



Conducting Human Research with Vulnerable Populations

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WELL BEYOND THE EXPECTED.

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Vulnerable Populations Defined

Vulnerable Population – When some or all of the subjects in a protocol are likely to be vulnerable to coercion or undue influence.

This definition is more than:

- Children
- Pregnant Women
- Prisoners
- Cognitively Impaired (Adults or Children)

Could Include:

- Elderly
- Educationally/Economically Disadvantaged
- Others...

Regulated Vulnerable Populations

Pregnant Women

Regulated by DHHS Subpart B

Prisoners

Regulated by DHHS Subpart C

Children

**Regulated by DHHS Subpart D, FDA regulations
state research with Children cannot be exempt**

Cognitively Impaired

Not regulated, institutional policy reigns

- **Know the policies applicable to the research you are conducting**
- **Train your staff on consent process applicable to conducting the research on the vulnerable population**
- **Continue to monitor the consent process throughout the study to ensure the rights and welfare of the subjects are protected**

Regulations for Pregnant Women

Pennington Biomedical does not differentiate between what is DHHS funded; Subpart B rules apply in all cases. Important as research collaborates with other institutions.

Definitions to Know

- **Delivery** - means complete separation of the fetus from the woman by expulsion, extraction, or any other means.
- **Fetus** - is the product of conception from the time of implantation until delivery.
- **Pregnant** - is the period of time from confirmation of implantation until expulsion or extraction of the fetus.
- **Neonates** - means newborn.
- **Neglect of a Neonate** - neglect of a neonate means a finding by a Louisiana licensed physician.
- **Viable Neonates** - means a fetus that is able, after delivery, to survive to the point of being able to independently maintain a heartbeat and respiration (given the benefit of available medical therapy).
- **Non-Viable Neonate (or “Non-Viable Fetus”)**: is a fetus ex utero that, although living, is not able to survive to the point of independently maintaining a heartbeat and respiration.

Research in Pregnant Women, cont.

- **Must have some data from animal studies or non-pregnant women to support the research**
- **The risk to the fetus must hold out a prospect of direct benefit**
- **Minimize the risk in the research to the greatest extent**
- **Pregnant Women must consent even if the research is for the fetus**
- **Father must consent for research that holds out a direct benefit for the fetus unless unavailable.**
- **Children (under the age of 17) that are pregnant must comply with Louisiana law to participate**

Research in Pregnant Women, cont.

- **Children (under the age of 17) must have parental consent and assent unless waived by the IRB.**
- **No money or inducements will be offered to terminate the pregnancy**
- **Individuals engaged in the research will have no part in the timing, methods or procedures to terminate a pregnancy.**
- **Individuals involved in the research will have no part in determining the viability of the neonate.**

After Delivery

Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, must be conducted only in accordance with any applicable federal, state, or local laws and regulations regarding such activities.

If information associated with material described above in this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research participants and all pertinent sections of this document are applicable.

Definitions to Know

- **Assent** - means a child's affirmative agreement to participate in research. Mere failure of a child to object may not, absent affirmative agreement, be construed as assent.
- **Children** - re 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.
- **Guardian** - means an individual who is authorized under applicable state or local law to consent on behalf of a child to (a) general medical care when general medical care includes participation in research; or (b) to participate in research.
- **Health Agent** - is an authorized representative legally acting for a person pursuant to a Durable Power of Attorney for Health Care (Medical Power of Attorney) or other legal document permitted within a jurisdiction that allows a person to appoint another person(s) to make medical decisions for the patient if the patient should become temporarily or permanently unable to make those decisions for himself/herself. Any adult (18 or older) can be granted this power.
- **Legally Authorized Representative**
 - Health Agent

