

INFORMED CONSENT

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DEFINITIONS

Consent: Consent is the common law right of an individual to not have his/her person or property trespassed without his/her consent. In the absence of consent, a person may sue for assault and battery.

Informed Consent: Informed consent is the right of a patient to be presented sufficient information by his/her physician, or a representative of the physician, which allows the patient to make an informed decision as to whether he/she wishes to consent to having his/her person intruded upon for specified purposes. For negligent or inadequate informed consent, a person may sue for medical malpractice.

- ◆ ***Express Consent:*** Consent that a patient gives by direct words, written or oral.
- ◆ ***Implied Consent:*** Consent that arises by reasonable inference from the conduct of the patient. For example, a person who joins a line of people awaiting a vaccination by injection has given his/her implied consent to be vaccinated.

NOTE: *Informed Consent* shall be simply referred to as consent throughout this booklet.

<p style="text-align: center;">ELEMENTS OF INFORMED CONSENT</p>
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- ◆ Diagnosis
- ◆ Nature and Purposes of Proposed Treatment
- ◆ Risks and Consequences of Proposed Treatment
- ◆ Alternative Choices of Treatment and Associated Risks
- ◆ Risks and Consequences of No Treatment

EXCEPTIONS***PROCEDURES DIFFERING FROM THE PATIENT'S AUTHORIZATION:***

- ◆ ***Extension Doctrine:*** When consent has been obtained for a specific purpose, but the physician subsequently encounters different or additional medical issues best resolved at the time, and the circumstances make it infeasible to consult the patient, or the person giving consent on behalf of the patient at the time, then the original consent is deemed to be extended to cover the unanticipated care or treatment. For example, a physician has undertaken surgery, agreed to by the patient, to remove the patient's spleen. In the course of the procedure the physician locates a tumor in the same area. The patient's original consent would be extended to include removal of the cancer at the same time, assuming removal of the cancer was medically appropriate.

- ◆ If a patient's reproductive capabilities will be affected, then the physician cannot extend the original consent. The physician must complete the original surgery, obtain the patient's informed consent for the additional procedure, and then proceed with performing that procedure.

- ◆ If a patient expressly prohibits a specific medical or surgical procedure, consent for that procedure cannot be implied unless circumstances change significantly from those anticipated at the time of the prohibition.

- ◆ If a physician anticipates the possible need for an extension of the original care or procedure, then he/she should obtain consent for extended care or procedure before proceeding.
- ◆ Generally, the patient's consent is applicable only for a specifically authorized practitioner. Substitution of health care providers is not generally acceptable, absent an emergency.

WHEN THE PATIENT'S CONSENT IS NOT REQUIRED:

- ◆ The most common exception to the requirement for a patient's consent is in the event of an emergency. When immediate treatment is required to preserve life or prevent a serious impairment to health and it is impossible to obtain the patient's consent or that of someone authorized to consent on the patient's behalf, the physician may undertake the required procedure without obtaining consent. In such instances the law presumes that a patient would want treatment necessary to preserve life or health. However, should a health care provider be aware that a patient would not authorize the care or treatment needed, then the care or treatment may not be undertaken, even in the event of an emergency.
- ◆ In rare instances where consent cannot be obtained from a patient or his/her representative or in some non-emergent instances where a patient has refused to consent to necessary care or treatment, a court order permitting care may be sought. A hearing is set for court-ordered consent by calling Medical Center administration. Generally, the administrative resident on duty requests such hearings. (Reference: Virginia Code §54.1-2969)

- ◆ From time to time, police may request tests or information from the patient's body (e.g. blood, urine or breath tests, removal of a bullet or drugs or other items swallowed by a patient). However, such tests or procedures may NOT be performed without the patient's consent or court order.

See section on *HIV testing*.

