Legally Authorized Representatives Under Federal and Texas Law[1]

The following information is provided to clarify the regulatory policy on legally authorized representatives and informed consent in research conducted at the University of Texas Health Science Center at San Antonio.

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Section 1 – Children and Consent to Research in Texas

The Common Rule and FDA regulations require parental or guardian consent for a child to participate in research, as well as the assent of the child.[2]

Who is a child?

The regulations define children as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."[3] This definition requires that one understand state law defining who is an adult, and also know when state law authorizes those who are not adults to make their own health care decisions.

Under Texas law, the following are considered adults, and thus are not children: [4]

(1) one who is 18 years of age or older; or
(2) someone under age 18 who has had the disabilities of minority removed by court order (what is commonly referred to as being "emancipated" though that word is not used in the statute). [Note: If there is a question as to whether a potential participant is emancipated, or whether the removal of disabilities was limited and does not include health care decision-making, the researcher should read the actual court order.]

Since a minor who is emancipated is legally considered an adult, any subsequent reference to the term "minor" is referring to a minor who is not emancipated.

Note that while the statues authorizing surrogates or a minor to consent on one's own speak in terms of treatment, these statutes also apply in the research setting since Texas does not have specific laws addressing consent for research (other than for foster children, as discussed infra). Special caution must be given before enrolling minors in research that imposes more than minimal risk but does not benefit, or offer the potential to benefit, the patient. Seek the guidance of the Director, Institutional Review Board, in such situations.

When may minors give consent without a surrogate?

There are times when minors can legally consent to medical care without a surrogate. While still considered children under state law, they are not "children" as that term is defined in the federal regulations since these individuals have reached the age (or are under other circumstances) to give legal consent to care for treatment, so they will be referred to as "minors" rather than "children." To be clear, minors in these situations are not emancipated; they simply have statutory authority to provide consent.

[2] 45 CFR § 46.408(b); 21 CFR § 50.55(e)
[3] 45 CFR § 46.402(a); 21 CFR § 50.3(o)
[4] Title 4, Tex. Health & Safety Code § 313.002(1); Title 6, Tex. Civ. Practice & Remedies Code § 129.001. A minor can have the disabilities of minority removed by a legal proceeding under Title 2, Tex. Family Code § 31.001

In Texas, a minor may consent to medical, dental, psychological, and surgical treatment for him or herself, and hence may also consent to research for the same circumstances/treatment, if the minor is:[5]

(1) is on active duty with the armed services of the United States of America;
(2) is:
    a. 16 years of age or older, and
    b. residing separate and apart from the his/her parents, managing conservator, or guardian (with or without consent and regardless of duration), and
    c. managing his/her own financial affairs (regardless of the source of the income);
(3) is seeking the diagnosis and treatment of an infectious, contagious, or communicable disease that is required by law or a rule to be reported by the licensed physician or dentist to a local health officer or the Texas Department of Health, including all diseases within the scope of Section 81.041, Health and Safety Code;
(4) is unmarried and pregnant and consents to hospital, medical, or surgical treatment, other than abortion,
related to the pregnancy;[6]
(5) is seeking an examination and treatment for drug or chemical addiction, drug or chemical dependency, or any other condition directly related to drug or chemical use; or
(6) is serving a term of confinement in a facility of the Texas Department of Criminal Justice.[7]

A provider may rely on the written statement of the child containing the grounds on which the child has capacity to consent to the medical treatment.[8]

The statute that authorizes a minor to consent contains an additional situation which can sometimes be the cause of confusion. A minor who is unmarried, is the parent of a child, and has actual custody of his or her child, may consent to medical, dental, psychological, or surgical treatment for the child – but not necessarily for him or herself.[9] Unless the minor's circumstances fall into one of the categories in the list above, or the minor is emancipated, he/she is in the unique situation of being able to consent to the medical care for his/her child, but not for himself. Simply being a parent does not in and of itself make one an adult or give one the authority to make health care decisions for oneself.

While not a consent issue, it is important to note that even though minors under these circumstances can consent to their own treatment, a health care provider may advise the minor's parent, managing conservator, or guardian of the treatment given and/or needed, even without the consent of the minor.[10]

Who may serve as a surrogate for a child who cannot consent on his own?

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[5] Title 2, Tex. Family Code § 32.003

[6] This raises the question of who can give consent for a minor who is *married*, pregnant, not in any of the other categories (e.g., still living at home) and not emancipated—technically under state law it would be the minor's parent but I do not know how this is applied in practice. Fortunately this situation will probably never arise, but if it does, seek guidance prior to enrolling the person in a trial.

[7] Unless the treatment would constitute a prohibited practice under Section 164.052(a)(19), Occupations Code (which deals with disciplinary actions and license denials).

[8] Title 2, Tex. Family Code §32.003(f).

[9] Title 2, Tex. Family Code §32.003(a)(6). Note that while this statute only applies to an *unmarried* minor, under Title 5, Tex. Family Code §151.001(6), a *married* minor parent has the right to give consent to treatment for his/her child.

