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Legal considerations in pediatric and adolescent obstetrics and gynecology

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STEVEN R. SMITH

INTRODUCTION

Health-care providers caring for the gynecologic and obstetric needs of adolescents and young adults face some of the thorniest legal issues in all of medicine. (We use the common legal word "minors" to refer to such patients.) With minor patients, gynecologic practice often involves difficult emotional, controversial, and unresolved questions of our society. The law reflects both the passion and ambiguity of these questions.[1]

Despite the complexity of the legal issues involved in treating minor patients, it is critical that clinicians understand the basic rights of their patients, parents, and others associated with care. This chapter discusses questions of consent to treatment, child abuse, and other required reporting. It also considers the conflicting obligations gynecologists have, both to minor patients and their parents, and, in some cases, to society. Legal issues related to confidentiality will be considered in less detail because of the specific consideration of that subject and an extensive list of resources in Chapter 27.

What is the law

One reason that discussing the law affecting minors and health care is complicated is that there is no such thing as "The Law." This is true for several reasons. First, state law has traditionally governed the regulation of medical care, the definition of the legal rights of minors, and the relationships between parents and minors. State law still plays the dominant role in defining and regulating the provision of medical care to minors, although federal law has become increasingly important. Laws in areas of adolescent rights and health care vary somewhat among the states. There are many common points in legal principles from one state to another—and we particularly focus on areas of common agreement. In some important ways, however, the differences among states can be quite significant—an example is the rules related to minors receiving abortion services.[2]

A second reason for the complexity in the law is the federal system in America. The federal government has legal authority that usually (but not always) trumps state law. The Constitution of the United States limits what states can do, an example being the limitation on the ability of states to prohibit abortion[3] or same-sex marriage.[4] The federal government, however, is also subject to constitutional limitations, so not every effort to control what states do is successful, as was the case when the federal government sought to require states to expand Medicaid as part of the Affordable Care Act.[5]

The third thing that makes it difficult to know what the law "is," is the multiplicity of sources of law, at the federal, state, and local levels. There are constitutions, statutes (or ordinances) passed by legislative bodies, regulations of various sorts adopted by administrative agencies, and decisions of courts throughout the country. Often the work of these bodies is ambiguous, inconsistent, or collectively does not address a legal question. And (except for the constitutions) these sources of law are changing frequently. It is sometimes not at all clear what the law actually is. This is, for example, sometimes because of ambiguity in the language of statutes or regulations and sometimes because it is not clear how various parts of the law (regulations and court decisions, for instance) will interact. For these reasons, the "practice of law" (like the practice of medicine) is often not an exact science but one involving judgment.

Federal statutes have directly or indirectly (notably through federal funding requirements) increasingly influenced medical practice.[7] Federal court decisions regarding the constitutional rights of minors are examples of federal rules that have generally changed the law affecting the rights of adolescents. While this trend is clear, state laws are still dominant in many areas of health care.

THE FUNDAMENTAL RIGHTS OF CHILDREN AND PARENTS

General rules of parents and children

Under traditional common law, children were virtually the property of their parents and were completely subject to parental decisions, direction, and discipline.[6] Throughout much of the last hundred years, however, the concept of parental ownership and control of children increasingly has weakened.[7] As a matter of statutory and constitutional law, parents still have wide latitude in raising their children.[77] However, minors have increasingly been recognized as separate legal entities with their own rights and interests.[8] As a result, the relative authority of parents and their children, especially older adolescent children, in making medical decisions is in flux and often uncertain.[9]

Children traditionally have been protected from their own immature judgment by their limited ability both to enter into contracts (except for necessities) and to consent to medical care (except under very limited circumstances).[10] The law generally considered minors to be incapable of making binding legal decisions until the age of majority. State law defines the age of majority, and most states now use 18 for general decision-making capacity.[11]