REFUSAL OF CONSENT

General Rule: Medical and surgical procedures that involve touching a patient's body must be authorized by the patient. Absent special circumstances, a patient has the right to refuse to authorize a procedure, whether the refusal is grounded on doubt of success, concern for risks, lack of confidence in the physician, religious belief, or whim.

REFUSAL ON RELIGIOUS GROUNDS

- ◆ The First Amendment gives a person the right to refuse treatment on religious grounds.
- ◆ An adult person of sound mind cannot be compelled to submit to medical treatment against his or her will, unless the State can show a "compelling, overriding interest."
- ◆ The State's interest in promoting the welfare of children could justify an order for compulsory medical care if it were necessary to save the life of a pregnant woman or a parent of young children. A court order should be sought if this is believed to be the case. A court hearing can be initiated by calling Medical Center administration. Generally, the administrative resident on duty requests such hearings.
- ◆ Where minor children are involved, the State's interest in preventing the abandonment of the children may be outweighed by the patient's right to refuse blood transfusions on religious grounds when the patient's family is capable and willing to provide for the children if the patient dies.
- ◆ A mature minor generally has a right to refuse treatment on religious grounds where the parents have also objected. (The legal concept "mature minor" does not exist in Virginia Law. See section on *Mature Minor*.)

See section on *Minors* for specific discussion of issues related to minors.

MINORS

General Rule: Consent of a minor to medical care or treatment is ineffective. A physician must secure the consent of the minor's custodial parent or a person standing *in loco parentis*. (Reference: Virginia Code §54.1-2969)

Statutory Exceptions recognized in Virginia are detailed in the following sections:

- ◆ Minors Treated as Adults
- ◆ Emancipated Minors
- ◆ Mature Minors
- ◆ Married Minors
- ◆ Minors Who are Parents
- ◆ Minors in Military Service
- ◆ Inpatient Psychiatric Treatment of Minors

Special Considerations relating to consent issues for minors are detailed in the following sections:

- ◆ Consent Issues with Minors
- ◆ Refusal of Treatment for Minors
- ◆ Abortions for Minors

**STATUTORY EXCEPTIONS:
*MINORS TREATED AS ADULTS***

A minor may consent as an adult for the following medical treatment:

- ◆ Health services to diagnose or treat venereal disease.
- ◆ Health services for birth control (except sterilization), pregnancy or family planning.
- ◆ Health services for *outpatient* treatment or rehabilitation for substance abuse.
- ◆ Health services for *outpatient* treatment or rehabilitation for mental illness.

Parents or legal guardians may also consent to this treatment for a minor.

(Reference: Virginia Code §54.1-2969)

**STATUTORY EXCEPTIONS:
*EMANCIPATED MINORS***

Where a court has legally recognized by court order a child as emancipated, that minor is to be treated as an adult for all purposes, including consenting to medical care or treatment. If a child states that he/she has been legally recognized by a court as emancipated and the health care provider has no reason to believe otherwise, the provider may rely on the minor's representation that he/she is an emancipated minor without actually seeing the court order. **(Reference: Virginia Code §16.1-334)**

In many states, a *court order* recognizing a minor as emancipated is not necessary. Rather, if a child lives on his/her own and supports himself/herself entirely on his/her own, he/she will be recognized as emancipated. This is not the case in Virginia; a court order is required.

**STATUTORY EXCEPTIONS:
*MATURE MINORS***

In some states, minors over the age of 14 or 15 years old may be considered a "mature minor" and given the right to consent to medical care or treatment. However, Virginia has not, to date, recognized mature minors as being legally empowered to consent to medical care or treatment.

**STATUTORY EXCEPTIONS:
*MARRIED MINORS***

Except for purposes of sexual sterilization, if a minor is married or has been married, the minor is treated as an adult. The minor may consent to his/her own medical treatment. If the minor is incapacitated, then the spouse, not the parents, is the most appropriate person to provide consent for the patient. (Reference: Virginia Code §54.1-2969)

**STATUTORY EXCEPTIONS:
*MINORS WHO ARE PARENTS***

If a minor is a parent, the minor parent is capable of consenting to the care of his/her child, unless legal custody has been awarded by a court to someone other than the minor parent. If this is the case, the legal custodian of the child is the appropriate person to consent to the child's care.