[10] Title 2, Tex. Family Code §32.003(d). This provision of state law was not preempted by the Privacy Rule to the Health Insurance Portability an Accountability Act (HIPAA) at 45 C.F.R. § 164.502(g)(3)(ii)(A) according to the Texas Attorney General (*see* http://www.oag.state.tx.us/notice/hipaa.pdf).

If the research is not of the type where a minor can consent on his own, then the minor is a "child" under the federal regulations, and a surrogate must give consent.[11] The federal regulations allow a "parent" or "guardian" to serve as the surrogate.[12]

State law defines a "parent" as:

> "the mother, a man presumed to be the father, a man legally determined to be the father, a man who has been adjudicated to be the father by a court of competent jurisdiction, a man who has acknowledged his paternity under applicable law, or an adoptive mother or father.[13]

The term "guardian" in the federal regulation means anyone who is authorized to consent on behalf of a child to general medical care under state or local law.[14] Do not be confused by this unconventional use of the term; it does not limit surrogacy to only those who are court-appointed guardians of a minor ward, which is to whom that term typically refers.

Parents:

Parents always have the highest "priority" in terms of who may act as a surrogate. A parent has the right to consent to medical care, absent a court order affecting rights of the parents with regards to health care decisions; relinquishment of parental rights; or an affidavit by the parent designating another as the managing conservator.[15]

For research involving no greater than minimal risk to participants,[16] or in which the research has greater than minimal risk but presents the prospect of direct benefit to the individual participant,[17] the IRB may find that the permission of one parent is sufficient.[18] This is generally consistent with state law, although in situations where divorced parents are appointed as joint managing conservators, they share all rights and duties with regard to the children, and thus the consent of both parents should be obtained if feasible.[19]

For research involving greater than minimal risk with no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the participant's disorder or condition,[20] both parents must give their consent.[21] Likewise, for research not otherwise approvable but which presents an opportunity to understand, prevent, or alleviate a serious

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[11] 45 CFR § 46.404-.408; 21 CFR § 50.51-.55
[12] 45 CFR § 46.404-.408; 21 CFR § 50.51-.55
[13] Title 5, Tex. Family Code § 101.024. Texas law has a broader definition than the federal regulations, which define "parent" as the "child's biological or adoptive parent" (45 CFR 46.402(d); 21 CFR 50.3(p)). Because state law gives a "parent" the right (Tex. Family Code § 151.001(a)(6)) to make health care decisions under state law, we cannot impinge the rights of non-biological and non-adoptive parents who are parents as the state defines that term. For purposes of establishing, determining the terms of, modifying, or enforcing an order, a reference in this title to a parent includes a person ordered to pay child support under Section 154.001(a-1) or to provide medical support or dental support for a child.
[14] 45 CFR 46.402(e), 21 CFR § 50.3(s)
[15] Title 5, Tex. Family Code §151.001(6)
[16] Research under 45 CFR § 46.404 and/or 21 CFR § 50.51
[17] Research under 45 CFR § 46.405 and/or 21 CFR § 50.52
[18] 45 CFR § 46.408(b); 21 CFR § 50.55(e)(1)
[19] Title 5, Tex. Family Code § 101.016
[20] Research under 45 CFR § 46.406 and/or 21 CFR § 50.53
[21] 45 CFR § 46.408(b); 21 CFR § 50.55(e)(2)

problem affecting the health or welfare of children,[22] both parents must give their consent.[23] The consent of just one parent will be sufficient for these categories of research when the other parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.[24] In situations where the parents are divorced or otherwise have a judicial determination of their rights and responsibilities, the research team should ask the parent about the nature of his custodial relationship. If there is doubt as to the authority of a parent to consent on behalf of the child, the research team may need to review the court order establishing conservatorship. A parent who is appointed as sole managing conservator of a child has the exclusive right to consent to medical, dental, and surgical treatment, including treatment involving invasive procedures, and psychiatric and psychological care, unless limited by court order.[25] A parent appointed as a "possessory" conservator of a child (one who has a "standard possession order") has the right during the period that the parent has possession of the child to consent to medical and dental care which does not involve invasive procedures.[26] Note that this authority does not extend to psychiatric or psychological care. The possessory conservator, unless restricted by court order, may also consent to medical, dental, and surgical treatment during an emergency involving an immediate danger to the health and safety of the child.[27] If the parents are appointed as joint managing conservators, they share all rights and duties, and the research team will need the consent of both parents.[28]

Other surrogates:

If the child does not have a living parent, or if the parent is not able to give consent, then other surrogates potentially may be available.

