



SOP: Legally Authorized Representatives, Children, and Guardians

NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-013	07/9/2019	L. Smith	C. Gates	1 of 2

1 PURPOSE

- 1.1 This procedure establishes how to determine which individuals meet the following DHHS and FDA definitions:
 - 1.1.1 Legally authorized representative
 - 1.1.2 Children
 - 1.1.3 Guardian

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None
- 2.2 Added language from Florida Statute for Section 3.1.1. Clarification to Section 3.2 for readability.
- 2.3 Added requirement for IRB determination for enrollment of subjects who lack capacity to consent.

3 GUIDING PRINCIPLES

- 3.1 The IRB determines whether subjects who lack capacity to consent can be included in a study conducted at the University of Miami.
- 3.2 Unless the IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a legally authorized representative.
 - 3.2.1 When research is conducted in Florida, the following individuals meet this definition:
 - 3.2.1.1 The judicially appointed guardian of the subject or the guardian advocate of the person having a developmental disability¹, who has been authorized to consent to medical treatment, if such guardian has previously been appointed; however, this paragraph shall not be construed to require such appointment before a treatment decision can be made under this subsection;
 - 3.2.1.2 The subject’s spouse;
 - 3.2.1.3 An adult child of the subject, or if the subject has more than one adult child, a majority of the adult children who are reasonably available for consultation;
 - 3.2.1.4 A parent of the subject;
 - 3.2.1.5 The adult sibling of the subject or, if the subject has more than one sibling, a majority of the adult siblings who are reasonably available for consultation;
 - 3.2.1.6 An adult relative of the subject who has exhibited special care and concern for the subject and who has maintained regular contact with the subject and who is familiar with the subject’s activities, health, and religious or moral beliefs; or

¹ “Developmental disability” means a disorder or syndrome that is attributable to intellectual disability, cerebral palsy, autism, spina bifida, or Prader-Willi syndrome; that manifests before the age of 18; and that constitutes a substantial handicap that can reasonably be expected to continue indefinitely.



SOP: Legally Authorized Representatives, Children, and Guardians				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-013	07/9/2019	L. Smith	C. Gates	2 of 2

- 3.2.1.7 A close friend of the subject.
- 3.2.1.8 A clinical social worker licensed pursuant to chapter 491, or who is a graduate of a court-approved guardianship program. Such a proxy must be selected by the provider’s bioethics committee and must not be employed by the provider. If the provider does not have a bioethics committee, then such a proxy may be chosen through an arrangement with the bioethics committee of another provider. The proxy will be notified that, upon request, the provider shall make available a second physician, not involved in the subject’s care to assist the proxy in evaluating treatment. Decisions to withhold or withdraw life-prolonging procedures will be reviewed by the facility’s bioethics committee. Documentation of efforts to locate proxies from prior classes must be recorded in the subject record.

3.2.2 For research outside Florida, a determination of who is a legally authorized representative is to be made with consultation from legal counsel.

3.3 Unless the IRB has waived the requirement to obtain consent, when research involves children, consent may only be obtained from biologic or adoptive parents or an individual legally authorized to consent on behalf of the child to general medical care². Before obtaining permission from an individual who is not a parent, contact legal counsel.

3.3.1 For research outside Florida, a determination of who is a child is to be made with consultation from legal counsel.

4 RESPONSIBILITIES

4.1 Investigators are to follow this policy when obtaining permission for adults unable to consent or children to take part in research.

5 PROCEDURE

5.1 None

6 MATERIALS

6.1 None

7 REFERENCES

- 7.1 45 CFR §46.102, 45 CFR §46.402
- 7.2 21 CFR §50.3
- 7.3 Florida Statutes sections 393.063, 765.201 – 765.205, and Chapter 491
- 7.4 Florida Administrative Code Section 65E-5.2301

² This is the DHHS and FDA definition of “guardian”