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| Policy#: 400.021 | HRP-021 Legally Authorized Representatives, Children and Guardians in Research |
| Executive Owner: Vice President of Research Operations | Effective Date: 6/11/2018 |
| | Review Date: 6/11/2018 |

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| Scope | This policy applies to all employees and agents of the AdventHealth Orlando conducting human subjects research adults lacking capacity or children. |
| Purpose | This policy describes the AdventHealth Orlando's determination of which individuals are <Legally Authorized Representatives> (LARs), <Children>, and <Guardians>. |
| Policy | <p>A. Adults - A LAR may consent to an adult individual participating in research, where that adult individual is not competent by reason of mental incapacity, if the research is approved by an IRB in conformance with federal regulations governing human subject protection.</p> <p>1. When research is conducted in Florida, the following individuals are <Legally Authorized Representatives>, in the following order of priority:</p> <ul style="list-style-type: none"> a) A health care surrogate designated in writing by the individual (when the individual was competent), which designation was witnessed by two adult witnesses b) A judicially appointed guardian or guardian advocate of the person having a developmental disability , who has been appointed pursuant to Fla. Stat. Title XLIII, Chapter 744, who has been authorized to consent to medical treatment c) A proxy designated pursuant to Florida law, in the following order of priority: <ul style="list-style-type: none"> i. Patient's spouse ii. An adult child or, if the patient has more than one adult child, a majority of the adult children who are reasonably available for consultation iii. A parent of the individual iv. The adult sibling or, if the individual has more than one sibling, a majority of the adult siblings who are reasonably available for consultation v. An adult relative of the individual who has exhibited special care and concern for the individual and who has maintained regular contact with the individual and is familiar with the individual's activities, health and religious and moral beliefs vi. A close friend of the individual who has exhibited special care and concern for the individual and who presents an affidavit stating that he or she is a friend of the individual, is willing and able to become involved in the individual's health care and has maintained such regular contact with the individual so as to be familiar with the individual's activities, health and religious and moral beliefs. Forms: 950-0059: Close Personal Friend Affidavit |

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- vii.A clinical social worker selected in accordance with Florida statutes. SOP 010.146 Social Worker Proxy
- 2. For research outside Florida, legal counsel determines which individuals are <Legally Authorized Representatives>
- B. Children - A LAR may consent to <Children> participating in research, only where the LAR is a parent or <Guardian>. Individuals who can document that they are legally authorized to consent on behalf of the child to general medical care may serve as a <Guardian>. Before obtaining permission for a child to take part in research from someone who is not a parent, contact legal counsel.
 - 1. When research is conducted in Florida, individuals under the age of 18 years are <Children> with the exception of:
 - a) Minors 16 or older who have had the disability of nonage removed by a circuit court
 - b) Minors who are married or have been married (including minors whose marriage is dissolved or who is widowed)
 - c) Unwed pregnant minors to the extent the research is related to such minor's pregnancy
 - d) Minors adjudicated as an adult and in the custody or under the direct supervision of the Department of Corrections, except in regard to medical services related to abortion or sterilization
 - 2. For research outside Florida, legal counsel determines which individuals are <Children>.

Definition(s)

[For <Angle Brackets> refer to Policy 400.001 HRP-001 Definitions](#)
[For \[Square Brackets\] refer to Policy 400.003 HRP-003 Designations](#)

Children: 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. In the State of Florida, this would include those under the age of 18.

Guardians: An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

Legally Authorized Representatives: An individual, 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.

- a) At AdventHealth Orlando, this is the Legally Authorized Person (LAP)

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- b) For <Research as Defined by HHS> NOT subject to FDA regulations and NOT subject to <2018 Requirements>: Where there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective <Human Subject as Defined by HHS> to the <Human Subject's> participation in the procedure(s) involved in the research.

Reference(s)

Florida Statutes. (2014). Title XLIV, Chapter 765: Health Care Advance Directives. §765.401: The proxy. [Click here.](#)

Florida Statutes. (2014). Title XLIV, Chapter 765: Health Care advance Directives. §765.113: Restrictions on providing consent. [Click here.](#)

Florida Statutes. (2014). Title XLIV, Chapter 743: Disability of Nonage of Minors Removed. §743.01: Removal of disabilities of married minors. [Click here.](#)

Florida Statutes. (2014).Title XLIV, Chapter 743: Disability of Nonage of Minors Removed §743.015: Disabilities of nonage:removal. [Click here.](#)

Florida Statutes. (2014).Title XLIV, Chapter 743: Disability of Nonage of Minors Removed. §743.065: Unwed pregnant minor or minor mother; consent to medical services for minor or minor's child valid. [Click here.](#)

Florida Statutes. (2014).Title XLIV, Chapter 743: Disability of Nonage of Minors Removed. §743.066: Removal of disability of minors adjudicated as adults. [Click here.](#)

Florida Statutes. (2014).Title XLIV, Chapter 743: Disability of Nonage of Minors Removed. §743.067: Unaccompanied homeless youths. [Click here.](#)

Related Document(s)

Policies:
AdventHealth Orlando Policy 010.040

SOP:
010.146 Social Worker Proxy
AdventHealth Orlando SOP 010.040A

AdventHealth Orlando Forms:
950-0059: Close Personal Friend Affidavit

Keywords

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