GENERAL DISCUSSION OF LEGAL ISSUES AFFECTING SEXUAL ASSIGNMENT OF INTERSEX INFANTS BORN WITH AMBIGIOUS GENITALIA

Glenn M. Burton, Esquire
Florida Board Certified Trial Attorney
Burton, Schulte, Weekley, Hoeler, Robbins & Beytin, P.A.
Post Office Box 1772
Tampa, Florida 33601-1772
GBURTON@LAW-BURTON.COM
Telephone: (813) 221-0955
Facsimile: (813) 490-0182

INTRODUCTION

The foregoing is a general discussion of various laws that may impact physicians and their patients in their determination of whether and when to assign a sex to an individual born with sexual ambiguity. The ambiguity may arise based upon chromosomal abnormalities or genital abnormalities. This article is aimed to assist the healthcare practitioner in identifying legal issues in hopes of improved patient care and avoiding liability. It is not the intent of this author to ”choose sides” on the debate, but rather to illustrate legal practices and thinking. There are several assumptions that have been made in the production of this material. This author assumes that between one and two percent of all children born today may be intersexual. That term implies either abnormal chromosomes or genitalia sufficient to create a genital ambiguity. It is furthermore assumed that these abnormalities are recognized either at birth or during the early childhood of the individual. It is assumed that the child has either parents or another legal surrogate whom are in agreement as to whatever course of action is decided by them to pursue. They have sought medical advice, first from the child's pediatrician and then probably thereafter, a pediatric urologist or general pediatric surgeon. This article does not address the actual surgical issues and it is presumed that the surgeon possesses the requisite skill and expertise to properly perform any surgery required. Rather, this article focuses on the issues of consent, whom makes the decision as to the type of surgery and when it is going to be performed, and adherence to the applicable standard of care for the healthcare individual.

INFORMED CONSENT ISSUES FOR INTERSEX CHILDREN

I. Who Decides? Determining the Decision-Maker

A. The Parents

Under Florida law, unless there is a judicial decree to the contrary, the decision-maker for a minor's health care decisions are the minor's natural parents. A "minor" is defined by Florida Statute as "any person who has not attained the age of 18 years." § 1.01(13), Fla. Stat. (2001). A natural parent has the right to the custody of his or her child absent conduct or conditions that justify a deprivation of the right in the interest of the welfare of the child and such a legal right should not be lightly regarded. Torres v. Van Eepoel, 98 So.2d 735 (Fla. 1958). The right to consent to medical treatment will typically reside in the parents who have the legal responsibility to maintain and support their child. O'Keefe v. Orea, 731 So.2d 680 (Fla. 1st DCA 1998). Although the parents' right to determine their child's health care decisions is not absolute and there is some judicial authority to override the parents' authority, the courts have repeatedly held that it is the parents and their medical advisors that generally must make these decisions. In re Guardianship of Barry, 445 So.2d 365 (Fla. 2d DCA 1984). The love and affection of another person, no matter how great, is insufficient to deprive a fit and proper parent of the decision-making authority over his or her child. Modacsi v. Taylor, 104 So.2d 664 (Fla. 1st DCA 1958). In situations where there has been an adoption or a dissolution of marriage, the judicial decree will typically assign the decision-making authority to the adoptive parents or custodial parent. See generally Ch. 61, 63, Fla. Stat. (2001).

B. Non-Parent Decision-Makers and the Doctrine of *Parens Patriae*

As noted above, the parents' right to make the health care decisions for their child is not an absolute right. Under very rare circumstances, the parents' right can be

overridden by a state court circuit judge. In these rare instances, the courts rely upon the doctrine of *parens patriae* or "substituted judgment" to justify judicial intervention. Occasionally, the courts find that their intervention is necessary on the basis that the parents have "abandoned" their child. This nomenclature is archaic and has given way to the more modern finding that the parents' decision, oftentimes based upon religious beliefs, is outweighed by the state's public policy of preserving life or the overriding concern for the ultimate welfare or best interest of the child. See C.E.S. v. State, Dept. of Health and Rehabilitative Services, 462 So.2d 1160 (Fla. 2d DCA 1984). Medical care may also be furnished in the absence of parental consent if the parents have refused to give permission because of religious beliefs. J.V. v. State, 516 So.2d 1133 (Fla. 1st DCA 1987); see also M.N. v. Southern Baptist Hospital of Florida, Inc., 648 So.2d 769 (Fla. 1st DCA 1994); In re Barry, 445 So.2d 365 (Fla. 2d DCA 1984).

In M.N., the parents challenged an "order by which medical treatment was authorized for their eight-month old child B.N., without their consent." M.N., 648 So.2d at 770. The child was admitted by the parents at the hospital, where she was diagnosed with acute monocytic leukemia, severe anemia and a low platelet count. Chemotherapy was then recommended as the most appropriate treatment for the child's life-threatening condition, which necessitated blood transfusions. The parents refused to consent to this procedure based on their religious beliefs. M.N., 648 So.2d at 770. The hospital filed an emergency petition requesting an order as to whether chemotherapy and blood transfusions might be administered to the child without parental consent. In addition to their religious objections, the parents expressed concern that the proposed medical treatment would cause undue suffering to their child. After an evidentiary hearing, the trial judge entered an order authorizing the

proposed medical treatment. M.N., 648 So.2d at 770. The parents then appealed the order to the First District Court of Appeal.

The First District then stated the law to be applied setting out the obligations of the trial court in applying the law.