A "guardian," as the term is typically used and defined as a person appointed by a court under state law with the authority and duty to care for a ward, has the authority to consent to medical, psychiatric, and surgical treatment, other than inpatient psychiatric commitment (but see also the separate section on wards of state agencies, infra). [29]

A non-parent who is appointed as the sole managing conservator of a child has the right "to consent for the child to medical, psychiatric, psychological, dental, and surgical treatment and to have access to the child's medical records."[30]

Texas has a statutory list of surrogates who may consent to medical, dental, psychological, and surgical treatment of a child (except immunizations – that's a separate section infra) when the person having the right to consent as otherwise provided by law (i.e., the parent, guardian, or managing conservator) cannot be contacted and that person has not given actual notice to the contrary. These surrogates should be used with some reservation, however, depending on the nature of the research (i.e., potential for therapeutic benefit in relation to risks involved) and the reason the parent, guardian, or managing conservator is unavailable. The surrogates, in order of priority, are: [31]

[22] Research under 45 CFR § 46.407 and/or 21 CFR § 50.54
[23] 45 CFR § 46.408(b); 21 CFR § 50.55(e)(2)
[24] 45 CFR § 46.408(b); 21 CFR § 50.55(e)(2)
[25] Title 5, Tex. Family Code § 153.132(2), (3)
[26] Title 5, Tex. Family Code § 153.074(2); Title 5, Tex. Family Code §101.029
[27] Title 5, Tex. Family Code § 153.073(a)(8)
[28] Title 5, Tex. Family Code § 101.016
[29] Tex. Probate Code, Chapter XIII, §767(a)(4)
[30] Title 5, Tex. Family Code § 153.371(4)
[31] Title 2, Tex. Family Code § 32.001

1. a grandparent of the child;
2. an adult brother or sister of the child;
3. an adult aunt or uncle of the child;
4. an educational institution in which the child is enrolled that has received written authorization to consent from a person having the right to consent;
5. an adult who has actual care, control, and possession of the child and has written authorization to consent from a person having the right to consent;
6. a court having jurisdiction over a suit affecting the parent-child relationship of which the child is the subject;
7. an adult responsible for the actual care, control, and possession of a child under the jurisdiction of a juvenile court or committed by a juvenile court to the care of an agency of the state or county;
8. a peace officer who has lawfully taken custody of a minor, if the peace officer has reasonable grounds to believe the minor is in need of immediate medical treatment; or
9. The Texas Youth Commission may consent to the medical, dental, psychological, and surgical treatment of a child committed to it under Title 3 when the person having the right to consent has been contacted and that person has not given actual notice to the contrary.

Who may give consent for research involving immunizations?

If the research involves immunizations, there is a different statute and thus a different list of who may give consent for the child and under what circumstances: [32]

(1) A parent;
(2) a guardian of the child (as appointed by court under state law) (but see separate section on wards of the state, infra); or
(3) a person authorized under the law of another state or a court order to consent for the child.
(4) If the persons listed above are not available and the authority to consent is not denied the following may give consent:
    a. a grandparent of the child;
    b. an adult brother or sister of the child;
    c. an adult aunt or uncle of the child;
    d. a stepparent of the child;
    e. an educational institution in which the child is enrolled that has written authorization to consent for the child from a parent, managing conservator, guardian, or other person who under the law of another state or a court order may consent for the child;
    f. another adult who has actual care, control, and possession of the child and has written authorization to consent for the child from a parent, managing conservator, guardian, or other person who, under the law of another state or a court order, may consent for the child;
    g. a court having jurisdiction of a suit affecting the parent-child relationship of which the minor is the subject;
    h. an adult having actual care, control, and possession of the child under an order of a juvenile court or by commitment by a juvenile court to the care of an agency of the state or county; or
    i. an adult having actual care, control, and possession of the child as the child's primary caregiver.

A person otherwise authorized to consent may not consent for the child if the person has

[32] Title 2, Tex. Family Code § 32.101

actual knowledge that a parent, managing conservator, guardian of the child, or other person who under the law of another state or a court order may consent for the child and has expressly refused to give consent to the immunization, has been told not to consent for the child, or has withdrawn a prior written authorization for the person to consent.

As is the case with surrogate consent for research that does not involve immunizations, researchers need to exercise caution when a parent, guardian, or managing conservator is only temporarily unavailable, especially in consideration of the benefits and risks of participation.

Is consent required under emergency circumstances?

No. Consent is not required for a minor who is suffering from what reasonably appears to be a life-threatening injury or illness and whose parent(s), managing or possessory conservator, or guardian is not present.[33]

Who may give consent, and to what types of research, if the child is a ward of the state or other agency, institution, or entity?

Federal regulations define a "ward" as "a child who is placed in the legal custody of the State or other agency, institution, or entity, consistent with applicable Federal, State, or local law." [34]

A "ward" as used in this Section then includes foster children,[35] children residing at a Texas Youth Commission facility,[36] and children who are otherwise in the care and control of the state or a state agency.

For research involving no greater than minimal risk to participants,[37] or in which the research has greater than minimal risk but presents the prospect of direct benefit to the individual participant,[38] there are no additional protections in addition to the standard rules for consent as covered in the sections below for foster children and children in the custody of the Texas Youth Commission apply.

For research involving greater than minimal risk with no prospect of direct benefit to individual subjects, [39] and for research not otherwise approvable but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children,[40] a child who is a ward can only be included if the research is: [41]

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[33] Title 9, Tex. Health & Safety Code § 773.008(3)

[34] 21 CFR § 50.3(q). This definition is different than how it is typically defined (Texas uses this term to refer to one for whom a legal guardian has been appointed by a court (Tex. Probate Code § 601(31))). Interestingly, the Common Rule (45 CFR Part 46) does not separately define the term though it makes clear in 45 CFR § 46.409(a) that the special rules for "wards" apply to those who are wards of the state, an institution, or an entity, rather than a ward of a person who has been appointed as a guardian.

