

Brief Overview of the Revised Common Rule and Subpart B – Pregnant Women

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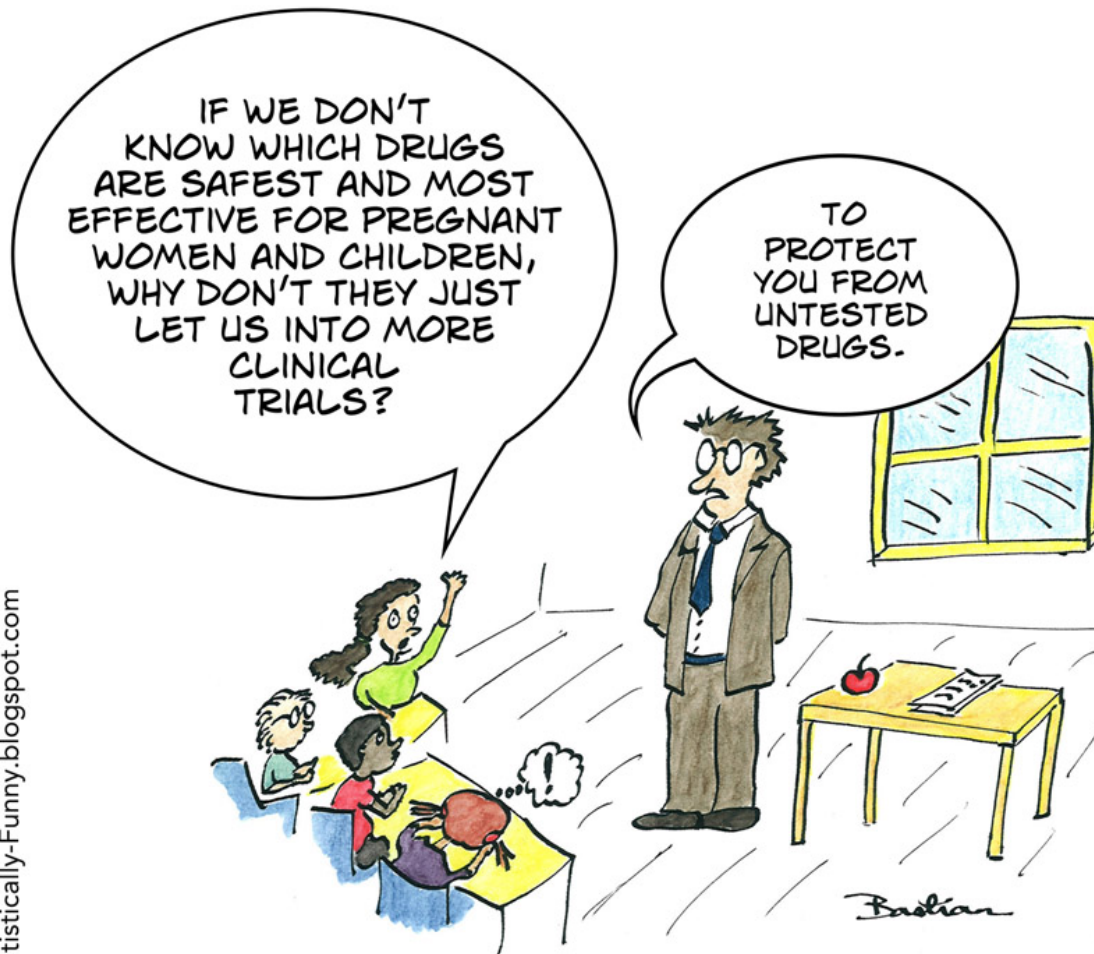


Summary of Goals and Major Changes of the 2018 Revisions



- **Promoting individual autonomy**
 - Changing requirements of informed consent
 - Adding broad consent option for secondary research
- **Reducing administrative burden, streamlining IRB processes**
 - Removing activities from the definition of research
 - Expanding exempt research
 - *Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.*
 - Updating and simplifying expedited review
 - Eliminating certain continuing reviews
 - Using single IRB review
 - Eliminating grant application review
 - Eliminating IRB roster reporting
 - Adding provision on screening and recruitment

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Revised Common Rule

- In agreement with the majority of public comments, the final rule no longer includes pregnant women or "handicapped" or physically disabled individuals as examples of populations that are potentially vulnerable to coercion or undue influence.
- Whether or not pregnant women are considered vulnerable to coercion or undue influence does not affect the applicability of Subpart B - Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research **§46.201-207**

IRB Approval under Subpart B: §46.204

- (a) Data for assessing potential risks to pregnant women and fetuses (preclinical studies, studies on pregnant animals, and clinical studies, studies on non-pregnant women).
- (b) 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; or, if no prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is important biomedical knowledge that cannot be obtained by any other means;
- (c) Risks minimized to the least possible to carry out the research;

IRB Approval under Subpart B: §46.204

- (d) For research that holds out the prospect of direct benefit to the pregnant woman, the prospect of direct benefit both to the pregnant woman and fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is provide important biomedical knowledge that cannot be obtained by other means, her consent must be obtained in accord with the informed consent provisions of [subpart A](#);
- (e) If research has prospect of direct benefit solely to the fetus then consent of the pregnant woman and father is obtained. The father's consent need not be obtained if he is unavailable, incompetent, or the pregnancy resulted from rape or incest.

IRB Approval under Subpart B: §46.204

- (f) Each individual providing consent under paragraph [\(d\)](#) or [\(e\)](#) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
- (g) For children as defined in [§46.402\(a\)](#) who are pregnant, assent and permission are obtained in accord with the provisions of [subpart D](#) ;
- (h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
- (i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
- (j) Individuals engaged in the research will have no part in determining the viability of a neonate.

Questions About the Revisions?



- Please refer to the text of the revised Common Rule available on OHRP's website for a complete and accurate description of the regulatory requirements: www.hhs.gov/ohrp
- Submit your questions to OHRP@hhs.gov

Thank You!