> Ordinarily, decisions regarding the care and upbringing of minor children will be left to the parents. This parent-child relationship is a fundamental liberty interest which is constitutionally protected. Padgett v. Department of Health and Rehabil-itative Services, 577 So.2d 565 (Fla.1991); In Re R.W., 495 So.2d 133 (Fla.1986); see In Re Dubreuil, 629 So.2d 819, 827 n. 11 (Fla.1993). But the parents' rights are not absolute, as the state has parens patriae authority to ensure that children receive reasonable medical treatment which is necessary for the preservation of life. J.V. v. State, 516 So.2d 1133 (Fla. 1st DCA 1987). And as between parent and child, the ultimate welfare of the child is the controlling factor. State v. Reeves, 97 So.2d 18 (Fla.1957). Indeed, the policy of advancing the best interests of the child is well rooted in this state and guides the courts in many diverse contexts. See, e.g., Department of Health and Rehabilitative Services v. Privette, 617 So.2d 305 (Fla. 1993); Padgett; Dinkel v. Dinkel, 322 So.2d 22 (Fla.1975).
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> The state may override the fundamental liberty interest in the parent-child relationship only when there is a sufficiently compelling state interest. In Re Guardianship of Browning, 568 So.2d 4 (Fla.1990); Dubreuil. Furthermore, the state's action must be narrowly tailored so as to produce the least intrusive interference with individual rights, although the preservation of life has been described as the most significant state interest. Browning. As with the parent-child relationship, the state's *parens patriae* authority is thus not entirely unfettered. Rather, the state's interest diminishes as the severity of an affliction and the likelihood of death increase:
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> > [T]here is a substantial distinction in the State's insistence that human life be saved where the affliction is curable, as opposed to the State interest where ... the issue is not whether, but when, for how long and at what cost to the individual ... life may be briefly extended.
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> Satz v. Perlmutter, 362 So.2d 160 (Fla. 4th DCA 1978), approved, 379 So.2d 359 (Fla.1980) (quoting Superintendent of Belchertown v. Saikewicz, 373 Mass. 728, 370 N.E.2d 417 (1977)); see also Browning; John F. Kennedy Hospital v. Blud-worth, 452 So.2d 921 (Fla.1984); In Re Guardianship of Barry, 445 So.2d 365 (Fla. 2d DCA 1984).
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> The constitutional right of privacy may afford an individual suffering

> from a terminal illness the right to refuse medical treatment. Satz v. Perlmutter, 379 So.2d 359 (Fla.1980); see also Public Health Trust v. Wons, 541 So.2d 96 (Fla.1989). This right has been extended to incompetent persons and to infants. John F. Kennedy Hosp.; Barry. As Barry indicates, courts sometimes rely on the doctrine of substituted judgment in effectuating the privacy right of incompetent patients. Under this doctrine the court attempts to ascertain the choice which would have been made by the patient, if competent. However, Barry recognizes the inherent difficulty in applying this concept to young children.
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> There is no brightline rule or presumption that applies to the dispute here at issue. An illustrative listing of cases addressing this problem can be found in Newmark v. Williams, 588 A.2d 1108 (Del. 1991). But the courts must carefully consider the facts and circumstances of each individual case as it arises, in weighing the various competing interests. Medical treatment may thus be rejected when the evidence is not sufficiently compelling to establish the primacy of the state's interest, or that the child's own welfare would be best served by such treatment. See Barry; Newmark. On the other hand, the parents' wishes may be overcome when there is sufficient medical evidence to invoke the state's parens patriae authority, and to establish that the child's welfare will be best served by the disputed treatment. See, e.g., In Re Cabrera, 381 Pa.Super. 100, 552 A.2d 1114 (1989); In Re Wilmann, 24 Ohio App.3d 191, 493 N.E.2d 1380 (1986); In Re Hamilton, 657 S.W.2d 425 (Tenn.App.1983); Custody of a Minor, 375 Mass. 733, 379 N.E.2d 1053 (1978).

M.N., 648 So.2d at 770-771.

The First District then concluded that ”in the present case it is not entirely clear whether the court fully considered all of the competing interests involved.” M.N., 648 So.2d at 771. ”Given the nature of this dispute, we conclude that the matter should be remanded so as to ensure a balanced weighing of the various interests.” M.N., 648 So.2d at 771. ”This necessitates [the] consideration of the parents’ interest in making fundamental decisions regarding the care of their child, the state's interest in preserving human life, and the child's own welfare and best interests, in light of the severity of the child's illness, the likelihood as to whether the proposed treatment will be effective, the child's chances of survival with and without such treatment, and the invasiveness and nature of the treatment with regard to its effect on

the child." M.N., 648 So.2d at 771. Accordingly, it remanded the case to the trial court for a further evidentiary hearing on these issues. M.N., 648 So.2d at 772. In view of the considerations set out by the First District, and the past history of the Florida courts in these types of cases, it appears quite evident that the majority of trial judges will authorize the medical treatment for minors in such circumstances.

C. Legal Standing

The state may have several interests in the issue of whether a patient may forego medical treatment. See In re Dubreuil, 629 So.2d 819, 822 (Fla. 1993); In re Guardianship of Browning, 568 So.2d 4, 11 (Fla. 1990); In re Guardianship of Schiavo, 780 So.2d 176 (Fla. 2d DCA 2001). The health care practitioner or provider, however, may not have standing to assert these interests in a petition to require medical treatment for a patient. See In re Dubreuil. At least for blood transfusion cases, the Florida Supreme Court removed standing from the health care practitioner and provider on grounds that there was a potential conflict of interest in requiring health care practitioners and providers to contest the wishes of their own patients. In re Dubreuil; Harrell v. St. Mary's Hospital, Inc., 678 So.2d 455 (Fla. 4th DCA 1996). Nevertheless, in the case of M.N., the hospital successfully brought a petition against the parents. If the health care provider does not have standing, the issue then becomes who does have standing. The answer to this question may lie in Rule 5.900, Florida Probate Rules.

D. Judicial Review

In 1989, the Second District Court of Appeal issued a lengthy decision describing in dicta a method for judicial review of a surrogate's decision regarding the substituted judgment of an incapacitated elderly patient. In re Guardianship of

Browning, 543 So.2d 258 (Fla. 2d DCA 1989). After the Florida Supreme Court reviewed the Second District's decision, it realized the importance of creating an expedited judicial procedure for these types of decisions and requested the Probate Rules Committee to submit to it a proposed rule. In re Guardianship of Browning, 568 So.2d 4 n. 17 (Fla. 1990). In 1991, the court created Rule 5.900, Florida Probate Rules, to assist this legal procedure. Rule 5.900, on its face, is not limited to situations involving elderly patients and appears to apply to all cases involving expedited judicial intervention concerning medical treatment procedures. It allows any "interested person" to file a petition. Rule 5.900 cautions attorneys to "note that the criteria and standards of proof contained in Browning differ from the criteria and standards of proof presently existing in chapter 765, Florida Statutes." Fla.Prob.R. 5.900. Accordingly, a careful review of Rule 5.900 is critical.