[35] A foster child is in the managing conservatorship of the Department of Family and Protective Services (Title 5, Tex. Family Code, §266.001(2), (4)) was renumbered as Chapter 267, §§ 267.001 and 267.002, by Acts 2007. "Managing conservatorship" means the relationship between a child and a managing conservator appointed by court order (Title 5, Tex. Family Code § 101.019). Given the extensive rights and duties of a non-parental managing conservator (see Title 5, Tex. Family Code § 153.371) it certainly appears foster children are under the "legal custody" of a state agency.

[36] Title 3, Human Resources Code, §§ 63.001-63.028

[37] Research under 45 CFR § 46.404 and/or 21 CFR § 50.51

[38] Research under 45 CFR § 46.405 and/or 21 CFR § 50.52

[39] Research under 45 CFR § 46.406 and/or 21 CFR § 50.53

[40] Research under 45 CFR § 46.407 and/or 21 CFR § 50.54

[41] 45 CFR § 46.409(a); 21 CFR § 50.56(a)

(1) Related to their status as wards; or
(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

For such research, the IRB shall require appointment of an advocate for each child who is a ward.[42] The rules on who may give consent for foster children and children in the custody of the Texas Youth Commission as covered in the sections below will then apply.

Who may give consent, and to what types of research, for foster children?

Texas has a statute that specifically addresses the enrollment and participation of a foster child in a "drug research program."[43] A foster child is one who is in the managing conservatorship of the Department of Family and Protective Services.[44]

A "drug research program" is"[a]ny clinical trial, clinical investigation, drug study, or active medical or clinical research that has been approved by an institutional review board in accordance with the standards provided in the Code of Federal Regulations, 45 C.F.R. Sections 46.404 through 46.407, regarding: (A) an investigational new drug; or (B) the efficacy of an approved drug."[45]

The statute does not apply to the following:[46]

(1) a drug research study regarding the efficacy of an approved drug that is based only on medical records, claims data, or outcome data, including outcome data gathered through interviews with a child, caregiver of a child, or a child's treating professional;
(2) a retrospective drug research study based only on medical records, claims data, or outcome data; or
(3) the treatment of a foster child with an investigational new drug that does not require the child's enrollment or participation in a drug research program.

The following persons can authorize a foster child's participation in a "drug research program":

(1) the child's parent (an actual parent as defined by Texas law, supra, not the foster parent) who is authorized by court order to make medical decisions for the child in accordance with Texas Family Code § 266.004;[47] or
(2) A person acting under a court order granting authority to enroll the child in a drug research program.[48]

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[42] 45 CFR § 46.409(b); 21 CFR § 50.56(b). Please consult the regulations for additional details on the requirements for advocates.
[43] Title 5, Tex. Family Code § 266.0041
[44] Title 5, Tex. Family Code, §266.001(2), (4) §§ 266.001 and 266.002 was renumbered as Chapter 267, §§ 267.001 and 267.002, by Acts 2007
[45] Title 5, Tex. Family Code § 266.001(2a) §§ 266.001 and 266.002 was renumbered as Chapter 267, §§ 267.001 and 267.002, by Acts 2007
[46] Title 5, Tex. Family Code § 266.0041(k)
[47] Title 5, Tex. Family Code § 266.0041(a)
[48] Title 5, Tex. Family Code § 266.0041(a). The court must consider many factors, including whether it is in the best interest of the child and whether the researchers appropriately informed the child of the risks and benefits of the trial. The court must appoint an independent medical advocate for the child as part of the proceeding to determine whether to allow enrollment. Anyone having authority to consent to medical treatment under Chapter 266 of the Family Code can petition the court for an order authorizing enrollment in a research study.

If the child is 16 years of age or older and determined by the court (as documented in a court order) to have capacity to consent to medical treatment,[49] the child may also consent to participation in a drug research program, provided that prior to enrolling the child the person conducting the research program must:

(1) inform the foster child in a developmentally appropriate manner of the expected benefits of participation in the drug research program, any potential side effects, and any available alternative treatments; and

(2) receive written informed consent to enroll the foster child for participation in the drug research program.[50]

If the study does not meet the definition of "drug research program" then the persons authorized to give consent for medical treatment may authorize participation unless the statute is clearly inapplicable, in keeping with the usual interpretation of Texas law on surrogate consent for treatment and how it relates to research. These individuals are:

(1) An individual designated by name in a court order, including a foster parent or parent; or
(2) The Department of Family and Protective Services.[51]

The laws with regards to consent for medical care for a foster child do not limit the ability of other persons, such as grandparents, etc., to consent to medical, dental, psychological, and surgical treatment by grandparents, etc. under Chapter 32 of the Family Code, as covered in the section on "Other Surrogates" above.[52]

Please also note limitations on wards participating in research as covered supra.