Emancipated minors and mature minors

There have been some well-recognized exceptions to minors' inability to make legally binding decisions. The most common is the "emancipated minors" rule.[12] Emancipated minors may make legally binding decisions, because they are viewed as formally free of the control and responsibility of their parents. This is usually as a result of marriage, military service, or (in some states) economic independence coupled with parental approval.[13] Most states also have recognized that "mature minors" may make legally binding decisions.[14] The concept of the mature minor generally refers to those who are able to understand and make complex decisions even though they have not reached the age of majority.[15]

Legal trends in recent decades

The legal tendency during the last three decades, consistent with studies of the decision-making ability of older minors, has been to give minors the legal authority to make legally binding decisions at an earlier age.[16] This is not an uninterrupted trend, however, and in some places the trend has been reversed for a while, leading to somewhat expanded parental control over fundamental decisions for adolescents under 18.[17] Special rules also have been applied to substance abuse treatment—generally allowing expanding authority for minors to seek treatment for substance abuse.[18]

An especially helpful state-by-state review of minor's consent laws is contained as part of the Guttmacher Institute website. It has specific consent reports dealing with minors' access to contraception, abortion, sexually transmitted infections (STIs) care, and prenatal care. It also has a comprehensive report covering all of these topics.[19] These reports are updated frequently.

THE LAW OF INFORMED CONSENT

Medical care may ordinarily be provided only if the patient (or someone legally authorized to act for the patient—a parent, for example) has given consent.[20] Consent to treatment is part of the general right of autonomy, the right of all adults to decide for themselves what will be done to their bodies. When the treatment is important or risky—surgery or invasive testing, for example—the patient must be informed of the risks and benefits and of alternative treatments and their consequences. That is, the patient must give "informed consent"[21] (Table 30.1).

Although informed consent is a general requirement of medical treatment, there are a few, limited exceptions—the most important being the "emergency exception." Emergency care generally can be provided to minors without parental consent, and lifesaving care may be undertaken on the intervention of state social service agencies or courts.[22]

Parents must generally consent to treatment for their unemancipated children. Some modifications of these general rules have been recognized, however, for adolescent obstetric and gynecologic care.[23] These have been made by statute in some states and by federal court decisions.[24] Virtually all states allow adolescents to consent to some kinds of gynecologic care, most often for treatment for STIs and commonly (but not universally) for pregnancy and contraception.[25] Several states, as part of the increased concern over child abuse, expressly allow the victims of abuse to consent to treatment for the sequela of abuse. Other changes in federal and state law have permitted adolescents to seek treatment without parental consent for drug or alcohol dependence. Many states have limited the scope of these minor consent laws so that they do not apply to abortion.[26]

By way of examples of the variations of state laws regarding kinds of care and consent, all states (and DC) allow minors to consent to STI services. Twenty-six states (and DC) allow all minors (who are at least 12 years old) to consent to contraceptive services, while 20 allow only some categories of minors to consent, and four states have no law on the subject. Most restrictive are the laws regarding consent to abortion. Two states (and DC) allow minors to consent to abortion services; 21 states require the consent of at least one parent, but some other states have notification provisions to be discussed subsequently. In addition, six states have parental involvement statutes (involving minors seeking abortion) that have been enjoined by the courts, and five other states have no policy or case law on the subject.[19] These laws also raise complex confidentiality-notification issues, as we discuss.

Most often the consent questions arise in the context of whether a minor may consent to treatment without the

Table 30.1 The general principles of informed consent.

Element of informed consent	Nature of the obligation
Nature of the proposed "procedure" (may include other intervention)	The practitioner provides an overview of the procedure that is proposed in ways the patient (or the patient's surrogate) can understand. This may include a procedure or an intervention such as pharmaceuticals.
Risks and benefits	The significant risks are generally measured by a combination of the probability of an event happening and how serious the consequences would be (loss of the use of a limb versus a rash, for example). This element is usually the most likely to cause difficulties and deserves careful attention.
Alternatives	The viable alternatives to the proposed treatment should be discussed with the patient.
Consequences of doing nothing	Where rejection of a proposed procedure (or an alternative) carries a risk of harm, that risk should be explained.

