AdventHealth Orlando

CHECKLIST: Pregnant Women

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This checklist is used to determine and document whether non-exempt <Human Research> involving <Pregnant Women> can be approved.

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All criteria in 1, 2, or 3 must be met

1. Research involving pregnant women as subjects that involves no more than <Minimal Risk> to subjects and is not subject to regulation

- 1.1 ☐ The research presents no more than <Minimal Risk> to subjects (see Footnote 1)
- 1.2 ☐ The research is not subject to DHS, EPA, HHS, or VA regulation

2. Research involving pregnant women that involves greater than <Minimal Risk> or is subject to regulation *45 CFR §46.203*

- 2.1 ☐ Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-<Pregnant Women>, have been conducted and provide data for assessing potential risks to <Pregnant Women> and <Fetuses>
- ⓘ
- 2.2 ☐ One of the following is true:
  - ○ The risk to the <Fetus> is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the <Fetus>
  - ○ The risk to the <Fetus> is not greater than <Minimal Risk> and the purpose of the research is the development of important knowledge which cannot be obtained by any other means
  - 2.2.1 ☐ One of the following is true:
    - ○ The research is not subject to DHS, EPA, or VA regulation and is not HHS-funded
    - ○ The important knowledge is important biomedical knowledge
- ⓘ
- 2.3 ☐ Any risk is the least possible for achieving the objectives of the research
- ⓘ
- 2.4 ☐ Consent of the mother is obtained and documented in accordance with Sections 2 and 3 of "WORKSHEET: Criteria for Approval (HRP-400)"
- ⓘ
- 2.5 ☐ One of the following is true:
  - ○ The research holds out the prospect of direct benefit to the pregnant woman
  - ○ The risk to the <Fetus> is not greater than <Minimal Risk>
  - ○ The consent of the father (in addition to the mother) will be obtained and documented in accordance with Sections 2 and 3 of "WORKSHEET: Criteria for Approval (HRP-400)", except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest
- ⓘ
- 2.6 ☐ Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the <Fetus> or neonate
- ⓘ
- 2.7 ☐ For <Children> who are pregnant, assent and permission are obtained and documented in accord with "CHECKLIST: Children (HRP-310)"
- ⓘ
- 2.8 ☐ No inducements, monetary or otherwise, will be offered to terminate a pregnancy
- ⓘ
- 2.9 ☐ Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy
- ⓘ
- 2.10 ☐ Individuals engaged in the research will have no part in determining the viability of a neonate
- ⓘ

3. Research involving pregnant women that is not otherwise approvable *45 CFR §46.207*

- 3.1 ☐ The research does not meet the above requirements
- ⓘ
- 3.2 ☐ The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of <Pregnant Women>, <Fetuses> or neonates
- ⓘ
- 3.3 ☐ An official, after consultation with a panel of experts in pertinent disciplines and after opportunity for public review and comment, including a public meeting, has determined either that the research meets the above conditions or (1) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of <Pregnant Women>, <Fetuses>, or neonates, (2) the research will be conducted in accord with sound ethical principles; and (3) consent will be obtained and documented as required. (see Footnote 2)

4. Notes

5. Footnotes

- 5.1 DOD requires application of HHS Subpart B to research involving <Pregnant Women> and <Fetuses> that is more than <Minimal Risk> and includes interventions or invasive procedures to the woman or the <Fetus>, and to research involving <Fetuses> or neonates as participants. This organization elects to apply HHS Subpart B to all research involving <Pregnant Women> and <Fetuses> and involving greater than <Minimal Risk>, regardless of funding.

5.2	For DHS, EPA, HHS, or VA research the official is the Department Secretary. For DOD research, the official is the Director, Defense, Research, and Engineering. For federal research, the meeting is announced in the Federal Register. For all other research , the official is the <Organizational Official>.