While not a consent issue, please note that no person may receive a financial incentive or any other benefit for recommending or consenting to the enrollment and participation of a foster child in a drug research program.[53] Also note that the Department of Family and Protective Services must file reports regarding the number of foster children enrolled in programs, the purpose of each program, and the number of children for whom an order was issued.[54]

Who can consent for children in a Texas Youth Commission facility?

The Texas Youth Commission may provide consent to any medical or psychiatric treatment that is necessary.[55] The commission may also consent to the immunization of a child committed to it if a parent, managing conservator, or guardian of the minor or other person who, under the law of another state or court order, may consent for the minor has been contacted and refuses to consent and does not expressly deny to the Texas Youth Commission the authority to consent for the child.[56]

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[49] Under Title 5, Tex. Family Code § 266.010
[50] Title 5, Tex. Family Code § 266.0041(h)
[51] Title 5, Tex. Family Code § 266.004
[52] Title 5, Tex. Family Code § 266.002 §§ 266.001 and 266.002 was renumbered as Chapter 267, §§ 267.001 and 267.002, by Acts 2007
[53] Title 5, Tex. Family Code § 266.0041(m)
[54] Title 5, Tex. Family Code § 266.0041(l)
[55] Title 3, Tex. Human Resources Code § 61.076(a)(3) Renumbered to Tex. Hum. Res. Code § 244.006 by Acts 2011, 82nd Leg., ch. 85 (S.B. 653), § 1.007, effective September 1, 2011.
[56] Title 2, Tex. Family Code §32.101(d)

Please also note limitations on wards participating in research as covered supra.

While not a consent issue, it is important to note that the commission must keep records relating to children committed to it that participate in research programs or studies, and must submit reports showing the number of children participating in such programs; the type of research program or study in which each is participating; the name of the principal investigator conducting the study; and the entity sponsoring the research program or study.[57]

Under what circumstances can the IRB waive consent for a child's participation?

Under the Common Rule, the IRB may waive the consent requirements if the IRB determines that "a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children),"[58] however this exception does not apply to drug or device studies governed by the FDA regulations.[59]
The IRB must ensure that an appropriate mechanism for protecting the participants is substituted.[60] The Common Rule is basically consistent with state law, which does not require the consent of the child or a surrogate decision- maker to examine the child when there are reasonable grounds to believe that a child's physical or mental condition has been adversely affected by abuse or neglect.[61] However, unless consent is otherwise obtained, a provider may not examine a child who is 16 years of age or older and who refuses to consent, or when consent is prohibited by a court order.[62]

Who may give consent for a minor when the research involves stem cells?

If the patient is a minor or lacks the mental capacity to provide informed consent, a parent, guardian, or conservator may provide informed consent on the patient's behalf.

Do you have a unique situation not adequately covered in this policy?

If so, please consult with the Director, Institutional Review Board for guidance. Enrolling a participant without adequate consent can subject the provider, employee and/or the institution to a lawsuit, so do not hesitate to seek guidance when an issue is not clear.

[57] Title 3, Tex. Human Resources Code § 61.0763 "Reporting Concerning Research Programs or Studies" (NOTE that there are two sections number as 61.0763 in the Human Resources Code). Renumbered to Tex. Hum. Res. Code § 244.006 by Acts 2011, 82nd Leg., ch. 85 (S.B. 653), § 1.007, effective September 1, 2011.
[58] 45 CFR § 46.408(c)
[59] 21 CFR Part 50 does not contain a similar waiver provision, and state law's exception is for examinations, not medications or devices.
[60] 45 CFR § 46.408(c)
[61] Title 2, Tex. Family Code § 32.005
[62] HB810 (2017)

Section 2– Adults and Consent to Research in Texas:

Adults and Consent to Research in Texas:

[Note that there are specific sub-sections within this section addressing adult surrogate consent at the VA and adult surrogate consent in UTHSCSA/VA mixed studies.]

Federal regulations require that an investigator get the "legally effective" consent of a participant or the participant's "legally authorized representative" in order for the person to participate in a clinical trial.[63]

The federal regulations define "legally authorized representative" as "an individual or judicial or other body authorized under applicable law [emphasis added] to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research."[64]

"Applicable law" for UTHSCSA is the law of the State of Texas.

Who can serve as the Legally Authorized Representatives (LAR) for Adult Patients in a Non-Emergent Situation?

Texas law allows surrogate consent for treatment for an adult patient who is "comatose, incapacitated, or otherwise mentally or physically incapable of communication."[65] "Incapacitated" is defined as "lacking the ability, based on reasonable medical judgment, to understand and appreciate the nature and consequences of a treatment decision, including the significant benefits and harms of and reasonable alternatives to any proposed treatment decisions."[66] Adults are presumed to have capacity, even those with a diagnosed mental illness.[67] In any case where there is question as to the patient's capacity to give informed consent, prior to enrolling the patient in a clinical trial the research team must consult the appropriate health care provider(s) to evaluate the patient.

