

# Informed Consent

## Latest Revision

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### Abstract

*Informed consent, essential in the delivery of health care, is the process by which a health care practitioner provides relevant information about diagnosis and treatment needs to a patient so he can make a voluntary and educated decision to pursue or refuse care. For minors and adults with intellectual disabilities, parents (as defined within this document) are authorized to provide or decline permission for treatment. Dentists must inform patients/parents about oral health conditions observed and the nature, risks, and benefits of recommended and alternative treatments, including no treatment. While young children do not possess the cognitive ability to participate in the informed consent discussion, older children and adolescents can participate and assent to care.*

*Dental providers are encouraged to familiarize themselves with the applicable laws and regulations in their state with respect to informed consent in health care. Although laws may differ, obtaining consent in writing before commencing treatment is recommended as it may reduce liability due to any miscommunication. Guidance regarding written consent forms is included. However, a conversation between the dental provider and patient/parent, not just completing a form, is the key component of obtaining informed consent.*

*This document was developed through a collaborative effort of the American Academy of Pediatric Dentistry Councils on Clinical Affairs and Scientific Affairs to offer updated information and guidance in obtaining informed consent for pediatric oral health care.*

**KEYWORDS:** INFORMED CONSENT; CONSENT FORMS, INFORMED CONSENT FORMS; INFORMED CONSENT BY MINORS; DOCUMENT, INFORMED CONSENT

### Purpose

The American Academy of Pediatric Dentistry (AAPD) recognizes that informed consent is essential in the delivery of health care. The informed consent process allows the patient or, in the case of minors, the parent\* to participate in and retain autonomy over the health care received. Informed consent also may decrease the practitioner's liability from claims associated with miscommunication. Informed consent is governed by the statutes and case laws of individual states; oral health care providers should review the applicable laws and regulations of their state.

### Methods

Recommendations on informed consent were originally developed by the Council on Clinical Affairs and adopted in 2005.<sup>1</sup> This document is a revision of the previous version, last revised in 2015.<sup>2</sup> This revision included a literature search of the PubMed®/MEDLINE database using the terms: informed consent, pediatric consent, pediatric informed consent, consent, informed refusal, cultural background informed consent, linguistic background informed consent, and interpreters informed consent; fields: all; limits: within the last 10 years, humans, English, review of legal cases. One hundred forty-two articles matched these criteria. Papers for review were chosen from this list and from references within selected articles. When data did not appear sufficient or were inconclusive,

recommendations were based upon expert and/or consensus opinion by experienced researchers and legal practitioners.

### Background

Informed consent is the process by which a health care provider gives relevant information concerning diagnosis and treatment needs to a patient so that the patient can make a voluntary, educated decision to accept or refuse treatment. Minor children are legally unable to give informed consent, and intellectually disabled adults lack capacity to give consent. Parents are authorized to grant or decline permission for treatment, with assent or agreement from the child or incompetent adult whenever possible.<sup>3-6</sup> All requirements of informed consent apply when the parent is acting on behalf of the child.<sup>3,4</sup>

Informed consent involves both ethical and legal obligations of the health care provider to the patient. The American Dental Association (ADA) states that dentists are “required to provide information to patients/parents about the dental health problems the dentist observes, the nature of any proposed treatment, the potential benefits and risks associated with that treatment, any alternatives to the treatment proposed, and the potential

#### ABBREVIATIONS

**AAPD:** American Academy Pediatric Dentistry. **ADA:** American Dental Association.

\* In all AAPD oral health care policies and clinical recommendations, the term “parent” has a broad meaning encompassing a natural/biological or adoptive father or mother of a child with full parental legal rights, a person recognized by state statute to have full parental legal rights, a parent who in the case of divorce has been awarded legal custody of a child, a person appointed by a court to be the legal guardian of a minor child, or a foster parent (a noncustodial parent caring for a child without parental support or protection who was placed by local welfare services or a court order). American Academy of Pediatric Dentistry. Introduction. *Pediatr Dent* 2018;40(6):5-7.

risks and benefits of alternative treatments, including no treatment.”<sup>7</sup> Following the informed consent discussion, an assessment of patient/parental understanding should be made, and any confusion about the treatment should be clarified by the provider before consent is granted.<sup>5,8</sup>

Autonomy over healthcare decisions is a patient’s right. A 1914 New York state court ruled that “every human being of adult years and sound mind has a right to determine what shall be done with his own body....”<sup>9</sup> Additionally, ruling from the Supreme Court of North Dakota found that laws pertaining to a physician’s duty to obtain informed consent also pertained to dentists.<sup>10</sup> As court rulings and laws differ in each state, it is difficult to develop an inclusive recommendation.

