., Dietz, P. M., Marks, J. S. (2001). Abused Boys, Battered Mothers and Male Involvement in Teen Pregnancy. *Pediatrics*, 107, e19. Website available at: http://www.pediatrics.org/cgi/content/full/107/2/e19.

Appelbaum, P., Roth, L. (1988, December 22). Assessing Patients' Capacities to Consent to Treatment. *New England Journal of Medicine*, 319, 1635-1638.

Arnold, L. E., et al. (1995). Ethical Issues in Biological Psychiatric Research with Children and Adolescents. *Journal of the Academy of Child and Adolescent Psychiatry*, 34(7), 929–939.

Bala, M. and Bala, N. (1996 September). A Canadian Perspective on Adolescent Sexuality and Public Policy: R equiring Parental Involvement Is Bad Law and Bad Medicine. *Politics and the Life Sciences,* 15(2), 285-7.

Beauchamp, T. L. and Childress, J. (1994). *Principles of Biomedical Ethics.* 4th ed. New York: Oxford University Press.

Beecher, H. K. (1970). *Research and the Individual: Human Studies*. Boston: Little, Brown and Company.

Belle R., Boardman S., Boutilier, C., Cap, D., et al. (2002, April). *Legislative Initiatives for Healthier Lives.* A Collaborative Partnership: The Health Law Institute, A Program of the Justice Resource Institute and Northeastern University School of Law. Law Office #2. Web site available at: www.bostoncoop.net/lcd/mature_minor/mature_minor.html

Boonstra, H. and Nash, E. (2000, August). Minors and the Right to Consent to Health Care. *The Guttmacher Report on Public Policy.* Website available at: http://www.guttmacher.org/graphics/gr030406_f1.html

Boutte-Queen, N. M. and Cheung, M. (2001). The TANF Co-Residence Requirement for Custodial Teen Parents: Implications for Promoting Social Justice. *Journal of Poverty*, 5, 51-65.

Brewster, K. L. (1994). Neighborhood Context and the Transition to Sexual Activity among Young Black Women. *Demography*, 31, 603-614.

Brock, D. W. (1994). Ethical Issues in Exposing Children to Risks in Research." In Michael A. Grodin and Leonard H. Glantz (Eds.), *Children as Research Subjects* (pp.81–101). New York: Oxford University Press.

Brody, B. A. (2001). Making Informed Consent Meaningful. *IRB: Ethics & Human Research*, 23(5), 1–5.

Brody, J. L., and Waldron, H. B. (2000). Ethical Issues in Research on the Treatment of Adolescent Substance Abuse Disorders." *Addictive Behaviors*, 25(2), 217–228.

Brody, J. L., Scherer, D. G., Annett, R. D., and Pearson-Bish, M. (2003). Voluntary Assent in Biomedical Research with Adolescents: A Comparison of Parent and Adolescent Views. *Ethics & Behavior*, 13(1), 79–95.

Brooks-Gunn J., and Rotheram-Borus M. J. (1994). Rights to Privacy in Research: Adolescents Versus Parents. *Ethics and Behavior*, 4(2), 109-121.

Bruzzese, J. M., and Fisher, C. B. (2003). Assessing and Enhancing the Research Consent Capacity of Children and Youth. *Applied Developmental Science*, 7(1), 13–26.

Candilis, P. J., Wesley, R. W., and Wichman, A. (1993). A Survey of Researchers Using a Consent Policy for Cognitively Impaired Human Research Subjects. *IRB: A Review of Human Subjects Research*, 15(6), 1-4.

Capron, A. M. (1982). "The Competence of Children as Self-deciders in Biomedical Interventions." In W. Gaylin and R. Macklin (Eds.), *Who Speaks for the Child: The Problems of Proxy Consent.* New York: Plenum Press.

Cardwell v. Bechtol, 724 S.W.2d 739, 745 (Tenn. 1987).

Carey v. Population Services International, 431 U.S. 678, 1977.

Centers for Disease Control and Prevention (1998). *Contraceptive use among women 15–44 years of age, according to age, race, Hispanic origin, and method of contraception: United States, 1982, 1988, and 1995*. Data from the National Survey of Family Growth. National Center for Health Statistics, Division of Vital Statistics.

Chamberlin, J. (2004, March). A Closer Look at Division 7: Facilitating Research with Children. *The Monitor, APA*, 35, 3.