Although a minor parent is able to consent to the care of his/her child, the minor may **not** consent to his/her own care unless he/she may consent as an adult for some other reason, e.g. marriage, legal emancipation, statutory exceptions, etc.

**STATUTORY EXCEPTIONS:
MINORS IN
MILITARY SERVICE**

If a minor is on active duty in a branch of the United States military, then the minor is treated as an adult and may consent to medical care or treatment.

**STATUTORY EXCEPTIONS:
INPATIENT PSYCHIATRIC TREATMENT
OF MINORS**

Minors who are 14 years of age or older may be admitted to a mental health facility on the *joint* application and consent of the minor and the parent. The minor must participate in the decision to obtain in-patient psychiatric treatment. (Reference: Virginia Code §16.1-338)

<p style="text-align: center;">SPECIAL CONSIDERATION: CONSENT ISSUES WITH MINORS</p>

(Reference: Virginia Code §54.1-2969)

- ◆ A *child left in the temporary custody of another* may be treated in the absence of parental consent only if:
 - The parent left written authorization with the temporary custodian of the child to consent to medical care or treatment.
 - A medical emergency exists creating an exception to the need for consent to care or treatment.

- ◆ Consent is given by an authorized representative of the Department of Social Services when a *child is in the custody of Social Services*. Parental consent is not valid when Social Services has taken custody of the minor.

- ◆ A *non-custodial parent is not authorized* to consent to his/her minor child's medical care or treatment. Consent must be sought from the custodial parent, except in the case of an emergency.

- ◆ When *two parents have custody of a minor child and they disagree* on what medical care or treatment should be provided, the law provides that only one parent's consent is required. However, where there is true conflict and significant care issues, consideration should be given to seek a court order for reasonable and necessary medical care or treatment for the minor child.

**SPECIAL CONSIDERATION:
*REFUSAL OF TREATMENT FOR
MINORS***

A parent or legal guardian of a minor may refuse to consent to medical care or recommended treatment for a minor child. If a health care provider believes the decision to refuse care or treatment is not in the minor's best interests and has exhausted all efforts to mediate the issues, a court order authorizing care may be sought. If there is a medical emergency which requires care immediately, the physician may choose to provide treatment over the objection of the parent and, after the fact, if challenged in court, defend the decision to provide care. Whenever a court order is necessary, it should be sought in advance of treatment.

Court Order: The State may order medical care or treatment for a seriously ill minor over the objections, religious or otherwise, of the minor's parents. The court will balance five considerations in making its decision:

- child's age
- risks of treatment
- benefits of treatment
- likelihood of benefit being achieved
- likelihood of serious consequence if treatment is withheld

**SPECIAL CONSIDERATION:
*ABORTION FOR MINORS***

A physician may not perform an abortion on an unemancipated minor unless notice has been given to an authorized person, with a few exceptions. The law defines "authorized person" as a parent or legal guardian or a person standing in *loco parentis*, including grandparents or adult siblings with whom the minor resides regularly and customarily and who has care and control of the minor.

Proper notice is achieved when:

- ◆ the physician notifies an authorized person by telephone or in person at least 24 hours before performance of an abortion;
- ◆ after a reasonable effort to notify an authorized person by telephone or in person, the physician mails notice by certified mail with return receipt requested at least 72 hours prior to performance of an abortion;
- ◆ at least one authorized person accompanies the minor, or
- ◆ the minor delivers a written statement that an authorized person knows of the minor's intent to have an abortion, signed by the authorized person and witnessed by a competent adult.