The law generally has several criteria for selecting information to provide to a patient/parent as part of an informed consent. Some states follow a patient-oriented standard—that information which a reasonably prudent patient/parent in same or similar circumstances would wish to know.<sup>11-13</sup> Other states follow a practitioner-oriented standard—that information which a health care provider, practicing within the standard of care, would reasonably provide to a patient/parent in the same circumstances.<sup>12-14</sup> A hybrid approach, combining the patient-oriented and practitioner-oriented standards, is followed by some states.<sup>13,14</sup> Finally, a subjective person standard requires the practitioner to give information that the particular patient in question would want to know.<sup>5,11</sup>

Regardless of the standard a state has chosen to follow, the treating practitioner must disclose information that he considers material to the patient’s/parent’s decision-making process and provide a warning of death or serious bodily injury where that is a known risk of the procedure.<sup>13,15</sup> The informed consent process generally excludes adverse consequences associated with a simple procedure if the risk of occurrence is considered remote and when such circumstances commonly are understood by the profession to be so.

The ADA Code of Ethics recommends that dentists provide information “in a manner that allows the patient to become involved in treatment decisions.”<sup>16</sup> Pediatric dental health care providers have the opportunity to guide and support the child patient to become involved in his own health care. Young children lack the cognitive ability to participate in the informed consent discussion, but older children and adolescents who have gained experience as dental patients may be included. Information should be provided to the patient in an age-appropriate manner, and practitioners should seek assent (agreement) from the patient whenever possible.<sup>17,18</sup> Although the child can be involved, the parent is the individual giving consent, and the parent is the individual who decides to accept or refuse treatment. The practitioner should be aware that the adult accompanying the pediatric patient may not be a legal guardian allowed by law to consent to medical procedures. Examples of such an adult include a grandparent, stepparent, noncustodial parent in instances of divorce, babysitter, or friend of the family. A child in foster care or a ward of the state may be accompanied by a caretaker who may or may not be

allowed to consent to medical procedures, according to individual state law. It is advisable that the oral health care provider obtain a copy of court orders appointing a guardian to verify who is authorized to consent for medical treatment for the patient.<sup>18</sup> One option to consider is obtaining a parent’s authorization via a consent by proxy or power of attorney agreement for any other individual to make dental treatment decisions for a child.<sup>13,18</sup> In situations where individuals other than the parent regularly bring the child to the dental office, this can help eliminate doubt as to whether such individual has the legal authority to provide informed consent. Practitioners, however, should consult their own attorney in deciding whether to utilize such a form in their own practice. Another option for obtaining authorization for treatment is a telephone conversation with the parent.<sup>18,19</sup> The parent should be told there are two people on the telephone and asked to verify the patient’s name, date of birth, and address and to confirm he/she has responsibility for the patient.<sup>19</sup> The parent is presented with all elements of a valid informed consent followed by documentation in the patient’s chart with signatures.<sup>18,19</sup>

Written consent is required by most states before treatment of a patient.<sup>13</sup> Even if not mandated by state law, written consent is advisable as it may decrease the liability from miscommunication.<sup>19</sup> A patient’s or parent’s signing a consent form should not preclude a thorough discussion. Studies have shown that even when seemingly adequate information has been presented to patients/parents, their ability to fully understand the information may be limited.<sup>8,11</sup> Dentists should be aware of the cultural and linguistic backgrounds of their patients and families and take care to ensure that information is available in culturally and linguistically competent formats to help parents in the decision-making process.<sup>20</sup> Also, to assure a person who is deaf or hearing impaired can consent, a dentist carefully should consider the patient’s self-assessed communication needs before any treatment. Practitioners may need to provide access to translation services (e.g., in person, by telephone, by subscription to a language line) and sign language services.<sup>3,20</sup> Practitioners who receive federal funding, as well as those in a significant number of states, are mandated to provide these services at no cost to the patient.<sup>3,20</sup> Supplements such as informational booklets, videos, or models may be helpful to the patient in understanding a proposed procedure. The oral discussion between provider and patient, not the completion of a form, is the important issue of informed consent. The consent form should document the oral discussion of the proposed therapy, including risks, benefits, and possible alternative therapy, as well as no treatment.<sup>4,17,20</sup>