Cronholm, P. F., Bennett, I. M., and Neill, R. (2002). Effects of Mandatory Parental Notification on Adolescents' Use of Sexual Health Care Services. *Journal of the American Medical Association*, 288(23), 2970.

Curr, N. D. (n.d.). Special Decision Making Concerns of Minors. Albert Einstein Hospital, Yeshiva University, New York. Web site available at: http://epi.aecom.yu.edu

Dailard, Cynthia (2003, March). New Medical Records Privacy Rule: The Interface with Teen Access to Confidential Care. *Guttmacher Report on Public Policy, State Policies in Brief, AGI, Minors Access to STD Services* (2003).

Darroch, J. E. and Singh S. (1999). *Why Is Teenage Pregnancy Declining? The Roles of Abstinence, Sexual Activity, and Contraceptive Use*. [Occasional Report, no. 1] New York: Alan Guttmacher Institute.

Davis, N. S., and Twombly, J. (2000, February). *State Legislators' Handbook for Statutory Rape Issues*. American Bar Association Center on Children and Law and U.S. Department of Justice, Office of Justice Programs, Office for Victims of Crime. Website available at: http://www.ojp.usdoj.gov/ovc/publications/infores/statutoryrape/handbook/cont.html

De Ville, K. (1997, June). Adolescent Parents and Medical Decision-making. *The Journal of Medicine and Philosophy*, 22(3), 253-270.

Derish, M. T., and Heuvel, K. V. (2000). Mature Minors Should Have the Right to Refuse Life-sustaining Medical Treatment. *Journal of Law, Medicine & Ethics*, 28, 109–124.

DeVille, K. (1997). Adolescent Parents and Medical Decision-making. *The Journal of Medicine and Philosophy*, 22, 253–270.

Dorn, L. D., Susman, E. J., and Fletcher, J. C. (1995). Informed Consent in Children and Adolescents: Age, Maturation and Psychological State. *Journal of Adolescent Health*, 16(3), 185-190.

Elders, J. (1996, September). Ignorance is Not Bliss. *Politics and the Life Sciences*, 15 (2), 288-290.

English, A. (2004, February). The HIPAA Privacy Rule: What Does it Mean for SBHCs? *Center for Adolescent Health and the Law*.

English, A. (1995). Guidelines for Adolescent Health Research: Legal Perspectives. *Journal of Adolescent Health*, 17, 277–286.

English, A., Morreale, M.C., Stinnett, A., et al. (2003). *State Minor Consent Laws: A Summary*. Chapel Hill, NC: Center for Adolescent Health and the Law.

Esbensen, F.-A., Miller, M. H., Taylor, T. J., He, N., and Freng, A. (1999, June). Differential Attrition Rates and Active Parental Consent. *Evaluation Review*, 23(3), 316–335.

FEHBP (Federal Employees Health Benefits Plans) Lawyers Discussion Group (2003, April). State Law Survey for Use in Applying the Personal Representative for Minor Section of the HIPAA Privacy Rule, 45 CFR 164.502(g)(3).

Fern, R. L. (1996, September). Adolescent Sexuality and the L-Word: How Liberal is Liberalism? *Politics and the Life Sciences*, 15 (2), 290-92.

Field, M. J., and Behrman, R. E. (Eds.) (2004). *Ethical Conduct of Clinical Research Involving Children*. Washington, DC: The National Academies Press.

Fisher, C. B. (1994). Reporting and Referring Research Participants: Ethical Challenges for Investigators Studying Children and Youth. *Ethics and Behavior*, 4(2), 87–95.

Fisher, C. B., and Wallace, S. A. (2000). Through the Community Looking Glass: Reevaluating the Ethical and Policy Implications of Research on Adolescent Risk and Psychopathology. *Ethics and Behavior*, 10(2), 99-118.

Flagel, D. C. (2000, September–October). Children as Research Subjects: New Guidelines for Canadian IRBs. *IRB: A Review of Human Subjects Research*, 22(5), 1–3.

Ford, C. A., and English, A. (2002). Limiting Confidentiality of Adolescent Health Services: What Are the Risks? *Journal of the American Medical Association*, 288(6),752-753.