Exceptions: Notice of an authorized person is not required when:

- ◆ the minor delivers a court order authorizing an abortion for the minor;

- ◆ the minor asserts she is abused or neglected and the physician has reason to suspect the assertion is true and reports the abuse or neglect to the Department of Social Services;
- ◆ the abortion is medically, immediately necessary to avert the minor's death; or
- ◆ there is insufficient time to obtain either notice or judicial authorization without creating serious risk of substantial physician impairment.

All exceptions require that the attending physician certify the facts justifying an exception in the minor's medical record.

(Reference: Virginia Code §16.1-241)

**SPECIAL CONSIDERATION:
*PATIENTS WITH LIMITED ENGLISH
PROFICIENCY***

Patients with limited English proficiency may need special assistance to insure they received adequate informed consent. The Medical Center provides, free of charge, 24-hour access to interpretive services (in-person, telephonic, or electronic) for all limited English speaking patients. Additionally, most, if not all of the departmental consent forms should be translated into Spanish and available. Whenever possible it is advisable to have non-family members serve as interpreters, and minor children should never be used as interpreters.

INCOMPETENTS

“Incapable of making an informed decision” means an adult has been found unable to understand the nature, extent or probable consequences of a proposed treatment, or unable to make a rational evaluation of the risks and benefits of the proposed treatment as compared with the risks and benefits of alternatives to that treatment. Persons with dysphasia or other communication disorders who are mentally competent and able to communicate shall not be considered incapable of giving informed consent. **(Reference: Virginia Code §37.2-1100)**

Any person may request authorization of a specific treatment, or course of treatment, for an adult person by filing a petition in the circuit court. **(Reference: Virginia Code §37.2-1101)**

Prior to authorizing treatment, the court shall find:

- ◆ there is no legally authorized person available to give consent;
- ◆ the person who is the subject of the petition is incapable either of making an informed decision regarding a specific treatment or course of treatment or is physically or mentally incapable of communicating such a decision;
- ◆ the person who is the subject of the petition is unlikely to become capable of making an informed decision or of communicating an informed decision within the time required for decision; and the proposed treatment or course of treatment is in the best interest of the patient. However, the court shall not authorize a proposed treatment or course of treatment which is proven by a preponderance of the evidence to be contrary to the

person's religious beliefs or basic values unless such treatment is necessary to prevent death or a serious irreversible condition. The court shall take into consideration the right of the person to rely on non-medical, remedial treatment in the practice of religion in lieu of medical treatment.

Upon the advice of a physician who has attempted to obtain consent and upon a finding of probable cause to believe that an adult person within the court's jurisdiction is incapable of making an informed decision regarding treatment of a physical or mental disorder, or is incapable of communicating such a decision due to a physical or mental disorder, and that the medical standard of care calls for treatment of the disorder within the next 24 hours to prevent death, disability, or a serious irreversible condition, the court may issue an order authorizing temporary detention of the person by a hospital emergency room or other appropriate facility and authorizing such treatment. If before completion of authorized treatment, the physician determines that a person subject to a temporary detention order has become capable of making and communicating an informed decision, the physician shall rely on the person's decision on whether to continue treatment. If before issuance of a temporary detention order or during its period of effectiveness, the physician learns of an objection by a member of the person's immediate family to the treatment, he shall so notify the court. The courts shall consider the objection in determining whether to issue, modify or terminate the temporary detention order.

(Reference: Virginia Code §37.2-1101)

<p style="text-align: center;">PATIENTS ADJUDICATED INCOMPETENT</p>
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- ◆ An *incapacitated person* means an adult who has been found by a court to be incapable of receiving and evaluating information effectively or responding to people, events or environments to such an extent that the patient lacks the capacity to either:
 - meet the essential requirements for his/her health, care, safety, or therapeutic needs without the assistance or protection of a guardian, or
 - manage property or financial affairs or provide for his/her support or for the support of his/her legal dependents without the assistance or protection of a conservator.

(n.b., a finding that the individual displays poor judgment, alone, shall not be considered sufficient evidence that the patient is an incapacitated person.)