While the statues authorizing surrogates speak in terms of treatment, this has been interpreted to include research.[68] Special caution must be given before enrolling an incapacitated patient in research that imposes more than minimal risk but does not benefit,

[63] 45 CFR § 46.116; 21 CFR § 50.20 Subpart A of Part 46 was revised at 82 FR 7149, 7273, Jan. 19, 2017, effective Jan. 19, 2018. 83 FR 2885,Jan. 22, 2018, provides: "This interim final rule is effective on July 19, 2018. This interim final rule delays until July 19, 2018, the effective date and general compliance date of the final rule published in the Federal Register (82 FR 7149, Jan. 19, 2017) and of the final rule published by the Consumer Product Safety Commission in the Federal Register (82 FR 43459, Sept. 18, 2017)." For the convenience of the user, Subpart A has been set out twice. The first version is effective until July 19, 2018. The second version is effective July 19, 2018.]

[64] 45 CFR § 46.102(c); 21 CFR § 50.3(l)

[65] Title 4, Tex. Health & Safety Code § 313.004(a) 2011 amendment, added "or an adult inmate of a county or municipal jail" in the introductory language of (a)

[66] Title 4, Tex. Health & Safety Code § 313.002(5)

[67] "There is a rebuttable presumption that a person is mentally competent unless a judicial finding to the contrary is made under the Texas Probate Code" (Title 7, Tex. Health & Safety Code § 576.002(b)).

[68] The UT System Office of General Counsel interpreted Chapter 313 of the Health & Safety Code, which allows statutory surrogate consent for treatment, to apply in the research context.

or offer the potential to benefit, the patient. Seek the guidance of the Director, Institutional Review Board, in such situations.

First and foremost, the agents have the authority to act as the LAR, unless the court order and/or document(s) granting such authority contain limitations regarding healthcare or research:

(1) a patient's legal guardian with the authority to make decisions regarding medical treatment;[69] or
(2) a person designated as a surrogate decision-maker by the patient in a medical power of attorney[70] or Advance Directive[71]

In the absence of either of the above, an adult surrogate from the following list, in order of priority, who is available after a reasonably diligent inquiry, may consent on behalf of the patient: [72]

(1) the patient's spouse (including a common law spouse);
(2) an adult child of the patient who has the waiver and consent of all other qualified adult children of the patient to act as the sole decision-maker;
(3) a majority of the patient's reasonably available adult children;
(4) the patient's parents; or
(5) the individual clearly identified to act for the patient by the patient before the patient became incapacitated, the patient's nearest living relative, or a member of the clergy.

Texas law recognizes common law marriages (technically called an "informal marriage" under state law), so a common law spouse has the same rights and responsibilities with regards to being a health care surrogate decision- maker as does someone who was formally married. In order to form a common law marriage, there are three requirements:

1. The couple must have "agreed to be married;"
2. The couple must hold themselves out as husband and wife by representing to others that they are married to each other.
3. They must have lived together in this state as husband and wife.[73]

There is no required amount of time which the couple must have lived together; even one-day cohabitation can form a marriage so long as the other two elements are met. As for what constitutes "holding out" as husband and wife, some examples are introducing their partner socially as "my husband" or "my wife," and indicating on documents (such as tax returns, deeds, insurance applications, utility bills) that they are married.

If a dispute arises as to the right of a party to act as a surrogate decision maker, it may only be resolved by a court of record having jurisdiction under Chapter V, Texas Probate Code.[74]

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[69] Either a guardian appointed by the patient prior to becoming incapacitated (under Tex. Probate Code, Chapter XIII, § 679) or one appointed by a court (under Tex. Probate Code, Chapter XIII, § 767(a)(4))
[70] Under Title 2, Health & Safety Code, §§ 166.151-166.166
[71] Under Title 2, Health & Safety Code, §§ 166.001-166.081
[72] The Texas Medical Consent Act, codified at Title 4 Tex. Health & Safety Code, Section 313.004(a), is the authority for individuals in (1) through (5) of this list. Please note that while technically Chapter 313 of the Health & Safety Code only applies to hospitals, the Act is generally applied to outpatient facilities as well.
[73] Title 1, Tex. Family Code, § 2.401(a)(2)
[74] Title 4, Tex. Health & Safety Code § 313.004(b)

Thus, researchers should not enroll a person in a trial if a dispute arises as to who has the authority to give consent and there is no court order granting such authority to someone (or some entity).

There are some limitations on the authority of a surrogate decision-maker who in categories (1) through (5) above. All decisions must be based on knowledge of what the patient would desire, if known.[75] Someone higher on the list can choose not to be the surrogate, in which case you would move on to the next person in the order of priority, however that person may not appoint someone else as the surrogate decision maker.[76] Furthermore, health care providers are obligated to file the wishes of a patient that are delineated in an Advance Directive[77] or a Declaration for Mental Health Treatment,[78] unless there are statutory provisions granting deviations from said documents.

