

	RESEARCH CONDUCTED OUTSIDE THE JURISDICTION OF THE STATE OF LOUISIANA			
	P & P	VERSION DATE	REPLACES P & P	PREVIOUS VERSION DATE
	8.06	02.07.2020	5.28	03.25.2019

In cases of human subjects research under the authority of the LSUHSC-NO IRB but conducted outside of the state of Louisiana, the LSUHSC-NO IRB confers with the LSUHSC-NO Senior Staff Counsel regarding the applicability of other state, national, or international laws to the particular project. These cases are identified in the pre-review process of an application to the IRB and the advice of counsel may be sought prior to the approval of the study. In general, if the study is conducted in the USA, the LSUHSC-NO IRB will apply the law of the state in which the research is being conducted.

Except in the case of children where NIH defines a child as being less than 21 years of age, the FDA and other DHHS agencies follow state law as to the definition of “child”, “legally authorized representative”, and “guardian”. Counsel assists in determining these definitions for jurisdictions outside the State of Louisiana.

Within Louisiana laws and codes, these terms are defined as follows:

Child is defined as a person not attaining the age of 18 years of age (adult) as described in LaRS 15:1503, 46:2132, and other sections of the LA Revised Statutes.

Legally authorized representative is not defined for research, *per se*, in Louisiana law but rather the Louisiana Medical Consent Law (LaRS 40:1299.53) is followed as to persons who may consent to surgical or medical treatment:

In addition to such other persons as may be authorized and empowered, any one of the following persons in the following order of priority, if there is no person in a prior class who is reasonably available, willing, and competent to act, is authorized and empowered to consent, either orally or otherwise, to any surgical or medical treatment or procedures including autopsy not prohibited by law which may be suggested, recommended, prescribed, or directed by a duly licensed physician:

- 1) Any adult, for himself.
- 2) The judicially appointed tutor or curator of the patient, if one has been appointed.
- 3) An agent acting pursuant to a valid mandate, specifically authorizing the agent to make health care decisions.
- 4) The patient's spouse not judicially separated.
- 5) An adult child of the patient.
- 6) Any parent, whether adult or minor, for his child.
- 7) The patient's sibling.
- 8) The patient's other ascendants or descendants.
- 9) Upon the inability of any adult to consent for himself and in the absence of any person listed in Paragraphs (2) through (8) of this Subsection, an adult friend of the patient. For purposes of this Subsection to consent, "adult friend" means an adult who has exhibited special care and concern for the patient, who is generally familiar with the patient's health care views and desires, and who is willing and able to become involved in the patient's health care decisions and to act in the patient's best interest. The adult friend shall sign and date an acknowledgment form provided by the hospital or other health care facility in which the patient is located for placement in the patient's records certifying that he or she meets such criteria.

- 10) Any person temporarily standing in loco parentis, whether formally serving or not, for the minor under his care and any guardian for his ward.

Guardianship of children:

Art. 7 Childrens Code Article 720. Motion for guardianship

After a child has been adjudicated to be in need of care, a motion for guardianship may be filed by the department, parent, or counsel for the child; or the department may submit a case plan along with the case review report to the court and all counsel of record recommending guardianship in accordance with Children's Code Articles 674, 688, and 689.

Art. 6 Childrens Code Article 681. Dispositional alternatives

In a case in which a child has been adjudicated to be in need of care, the child's health and safety shall be the paramount concern, and the court may do any of the following:

- 1) Place the child in the custody of a parent or such other suitable person on such terms and conditions as deemed in the best interest of the child including but not limited to the issuance of a protective order pursuant to Article 618.
- 2) Place the child in the custody of a private or public institution or agency.
- 3) Commit a child found to have a mental illness to a public or private institution for persons with mental illness.
- 4) Grant guardianship of the child to a nonparent.
- 5) Make such other disposition or combination of the above dispositions as the court deems to be in the best interest of the child.