(Reference: Virginia Code §37.2-1100)

- ◆ A *guardian* is a person appointed by a court who is responsible for the personal affairs of an incapacitated persons, including responsibilities for making decision regarding the person's support, care, health, safety, habilitation, education and therapeutic treatment.
- ◆ A *limited guardian* is a person appointed by a court who has only those responsibilities for the personal affairs of an incapacitated person as specified in the court's order of appointment.

- ◆ If treatment is an extraordinary, irreversible procedure that would effect the patient's bodily integrity (such as amputation or psychosurgery), a court order may be required even where the legal guardian has consented to the surgery.

- ◆ Courts generally will not authorize care that is not indisputably necessary and advisable.

- ◆ Some courts have found that incompetent (incapacitated) patients have a right to choose whether to accept or reject treatment where such treatment is life sustaining.

INSTITUTIONALIZED PATIENTS

- ◆ Institutionalized patients, voluntarily or involuntarily committed, are not treated the same as those adjudicated legally incompetent.
- ◆ A person is committed based on a finding by a court of probable cause to believe that the person is mentally ill or in need of hospitalization, and that the person presents an imminent danger to self or others as a result of mental illness, or is so seriously mentally ill as to be substantially unable to care for him/herself.
- ◆ Even a person involuntarily committed may be competent to decide (consent to) his/her medical care or treatment.
- ◆ When found not competent to consent, substituted consent should be sought.
- ◆ Involuntarily committed patients have been found to be protected under the 14th Amendment Privacy Rights of the Constitution, which require reasonably safe conditions of confinement, freedom from unreasonable bodily restraints, and minimally adequate training or habilitation. Confinement must be by the least restrictive means.

(Reference: Virginia Code §37.2-808)

**SUBSTITUTED CONSENT
PATIENTS LACKING ABILITY TO
CONSENT**

- ◆ **General Rule:** Substituted consent is first sought from the next of kin, but if not available, a court order authorizing care or treatment should generally be sought.

- ◆ When two or more person with primary and equal decision-making authority disagree, the attending physician may rely on the authorization of a majority of the reasonably available members. If efforts to reach a consensus have be exhausted and there is an equal split of decision-making regarding treatment decisions, the best approach is to seek a court order authorizing care.

- ◆ Consideration in entering a court order:
 - that there is no legally authorized person available to give consent;
 - that the person who is the subject of the petition is incapable either of making an informed decision regarding a specific treatment or course of treatment or is physically or mentally incapable of communicating such a decision;
 - that the person who is the subject of the petition is unlikely to become capable if making an informed decision or of communicating an informed decision within the time required for the decision; and
 - that the proposed treatment or course of treatment is in the best interest of the patient. However, the court shall not authorize a proposed treatment of course of treatment which

is proven by a preponderance of the evidence to be contrary to the person's religious beliefs or basic values unless such treatment is necessary to prevent death or a serious irreversible condition. The court shall take into consideration the right of the person to rely on non-medical, remedial treatment in the practice of religion in lieu of medical treatment.

See also *Advance Directives* and *Power of Attorney* for related information.

(Reference: Virginia Code §37.2-1101)

ADULT PATIENTS LACKING ABILITY TO CONSENT

◆ Patient has an Advance Directive:

Generally, follow the decisions of the patient expressed in an appropriately completed and authorized Advance Directive. (Refer to Medical Center Policy 0142.)

◆ Patient does not have an Advance Directive:

Consent shall be obtain from the following, in order of priority: (if person in listed category is unavailable or unwilling to make decisions, go to the next category):

- legally appointed guardian;
- spouse unless divorce proceedings have been initiated;
- adult child;
- parent;
- adult sibling;
- any other relative.

If there are three or more individuals in a category, decision of majority will govern.

- ◆ Patient does not have an Advance Directive and there is no surrogate decision maker:
 - Seek judicial treatment order. (Refer to Medical Center Policy 0140.)