Table 30.2 Permutations of consent/involvement.

	Consents	Refuses consent	Not involved/ does not decide
AA	AA agrees	AA refuses	AA cannot or will not decide
Mother	AA and mother agree	AA and mother refuse	AA and mother cannot or will decide
Father	AA, mother, and father agree	AA, mother, and father refuse	AA, mother, and father cannot or will not decide

additional consent of her parents.[27] In some cases, it is even more complicated. For example, may treatment be provided over the minor's objection?[78] The complexity that can occur with consent to the treatment of adolescents is illustrated in the example of Patient AA, a 16-year-old, who is brought to the office by her mother for a complaint that ordinarily would call for a gynecologic examination. In the examining room, AA tells the nurse she does not want the exam, essentially refusing the examination to which her mother has given consent. There are several permutations of consent/involvement that can occur, as illustrated in Table 30.2.

To make this case even more complex, the parents of AA could disagree about the desirability of her receiving the examination.

In this case where the father is not involved, at least three legal issues face the health-care provider: (1) whether AA can withdraw the consent that her mother gave, (2) whether the provider can or must tell the mother about this, and (3) whether the provider physician has additional "informed consent" obligations. In light of AA's age, absent a meaningful medical issue requiring the examination, it is likely that she can refuse this examination, but her mother should be informed of the refusal. Furthermore, the provider will have the additional obligation of informed consent to tell AA of the health risks of refusing the examination. If, for example, an STI is a possibility, AA must be informed of the risks of not being tested or leaving the disease untreated.[22]

It is also important to note that although consent is a legal requirement, it also presents excellent opportunities for communication with patients and their parents. For example, the provider may want to consider why AA does not want the examination and what medical importance that may have. Furthermore, it is an opportunity to discuss the continuing importance of such examinations.

REPORTING ABUSE AND NEGLECT

All states require that physicians report child abuse or neglect. The statutes vary somewhat from state to state, but they usually have broad definitions of reportable events. Often "known" or "suspected" abuse or neglect must be reported. Abuse includes physical, sexual, or emotional abuse.[28] Sexual abuse usually includes sexual assault or molestation, sexual exploitation, and human trafficking or prostitution.[29]

Child abuse reporting statutes are mandatory. Failure to report known or suspected abuse, neglect, or sexual exploitation is a criminal offense in most states and may also give rise to civil liability. States generally provide immunity, however, against liability for those who in good faith report cases of suspected child abuse.[30]

Difficult questions of reporting arise when a patient seeks medical attention but has probably been abused. Consider a 12-year-old patient who is pregnant. Almost by definition, she has been the subject of statutory rape (sexual contact with someone under the age of legally recognized consent).[31] Theoretically, this might trigger the reporting requirement, but a provider (or the provider's attorney) can determine the necessity of reporting only by carefully examining the state statutes and related regulations and court decisions.[32]

Every health-care organization and practitioner should have in place a routine system for reporting known or suspected abuse.

LAWS REGARDING DISCLOSURE AND CONFIDENTIALITY

Patient confidentiality is among the most important and enduring values of medicine.[33] Maintaining confidentiality is an ordinary part of the physician–patient relationship. The law provides substantial protection of that value through physician licensing, potential malpractice liability, state and federal regulations, the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act.[34] Chapter 27 explains these concepts in detail, so here we only highlight select legal issues.