Additionally, there are separate statutes addressing the following situations, thus overriding the normal statutory scheme for surrogate consent. Although some of these are unlikely to arise in the research context, a brief explanation of each is provided:

(1) voluntary inpatient mental health services:[79]
   - one who is 16 years of age or older, or who is younger than 16 but is or was married, may consent to a voluntary admission. Furthermore, for someone who is younger than 18 years of age and is not and has not been married, the person's parent, managing conservator, or guardian may consent to the admission.[80]
   - A guardian of someone who is 18 years of age or older may not voluntarily admit the ward, and the ward will not have capacity to consent either[81]

(2) psychoactive medications for those with a mental illness who are undergoing court ordered voluntary or involuntarily mental health treatment
   - There are specific statutes addressing the administration of such medications, with some allowances for court-appointed guardians, though a court proceeding may be necessary.[82]

(3) electro-convulsive treatment[83]
   - Only the patient or a court-appointed guardian can consent to electroconvulsive treatment.[84]

(4) withholding or withdrawing life support[85]
   - Texas has a separate statute that deals with surrogate authority to withhold or remove life support which is beyond the scope of this policy since this issue should not arise in the context of clinical research.[86]

(5) hospital patient transfers for patients in an emergent situation who are not stabilized[87]

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[75] Title 4, Tex. Health & Safety Code, § 313.004(c)
[76] Title 4, Tex. Health & Safety Code, § 313.004(d)(3)
[77] Under Title 2, Health & Safety Code, §§ 166.001-166.081
[78] Title 6, Tex. Civ. Prac. & Rem. Code §§ 137.001-137.011
[79] Title 4, Tex. Health & Safety Code, § 313.004(d)(1)
[80] Title 7, Tex. Health & Safety Code § 572.002(3). Note that consent is not an issue with regards to involuntary mental health treatment since only a court can order an outpatient or inpatient commitment
[81] Tex. Probate Code § 767(a)(4) prohibiting a court-appointed guardian appointed under that chapter of the Probate Code from consenting to inpatient mental health services
[82] Title 7, Tex. Health & Safety Code §§ 574.103(b), 574.104, 576.025(a)
[83] Title 4, Tex. Health & Safety Code § 313.004(d)(2).
[84] Title 7, Tex. Health & Safety Code § 578.002(c)
[85] Title 4, Tex. Health & Safety Code § 313.003(b).
[86] *See* Title 2, Tex. Health & Safety Code § 166.039 for more information.
[87] Title 4, Tex. Health & Safety Code § 313.003(a)(5)

- If a patient is in a hospital in an emergent condition and is not stabilized, only "the patient or a legally responsible person acting on the patient's behalf" can request transfer to another hospital [emphasis added].[88]

(6) psychosurgery:
- An agent appointed under a medical power of attorney may not consent to psychosurgery, unless the power of attorney specifically states otherwise.[89] Interestingly, the statute on general surrogate consent does not prohibit a surrogate decision maker such as a spouse, next of kin, etc. from consenting to such treatment.

What consent is needed, if any, for "emergency research"? What if it is not "emergency research" but the patient is in an emergent condition?

Federal regulations allow an IRB to approve research that involves patients in life-threatening conditions without requiring that informed consent be obtained,[90] and they also allow the use of an investigational device or drug in patients with life-threatening conditions,[91] though with a list of requirements that must be met. Texas law also allows treatment absent consent if the individual is unable to communicate because of an injury, accident, or illness or is

unconscious and is suffering from what reasonably appears to be a life-threatening injury or illness.[92] While probably rarely applicable to the research setting, the statute also allows treatment if a court of record orders the treatment of an individual who is in an imminent emergency to prevent the individual's serious bodily injury or loss of life.[93] This state statute also applies to minors as discussed in the section on children, supra.[94]

What about patients undergoing outpatient or voluntary inpatient mental health treatment?

A person who is voluntarily admitted to an inpatient mental health facility, for whom a motion for court-ordered mental health services is filed or for whom a final order on that motion has not been entered, may not participate in a research program unless the patient provides written consent to a research program under a protocol which has been approved by an IRB.[95]

All patients undergoing mental health treatment (even those voluntarily admitted to an inpatient mental health facility) have the right to refuse to participate in a research program (regardless of whether the research is related to their mental illness or is entirely unrelated), and this right may not be waived by the patient, the patient's attorney or guardian, or any other person acting on behalf of the patient.[96] Thus, even if a guardian or another person consents to the patient's participation in the research, the research team needs to also seek the assent of the participant himself prior to enrolling the patient and should document the

[88] Title 4, Tex. Health & Safety Code § 241.027
[89] Title 2, Tex. Health & Safety Code §166.152(f)
[90] 46 CFR § 46.116(d); 21 CFR § 50.24(a)
[91] 45 CFR § 46.116(f); 21 CFR § 50.23(a)
[92] Title 9, Tex. Health &Safety Code § 773.008(1)
[93] Title 9, Tex. Health &Safety Code § 773.008(2)
[94] Title 9, Tex. Health &Safety Code § 773.008(3)
[95] Title 7, Tex. Health & Safety Code §§ 574.151, 574.154
[96] Title 7, Tex. Health & Safety Code §§ 576.153, 576.021

participant's agreement on the consent form. If the potential participant refuses to give consent, then do not enroll the patient.

Who can be a surrogate for research that is "pure" VA research that involves UTHSCSA only by the use of the UTHSCSA IRB?