PATIENTS UNDER AGE 18

- ◆ ***General Rule***, unless exceptions below apply:
 - Consent must be obtained from at least one of a minor's biological or adoptive parents or a legally appointed guardian.
- ◆ Minors who have decision making capacity can give consent for certain treatment:
 - medical or health services needed to diagnose or treat venereal disease or other infectious/contagious disease that is reported to the Virginia Department of Health;
 - medical or health services required in the case of birth control, pregnancy or family planning except for sexual sterilization. Consent for abortion must be obtained as required by Virginia law;
 - medical or health services needed for outpatient care, treatment or rehabilitation of substance abuse;
 - medical or health services needed for outpatient care, treatment or rehabilitation for mental illness or emotional disturbance.

- ◆ Minors who have decision making capacity and are married:
 - Consent for all treatment for themselves.

- ◆ Emancipated minors have decision making capacity:
 - Upon presentation of a court order documenting emancipation, can provide consent for all treatment for themselves.

- ◆ Pregnant minors who have decision making capacity:
 - Consent for hospital admission and all treatment for themselves and her child provided during the delivery of the child. Consent to subsequent surgical and medical treatment for the child.

ABORTION

- ◆ Virginia law requires that prior to performing an abortion (including inducing a miscarriage or terminating pregnancy in any other way) a physician must obtain an informed written consent of the pregnant woman, such consent is to include the nature of the proposed procedure to be utilized, and the risks in the woman's particular case for terminating or continuing the pregnancy.
- ◆ If a patient is incapacitated, then consent must be given in writing by the parent, guardian, committee or other person standing *in loco parentis*. (Reference: Virginia Code §18.2-76) Also, see section on *Minors*.
- ◆ Encouraging or promoting abortion or the inducing of a miscarriage is illegal in Virginia. (Reference: Virginia Code §18.2-76.1)
- ◆ *Partial Birth Abortion:* Except when necessary to save the life of the mother, partial birth abortions are illegal. If the medical necessity of a partial birth abortion is challenged, a physician may seek a review before a medical advisory committee. (Reference: Virginia Code §18.2-71.1)



BREAST TUMORS

(Reference: Virginia Code §54.1-2971)

The following specific language must be included in a consent form signed by the patient prior to being operated upon:

“CONSENT FOR TREATMENT OF BREAST TUMOR”

Option A and/or B Must Be Signed:

- A. I authorize Dr. _____ to perform a breast biopsy on the _____.
(right and/or left side)

Signature of Patient or Other
Authorized Person's Signature

- B. If it is determined that I have a malignant tumor in my breast or other breast abnormality requiring surgery, I authorize Dr. _____ to perform such operations or procedures, including breast removal, which are deemed necessary.

Procedure: _____

Signature of Patient or Other
Authorized Person's Signature

HIV TESTING

A finding that an individual is HIV positive carries immense social implications. Thus, Virginia law has sought to provide added protection to HIV individuals, and thus to HIV testing. *Virginia Code §32.1-37.2* sets forth specific informed consent requirements that must be met for HIV testing. These requirements are, as follows:

- ◆ Prior to performing the test, the person to be tested must be given an oral or written explanation of the meaning of the HIV test.
- ◆ Informed consent must be obtained before performing the test.
- ◆ Insurers requiring testing of an individual who has applied for accident, sickness or life insurance must comply with the requirements set forth above.
- ◆ Informed consent is implied when:
 - an individual is tested at an anonymous testing site;
 - blood specimens are drawn for routine diagnostic purposes are tested in order to conduct seroprevalence studies for HIV, if such studies are designed to prevent any specimen from being identified with any specific individual; or
 - when an individual donates blood.

- ◆ Test results are to be given in person with appropriate counseling. Appropriate counseling includes the meaning of the test results; the need for additional testing; the etiology, prevention and effects of HIV; availability of health care, mental health care and social services; the need to notify other exposed individuals of the results of the test; and the availability of the Department of Health in notifying such individuals.

