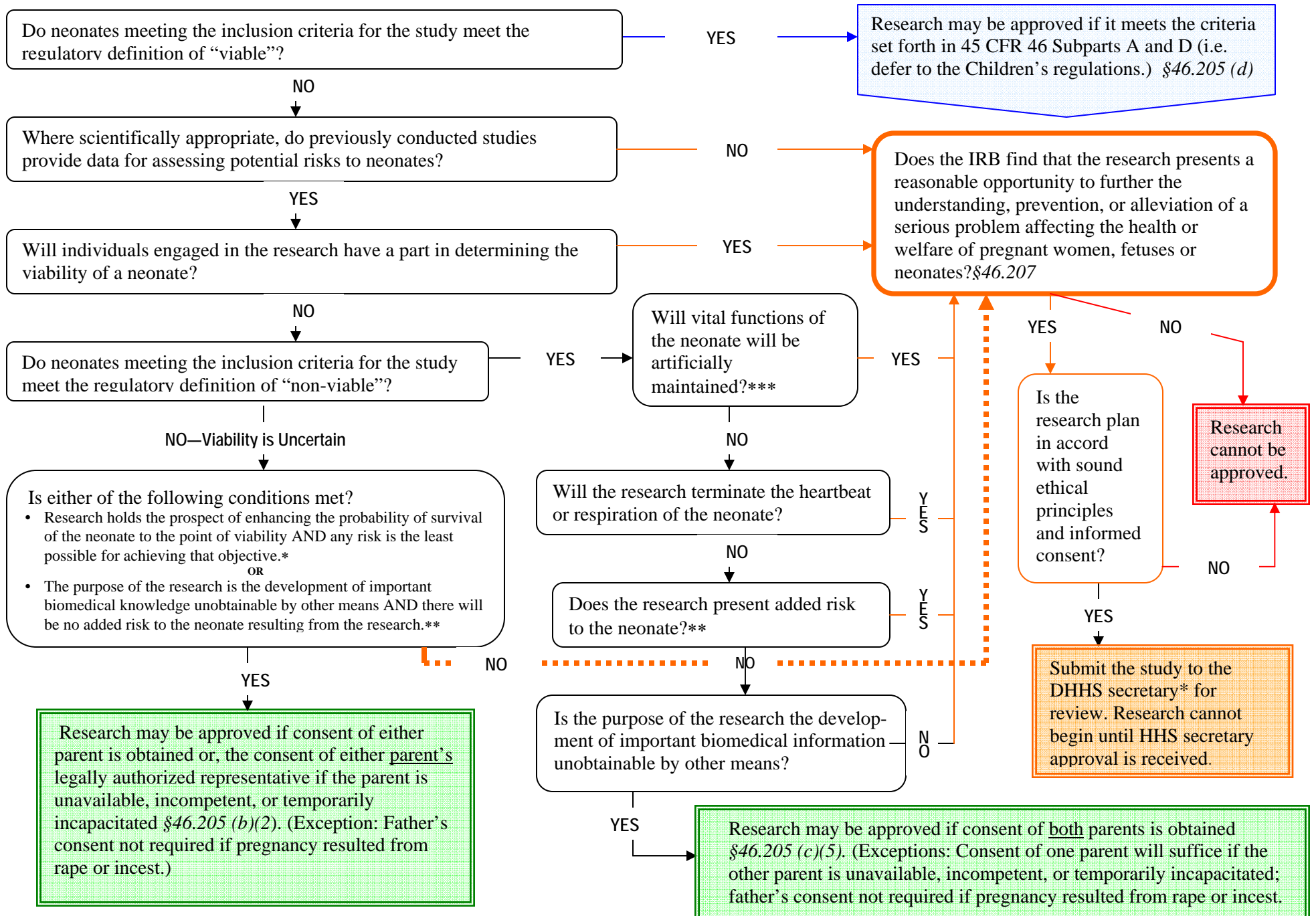


NEONATAL RESEARCH

ALGORITHM FOR THE APPLICATION OF 45 CFR 46 SUBPART B (WITH REFERENTS TO MCL 368)



*HHS secretary approval needed for federally funded studies. Studies involving no support from federal sources go to OVPR for review.