Rule 5.900. Expedited Judicial Intervention Concerning Medical Treatment Procedures

(a) Petition. Any proceeding for expedited judicial intervention concerning medical treatment procedures may be brought by any interested adult person and shall be commenced by the filing of a verified petition which states:

(1) the name and address of the petitioner;

(2) the name and location of the person who is the subject of the petition (hereinafter referred to as the "patient");

(3) the relationship of the petitioner to the patient;

(4) the names, relationship to the patient, and addresses if known to the petitioner, of:

(A) the patient's spouse and adult children;

(B) the patient's parents (if the patient is a minor);

(C) if none of the above, the patient's next of kin;

(D) any guardian and any court-appointed health care decision-

maker;

(E) any person designated by the patient in a living will or other document to exercise the patient's health care decision in the event of the patient's incapacity;

(F) the administrator of the hospital, nursing home, or other facility where the patient is located;

(G) the patient's principal treating physician and other physicians known to have provided any medical opinion or advice about any condition of the patient relevant to this petition; and

(H) all other persons the petitioner believes may have information concerning the expressed wishes of the patient; and

(5) facts sufficient to establish the need for the relief requested, including, but not limited to, facts to support the allegation that the patient lacks the capacity to make the requisite medical treatment decision.

(b) Supporting Documentation. Any affidavits and supporting documentation, including any living will or designation of health care decision-maker, shall be attached to the petition.

(c) Notice. Unless waived by the court, notice of the petition and the preliminary hearing shall be served on the following persons who have not joined in the petition or otherwise consented to the proceedings:

(1) the patient;

(2) the patient's spouse and the patient's parents, if the patient is a minor;

(3) the patient's adult children;

(4) any guardian and any court-appointed health care decision-maker;

(5) any person designated by the patient in a living will or other document to exercise the patient's health care decision in the event of the patient's incapacity;

(6) the administrator of the hospital, nursing home, or other facility where the patient is located;

(7) the patient's principal treating physician and other physicians believed to have provided any medical opinion or advice about any condition of the patient relevant to this petition;

(8) all other persons the petitioner believes may have information

concerning the expressed wishes of the patient; and

(9) such other persons as the court may direct.

(d) Hearing. A preliminary hearing on the petition shall be held within 72 hours after the filing of the petition. At that time the court shall review the petition and supporting documentation. In its discretion the court shall either:

(1) rule on the relief requested immediately after the preliminary hearing; or

(2) conduct an evidentiary hearing not later than 4 days after the preliminary hearing and rule on the relief requested immediately after the evidentiary hearing.

Fla.Prob.R. 5.900.

While Rule 5.900, Florida Probate Rules, which is designed for expedited cases, may not be the most optimum avenue to seek judicial relief for cases of surgical intervention of intersex children with genital abnormalities, it may provide some guidance to attorneys and physicians of how to proceed. Most likely, if such a case were brought in Florida, the person disagreeing with the parents' decision would file a petition for injunctive relief in a state circuit court. He or she would then have the initial burden of establishing standing as well as the very heavy burden of establishing that the parents were unfit to make such a decision for their minor child. There are no reported cases in Florida involving this situation.

II. Informed Consent Issues

A. Introduction

The legal doctrine of informed consent is well accepted in the health care profession and the law. By now, generally limited by only their own financial constraints and resources, almost all patients understand that they have the right to make their health care decisions. This right, of course, exists even if the patients' health care provider knows better. As set out above, in the case of a minor, the

minor's parents typically make the minor's health care decisions. In the case of an incompetent person, a guardian or surrogate or proxy makes the health care decisions after determining what health care is in the best interest of the incompetent person. The right to make a health care decision, of course, rests upon an informed basis for the decision, hence the term "informed consent." Informed consent has been enumerated in several different sources of law, including the federal constitution, state constitutions, federal statutes, state statutes, and of course, the common law. As a general rule, a health care provider must obtain the informed consent of a patient for treating, examining, or operating on that individual. § 766.103(3), Fla. Stat. (2001). A failure to do so may result in liability for negligent treatment. An exception exists for emergency medical treatment that falls within the "Good Samaritan Act." § 768.13, Fla. Stat. (2001).

B. The United States Constitution

In Cruzan v. Director, Missouri Department of Health, 497 U.S. 261, 110 S.Ct. 2841, 111 L.Ed.2d 224 (1990), the United States Supreme Court made clear that "a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment." Cruzan, 497 U.S. at 278. "This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment." Cruzan, 497 U.S. at 269. "The informed consent doctrine has become firmly entrenched in American tort law. Cruzan, 497 U.S. at 269. "The logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment." Cruzan, 497 U.S. at 270. Although Cruzan involved the right to refuse life-sustaining treatment issue due to "the advance of medical technology capable of sustaining life well past the point where natural forces would have brought certain death in earlier times," Cruzan, 497

U.S. at 270, its holding on informed consent applies with equal force to any issue involving informed consent. In fact, most of the early cases that discussed informed consent involved the right to refuse medical treatment based upon a patient's religious beliefs. When the courts base decisions on the federal constitution, it typically means that the federal government or a state government has enacted a statute that encroached upon or limits a patient's right to consent to a health care procedure or treatment or the right to receive information in order to make an informed consent.

"But determining that a person has a 'liberty interest' under the Due Process Clause does not end the inquiry." Cruzan, 497 U.S. at 279. Rather, the issue of " whether [a person's] constitutional rights have been violated must be determined by balancing his liberty interests against the relevant state interests." Cruzan, 497 U.S. at 270. Thus, although a competent person may have the right to refuse unwanted medical treatment, the Supreme Court recognized that there are situations where that liberty right may not be violated by a state that prohibits the exercise of that right under certain circumstances. The Supreme Court then reviewed the factual circumstances involving Ms. Cruzan, an incompetent, where Missouri had a statute that "requires that evidence of the incompetent's wishes as to the withdrawal of treatment be proved by clear and convincing evidence." Cruzan, 497 U.S. at 280. " The question, then, is whether the United States Constitution forbids the establishment of this procedural requirement by the State." Cruzan, 497 U.S. at 280. The Supreme Court held that it did not. Cruzan, 497 U.S. at 280.