Gaylin, W. (1982). "Competence: No Longer All or None." In W. Gaylin and R. Macklin (Eds.), *Who Speaks for the Child: The Problems of Proxy Consent.* New York: Plenum Press.

Geller G., Tambor, E. S., Bernhardt, B. A., Fraser, G., and Wissow, L. S. (2003). Informed Consent for Enrolling Minors in Genetic Susceptibility Research: A Qualitative Study of At-Risk Children's And Parents' Views about Children's Role in Decision-Making. *Journal of Adolescent Health*, 33(1), 49.

Goldblatt, A. D. (1996, September). Imposing Morality: The Pediatrician as Parental Agent. *Politics and the Life Sciences*, 15(2), 292-295.

Gregory, M. M., Lohr M. J., and Gilchrist, L. D. (1992, February). Methods for Tracking Pregnant and Parenting Adolescents. *Evaluation Review*, 17(1), 69–81.

Grisso, T., and Vierling, L. (1978). Minors' Consent to Treatment: A Developmental Perspective. *Professional Psychology* 9(3), 412-427.

Harrison, L., and Hunt, B. (1999, winter). Adolescent Involvement in the Medical Decision Making Process. *Journal of Applied Rehabilitation Counseling,* 30(4), 3–9.

Henry, K. L., Smith, E. A., and Hopkins, A. M. (2002, December). The Effect of Active Parental Consent on the Ability to Generalize the Results of an Alcohol, Tobacco, and Other Drug Prevention Trial to Rural Adolescents. *Evaluation Review,* 26(6), 645–655.

Hoagwood, K., Jensen, P. S., and Fisher, C. B. (Eds.) (1996). *Ethical Issues in Mental Health Research with Children and Adolescents*. Mahway, NJ: Lawrence Erlbaum Associates.

Holder A. R., and Veatch R. M. (1981, February). Can Teenagers Participate in Research Without Parental Consent? *IRB: Ethics & Human Research,* 3(2), 5-8.

Holder, A. R. (1985). *Legal Issues in Pediatrics and Adolescent Medicine*. New Haven: Yale University Press.

Jackson, S., and Hafemeister, T. L. (2001). Impact of Parental Consent and Notification Policies on the Decisions of Adolescents to Be Tested for HIV. *Society for Adolescent Medicine,* 29, 81–93.

Jason, L. A., Pokorny, S., and Katz, R. (2001, January). Passive versus Active Consent: A Case Study in School Settings. *Journal of Community Psychology*, 29(1), 53-68.

Klein, J. D., Graff, C. A., Santelli, J. S., Hedberg, V. A., Allan, M. J., and Elster, A. B. (1999, April). Developing Quality Measures for Adolescent Care: Validity of Adolescents' Self-Reported Receipt of Preventive Services. *Social Health Services Research,* 34(1), 391-404.

Koocher, G. P., and Keith-Spiegel, P. (1994). "Scientific Issues in Psychosocial and Educational Research with Children." In M. A. Grodin and L. H. Glantz (Eds.), *Children as Research Subjects,* (pp. 47–80). New York: Oxford University Press.

Leikin S. (1993, March-April). Minors' Assent, Consent, or Dissent to Medical Research. *IRB: A Review of Human Subjects Research,* 15(2), 1-7.

Leikin, S. L. (1983). Minors' Assent or Dissent to Medical Treatment. *The Journal of Pediatrics,* 102(2), 169–76.

Leikin, S. L. (1983). An Ethical Issue in Biomedical Research: The Involvement of Minors in Informed and Third Party Consent. *Clinical Research,* 31**,** 34-40.

Levine, R. J. (1995). Adolescents as Research Subjects Without Permission of Their Parents or Guardians: Ethical Considerations. *Society for Adolescent Medicine,* 17, 287–297.

Litt, I. F. (2003). Research *With*, Not *On*, Adolescents: Community-based Participatory Research. *Journal of Adolescent Health*, 33, 315-316.

Lothen-Kline, C., Howard, D.E., Hamburger, E.K., Worrell, K.D., and Boekeloo, B.O. (2003). Truth and Consequences: Ethics, Confidentiality, and Disclosure in Adolescent Longitudinal Prevention Research. *Journal of Adolescent Health,* 33(5), 385-394.

Lynskey, M. (1996, September). Universal Solutions or Individual Choices. *Politics and the Life Sciences,* 15(2), 295-296.