Special problems regarding disclosure to parents are common in treating minors and are worth emphasizing.[79] As a general rule of thumb, absent a statute requiring disclosure, if a minor can legally consent to a medical procedure or may receive it without the consent of parents, parents usually do not have the right to have the minor's health information. (Like all rules of thumb, this one is generally, but not universally, true.) In addition, if the parent has agreed to confidentiality between the doctor and child, the parent has probably given up the right to access the information.[35] Both HIV testing and the more recent human papillomavirus vaccination have demonstrated the risks of breaches of confidentiality to important medical treatment for minors.[36]

The terms "disclosure" or "provide information" to parents may have several meanings. The first question is whether disclosure is "permissive" or "mandated." A permissive statute makes it clear that in some circumstances (e.g., "in the best interest of the minor"),[37] the health-care provider *may*, but is not required to, provide the information to the parents or others. If it is "mandated," then the provider must provide the information to the parents, absent a specific exception in the statute or one created by regulation or the courts.

A second basic disclosure question is whether it is "reactive" or "proactive." Reactive means that should the parents contact the physician and request information, it must be

provided. Proactive means that the physician must reach out to the parent(s) with the information. Proactive is required, for example, where the rule says that "as part of providing this service, the parents must be notified." Some states, as we see, have such a requirement for abortion services.

Having an understanding of the disclosure laws regarding the services provided is essential for any provider. Several principles can help in the everyday application of the laws:

- It is important that minor patients (and to the extent possible, their families) have a clear understanding of, and reasonable expectations concerning, the protection of confidentiality during the course of treatment.[38] The minor patient especially should know ahead of time how confidential her medical information will be. Where it is practical, families should have a sense of the physician's intention. For example, compare, "In my medical practice I have found that the confidentiality of patients is important to successful treatment, so my policy has been to avoid disclosing patient information, except where required by the ethical principles, the law, or good medical practice," with, "In my practice, I feel that the family is an integral part of all treatment, so I generally share with the family all of the information about treatment, except where prohibited by the law or extraordinary circumstances." Those create very different expectations.[39]
- Where the treatment involves issues of sexuality or substance abuse, an understanding of the limits of confidentiality is especially important.
- The initial presumption should be against disclosure without careful thought. It is possible to disclose information later but impossible to "undisclose" things.
- It is important to find out who really has the right to information. Minors seeking treatment may come from single-parent homes in which one parent may not have custody rights. In such cases, that parent probably does not have a right to the medical information about his or her child, and it may be a violation of the law to provide the information.[13]
- The possibility of parental abuse warrants caution in some cases. If the disclosure would harm the child, it is almost never required. But if abuse is found or suspected, it probably has to be reported to a state agency.
- Electronic health records pose additional problems of maintaining confidentiality—a topic covered extensively in Chapter 27.[40]
- The disclosure of a minor's information to parents, or to a state abuse reporting agency, is not a waiver of confidentiality. It is a limited disclosure only. The minor, and her family, retains an interest in the privacy of the information, and the physician has the obligation to continue to protect the general confidentiality of the patient's information.

SPECIAL LEGAL ISSUES IN OBSTETRICS AND GYNECOLOGY CARE FOR MINORS

Sexually transmitted infections

Patient BB (age 15) arrives in your office seeking treatment for an STI and asking for assurance of complete confidentiality. All states permit physicians to provide treatment for the STI and to give related advice with the minor's consent (not the parents'). Eighteen states allow, *but do not require*, a physician to provide parental notification if such notification is in the best interest of the minor. Physicians must remember, however, that *informed* consent is still required and must include reasonable information about the benefits and risks of the proposed treatment and about alternatives.[41]

Confidentiality cannot be absolute, however. States require physicians to make a report to the state about the diagnosis of STIs by informing the department of health of basic information about the disease. The reports generally are mandatory. In addition, questions regarding reimbursement for the treatment (including pharmaceuticals) will likely require the release of pertinent information. This may be a special concern where a claim is made through the parents' insurance.