> Petitioners go on to assert that an incompetent person should possess the same right in this respect as is possessed by a competent person. . . . The difficulty with petitioners' claim is that in a sense it begs the question: An incompetent person is not able to make an informed and voluntary choice to exercise a hypothetical right to refuse treatment or any other right. Such a "right" must be exercised for her, if at all, by some sort of surrogate. Here, Missouri has in effect recognized that under certain circumstances a surrogate may act for the patient in electing to have hydration and nutrition withdrawn in such a way as to

cause death, but it has established a procedural safeguard to assure that the action of the surrogate conforms as best it may to the wishes expressed by the patient while competent. Missouri requires that evidence of the incompetent's wishes as to the withdrawal of treatment be proved by clear and convincing evidence. The question, then, is whether the United States Constitution forbids the establishment of this procedural requirement by the State. We hold that it does not.

Whether or not Missouri's clear and convincing evidence requirement comports with the United States Constitution depends in part on what interests the State may properly seek to protect in this situation. Missouri relies on its interest in the protection and preservation of human life, and there can be no gainsaying this interest. As a general matter, the States--indeed, all civilized nations--demonstrate their commitment to life by treating homicide as a serious crime. Moreover, the majority of States in this country have laws imposing criminal penalties on one who assists another to commit suicide. We do not think a State is required to re-main neutral in the face of an informed and voluntary decision by a physically able adult to starve to death.

But in the context presented here, a State has more particular interests at stake. The choice between life and death is a deeply personal decision of obvious and overwhelming finality. We believe Missouri may legitimately seek to safeguard the personal element of this choice through the imposition of heightened evident-iary requirements. It cannot be disputed that the Due Process Clause protects an interest in life as well as an interest in refusing life-sustaining medical treatment. Not all incompetent patients will have loved ones available to serve as surrogate decision-makers. And even where family members are present, "[t]here will, of course, be some unfortunate situations in which family members will not act to protect a patient." In re Jobes, 108 N.J. 394, 419, 529 A.2d 434, 447 (1987). A State is entitled to guard against potential abuses in such situations. Similarly, a State is entitled to consider that a judicial proceeding to make a determination regarding an incompetent's wishes may very well not be an adversarial one, with the added guarantee of accurate factfinding that the adversary process brings with it. See Ohio v. Akron Center for Reproductive Health, 497 U.S. 502, 515-516, 110 S.Ct. 2972, 2981-2982, 111 L.Ed.2d 405 (1990). Finally, we think a State may properly decline to make judgments about the "quality" of life that a particular individual may enjoy, and simply assert an unqualified interest in the preservation of human life to be weighed against the constitutionally protected interests of the individual.

* * *

We think it self-evident that the interests at stake in the instant proceedings are more substantial, both on an individual and societal level, than those involved in a run-of-the-mine civil dispute. But not only does the standard of proof reflect the importance of a particular adjudication, it also serves as "a societal judgment about how the risk

> of error should be distributed between the litigants." Santosky, supra, 455 U.S. at 755, 102 S.Ct., at 1395; Addington, supra, 441 U.S., at 423, 99 S.Ct., at 1807-1808. The more stringent the burden of proof a party must bear, the more that party bears the risk of an erroneous decision. We believe that Missouri may permissibly place an increased risk of an erroneous decision on those seeking to terminate an incompetent individual's life-sustaining treatment. An erroneous decision not to terminate results in a maintenance of the status quo; the possibility of subsequent developments such as advancements in medical science, the discovery of new evidence regarding the patient's intent, changes in the law, or simply the unexpected death of the patient despite the administration of life-sustaining treatment at least create the potential that a wrong decision will eventually be corrected or its impact mitigated. An erroneous decision to with-draw life-sustaining treatment, however, is not susceptible of correction.

Cruzan, 497 U.S. at 279-283.

Significantly, in addition to the clear and convincing evidence standard, the United States Supreme Court also held that states are not constitutionally required to accept the "substituted judgment" of a patient's close family member absent substantial proof that their views reflected the views of the incompetent patient. Cruzan, 497 U.S. at 286.

> It is also worth noting that most, if not all, States simply forbid oral testimony entirely in determining the wishes of parties in transactions which, while important, simply do not have the consequences that a decision to terminate a person's life does. At common law and by statute in most States, the parol evidence rule prevents the variations of the terms of a written contract by oral testimony. The statute of frauds makes unenforceable oral contracts to leave property by will, and statutes regulating the making of wills universally require that those instruments be in writing. See 2 A. Corbin, Contracts § 398, pp. 360-361 (1950); 2 W. Page, Law of Wills §§ 19.3- 19.5, pp. 61-71 (1960). There is no doubt that statutes requiring wills to be in writing, and statutes of frauds which require that a contract to make a will be in writing, on occasion frustrate the effectuation of the intent of a particular decedent, just as Missouri's requirement of proof in this case may have frustrated the effectuation of the not-fully-expressed desires of Nancy Cruzan. But the Constitution does not require general rules to work faultlessly; no general rule can.

Cruzan, 497 U.S. at 284. Thus, the Cruzan decision also impacts the determination of "who" may make a minor's health care decision.

C. The Florida Constitution

Separate from the United States Constitution, the Florida Supreme Court has recognized that the Florida Constitution "guarantees that 'a competent person has the constitutional right to choose or refuse medical treatment, and that right extends to all relevant decisions concerning one's health.'" In re Dubreuil, 629 So.2d 819, 822 (Fla. 1993); In re Guardianship of Browning, 568 So.2d 4, 11 (Fla. 1990); Public Health Trust of Dade County v. Wons, 541 So.2d 96 (Fla. 1989). The Florida Supreme Court premised this right upon a person's right to privacy under Article I, section 23, of the Florida Constitution. It recognized, however, that where the issue involves a blood transfusion, the privacy right "overlaps with the right to freely exercise one's religion." In re Dubreuil, 629 So.2d at 822. In a prior decision, the court held that a terminally ill incompetent person's right to refuse medical treatment is the same as a competent person's right to refuse medical treatment. John F. Kennedy Memorial Hospital, Inc. v. Bludworth, 452 So.2d 921 (Fla. 1984). In so doing, the court recognized the doctrine of "substituted judgment" under certain circumstances. Bludworth. Should there be any doubt in the determination of the patient's wishes about living or dying, the default position favors life. In re Guardianship of Schiavo, 780 So.2d 176 (Fla. 2d DCA 2001).