Mahowald, M. (1996, September). Flawed Laws, Better Ethics: Not All Teenagers are Alike. *Politics and the Life Sciences,* 15(2), 297-298.

Malamitsi-Puchner, A. (1996, September). Adolescent Sexuality and Public Policy: Adolescent Sexuality: A Greek Perspective. *Politics and the Life Sciences,* 15(2), 299-300.

Mammel, K. A., and Kaplan, D. W. (1995). Research Consent by Adolescent Minors and Institutional Review Boards. *Society for Adolescent Medicine,* 17, 323–330.

Mastroianni, A.C., Faden, R., and Federman, D. (Eds.) (1994). *Women and Health Research: Ethical and Legal Issues of Including Women in Clinical Studies,* Volume I. Washington, DC: Institute of Medicine, National Academy Press.

McCabe, M. A. (1996). Involving Children and Adolescents in Medical Decision Making: Developmental and Clinical Considerations. *Journal of Pediatric Psychology*, 21(4), 505–516.

McCabe, M.A., Rushton, C.H., Glover, J., Murray, M.J., and Leiken, S. (1996). Implications of the Patient Self-Determination Act: Guidelines for Involving Adolescents in Medical Decision Making. *Journal of Adolescent Health*, 19(5), 319-324.

McGee, G., and Burg, F. (1996, September). When Paternalism Runs Amok. *Politics and the Life Sciences,* 15(2), 308-309.

Melton, G. B. (1983, January). Toward "Personhood" for Adolescents. *American Psychologist,* 99–103.

Merrick, J.C. (1996, September). Kids, Sex, and Contraceptives: Dilemmas in a Liberal Society. *Politics and the Life Sciences,* 15(2), 281-282.

Meyers, K., Webb, A., Frantz, J., and Randall, M. (2003, January). What Does It Take to Retain Substance-Abusing Adolescents in Research Protocols? Delineation of Effort Required, Strategies Undertaken, Costs Incurred, and 6-Month Post-Treatment Differences by Retention Difficulty. *Drug and Alcohol Dependence,* 69(1), 73-85.

Middleman, A. (1996, September). Public Policy Regarding Adolescent Sexuality in a Truly Liberal State. *Politics and the Life Sciences,* 15(2), 305-307.

Moolchan, E. T., and Mermelstein R. (2002). Research on Tobacco Use Among Teenagers: Ethical Challenges. *Journal of Adolescent Health*, 30, 409–417.

Murphy T. F. (2003, Autumn). Assent and Dissent in 407 Research with Children. *American Journal of Bioethics*, 3 (4), 18-9.

National Bioethics Advisory Commission. (2001, August). *Ethical and Policy Issues in Research Involving Human Participants: Protecting Research Participant—A Time for Change.*

National Children's Study (2003). *What Is the National Children's Study?* Web site accessed June 22, 2004: http://nationalchildrensstudy.gov/about/index.cfm

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1977). *Report and Recommendations: Research Involving Children.* Washington, DC: U.S. Government Printing Office.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1978). *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (DHEW publication no. [OS] 78-0012) Washington, DC: US Government Printing Office.

National Human Research Protections Advisory Committee (2002). Report from NHRPAC: *Clarifying Specific Portion of 45 CFR 46 Subpart D that Governs Children's Research.* Retrieved July 12, 2004, from, http://ohrp.osophs.dhhs.gov/nhrpac/documents/nhrpac16.pdf.

National Institutes of Health, *Frequently Asked Questions on Certificates of Confidentiality.* (2003, July 21). Retrieved July 24, 2004, from, http://grants.nih.gov/grants/policy/coc/faqs.htm.

National Institutes of Health (1998, March). NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects. Retrieved June 19, 2004, from http://grants1.nih.gov/grants/guide/notice-files/not98-024.html.

Nelson, R. M., and Rushton, C. H. (2001, May). Commentary on Special Issue on Informed Consent with Families of Ill Children (February 2001): Understanding Devastation and Difference in Informed Permission and Assent. *Journal of Family Nursing*, 7(2), 208-213.

Nelson, R.M. (2001). Nontherapeutic Research, Minimal Risk, and the Kennedy Krieger Lead Abatement Study. *IRB: Ethics & Human Research*, 23(6), 7-11.