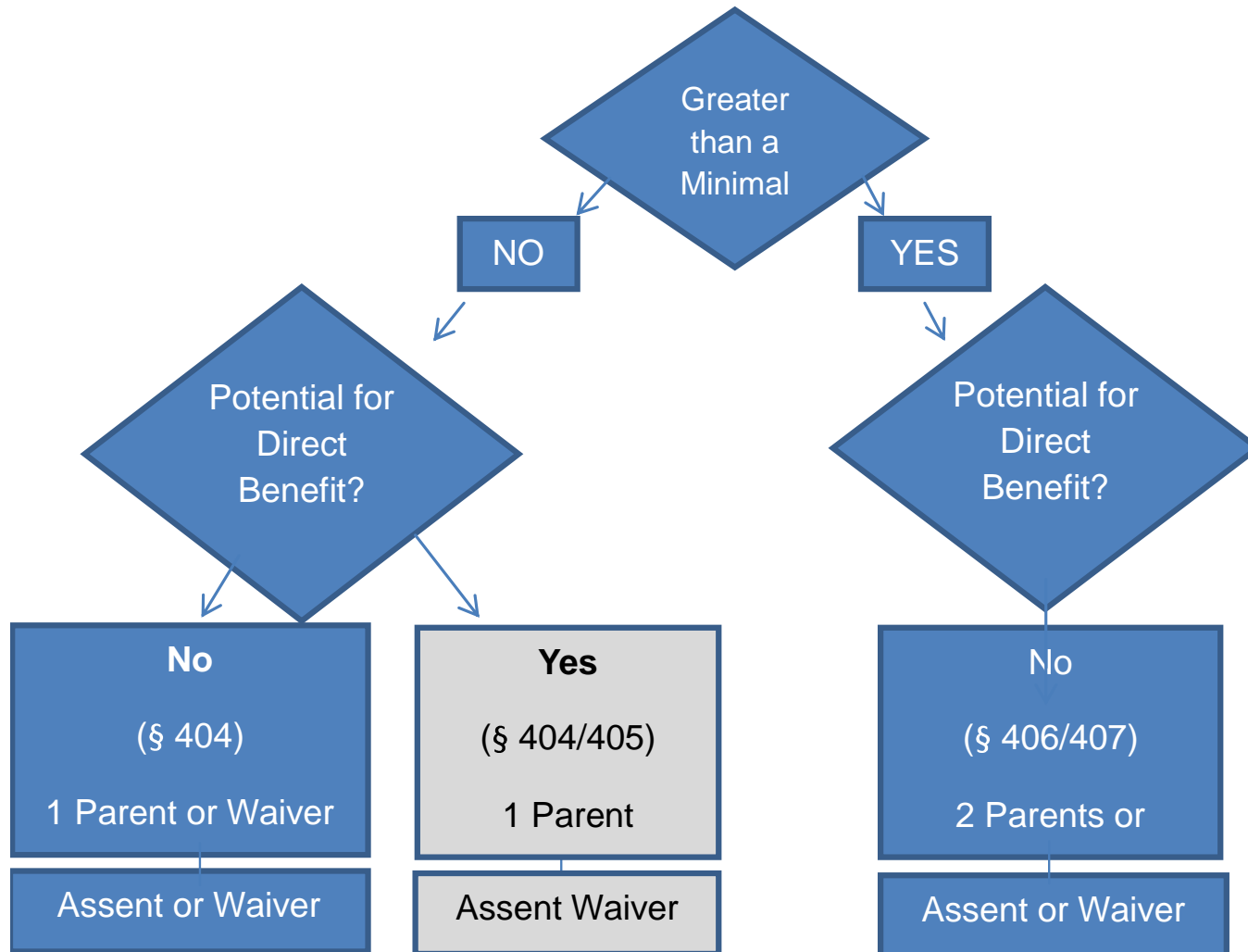
Definitions to Know, cont.

- **Legally Authorized Representative** - is an individual, judicial, or other body authorized under applicable law to consent or otherwise provide permission on behalf of a subject, either prospectively or during the course of research, to the subject's participation in the procedure(s) involved in the research.
 - Order of Priority**
 - Health Agent
 - Legal Guardian
 - Spouse
 - Adult Children
 - Grandparent
 - Adult Grandchildren
- **Minor** - means any person under the age of 18 years. Do not confuse the definitions of minor (pertaining to a person's age) with child/children (pertaining to a person's ability to consent).
- **Parent** - means a child's biological or adoptive parent.

Classified by the following:

- **Proposed direct benefit vs. not a direct benefit**
- **Minimal risk vs. not a minimal risk**
- **Minimal Risk (DOD)** - Minimal risk is based on the phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests”; minimal risk shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain.)
- **Comparison to a child’s well-visit to the physician.**

Research in Children, cont.



Research with Cognitively Impaired Adults is not regulated by Federal regulations and there is little guidance.

Pennington Biomedical review of research with cognitively impaired is based on AAHRPP guidelines and regulatory guidance.

Research in Cognitively Impaired Adults, cont.

**Slight Diminished
Capacity, Able to
Consent**

Not Able to Consent



Research in Cognitively Impaired Adults, cont.

- **Have to be incompetent persons as determined by a licensed health care professional qualified to make such a determination.**
- **The proposed research CANNOT entail significant risks unless there is a probability of direct benefit to the subject.**
- **Procedures have been devised to ensure subject's representatives are well-informed regarding their obligations and role to the protect the impaired individual.**
- **A trial with no direct benefit should be conducted in a population who can personally give consent and sign the consent document.**
 - **The objectives can't be met by means of a trial in subjects who can give consent personally**
 - **Foreseeable risks are low**
 - **Negative impact on subject is minimized and low**
 - **Trial is not prohibited by law**

Research in Cognitively Impaired Adults, cont.

- **The investigator and research staff must have adequate procedures in place for assessing and ensuring subjects' capacity, understanding, and informed consent or assent.**
- **For individuals with fluctuating capacity, may ask investigator to re-consent frequently, maintain on-going communications with caregivers and/or require third party monitoring of the consent and recruitment.**
- **Fluctuating capacity to consent, may involve visual cues, video-taping, follow-up questions to assess understanding, oral or written recall tests and other measures...**
- **Unlike the law with children, under no circumstances can a person with diminished capacity be forced to participate. No matter the direct benefit it may provide.**

Research in Cognitively Impaired Adults, cont.

- **Legally Authorized Representative as per LA law -**
 - **Health Agent**
 - **Legal Guardian**
 - **Spouse**
 - **Adult Children**
 - **Grandparent**
 - **Adult Grandchildren**

**Guidance on Conducting Research Under the
Department of Education can be found on the HRPP
website.**

www.pbrc.edu/HRPP/guidance

Policy on Conducting Research Funded by the Department of Defense can be found on the HRPP website.

www.pbrc.edu/HRPP/policies