Color Scheme	Definitions	Federal Regulations	Michigan Regulations
Green— Research is approvable.	LIVE NEONATE means neonate shows evidence of life as determined by the same medical standards as are used in determining evidence of life in a spontaneously aborted embryo or fetus at approximately the same stage of gestational development. <i>MCL 333.2687 Sec. 2687</i>	§46.205 Research involving neonates. (a) Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met: (1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates. (2) Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate. (3) Individuals engaged in the research will have no part in determining the viability of a neonate. (4) The requirements of paragraph (b) or (c) of this section have been met as applicable.	PUBLIC HEALTH CODE (EXCERPT) Act 368 of 1978, PART 26 DATA, INFORMATION, AND RESEARCH 333.2685 Use of live human embryo, fetus, or neonate for nontherapeutic research; prohibitions; presumption.
Blue—Consider research under subpart C rather than subpart B	NEONATE means a newborn §46.202 (d). FDA guidance defines a neonate as an infant less one month ¹ or less than 28 days old. ²	(b) Neonates of uncertain viability. Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met: (1) The IRB determines that: (i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or (ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and (2) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.	333.2685 Use of live human embryo, fetus, or neonate for nontherapeutic research; prohibitions; presumption. Sec. 2685. (1) A person shall not use a live human embryo, fetus, or neonate for nontherapeutic research if, in the best judgment of the person conducting the research, based upon the available knowledge or information at the approximate time of the research, the research substantially jeopardizes the life or health of the embryo, fetus, or neonate. Nontherapeutic research shall not in any case be performed on an embryo or fetus known by the person conducting the research to be the subject of a planned abortion being performed for any purpose other than to protect the life of the mother. (2) For purposes of subsection (1) the embryo or fetus shall be conclusively presumed not to be the subject of a planned abortion if the mother signed a written statement at the time of the research, that she was not planning an abortion.
Orange— Research is slowed by at least 6 months to two years during HHS secretary approval process.	NON-THERAPEUTIC RESEARCH means scientific or laboratory research, or other kind of experimentation or investigation not designed to improve the health of the research subject. <i>MCL 333.2692 Sec. 2692. As used in sections 2685 to 2691</i>	(c) Nonviable neonates. After delivery nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met: (1) Vital functions of the neonate will not be artificially maintained; (2) The research will not terminate the heartbeat or respiration of the neonate; (3) There will be no added risk to the neonate resulting from the research; (4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and (5) The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part,	333.2686 Diagnostic, assessment, or treatment procedures not prohibited. Sec. 2686. Sections 2685 to 2691 shall not prohibit or regulate diagnostic, assessment, or treatment procedures, the purpose of which is to determine the life or status or improve the health of the embryo, fetus, or neonate involved or the mother involved. 333.2687 Embryo, fetus, or neonate considered live. Sec. 2687. An embryo, fetus, or neonate is a live embryo, fetus, or neonate for purposes of sections 2685 to 2691 if, in the best medical judgment of a physician, it shows evidence of life as determined by the same medical standards as are used in determining evidence of life in a spontaneously aborted embryo or fetus at approximately the same stage of gestational development.
Red—Research cannot be approved.	NONVIABLE NEONATE means a neonate after delivery that, although living, is not viable §46.202 (e).		333.2688 Research on dead embryo, fetus, or neonate; consent of mother; presumption; authorized transfer to medical research facilities; research standards. Sec. 2688. (1) Research may not knowingly be performed upon a dead embryo, fetus, or neonate unless the consent of the mother has first been obtained. Consent shall not be required in the case of a routine pathological study. (2) For purposes of this section, consent shall be conclusively presumed to have been granted by a written statement, signed by the mother that she consents to the use of her dead embryo, fetus, or neonate for
	SECRETARY means the Secretary of Health and Human Services and any		

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	<p>other officer or employee of the Department of Health and Human Services to whom authority has been delegated §46.202 (g).</p> <p>VIABLE, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration §46.202 (h).</p>	<p>except that the waiver and alteration provisions of §46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).</p> <p>(d) Viable neonates. A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.</p>	<p>research.</p> <p>(3) Written consent shall constitute lawful authorization for the transfer of the dead embryo, fetus, or neonate to medical research facilities.</p> <p>(4) Research being performed upon a dead embryo, fetus, or neonate shall be conducted in accordance with the same standards applicable to research conducted pursuant to part 101.</p> <p>333.2689 Abortion; consideration. Sec. 2689. A person shall not perform or offer to perform an abortion where part or all of the consideration for the performance is that the embryo, or fetus, whether alive or dead, may be used for research or study.</p> <p>333.2690 Sale, transfer, distribution, or giving away of embryo, fetus, or neonate. Sec. 2690. A person shall not knowingly sell, transfer, distribute, or give away an embryo, fetus, or neonate for a use which is in violation of sections 2685 to 2689.</p> <p>333.2691 Violation; penalty. Sec. 2691. A person who violates sections 2685 to 2690 is guilty of a felony, punishable by imprisonment for not more than 5 years.</p> <p>333.2692 “Nontherapeutic research” defined. Sec. 2692. As used in sections 2685 to 2691, “nontherapeutic research” means scientific or laboratory research, or other kind of experimentation or investigation not designed to improve the health of the research subject.</p>

*Michigan law allows this type of research under MCL 368 333.2685 in that it may be considered ‘therapeutic’ and hence not prohibited.

** Non-therapeutic research approved under noted federal regulations as “presenting no added risk to the neonate” may be approved by the IRBMED if and only if it also meets the state law standard wherein it “does not substantially jeopardize the life or health of the . . . neonate” *MCL 368 333.2685*.

***The research itself cannot artificially maintain the neonate solely in order to conduct an experiment.

¹ *Guidance for Industry—Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act*, June 1998, page 6. Repeated at <http://www.fda.gov/cder/guidance/2414fnl.htm>, last updated 3/8/01.

² http://www.fda.gov/cder/pediatric/presentation/mercury-lead_osorio/tsld005.htm