

UMB Human Research Protections Program
Review of Research Involving Pregnant Women and Fetuses
Checklist #13

PROTOCOL NUMBER: _____
PRINCIPAL INVESTIGATOR: _____
TITLE OF STUDY: _____

KEY: Solid box: All items in the box must be true Dotted box: One item in the box must be true

All of the following are true:

- (1)** Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses.

(State reasons here)

- (2)** Either of the following are true:

- (3)** 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.

(State reasons here)

- (4)** All of the following are true:

- (5)** There is no prospect of direct benefit for the woman or the fetus.

- (6)** The risk to the fetus is not greater than minimal.

(State reasons here)

- (7)** The purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.

(State reasons here)

- (8)** The biomedical knowledge cannot be obtained by any other means.

(State reasons here)

Continued on the next page.

(9) Any risk is the least possible for achieving the objectives of the research.

(10) Both of the following are true:

(11) The research holds out the prospect of direct benefit to the pregnant woman

(State reasons here)

(12) The woman's consent will be obtained (See checklist for Informed Consent Requirements)

(13) Both of the following are true:

(14) The research holds out the prospect of a direct benefit both to the pregnant woman and the fetus

(State reasons here)

(15) The woman's consent will be obtained (See checklist for Informed Consent Requirements)

(16) All of the following are true:

(17) The research holds out no prospect of benefit for the woman nor the fetus

(State reasons here)

(18) The risk to the fetus is not greater than minimal

(State reasons here)

(19) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means

(State reasons here)

(20) The woman's consent will be obtained (See checklist for Informed Consent Requirements)

(21) All of the following are true:

(22) The research holds out the prospect of direct benefit solely to the fetus

(State reasons here)

(23) The consent of the pregnant woman and the father will be obtained, 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.

(24) Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate

Continued on the next page.

- (25) Either of the following is true:
 - (26) The research does not involve children as participants
 - (27) The requirements for research involving children are met. (See checklist for Review of Research Involving Children)
- (28) No inducements, monetary or otherwise, will be offered to terminate a pregnancy
- (29) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy
- (30) Individuals engaged in the research will have no part in determining the viability of a neonate

VA Research related to pregnant women and fetuses (Complete #s 31-55 if this is a VA research study)

KEY: Solid box: All items in the box must be true Dotted box: One item in the box must be true

All of the following are true:

- (31) Adequate provisions have been made to monitor the risks to the participant and the fetus.

(Describe here)
- (32) Adequate consideration has been given to the manner in which potential participants are going to be selected, and that adequate provision has been made to observe the informed consent process
- (33) Overseeing the process by which individual consents required are secured by one of the following:
 - (34) Approving enrollment of each individual into the activity
 - (35) Verifying, perhaps through sampling, that approved procedures for enrollment of individuals into the activity are being following
- (36) Monitoring the progress of the activity and intervening, as necessary, through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen.
- (37) Appropriate studies on animals and non-pregnant individuals have been completed, and data for assessing potential risks to pregnant women and fetuses is provides.

(State reasons here)
- (38) One of the following is true
 - (39) The purpose of the activity is to meet the health needs of the mother **or** the particular fetus.

- (40) The risk to the fetus is minimal

(State reasons here)
 - (41) The risk is the least possible risk for achieving the objectives of the activity.
 - (42) Either of the following is true:
 - (43) Individuals engaged in the activity will have no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy
 - (44) Determining the viability of the fetus at the termination of the pregnancy
 - (45) Introducing any procedural changes for research purposes, into the procedures for terminating the pregnancy
 - (46) No inducements, monetary or otherwise, will be offered to terminate pregnancy for purposes of the research activity

Continued on the next page

- (47) The purpose of the activity is to meet the health needs of the mother
 - (48) Either of the following is true:
 - (49) The fetus will be placed at risk only to the minimum extent necessary to meet the to meet such needs
 - (50) The risk to the fetus is minimal
 - (51) Either of the following is true:
 - (52) The mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus
 - (53) The father's informed consent need not be secured if any of the following are true:
 - The purpose of the activity is to meet the health needs of the mother
 - His identity or whereabouts cannot reasonably be ascertained
 - He is not reasonably available
 - The pregnancy resulted from rape

VA Research: Confirm that the following are not being conducted

- (54) Research in which the subject is a fetus, in-utero or ex-utero (including human fetal tissue) by VA investigators while on official duty, or at VA facilities, or at approved off-site facilities.
- (55) Research related to in vitro fertilization by VA investigators while on official duty, or at VA facilities, or at approved off-site facilities.

For UMB studies, the proposed involvement of pregnant women and human fetuses is: Approvable Not approvable

If applicable, research *involving pregnant women* is allowed to be conducted by VA investigators: Approvable Not approvable

Signed _____

Dated _____

References: 45 CFR 46.205, VHA Handbook 1200.5, UMB HRPP and IRB P&Ps II.4.C and II.4.C.1