O'Donnell, L. N., Duran, R. H., San Doval, A., Breslin, M. J., Juhn, G. M., and Stueve, A. (1997). Obtaining Written Parent Permission for School-Based Health Surveys of Urban Young Adolescents. *Journal of Adolescent Health*, 21, 376–383.

Oberman, M. (1996). Minor Rights and Wrongs. *Journal of Law, Medicine and Ethics*, 24, 124–38.

O'Donovan, K. (1996, September). Mature Minors Are Individuals. *Politics and the Life Sciences,* 15(2), 301-302.

Olds, R. S. (2003). Informed Consent Issues with Adolescent Health Behavior Research. *American Journal of Health Behavior*, 27(Suppl3): S248-S263.

O'Sullivan C., and Fisher, C. B. (1997). The Effect of Confidentiality and Reporting Procedures on Parent Child Agreement to Participate in Adolescent Risk Research. *Applied Developmental Science*, 1(4), 187-199.

Petersen, A. C., and Leffert, N. (1995, November). Developmental Issues Influencing Guidelines for Adolescent Health Research: A Review. *Journal of Adolescent Health,* 17(5), 298–305.

Phillips, S. R. (1994, November-December). Asking the Sensitive Question: The Ethics of Survey Research and Teen Sex. *IRB: A Review of Human Subjects Research,* 16(6), 1-7.

Piaget, J., and Inhelder, B. (1969). *The Psychology of the Child.* Basic Books, New York.

Policy and Communications Bulletin, Medical Administrative Series, The Clinical Center, National Institutes of Health (2002). Research Involving Children and Children's Assent to Research.

Policy and Communications Bulletin, Medical Administrative Series, The Clinical Center, National Institutes of Health (2003, March). Informed Consent.

Purdy, L. (1996, September). Children, Sex, and Liberal Societies: A Response to Lainie Ross. *Politics and the Life Sciences,* 15 (2), 302-4.

Range L. M., and Cotton, C. R. (1995). Assent and Permission Rejoinder. *Ethics and Behavior*, 5(4), 345-7.

Rau, J. M. B. (1997, October). The Ability of Minors to Define and Recognize Their Rights in Research. *Dissertation Abstracts International: Section B: The Sciences and Engineering*, 58(4-B), 2156.

Reddy, D. M., Fleming, R., and Swain, C. (2002). Effect of Mandatory Parental Notification on Adolescent Girls' Use of Sexual Health Care Services. *Journal of the American Medical Association,* 288, 710–714.

Renger R., Gotkin V., Crago M., and Shisslak, C. (1998). Research and Legal Perspectives on the Implications of the Family Privacy Protection Act for Research and Evaluation Involving Minors. *American Journal of Evaluation*, 19(2), 191-202

Resnick, M. D., Bearman, P. S., Blum, R. W., et al.. (1997). Protecting Adolescents from Harm. Findings from the National Longitudinal Study of Adolescent Health. *Journal of the American Medical Association*, 278**,** 823-832.

Rew, L., Taylor-Seehafer, M., and Thomas, N. (2000, July-September). Without Parental Consent: Conducting Research with Homeless Adolescents. *Journal of the Society of Pediatric Nurses*, 5(3), 131–138.

Reynolds, S. (2002, February). Consent of Minors to Research Activities. *The Investigator*.

Rhode, D. L. (Ed) (1993). *The Politics of Pregnancy: Adolescent Sexuality and Public Policy.* New Haven, CT: Yale University Press.

Risjord, M., and Greenberg, J. (2002, March-April). When IRBs Disagree: Waiving Parental Consent for Sexual Health Research on Adolescents (CS). *IRB: A Review of Human Subjects Research*, 24(2), 8-14.

Roberts M. C., and Buckloh, L. M. (1995). Five Points and a Lament about Range and Cotton's "Reports of Assent and Permission in Research with Children." *Ethics and Behavior*, 5(4), 333-44.

Rogers, A. S., Kinsman, S. B., Santelli, J. S., and Silber, T. J. (1999). Code of Research Ethics: A Position Paper of the Society for Adolescent Medicine. *Journal of Adolescent Health,* 24, 277–82.

Rogers, A. S., D'Angelo, L., and Futterman, D. (1994). Guidelines for Adolescent Participation in Research: Current Realities and Possible Solutions. *IRB: A Review of Human Subjects Research*, 16(4), 1–6.