Informed refusal occurs when the patient/parent refuses the proposed and alternative treatments.<sup>7,19</sup> The dentist must inform the patient/parent about the consequences of not accepting the proposed treatment. It is recommended by the ADA that informed refusal be documented in the chart and that the practitioner should attempt to obtain an informed refusal signed by the parent for retention in the patient record. An informed refusal, however, does not release the dentist from

the responsibility of providing a standard of care.<sup>7</sup> If the dentist believes the informed refusal violates proper standards of care, he/she should recommend the patient seek another opinion<sup>7</sup> and/or dismiss the patient from the practice. If the dentist suspects dental neglect, appropriate authorities should be informed.<sup>21</sup>

When a consent form is utilized, it is best to use simple words and phrases. A modified or customized form is preferred over a standard form and should be written so that it is readily understandable to a lay person.<sup>4,7,19,20</sup> Overly broad statements such as “any and all treatment deemed necessary...” or “all treatment which the doctor in his/her best medical judgment deems necessary, including but not limited to...” should be avoided. Courts have determined it to be so broad and unspecific that it does not satisfy the duty of informed consent. Informed consent discussion, when possible, should occur on a day separate from the treatment, and the practitioner should avoid downplaying the risks involved with the proposed therapy.<sup>8</sup> Items that should appear on a consent form are listed under Recommendations.

Informed consent and informed refusal forms<sup>22</sup> should be procedure specific, with multiple forms likely to be used. For example, risks associated with restorative procedures will differ from those associated with an extraction. Separate forms, or separate areas outlining each procedure on the same form, would be necessary to accurately advise the patient regarding each procedure.<sup>7</sup> Consent for sedation, general anesthesia, or behavior guidance techniques such as protective stabilization (i.e., immobilization) should be obtained separately from consent for other procedures.<sup>6,23</sup> Consent may need to be updated or changed accordingly as changes in treatment plans occur. When a primary tooth originally planned for pulp therapy is determined to be nonrestorable at the time of treatment, consent will need to be updated to reflect the change in treatment. Depending on state laws, this update may be in oral or written form. Dentists should consult their own attorney and state dental association as informed consent laws vary by state.<sup>7</sup>

### Recommendations

Informed consent is the process of providing the patient with relevant information regarding diagnosis and treatment needs so that an educated decision regarding treatment can be made by the patient. In the case of a minor or intellectually disabled adult, the parent gives informed permission with assent or agreement from the patient whenever possible. The oral discussion between provider and patient or parent, not the completion of a form, is the important issue of informed consent. A written consent form serves as documentation of the consent process and is required by most states. Other states allow the oral discussion to be documented in the patient record. Dentists should be aware of the cultural and linguistic backgrounds of their patients and families and take care to ensure that information is available in culturally- and linguistically-competent formats to help patients and parents in the decision-making process.

Statutes and case law of individual states govern informed consent. Oral health practitioners should review applicable state laws to determine their level of compliance. Consent forms should be procedure specific, utilize simple terms, and avoid overly broad statements. When a practitioner utilizes an informed consent form, the following should be included:

1. legal name and date of birth of pediatric patient.
2. legal name and relationship to the pediatric patient/legal basis on which the person is granting permission on behalf of the patient.
3. patient’s diagnosis.
4. nature and purpose of the proposed treatment in simple terms.
5. potential benefits and risks associated with that treatment.
6. professionally-recognized or evidence-based alternative treatment – including no treatment – to recommended therapy and risk(s).
7. place for parent to indicate that all questions have been asked and adequately answered.
8. places for signatures of the parent, dentist, and an office staff member as a witness.

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