Contraception

During the office visit, BB also asks for contraceptives—again asking for confidentiality. Whether you can provide for contraceptives, and do so without any parental notification, depends on the state.[42,43] A few states limit the right of minors to consent to contraceptive services (e.g., to those married, or previously pregnant).[44] In addition to state law, there is a constitutional right of adolescents involved. In *Carey v. Population Services*, the U.S. Supreme Court held that the right of privacy includes the right of minors to have access to some contraceptives.[45] It struck down a New York statute that limited access by minors younger than 16, holding that a state cannot completely prohibit the use or availability of nonprescription contraceptives to minors. Thus, even in states without a specific statute allowing minors to consent to contraceptive services, there is some constitutional protection for obtaining the services.

Sterilization

Unlike contraception, permanent sterilization of competent minors is disfavored, and ordinarily a minor (or even her parents) would not be able to consent to it without a strong health justification. Sterilization is sometimes sought because minors with a serious intellectual disability are unable to understand their own sexuality and the consequences of sexual contacts. They would be unable to care for any children they might bear.[46] There is, of course, a very sad history of the use of eugenic sterilization in the United States. For good reason, therefore, courts currently permit sterilization only in very limited cases after a process to determine that such a step is justified. Courts are reluctant to remove the fundamental right to procreation and are concerned about the potential for abuse.

Pregnancy

Most states expressly allow minors to consent to prenatal care, and almost all, by implication, probably allow such consent.[47] In a few states, parents of the soon-to-be mother may be notified, but that is generally not required.[48]

Abortion

It probably comes as no surprise that abortion is a legal and political tempest.[49] As we noted earlier, two states and DC allow minors to consent to abortion. Among the 37 states that require parental involvement, 26 require parental consent, and the other 11 require parental notification.[50] It is clear that state statutes are not the end of the story.

The Supreme Court has required that states recognize the right of minors to have some access to abortion services.[51] In *Planned Parenthood v. Danforth*, the Supreme Court held that the right of privacy to decide to have an abortion extends to minors. A state, therefore, does not have the constitutional authority to delegate to parents the decision of a "competent and mature minor" to have an abortion.[52] The Court held unconstitutional an ordinance that provided that all minors younger than 15 years old were too immature to make abortion decisions,[53] but in *Planned Parenthood Association of Kansas City v. Ashcroft*, the Court upheld a state statute requiring all minors to obtain either parental or judicial consent for an abortion.[54] In a judicial bypass process, a minor goes to state court to seek permission (without parental consent) to have an abortion.[55] These courts are *required* to give consent to the abortion if the minor is mature enough to make the decision or if the abortion is in her best interest.

The judicial bypass exception is so complicated that it is unlikely that most minors would be able to negotiate it by themselves. In some areas of the country, there are organizations that will assist adolescents with the bypass procedures, and minor patients may know of these from their friends. Physicians treating minors who may need or want to have an abortion, however, should determine whether a parental consent or notification statute exists and whether they are permitted to assist the minor in completing the bypass.[56] Several studies suggest that courts overwhelmingly approve abortions when application is made through the bypass process, but the adolescent patient is likely to need assistance in going through the court process.[57,58]

In terms of informed consent, the Supreme Court has upheld state laws that require graphic informed consent.[59] This includes information about the development of the fetus. A number of states have adopted such laws.[60]

The Court has held that states may regulate aspects of abortion but may not do so in a way that "unduly burdens" the right to have an abortion. Applying this principle, in 2016 the Court struck down Texas laws requiring medical facilities and arrangements that did not in fact meaningfully contribute to the safety of abortions.[61]

Most states require parental notification, and about half the states require parental consent (in both cases subject to a judicial bypass).[50] In *Ohio v. Center for Reproductive Health*[62] and *Hodgson v. Minnesota*,[63] the Court held that a state may constitutionally require the notification of one or even both parents when a minor seeks an abortion as long as the state also provides for a "judicial bypass." In jurisdictions requiring parental notification for certain types of obstetric and gynecologic care, the practitioner should inform minors at the beginning of treatment of this reporting requirement. This is another area where significant changes may occur in the future, so particularly careful monitoring of changes in federal, state, and local law is important.

