CUMMINGS
GRADUATE INSTITUTE FOR
BEHAVIORAL HEALTH STUDIES

TITLE: **Cognitive Impairment, Legally Authorized Representatives, Children, Guardians for Non-Emergency Research**

PURPOSE: Define which individuals may function as legally authorized representatives to consent on behalf of a prospective subject to participate in non-emergency research.

RESPONSIBILITIES: IRB Members

PROCEDURES:

During pre-review of research proposals, CGI IRB will compare the population to be recruited to the definitions below. If any potential subjects appear to meet the criteria of a child or cognitively impaired adult, the IRB will ensure that:

- The appropriate information is completed by the investigator and submitted with the application; and
- The protocol includes a discussion of what safeguards will be in place to protect the rights and welfare of the vulnerable subjects.

The complete application will be forwarded for review at the appropriate level.

Definitions:

Cognitively Impaired: Having either a severe mental illness (SMI) diagnosis (e.g., active psychosis), an organic impairment (e.g., dementia or other cognitive impairment) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

Incapacitated Adults: Under DHHS and FDA regulations a "legally authorized representative" (LAR) means "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." Unless the IRB has waived the requirement to obtain consent, when research involves an adult who does not have the capacity to consent, consent must be obtained from a LAR. Because Arizona does not have a state statute that specifically addresses who may function as a LAR for research participation, in accordance with federal regulations and guidance from the OHRP, CGI has established that the informed consent laws applicable to clinical care in Arizona will be followed to determine who may function as a LAR for research. Under Arizona law, where an adult lacks the capacity to consent to clinical care, the LAR of the subject will be determined by the following order of priority:

1) A court-appointed legal guardian who has been granted "general" guardianship or "guardian of the person" (but not a guardian granted only guardianship over financial matters) may provide surrogate consent for research participation. This would not apply if a court has revoked or suspended a guardian's authority. The investigator should obtain a copy of the court order appointing the individual as the guardian, and should maintain the copy with the research records.
2) An agent under an individual's health care power of attorney (HCPOA) may provide surrogate consent for research participation. A HCPOA is effective following a physician's determination that the individual lacks adequate capacity to make her/his own health care decisions. This would not apply if the HCPOA expressly limits the agent's authority to consent to research or for the types of procedure(s) involved in the research. The investigator should obtain a copy of the HCPOA and should maintain the copy with the research records. Note that a Durable Power of Attorney under A.R.S. 14-5501 et seq. does NOT confer authority to the agent to consent to health care decision-making, unless it expressly includes the authority to consent to health care.
3) In the event there is neither a court-appointed guardian nor an agent under a HCPOA, surrogate consent for research may be given by other individuals listed below, in order of priority, unless there is evidence that the participant did not want the individual to act as his or her surrogate:
    (a) The participant's spouse, unless the participant and spouse are legally separated.
    (b) An adult child of the participant. If the participant has more than one adult child, the investigator shall seek the consent of a majority of the adult children who are reasonably available for consultation.
    (c) A parent of the participant.
    (d) A brother or sister of the participant.
4) If there is any doubt as to which individual is the appropriate LAR for the participant, CGI must contact legal counsel for advice.
5) Beyond the categories described above, others may not give surrogate consent for research enrollment. Institutional custodians or caretakers are not LARs unless they meet the requirements above.
6) Where an individual does not have the capacity to decide whether to participate in research, primary consent will be obtained from the LAR. However, there may be occasions when it is possible to seek the assent of the participant, in addition to the consent of the LAR. The IRB will determine whether assent of the participant is a requirement, and if so, whether the plan for assent is adequate.
7) For research outside Arizona, a determination of who meets the DHHS and FDA definitions of "legally authorized representative" is to be made by the CGI IRB with consultation with legal counsel as the CGI IRB deems appropriate.
8) A LAR may not consent for the individual to participate in research if:
    (a) The LAR knows, or upon reasonable inquiry ought to know, that any aspect of the research protocol is contrary to the religious beliefs or basic values of the prospective participant, whether expressed orally or in writing.

(b) Two or more persons who qualify as LARs and have equal decision-making priority inform the principal investigator or attending physician that they disagree with each other as to the participation of the prospective participant in the research.
(c) The investigator conducting the research knows that the prospective participant has expressed disagreement about participating in the research.

Children: Under DHHS and FDA regulations "children" are 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. Individuals under the age of 18 years are considered "children" under Arizona law (requiring the application of 45 CFR Subpart D requirements), with the following exceptions:

1) An emancipated minor, provided the minor can produce evidence of court documentation of emancipated status.
2) A married minor. A subsequent divorce or annulment does not negate the minor's ability to consent.
3) A homeless minor, which is defined as a minor living apart from parents, lacks a fixed and regular nighttime residence or whose primary residence is either a supervised shelter described to provide temporary accommodations, a halfway house or a place not designed for or ordinarily used for sleeping by humans.
4) For research outside Arizona, a determination of who meets the DHHS and FDA definitions of "children" and when those children may consent is to be made with consultation with CGI's IRB and legal counsel as CGI's IRB deems necessary.

When research involves children who may not consent to their own health care as described in Section 1.4, consent for a child to participate in research may only be obtained from one of the child's parents (biologic or adoptive) or an individual appointed by a court as a child's guardian. Under DHHS and FDA regulations a "guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. If consent for a child to participate in research is to be obtained from an individual other than biological or adoptive parents, the individual providing such permission must provide written documentation of the legal ability to consent to the child's medical care. A copy of this documentation is to be kept with the consent document in the research records.

MATERIALS:

- C421: Research Involving Children
- C422: Research Involving Cognitively Impaired Adults
- SOP-011: Pre-Review
- SOP-041: Non-Committee Review Preparation
- SOP-022: IRB Meeting Preparation

REFERENCES:

- 45 CFR §46.102, 45 CFR §46.402.

- 21 CFR §50.3.
- A.R.S. § 12-2455 (Arizona minor emancipation statute).
- A.R.S. § 14-5101 (Arizona statute defining incapacity to make health care decisions).
- A.R.S. § 14-5301, et. seq. (Arizona guardianship statutes).
- A.R.S. § 36-2271 (Arizona statute requiring parental consent to surgical procedures for minors).
- A.R.S. § 36-3201, et. seq. (Arizona health care power of attorney statute and other surrogacy statutes)
- A.R.S. § 36-3231 (Arizona statute listing order of surrogates).
- A.R.S. § 44-132(A) (Arizona statute allowing emancipated, married and homeless minors to consent to own health care).
- OHRP IRB Guidebook, Chapter 6 (http://www.hhs.gov/ohrp/irb/irb_chapter6.htm#g5)