- ◆ If a person's donated blood tests seropositive, the blood collection agency is not required to inform the individual of his/her HIV status face-to-face, but the blood collection agency must notify the Board of Health of its positive tests.

Virginia has also seen fit to deem consent to testing a person for HIV under certain circumstances, as set forth in *Virginia Code §32.1-45.1*, as follows:

- ◆ If a health care provider, or a person employed by or under his/her direction or control, is exposed to body fluids of a patient in a manner that may, according to CDC guidelines, transmit HIV, the patient whose body fluids were involved, is deemed to have consented to those fluids being tested. Except in an emergency, the health care provider is required to make the same disclosures normally required for requested HIV testing, as set forth in *Virginia Code §32.1-37.2* and as set forth above.

- ◆ If a patient is exposed to the body fluids of a health care provider, or any person employed by, or in the control of a health care provider, in any manner that may, according to CDC guidelines, transmit HIV, the person whose body fluids were involved shall be deemed to have consented to

- ◆ HIV testing and to release of such test results to the patient exposed.

The result of HIV tests are specifically protected as confidential pursuant to **Virginia Code §32.1-36.1**. The only persons who may receive the test results are as follows:

- ◆ The subject of the test or his/her legally authorized representative.

- ◆ Any person designated in a release signed by the subject of the test or his/her legally authorized representative.

- ◆ The Department of Health.

- ◆ Healthcare providers for purposes of consultation or providing care and treatment to the person who is the subject of the test.

- ◆ The parents of the subject of the test if the subject is a minor.

- ◆ The spouse of the subject of the test.

- ◆ Health care facility staff committees which monitor, evaluate, or review programs or services.
- ◆ Medical or epidemiological researchers for use as statistical data only.
- ◆ Health care providers for purposes of consultation or providing care and treatment to a child of a woman who, at the time of the child's birth, was known to be infected with HIV.
- ◆ Any person allowed access to such information by court order.
- ◆ Any facility which procures, processes, distributes or uses blood, other body fluids, tissues or organs.
- ◆ Any person authorized by law to receive such information.

It is imperative that these statutory requirements be met when testing for HIV. Cases have already proven that faulty consent in HIV cases can lead to large malpractice payments on behalf of involved doctors and hospitals.

HUMAN INVESTIGATION/ EXPERIMENTATION

The Department of Health and Human Services regulates medical experimentation. The primary regulation comes from the Institutional Review Board (IRB) of the Medical Center.

Informed consent must be obtained from a recipient of experimental treatment or a participant in a study. Consent shall include the following:

- ◆ A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
- ◆ A description of any reasonably anticipated discomforts and/or risks;
- ◆ A description of expected benefits;
- ◆ Disclosure of alternative procedures;
- ◆ An explanation of any costs, or compensation which may accrue to the person and, if applicable, the availability of third party reimbursement for the proposed procedures and protocols;
- ◆ A statement describing the extent to which confidentiality of patient information or records will be maintained;

- ◆ An explanation as to whether and what medical treatments are available if the patient suffers some adverse effect(s);
- ◆ An offer to answer any inquiries concerning the procedures; and,
- ◆ A statement that the patient is free to withdraw his/her consent and discontinue participation in the treatment or study at any time without prejudice to the patient.

If a subject is an incapacitated person, then informed consent is given by and an informed written consent is signed by the person's legally authorized representative and the signature is witnessed.

If a subject is a minor, who is otherwise capable of rendering informed consent, then informed consent is given by and an informed written consent is signed by both the minor and the legally authorized representative.