Rogers, A. S., et al., (1999, January–February). A Case Study in Adolescent Participation in Clinical Research: Eleven Clinical Sites, One Common Protocol, and Eleven IRBs. *IRB: A Review of Human Subjects Research*, 6–10.

Rosoff, J. I. (1996, September). Paternal Control is Not a Panacea. *Politics and the Life Sciences,*15(2), 310-311.

Rossi, W. C., Reynolds, W., and Nelson, R. M. (2003). Child Assent and Parental Permission in Pediatric Research. *Theoretical Medicine*, 24, 131–148.

Ruck, M. D., Keating, D. P., Abramovitch, R., and Koegl, C. J. (1998). Adolescents' and Children's Knowledge About Rights: Some Evidence for How Young People View Rights in Their Own Lives. *Journal of Adolescence*, 21, 275–289.

Ryan, M. (1996, September). Religion and Adolescent Sexuality. *Politics and the Life Sciences*, 15(2), 312-14.

Sanci L. A., Sawyer, S. M., Weller, P. J., Bond, L. M., and Patton, G. C. (2004). Youth Health Research Ethics: Time for a Mature-Minor Clause? *Medical Journal of Australia*. 180(7), 336-338.

Santelli J., Kaiser, J., Hirsch, L., Radosh, A., Simkin, L., and Middlestadt, S. (2004). Initiation of Sexual Intercourse among Middle School Adolescents: The Influence of Psychosocial Factors. *Journal of Adolescent Health*, 34, 200-208.

Santelli J., and Rogers, A. S. (2002). Parental Permission, Passive Consent, and "Children" in Research. *Journal of Adolescent Health*, 31, 303-304.

Santelli, J. S., Rosenfeld, W. D., DuRant, R. H., Dubler, N., Morreale, M., English, A., and Rogers, A. S. (1995). Guidelines for Adolescent Health Research: A Position Paper of the Society for Adolescent Medicine. *Journal of Adolescent Health*, 17, 270-276.

Santelli, J. (1997). Human Subjects Protection and Parental Permission in Adolescent Health Research. *Journal of Adolescent Health*, 21, 384–387.

Santelli, J. S., Rogers, A. S., Rosenfeld, W. D., DuRant R. H., Dubler, R., Morreale, M. English, A., Lyss, S., Wimberly, Y., and Schissel, A. (2003). Guidelines for Adolescent Health Research (A position paper of the Society for Adolescent Medicine). *Journal of Adolescent Health*, 33(5), 396–409.

Scarr, S. (1994). Ethical Problems in Research on Risky Behaviors and Risky Populations. *Ethics and Behavior*, 4(2), 147-155.

Schulte, D.J. (2004). When is the Consent of a Parent or Legally Appointed Guardian Not Required for Providing Treatment to a Minor? *Michigan Medicine*, 103(1), 4.

Shearer, D. L., Mulvihill, B. A., Klerman, L. V., Wallander, J. L., Hovinga, M. E., and Redden, D. T. (2002). Association of Early Childbearing and Low Cognitive Ability. *Perspectives on Sexual and Reproductive Health*, 34, 236–243.

Shield, J. P. H., and Baum, J. D. (1994). Children's Consent to Treatment. *British Medical Journal*, 308, 1182-1183.

Shields, J. M., and Johnson, A. (1992). Collision between Law and Ethics: Consent for Treatment with Adolescents. *Bulletin of the American Academy of Psychiatry and the Law*, 20(3), 309-323.

Sigman, G., Silber, T., English, A., and Gans, J. (1997). A Position Paper of the Society for Adolescent Medicine: Confidential Health Care for Adolescents. *Journal of Adolescent Health*, 21, 408-415.

Sikand, A., Schubiner, H., and Simpson, P. M. (1997, June). Parent and Adolescent Perceived Need for Parental Consent Involving Research with Minors. *Archives of Pediatric and Adolescent Medicine*, 151, 603–607.

Simkin, L. S., Hirsch, L., Radosh, A., Middlestadt, S. E., Kaiser, J., and Santelli, J. S. (2000). Strategies to Maximize Retention of a Sample of Young Adolescents in a Longitudinal Evaluation of "Healthy & Alive!" *Journal of School Health,* 70(7), 286-291.