Perhaps the most controversial of the right to refuse medical treatment cases are the ones where the patient refuses blood transfusions based upon religious reasons. In re Dubreuil, Wons, Harrell v. St. Mary's Hospital, Inc., 678 So.2d 455 (Fla. 4th DCA 1996); M.N. v. Southern Baptist Hospital of Florida, Inc., 648 So.2d 769 (Fla. 1st DCA 1994); St. Mary's Hospital, Inc. v. Ramsey, 465 So.2d 666 (Fla. 1985). The Florida Supreme Court has clearly held that a health care provider must comply with the wishes of a patient who refuses a blood transfusion unless otherwise ordered by a

court of competent jurisdiction. See In re Dubreuil, Wons. The issue is clouded where the patient is a parent of a young child. Wons. The state has an interest in seeing that the child is not abandoned by the parent. In In re Dubreuil and Wons, the Florida Supreme Court held that there was insufficient evidence of child abandonment because the patient had a spouse or an extended family member that would care for the child. In view of the fact that the Florida Supreme Court decided the issue of informed consent on an express ”right of privacy,” a right that was created in the state constitution after the creation of the right of informed consent, many of the court’s decisions look to Florida’s common law for its reasoning.

D. The Florida Statutes

1. The Various Informed Consent Statutes

a. The ”Florida Medical Consent Law”

The ”Florida Medical Consent Law” is found in section 766.103, Florida Statutes (2001). It is the most widely employed statute for informed consent, but is typically relied upon in cases involving competent adults making decisions about their ordinary medical care. It states in part:

> (3) No recovery shall be allowed in any court in this state against any physician licensed under chapter 458, osteopathic physician licensed under chapter 459, chiropractic physician licensed under chapter 460, podiatric physician licensed under chapter 461, or dentist licensed under chapter 466 in an action brought for treating, examining, or operating on a patient without his or her informed consent when:
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> (a)1. The action of the physician, osteopathic physician, chiropractic physician, podiatric physician, or dentist in obtaining the consent of the patient or another person authorized to give consent for the patient was in accordance with an accepted standard of medical practice among members of the medical profession with similar training and experience in the same or similar medical community; and
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> 2. A reasonable individual, from the information provided by the physician, osteopathic physician, chiropractic physician, podiatric physician, or dentist, under the circumstances, would have a general understanding of the procedure, the medically acceptable alternative

procedures or treatments, and the substantial risks and hazards inherent in the proposed treatment or procedures, which are recognized among other physicians, osteopathic physicians, chiropractic physicians, podiatric physicians, or dentists in the same or similar community who perform similar treatments or procedures; or

(b) The patient would reasonably, under all the surrounding circumstances, have undergone such treatment or procedure had he or she been advised by the physician, osteopathic physician, chiropractic physician, podiatric physician, or dentist in accordance with the provisions of paragraph (a).

(4)(a) A consent which is evidenced in writing and meets the requirements of subsection (3) shall, if validly signed by the patient or another authorized person, raise a rebuttable presumption of a valid consent.

(b) A valid signature is one which is given by a person who under all the sur-rounding circumstances is mentally and physically competent to give consent.

§ 766.103(3)-(4), Fla. Stat. (2001).

b. The "Florida Patient's Bill of Rights and Responsibilities"

The Florida Patient’s Bill of Rights and Responsibilities law provides in relevant part:

(4) RIGHTS OF PATIENTS. Each health care facility or provider shall observe the following standards.

(b) Information.--

1. A patient has the right to know the name, function, and qualifications of each health care provider who is providing medical services to the patient. A patient may request such information from his or her responsible provider or the health care facility in which he or she is receiving medical services.

2. A patient in a health care facility has the right to know what patient support services are available in the facility.

3. A patient has the right to be given by his or her health care provider information concerning diagnosis, planned course of treatment, alternatives, risks, and prognosis, unless it is medically inadvisable or impossible to give this information to the patient, in which case the information must be given to the patient's guardian or a person designated as the patient's representative. A patient has the right to refuse this information.

4. A patient has the right to refuse any treatment based on

information required by this paragraph, except as otherwise provided by law. The responsible provider shall document any such refusal.

> 5. A patient in a health care facility has the right to know what facility rules and regulations apply to patient conduct.
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> 6. A patient has the right to express grievances to a health care provider, a health care facility, or the appropriate state licensing agency regarding alleged violations of patients' rights. A patient has the right to know the health care provider's or health care facility's procedures for expressing a grievance.
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> 7. A patient in a health care facility who does not speak English has the right to be provided an interpreter when receiving medical services if the facility has a person readily available who can interpret on behalf of the patient.

§ 381.026(4)(b), Fla. Stat. (2001). As with the state constitution right of privacy, the statutory bill of rights for patients was created well after the common law doctrine of informed consent. Thus, it too will most likely be interpreted in accordance with Florida's common law.

E. The Operation of the Informed Consent Provisions

1. The Duty to Obtain the Patient's Informed Consent

Generally, unless the patient's treating physician is a hospital employee, a hospital cannot be held liable for the physician's failure to obtain his or her patient's informed consent because the duty falls upon the physician, not the hospital, to obtain the patient's informed consent for the care and treatment being provided. Hospitals are not listed in the Florida Medical Consent Law, and in fact, are specifically excluded from this provision. § 766.103, Fla. Stat. (2001). The reasons for this exclusion are that: (1) in most situations, only a qualified physician has the training, experience and skill to obtain the patient's informed consent for whether any particular medical procedure should be performed, (2) the physician is in a superior position to know the patient as well as the patient's medical history, and (3) requiring only the physician to obtain the patient's informed consent eliminates any potential

conflict between the physician and the hospital. Thus, it appears to be Florida's stated policy to protect hospitals from liability for obtaining a patient's consent for a medical procedure performed at its facility by a non-employee physician. Cedars Medical Center, Inc. v. Ravelo, 738 So. 2d 362 (Fla. 3d DCA 1999), review denied, 751 So.2d 1253 (Fla. 2000); Valcin v. Public Health Trust of Dade County, 473 So.2d 1297 (Fla. 3d DCA 1984), approved in part disapproved in part, 507 So. 2d. 596 (Fla. 1987).

In a medical malpractice action based upon the failure to obtain a patient's informed con-sent, the informed consent requirement is met where the following elements are established.

> (1) The action of the health care practitioner in obtaining the consent of the patient or of a person authorized to give consent for the patient, was in accordance with the accepted standard of medical practice among members of the medical profession with similar training and experience in the same or similar medical community.
>
> (2) From the information furnished by the health care practitioner, a reasonable individual would have a general understanding of the procedure, the medically acceptable alternative procedures or treatments, and the substantial risks and hazards inherent in the proposed treatment or procedures.