In both, the case of the incapacitated or minor subject, a legally authorized representative may not consent to non-therapeutic research unless it is determined by the human research committee that such research presents no more than a minor increase over minimal risk to the subject. (Reference: Virginia Code §37.1-162.18)

INFERTILITY TREATMENT

Before a physician commences treatment of a patient by in vitro fertilization, gamete intrafallopian tube transfer, or zygote intrafallopian tube transfer, including the administration of drugs for the stimulation or suppression of ovulation, the patient must have signed a consent form which includes a statement of the rate of success for the particular procedure at the clinic or hospital where the procedure is to be performed. The information disclosed to the patient shall include the testing protocol used to ensure that gamete donors are free from known infection with HIV, the total number of live births, and the number of live births as a percentage of completed retrieval cycles, and the rates for clinical pregnancy and delivery per completed retrieval cycle bracketed by age groups consisting of women under 30 years old, women 30 to 34 years old, women 35 to 39 years old, and women over 40 years old.

(Reference: Virginia Code §54.1-2971.1)

NON-THERAPEUTIC SEXUAL STERILIZATION

- ◆ A procedure for non-therapeutic sexual sterilization may be performed on any person 18 years old or older by any licensed physician after the person has requested the procedure in writing, received a reasonable and comprehensive medical explanation of the meaning and consequences of the procedure and alternative methods of contraception, provided that, if a person does not have any natural or adoptive children, the procedure may not be performed prior to 30 days from the date of the written request for the procedure. **(Reference: Virginia Code §54.1-2974)**

- ◆ If the person requesting the procedure is married, the spouse need *not* consent to the sterilization procedure. **(Reference: Virginia Code §54.1-2974)**

- ◆ A procedure for sexual sterilization may be performed on a *minor between the ages of 14 years and 18 years* 30 days or more after a court order authorizing a qualified physician to perform the sterilization has been entered, following a petition requesting the procedure be performed and a hearing in front of the judge has taken place in which the meaning, consequences and risks of the sterilization procedure are provided to the minor and his/her parents or guardian, and the child's interests and/or desires have been heard by the judge.

The court order shall state the date on and after which the sterilization operation may be performed. **(Reference: Virginia Code §54.1-2975)**

- ◆ A procedure for sexual sterilization may be performed on an adult incapable of giving consent 30 days or more after a court order authorizing a qualified physician to perform the sterilization has been entered, following the filing of a petition requesting the procedure be performed and a hearing in front of the judge has taken place in which the meaning, consequences and risk of the sterilization procedure are provided to the person to be sterilized, his/her guardian, spouse or parent (in order of priority), and the person has previously been found by a court to be incompetent or legally incapacitated to give consent and the court has fully considered the desires of the person to be sterilized. **(Reference: Virginia Code §54.1-2976)**

SURROGATE DECISION MAKING

Advance Directive: (Reference: Virginia Code §54.1-2982 & 2986) A voluntary, witnessed written document (declarant's signature must be witnessed by two persons who also sign the document), or a witnessed oral statement (made in the presence of two attending physicians and two witnesses), made by a competent adult, authorizing the providing, withholding or withdrawal of life-prolonging procedures in the event such person should have a terminal condition. This document or oral statement may indicate an agent to make decisions for them and is relied upon in the event a patient is no longer capable of making medical decisions.

If there is no *advance directive*, Virginia law has established a priority list for persons authorized to make decisions for an incompetent patient:

- a guardian;
- the patient's spouse;
- adult children
- parents;
- adult siblings;
- any other relative in descending order of blood relationship

Power of Attorney: Power of Attorney is a formal and legal document in writing, which authorizes another person to act as one's agent or attorney. The agent "attorney in fact" and his power is revoked on the death of the authorizing principal.

Durable Power of Attorney: Durable power of attorney exists when a person execute a power of attorney which will become or remain effective in the event he or she should later become incapacitated.

COURT HEARINGS

When consent disputes arise, which cannot be settled through discussion, mediation or other such measures, it may become necessary to request a court hearing to settle a consent issue. A hearing may be requested by contacting the Charlottesville City Magistrate's Office at (434) 977-0220.

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