Simon, C. (2002). Child assent and parental permission for clinical research—Some considerations. *Bioethics Forum*, 18(3-4), 36-42.

Sterling, C. M., amd Walco, G. A. (2003). Protection of Children's Rights to Self-Determination in Research. *Ethics and Behavior*, 13(3), 237-247.

Stewart, F. H., and Shields, W. C. (2004.) Faulty Assumptions, Harmful Consequences: Coming to Terms with Adolescent Sexuality. *Contraception,* 69(5), 345-346.

Strasburger v. Parental Permission in Adolescent Health Research (1998). *Journal of Adolescent Health*, 22, 362.

Stuart-Smith, S. (1996). Adolescent Sexuality and Public Policy: The Role of Cognitive Immaturity. *Politics and the Life Sciences,* 15(2), 317-19.

Susman, E. J., Dorn, L. D., and Fletcher, J. C. (1992). Participation in Biomedical Research: The Consent Process as Viewed by Children, Adolescents, Young Adults, and Physicians. *Journal of Pediatrics,* 121, 547–552.

Tahir, M. A. Mohamed, Mason, C., and Hind, V. (2002). Informed Consent: Optimism versus Reality. *British Dental Journal*, 193(4), 221–224.

The Sullivan Group. Physician's Law Review. Chapter 2. *Refusal of Care*. Website accessed June 25, 2004: http://www.thesullivangroup.com/physician_law_review/refusal/refusal_2_refusal.html

Tigges, B. B. (2003). Parental Consent and Adolescent Risk Behavior Research. *Journal of Nursing Scholarship,* 283–289.

Toner, K., and Schwartz, R. (2003). Why a Teenager over Age 14 Should Be Able to Consent, Rather than Merely Assent, to Participation as a Human Subject of Research. *American Journal of Bioethics*, 3(4), 38–40.

University of Rochester (1997). Consent Issues in Research Involving Minors, Research Subjects Review Board. Retrieved from http://www.urmc.rochester.edu/rsrb/pdf/minor.pdf

Upchurch, D. M, Lillard L. A., Aneshensel C. S., and Li, N. F. (2002). Inconsistencies in Reporting the Occurrence and Timing of First Intercourse Among Adolescents. *Journal of Sex Research,* 39(3), 197-206.

Vitiello, B. (2003). Ethical Considerations in Psychopharmacological Research Involving Children and Adolescents. *Psychopharmacology*, 171(1), 86-91

Weiss, J. W., and Weiss, D .J. (2002). Recruiting Asian-American Adolescents for Behavioral Surveys. *Journal of Child and Family Studies*, 11(2), 143-149.

Weithman, P. (1996). Neutrality and Autonomy, Equality and Confidentiality. *Politics and the Life Sciences*, 15(2), 319-321.

Weithorn, L. A. (1983). Children's Capacities to Decide About Participation in Research. *IRB: A Review of Human Subjects Research*, 5(2), 1–5.

Weithorn, L. A., and Scherer, D. G. (1994). "Children's Involvement in Research Participation Decisions: Psychological Considerations." In M. A. Grodin and L. H. Glantz (Eds.), *Children as Research Subjects: Science, Ethics, and Law*. New York, Oxford University Press.

Wender, E. H. (1994). "Assessment of Risk to Children." In M. A. Grodin and L. H. Glantz (Eds.), *Children as Research Subjects*. New York: Oxford University Press.

Wendler, D., and Shah, S. (2003). Should Children Decide Whether They are Enrolled in Nonbeneficial Research? *The American Journal of Bioethics*, 3(4), 1–7.

Wertz, D. C., Fanos, J. H., and Reilly, P. R. (1994). Genetic Testing for Children and Adolescents: Who Decides? *Journal of the American Medical Association*, 272(11), 875–881.

Wilcoxon,S A. (2002). "Permission to Speak Freely: Consent and Intervention with the Noncustodial Parent and Children." In R. E. Watts and J. Carlson (Eds.), *Techniques in Marriage and Family Counseling*, Vol. 2. *The Family Psychology and Counseling Series.* (pp. 109-116). Alexandria, VA, US: American Counseling Association.

Wolpe, P. R. (1996). Adolescent Contraception and the Just Society. *Politics and the Life Sciences*, 15(2), 321-23.