The VA allows an LAR to give consent on behalf of a patient for research studies when the patient is incompetent (a term not used in Texas but which generally refers to someone who has been appointed the ward of another) or has an impaired decision-making capacity (the inability to understand and appreciate the nature and consequences of health care treatment decisions).[97] The VA defines LAR as "an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research."[98] The following may act as surrogates for research: [99]

(1) a health care agent appointed by the person in a DPAHC or similar document;
(2) court-appointed guardians of the person,
(3) next-of-kin in the following order of priority:
    a. spouse (including a common law spouse)[100];
    b. adult child (18 years or older);
    c. parent;
    d. adult sibling (18 years of age or older);
    e. grandparent; or
    f. adult grandchild (18 years of age or older).

There are, of course, additional restrictions on research involving incompetent patients beyond the issue of who may consent, which is beyond the scope of this policy.

Who can provide surrogate consent for research for adult incompetent patients in research involving both the VA and UTHSCSA?
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APPLICABILITY NOTE: This applies to any research that is a UTHSCSA study or which has significant involvement of UTHSCSA personnel and which is conducted, supported or otherwise subject to regulation by the VA, and/or which involves patient care furnished by the VA under Title 38, United States Code. It does not apply to "pure" VA research in which the only UTHSCA involvement is the use of the UTHSCSA Institutional Review Board.

Federal regulations require that an investigator get the "legally effective" consent of a participant or the participant "legally authorized representative" in order for the person to participate in a clinical trial.[101]

The federal regulations define "legally authorized representative" as "an individual or judicial or other body authorized under applicable law [emphasis added] to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the

[97] VHA Handbook 1200.5, "Requirements for the Protection of Human Subjects in Research," (July 15, 2003), paragraph 11(a)(3) (hereafter, "VHA handbook"); 38 CFR § 17.32(a).
[98] 38 CFR § 16.102(c)
[99] VHA Handbook, paragraph 11(a)(2)
[100] See discussion on page 10 under "*Who can serve as the Legally Authorized Representatives (LAR) for Adult Patients in a Non-Emergent Situation?"* for explanation of what establishes a common law marriage in Texas.
[101] 45 CFR § 46.116; 21 CFR § 50.20

research."[102]

"Applicable law" for UTHSCSA is the law of the State of Texas.[103] "Applicable law" for Department of Veterans Affairs (VA) facilities is federal law under Title 38, United States Code, and Title 38, Code of Federal Regulations.[104]

Occasionally UTHSCSA research is conducted in VA facilities since UTHSCSA does not have an inpatient facility. In any trial in which there is VA involvement, such as co-researchers or inpatient services, the VA is supporting the research and their regulations apply.[105] So However, Texas law also applies because state employees are engaged in the research, UTHSCA is involved with the research (beyond the mere use of the IRB), and it is being conducted within the state of Texas. Since the Texas statutes and VA regulations are not entirely consistent with regards to who may give surrogate consent, a blending of the surrogate lists is required to create a hybrid list that complies with both federal and state law.

This is the list and order of priority for surrogates for UTHSCSA research conducted utilizing VA facilities or that is otherwise supported by the VA:

(1) guardian (legal or special);
(2) health care agent (in a medical power of attorney or advance directive);
(3) the patient's spouse (including a common law spouse)[106];
(4) an adult child of the patient who has the waiver and consent of all other qualified adult children of the patient to act as the sole decision-maker (following Texas law because more restrictive than VA);
(5) a majority of the patient's reasonably available adult children (following Texas law because more restrictive than VA);
(6) the patient's parents;
(7) sibling (assuming he/she is the nearest living relative to comply with Texas law priority order that does not specifically list sibling);
(8) grandparent (assuming he/she is the nearest living relative to comply with Texas law priority order that does not specifically list sibling); or
(9) or grandchild (assuming he/she is the nearest living relative to comply with Texas law priority order that does not specifically list sibling).

There are limitations regarding the types of treatment (and hence research involving said treatment) to which a surrogate may consent. Please consult the section entitled "Who can serve as the Legally Authorized Representatives (LAR) for Adult Patients in a Non-Emergent Situation?" for details regarding the limitations of surrogates under Texas law.

Do you have a unique situation regarding an incapacitated adult which is not adequately covered in this policy?

If so, please consult with the Director, Institutional Review Board for guidance. Enrolling a

[102] 45 CFR § 46.102(c); 21 CFR § 50.3(l)
[103] Tex. Probate Code Chapter XIII (Guardians); Tex. Probate Code § 490 (Medical Power of Attorney); Title 2 Tex. Health & Safety Code § 166.001 et. seq. (Advance Directive); Title 4 Tex. Health & Safety Code § 313.004 (Medical Consent Act); Emergency Situations: Title 9 Tex. Health &Safety Code § 773.008
[104] 38 CFR § 16.16 (Informed Consent for Research); 38 CFR § 17.32(e) (Surrogates)
[105] 38 CFR § 16.101(a); 38 C.F.R. § 17.32(b)
[106] See discussion on page 10 under "*Who can serve as the Legally Authorized Representatives (LAR) for Adult Patients in a Non-Emergent Situation?"* for explanation of what establishes a common law marriage in Texas

participant without adequate consent can subject the provider, employee and/or the institution to a lawsuit, so do not hesitate to seek guidance when an issue is not clear.