Abortion is fraught with political, religious, and social concerns that play out in the laws. The statutes change frequently, and in some states there are ongoing cat and mouse struggles between state lawmakers and federal courts. This all makes for a very difficult legal landscape for practitioners (Table 30.3).

RESEARCH INVOLVING CHILDREN

Special legal and ethical issues arise when children are engaged in research studies. This section briefly reviews a few issues, primarily federal regulations. In addition, a number of states have laws directly or indirectly regulating research involving children. At the end of this section, we note some legal issues involving "near research." "Children" is used in this section (rather than "minors"), because that is the term used in the federal regulations. The definition of children essentially looks to the state law of consent. That is, a child in the federal regulations is someone who is not of legal age to consent to the procedures involved in the research.[65]

Federal law defines research broadly—as "a systematic investigation…designed to develop or contribute to generalizable knowledge."[66] Almost any research funded by the federal government is subject to regulation under the "Common Rule" regarding human subjects, established by the Department of Health and Human Services (HHS).[67] In addition, many foundations, other sponsors, publishers, and institutions (universities and teaching hospitals) require that research comply with the same rules. The U.S. Food and Drug Administration has similar rules regarding research related to pharmaceuticals and devices.[68] The Common Rule was under review for several years. In January 2019, revisions to the rule (known as the "Common Rule 2018") became effective.[80] In addition to the regulations regarding the use of children as research subjects (discussed next), the Common Rule has specific regulations regarding the use of pregnant women, human fetuses, and neonates in research.[81]

Any practitioner who is involved in a research project should contact the sponsor, principal investigators, and institutions in which the research will be done to determine that the research has been approved by the Institutional Review Board (IRB), what the obligations of the practitioner will be in protecting the child and her parents, the rules regarding obtaining consent and assent, and the procedures involved in reporting adverse events. There may be potential professional and legal problems in undertaking unapproved research. Seeking "forgiveness rather than permission" is not a good strategy when using children in research. The institution's IRB staff can be invaluable in advising researchers and answering questions. Because children are a vulnerable population, their participation in research can be especially complex.[69]

Table 30.3 Summary of the legal principles.

Legal principle	Explanation
The law varies from state to state and may change quickly.	The result is that definitive and permanent answers about treating pediatric and adolescent patients (minors) are usually not possible.
Diagnosis and treatment can be undertaken only with consent.	For minors, parents ordinarily have the legal authority to give consent to treatment. Where minors have the right to consent themselves, the rules of *informed* consent still apply.
"Informed consent" requires that the patient or decision-maker be given sufficient information on which to base a sensible decision.	This generally includes a description of the treatment or procedure proposed, its costs and benefits, alternatives, and the consequences of refusing treatment. The informed consent process is an excellent opportunity for communication with patients.
There are exceptions to parental consent rules for some minors or for some kinds of health care.	"Emancipated minors" may generally make decisions for themselves.[64] "Mature minors" in most states may make certain basic decisions for treatment related to pregnancy, contraception (not including sterilization), sexually transmitted diseases, and the like.
Where there is disagreement between a minor patient and parents regarding care, or between parents of a minor patient, the law in practice often becomes murky.	Where the life or health of a minor is at stake, the bias should be toward providing emergency or necessary treatment. A health-care provider should be prepared for these disagreements by establishing (generally with the assistance of an attorney) good practices for dealing with the problem when it arises.
Physicians have a general obligation to protect patient confidentiality.	Parents generally, but not always, have a right to information about their minor children. State and federal laws, including the Health Insurance Portability and Accountability Act, are further limiting the release of confidential medical information. Where there is doubt about the propriety of releasing information to parents, it is generally better to be conservative under the theory that it is difficult to retract information improperly released.
Many states have laws permitting providers to withhold some kinds of sensitive information from parents.	This information generally includes information about sexually transmitted infections, contraception, and pregnancy. These rules vary from state to state, however.
Laws regarding consent to abortions and parental notification are complex.	It is common for states to require parental consent or a "judicial bypass" for a minor to obtain an abortion. Parental notification laws (regarding abortion) are common, but there may well be judicially described exceptions to these laws.
All states require the reporting of child abuse.	There can be legal consequences for failure to report, including civil liability and even criminal liability. In addition, there may be licensing consequences. Such liability is uncommon but possible. It is essential to know what the reporting requirements are and to have a system to ensure that reports are actually made.