§ 766.103(3)(a), Fla. Stat. (2001). Ritz v. Florida Patient's Compensation Fund, 436 So.2d 987 (Fla. 3d DCA 1983), review denied, 450 So.2d 488 (Fla. 1984). If these two elements are not satisfied, the physician may still nonetheless avoid liability if it can be shown that "the patient would reasonably, under all the surrounding circumstances, have undergone such treatment or procedure had he or she been advised by the physician, osteopathic physician, chiropractic physician, podiatric physician, or dentist in accordance with" paragraph (a). § 766.103(3)(b), Fla. Stat. (2001). Proof of a violation of the standard of care for the lack of an informed consent requires expert medical testimony. Valcin v. Public Health Trust of Dade County, 473 So.2d 1297 (Fla. 3d DCA 1984), approved in part disapproved in part,

507 So. 2d. 596 (Fla. 1987); Meretsky v. Ellenby, 370 So.2d 1222 (Fla. 3d DCA 1979).

2. The Scope of Consent

A physician is not under a duty to explain all of the risks associated with a procedure, but only those risks that are substantial and inherent in the proposed treatment. A substantial risk inherent in a procedure or treatment is one that is recognized among other medical professionals with similar training and experience in the same or similar medical community. Public Health Trust of Dade County v. Valcin, 507 So. 2d. 596, 598-599 (Fla. 1987); Ritz. Accordingly, in a case where the physician failed to inform the patient who underwent a tubal ligation that an ectopic pregnancy was a risk of the surgery, the patient was required to produce expert testimony as to the necessity of informing her of the risk of ectopic pregnancy. Faced with the medical expert witness testimony, the physician was required to rebut it with qualified expert witness testimony establishing that the risk of ectopic pregnancy was insubstantial or the failure to inform was still in accordance with accepted medical practice within the medical community. Valcin.

3. The Presumption of a Valid Consent

"A consent which is evidenced in writing and meets the requirements of subsection (3) shall, if validly signed by the patient or another authorized person, raise a rebuttable presumption of a valid consent." § 766.103(4)(a), Fla. Stat. (2001). "A valid signature is one which is given by a person who under all the surrounding circumstances is mentally and physically competent to give consent." § 766.103(4)(b), Fla. Stat. (2001). The Florida Supreme Court has ruled that this presumption of validity arising from a signed informed consent does not violate due process. Parikh v. Cunningham, 493 So.2d 999, 1001 (Fla. 1986). In determining the application of

the statutory presumption of the validity of a signed written consent, all of the circumstances must be taken into consideration. These include the medical procedure itself, the inherent risks of the medical procedure and the adequacy and reliability of the physician's means to communicate the medical information to the patient taking into account known language difficulties. Dandashi v. Fine, 397 So.2d 443 (Fla. 3d DCA 1981).

F. Informed Consent for Minors

Generally, the physician must obtained the informed consent from a parent or guardian in those situations where the patient is a minor, i.e., a person less than 18 years of age. § 743.01, Fla. Stat. (2001). A minor who has had the disability of non-age removed pursuant to the various provisions of chapter 743 may consent to his or her own treatment. There are exceptions to the general rule. Emergency medical care or treatment may be provided to a minor by a physician without parental consent if delaying treatment would endanger the health or physical well-being of the minor. § 743.064(1), Fla. Stat. (2001). Notification to the parents, however, "shall be accomplished as soon as possible after the emergency medical care or treatment is administered." § 743.064(1), Fla. Stat. (2001). As set forth above, in rare instances, the courts have held that it may be proper to intervene to preserve a minor's life. See J.V. v. State, 516 So.2d 1133 (Fla. 1st DCA 1987); see also M.N. v. Southern Baptist Hospital of Florida, Inc., 648 So.2d 769 (Fla. 1st DCA 1994); In re Barry, 445 So.2d 365 (Fla. 2d DCA 1984).

G. The Ultimate Issue.

The ultimate issue presented at this conference rests upon a decision with respect

to the timing of surgical intervention. It is the informed consent and specifics of the

information provided that will ultimately determine whether or not the healthcare provider has adhered to the applicable standard of care in dealing with the situation. Recent events and studies have raised some concerns about the traditional of early surgical intervention and the psychological ramifications. It is the recommendation of this author that these issues be communicated to the patients and/or their parents. Thus, the recommendation is for a more expansive informed consent that has traditionally been given when confronting these issues. This author recognizes that there is not legal decision in this country squarely on point. However, the emergence of peer reviewed literature suggesting potential harm for early surgical treatment to patients creates a situation where the healthcare practitioner must take these matters into account. Therefore, the more cautious approach should be to at least notify the decision-maker of the issues. It is recommended that this additional component be incorporated into the more traditional informed consent document, so that there is a clear written record that the information was in fact communicated. Of course, the precise information and language of the informed consent will be determined based upon the specifics of the individual set of patient circumstances.

III. Liability Issues.

A. Standard of Care

As discussed above, a healthcare provider may have some liability to an individual based upon the failure to obtain an appropriate informed consent. Additionally, healthcare professionals risk exposure to suit if their conduct in providing medical care falls below the applicable standard of care. Issues concerning the technical aspects of rendering medical care are not addressed in this article but instead negligence issues would center upon the advice, recommendation, providing of information, and referral issues. As a professional, the healthcare practitioner is

imposed under the law of the State of Florida with the duty to perform requested services in accordance with the standard of care used by similar professionals in the community under similar circumstances. Moransails vs. Heathman, 744 So.2d 973 (Fla. 1999). It is likewise defined in standard jury instructions as the failure to use reasonable care. ”Reasonable care on the part of the physician is that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by similar and reasonably careful physicians.” Florida Standard Jury Instruction 4.2(a). The healthcare professionals are therefore expected to conduct themselves in accordance with the practices that are generally accepted amongst the medical community.

It appears to be generally accepted that at the present time, physicians reassign the sex of infants with ambiguous genitalia at birth or as soon thereafter as is practical, but in any event within the first two years of the child’s life. This appears to be based upon the initial research and opinions set forth by Dr. John Money. Additionally, support for early intervention has been set forth by the American Academy of Pediatrics in a policy statement issued April 1996. American Academy of Pediatrics Volume 97, Number 4, April 1996. In the policy statement, the academy recommended surgery for orchidopexy and hypospadias to be performed between six and 12 months of age. This policy statement helps define the standard of care with respect to the timing of elective surgery on the genitalia of children born with genital abnormalities. It should be noted that the American Board of Pediatrics issued an addendum to their 1996 position as published in Pediatrics 2000; 106:138-142. The Academy stated ”the 2000 policy on Developmental Anomalies of the External Genitalia acknowledges the considerable recent debate about the appropriate general assignment of newborns with the most extremes forms of genitalia ambiguity, and

notes that some have suggested that the current early surgical treatment be abandoned in favor for allowing the affected person to participate in gender assignment at a later time." Recent studies and literature suggests that there is an emerging issue with regard to the appropriate timing of surgical intervention. As greater and more expansive studies are undertaken, the standard of care with respect to the timing of surgical intervention may in fact evolve. It is during this interim time period that the practitioner faces a true gray area.

Where the standard of care in this country is to surgically intervene within

the first year of the infant's life, the standard would also require that the medical advice given to parents be in accordance with this early intervention. It can be argued that falling out side the main stream and recommending to parents that they delay surgical intervention does pose some potential risk to the healthcare practitioner.

It is the recommendation of this author that the practitioner avoid this pitfall by disclosing both schools of thinking to the parents. In this rather unusual set of circumstances, greater time and effort should be spent with a more extensive discussion and consent process than as traditionally undertaken.

These issues would certainly be much simpler if a legislature or a court of

competent jurisdictions were able to define the rights, responsibilities, and standards with respect to these individuals. At the present time however, this author has not located any legislature or court within the United States that has directly addressed these issues and the responsibilities of the healthcare practitioner with respect to them. There has been, however, one case decided in Columbia that has considered the issues.

B. Columbia's Decision

The Columbian Constitution Court issued two decisions. One on May 12, 1999 and the other on August 2, 1999 which addressed issues of surgical intervention in sexually ambiguous infants. The Court found that ”parents cannot give consent on a child's behalf on surgeries intended to determine sexual identity.” The Court indicated that children older than five (5) years of age are the appropriate persons to consent to surgeries to determine their sex. Additionally, in the other Order the Court found the Informed Consent given to parents of a child under the age of five (5) to be insufficient. At the present time I have been unable to obtain an English translation of these decisions. Assuming, however, that the English articles are accurate several questions come immediately to mind. First, a comparison of the Constitution of Columbia would need be compared to our own. There are perhaps some fundamental differences which could have a bearing upon the basis of the decision. Secondly, it is virtually impossible to imagine a scenario where a United States Court would allow a minor to consent to a surgical procedure. As stated previously in this article minors do not have the ability to enter into a legally binding contract. Since a medical consent is in fact a binding agreement minors would lack capacity to enter into it. One final thought on the Columbia case centers on their displeasure with the Informed Consent. As stated again it is likely that any decision in the United States will turn upon the issue of Informed Consent. Therefore, the issue that is presented in the Columbia case may be relevant to demonstrate to healthcare professionals Courts general attitude towards an adequate Informed Consent.

C. Related Cases

There are a number of related cases that although they are not authoritative on the issues at hand are none the less illustrative of the Court's attitude towards a variety

of issues respecting surgical sex changes. I include the Littleton v. Prange case cited in the 288th Judicial District Court, Bexar County, Texas, Case No. 98-CI-15220. This case did not involve an intersex issue but instead involved an individual who as an adult had surgery to transform themselves from a man to the physical characteristics of a woman. As a woman Ms. Littleton married Jonathan Littleton where they lived as husband and wife for seven (7) years. Jonathon Littleton died in 1996 allegedly as a result of malpractice of his treating physician. Ms. Littleton attempted to file an action under the Texas Wrongful Death Statute as a surviving spouse. The Defendant's alleged that since Mrs. Littleton was in fact born a man and Texas did not recognize same sex marriages that she did not have standing to bring the action under the Wrongful Death Statute. The Trial Court agreed, granting Summary Judgment, and the issue was affirmed on appeal. Despite the fact that Christy Littleton had her birth certificate changed to reflect her as a female, the Texas Court looked beyond the ministerial act of the change of a birth certificate and found that since she was born a male she was unable to bring the action.

There are also a series of cases that discuss whether transsexuals are in fact capable of marrying members of the same sex as defined at the time of their birth. There are some conflicting cases which may be more properly based upon that states a set of individual laws. These cases include Baehr v. Lewin, 852 P.2d 44 (Hawaii, abbr. 1993); MT v. JT, 355 A. 2d 204 Superior Court of New Jersey (1976); and In re: Ladrach, 513 N.E.2d 828 (Ohio, 1987); Anonymous v. Anonymous, 325 N.Y.S.2d 499 S.C. Queens County, New York (1971); Baker v. Nelson, 191 N.Y.2d 185 Minnesota, abbr. (1971) and Jones v. Halahan, 501 S.W. 2d 588 Kentucky abbr. (1973).

Several of these cases have been discussed in various Law Review articles.

They would include an article titled ”Sex Changes and Opposite Sex Marriages: Apply the Full Faith and Credit Clause to Comply Interstate Recognition of Transgendered Persons Amended Legal Sex for Marital Purposes.” 38 San Diego Law Review 1113 Fall, 2001 and ”The Transsexual and the Damage Done: The Fourth Court of Appeals Opens Pandora’s Box by Closing the Door on Transsexuals Right to Marry.” 9 Law in Sex No. 1, 199-2000.

Other articles of interest include ”Race, Sexual Orientation, Gender and Disability,” Ohio State Law Journal, 1985; ”First do no Harm- The Fiction of Legal Parental Consent to Genital Normalizing Surgery on Intersexed Infants,” 19 Yale Law and Policy Review, 2001 and ”An Emerging Ethical and Medical Dilemma; Should Physicians Perform Sex Assignment Surgery on Infants with Ambiguous Genitalia,” 7 Michigan Journal of Gender and Law, 2000.

D. Conclusion

While there presently exists a great deal of concern for the well-being of the individuals involved and the professionals continue to search for the answers, the focus for the health care professionals seem to have two rather clear pathways. The first is the pathway of inquiry and testing designed to determine whether or not the majority of persons treated by early surgical intervention derived a benefit or a harm from the surgery. At the present time it appears that there is a good faith effort on-going to arrive at sound conclusions in this regard.