Table 30.4 is an overview of the mix of risks, direct benefits to the child, importance to generalized knowledge, and permission–assent that are contained in the federal regulations regarding children.

In addition, in each of these categories, the research must provide for the following:

1. Permission of the parent or guardian for the child to participate.
2. "Assent" of the child (meaning that if capable, the child must express a willingness to participate).[74]

Valuable additional guidance regarding adolescents in research and when parental permission may be waived is available from the American College of Obstetricians and Gynecologists.[75]

In addition to the regulation of formal research, "near research" (new techniques and approaches that are innovative but not in standard or common use) also may raise legal issues. If these do not involve pharmaceuticals or devices, they are often not regulated. They may be used but require caution and generally a special informed consent that calls attention to the option of standard (versus the innovative, nonstandard) care.[76]

PRACTICAL ADVICE

By way of conclusion, there are several practical tips that those treating pediatric and adolescent patients should consider to avoid unnecessary problems and complications:

- Establish an ongoing relationship with an attorney you trust. Ask the attorney to help you understand the legal requirements in your state, and seek help establishing procedures and practices that will help you comply with legal requirements. Do not hesitate to contact the attorney as questions or problems arise in practice.
- Have annual "checkups." (You should take the advice you give patients.) Your attorney should help you do

Table 30.4 Federal regulations associated with research in children.

Risk	Direct benefits to the child	Review required	Other considerations
1. Minimal risk[70]	None required	May be approved by the Institutional Review Board (IRB)	
2. Minor increase in risk over "minimal risk"; intervention is similar to those inherent in everyday medical situations[71]	None required, but likely to yield generalizable knowledge about the child's disorder that is vital to understanding the condition generally	May be approved by the IRB	Risk is justified by benefits to the subjects, and the risk–benefit ratio is at least as favorable as alternative approaches
3. Greater than minimal risk[72]	Direct benefit to the child must exist	May be approved by the IRB	Likely to yield "generalizable knowledge" about the child's condition, which is vitally important
4. Greater than minimal risk[73]	No direct benefit to the child	Must first be approved by the IRB and then submitted to the Department of Health and Human Services (HHS) for additional review	Reasonable opportunity to understand "serious problem" affecting children; research will be conducted with sound ethical principles

an annual review of your practice to make adjustments that respond to changes in the law.

- Understand the elements of informed consent in your state and who may give consent to what procedures involving minors.
- Understand the limits and obligations of confidentiality. Have a plan regarding disclosure to parents that meets the legal requirements and is consistent with HIPAA.
- Discuss confidentiality issues with patients, especially adolescent patients. They should generally understand the limits of confidentiality. Consider making agreements with parents regarding confidentiality, so that they agree in appropriate cases that you will not disclose information to them (parents can agree to give up the right to information).
- Take *informed* consent seriously. Use it as a way of communicating important information with patients and parents.
- If you are involved with abortions or sterilizations, be very clear on the legal requirements of your state.
- Have a system in place to report abuse and neglect.
- Maintain good records. Keep them honestly and accurately.

It is ultimately important to remember that the law is not a series of random rules. Rather, with all of its faults, it is an effort by society to implement the most important values and goals of society. Inevitably, there are conflicting values and compromises that produce changing and imperfect rules. Physicians, in cooperation with attorneys when needed, can work sensibly through these rules. The two professions, when they work together over time, can also improve the law to make it a better vehicle for achieving important values.

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