The parallel path is the path of the health care professional who is proceeding in accordance with the well established standard of care for surgical treatment of these individuals within the first year of their life. While these two paths may appear to be inconsistent with one another, in reality they may both be standard of care, if the standard is defined as such by the medical community. While it is certainly logical to

assume that the standard of care cannot or should not be changed until the results of the on-going studies are known there does none the less arise a concern that the results may differ from the traditional recommendation course of action. As such perhaps the only prudent way to proceed is to outline to the decision-maker the present state of medicine and its potential evolution. Only in this manner can a reasonably prudent health care practitioner proceed with either treatment or delay with any degree of comfort. Because of this scenario a traditional Consent Form may not be legally adequate. It is recommended that a Consent Form contain not only the traditional risks of surgery and anesthesia but should include the potential future mental or emotional component in the event the chosen sex becomes inappropriate. In this regard there is attached as an addendum hereto a proposed Consent Form for treatment. It is hoped that either this Consent or one revised in accordance with the wishes of the participants herein becomes utilized.

MEDICAL CONSENT

Comes now Mr. _______________ and Mrs. ______________________ both individually and as the parents and natural guardians of ___________________ and hereby execute this Consent Agreement on this __________ day of ______________. 20__ at _____a.m./p.m. This Consent is entered into pursuant to the Florida Medical Consent Law which requires our health care practitioners to advise us of the general nature of the treatment or procedures and the medically acceptable alternative procedures and treatments and the substantial risks and hazards inherent in the proposed treatment or procedures. We understand that our child has been diagnosed with a developmental anomaly of the external genitalia. We understand and acknowledge that this is not a life threatening condition and it is therefore not an emergency procedure. We recognize that the child faces potential mental or emotional harm from this condition. I have been informed that this procedure may be urgently needed in order to reduce or eliminate the potential harm to our child. It has been recommended to us by our health care providers that surgical intervention is in the best interest of our child based upon the current status of medical thinking. We have been informed that presently the American Academy of Pediatrics recommends surgery for this condition to be conducted within the first twelve (12) months of the infants life. We have likewise been informed that although the present standard of care is to operate within the first twelve (12) months on the infant for these conditions, there is presently an on-going debate as to whether or not it is in the best interest of the child. We have been informed that studies are on-going in an effort to determine the long term effects of surgical intervention on children born with genital abnormalities. These studies have not yet been completed, however, several individuals have come forward suggesting that surgery was not appropriate for their

circumstances. Since the individuals that have come forward represent a minority of those who have undergone surgery of this type, greater research is needed in order to fully understand the ramifications.

We have been informed that we have the right to obtain other opinions to those expressed by our health care provider and have been encouraged to do so. We have been made aware of the Intersex Society of North America and the information from them that is available both on the internet and through other means. We are satisfied that we have been properly educated and informed about the status of medicine as it presently exists concerning our child's medical condition. Therefore, we hereby enter into this Agreement as follows:

1. We hereby consent and authorize Dr. ________________________ and such assistants as may be selected by him, to perform upon our minor child the following procedure:

____

____

____

2. If any unforeseen conditions arise during the course of the procedure, we do hereby authorize and request our health care providers to take whatever steps necessary and perform whatever procedures they deem advisable even though they may be different from those procedures now planned.

3. Our doctor and/or other members of his staff have explained to us the purpose of the procedure(s). They also explained to us the risks and potential complications of this surgical procedure and we understand that there are always certain risks and consequences that are associated with any procedure, which may include but are not limited to allergic reactions and/or damage to blood vessels,

nerves, internal organs and/or infections, bleeding, failure of healing or death. We also specifically recognize that these abnormalities may take more than one procedure to correct and may in fact involve multiple procedures. We also specifically recognize that our child may in the future have conflict with their chosen sex and therefore may require further medical care in this regard.

4. The alternative to these procedures have been fully explained to us and we have been informed that one of the alternatives to is that we refuse surgical options all together.

5. We hereby consent to the administration of such anesthetics as may be considered necessary or advisable by a member of the Anesthesia Medical Staff, we further request and authorize the person(s) administering the anesthetic to do whatever they deem advisable and necessary under the circumstances including but not limited to the insertion of blood pressure and blood volume monitoring devices.

6. We hereby consent to the disposal by _______(HOSPITAL) ___________________ of any tissue or part which may be removed from our child.

7. We hereby consent to the taking of photographs or video taping in the course of this procedure for the purposes of advancing medical education as may be authorized by physician and to the admittance of the qualified observers to the operating room as determined by ____________(HOSPITAL)____________.

8. We understand and read the English language and/or adequate interpretation and have had the procedure adequately explained and have not had any mind-altering medications prior to signing this document. Any and all questions regarding this procedure have been answered to our satisfaction. We understand that any existing Do Not Resuscitate (DNR) status is voided upon entering the Surgical Department and will remain void until discharge from the Surgical Department. _____

9. WE ACKNOWLEDGE THAT NO GUARANTEE OR ASSURANCE HAS BEEN MADE TO US AS TO ANY OF THE RESULTS OR RISKS, AND THAT WE SPECIFICALLY ASSUME SUCH RISKS.

10. In signing this document we hereby acknowledge that we have read and understand all of the terms contained within this document and to the extent we did not understand any aspect we have inquired and our inquiries have been answered to our satisfaction. As of the time of our entering into this Consent, we maintain and believe that this procedure is in the best interests of our child. As of the timing of the signing of this agreement, any and all blanks located within this document have been filled in.

____
____

Signature of Parent Date/Time Witness to Signature
Date/Time

____
____

Signature of Parent Date/Time Witness to Signature
Date/Time

____
____

Signature of Guardian Date/Time Witness to Signature
Date/Time
If not a natural parent

____
Relationship to Patient

WE CERTIFY THAT I HAVE INFORMED THE PATIENT OF THE PRESENT STATUS OF MEDICINE CONCERNING SURGICAL TREATMENT OF THE PATIENT'S CONDITIONS. I ALSO CERTIFY THAT I HAVE INFORMED THE LEGAL REPRESENTATIVE OF THE PATIENT OF THE AVAILABLE ALTERNATIVES WITH RESPECT TO THE PROPOSED SURGICAL PROCEDURE AND OF THE INHERENT POTENTIAL SURGICAL RISKS, COMPLICATIONS AND RESULTS WHICH I CONSIDER LIKELY TO OCCUR AS A RESULT OF SAID PROCEDURE.

____

______M.D.