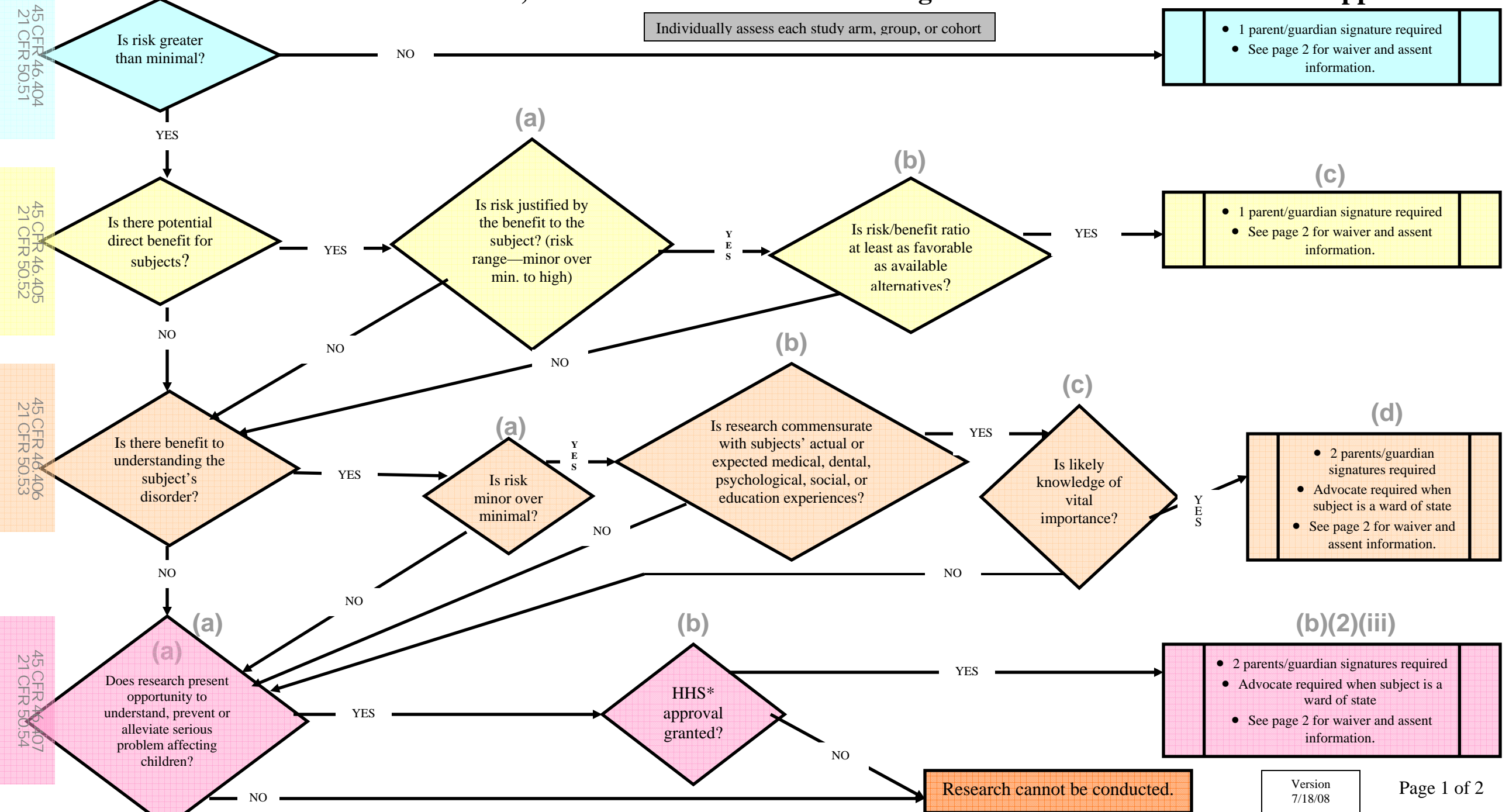


# RESEARCH INVOLVING CHILDREN (<18 YEARS OLD)† AS SUBJECTS

After risk and benefit are determined, use this flow-chart to find the regulations under which research is approvable.



45 CFR 46.404  
21 CFR 50.51

45 CFR 46.405  
21 CFR 50.52

45 CFR 46.406  
21 CFR 50.53

45 CFR 46.407  
21 CFR 50.54

†See UM-HRPP OM for exceptions to 18 as the age of legal consent in Michigan.

The IRB must determine if assent will be required. If required:

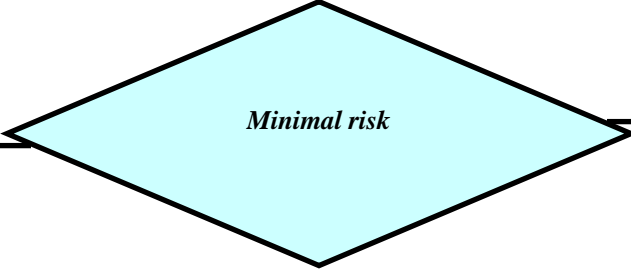
- the IRB must determine if exceptions can be made by the investigator or by the IRB
- whether and how assent must be documented

# CHILDREN IN RESEARCH

## REQUIRED ELEMENTS FOR PARENTAL PERMISSION AND ASSENT

Determine risk and category of allowable children's research

45 CFR 46.404  
21 CFR 50.51



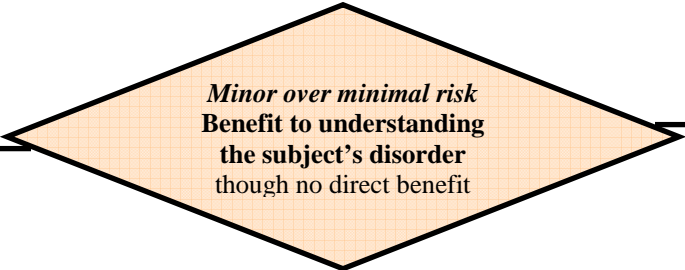
PERMISSION/SIGNATURES	ASSENT OF SUBJECT	PARENTAL PERMISSION WAIVERS THAT MAY BE GRANTED
1 parent/guardian	Usually required for $\geq 7$ unless <b>IRB determines</b> one of the following applies: 1. Capabilities of children so limited they cannot be consulted. 2. Study offers important benefit unavailable outside of the research. 3. Assent can be waived under same criteria as allowed for informed consent.	<b>OHRP</b> —permission, parental permission w/alternate mechanisms, waiver of documentation of parental permission <b>FDA</b> —waiver of documentation of parental permission

45 CFR 46.405  
21 CFR 50.52



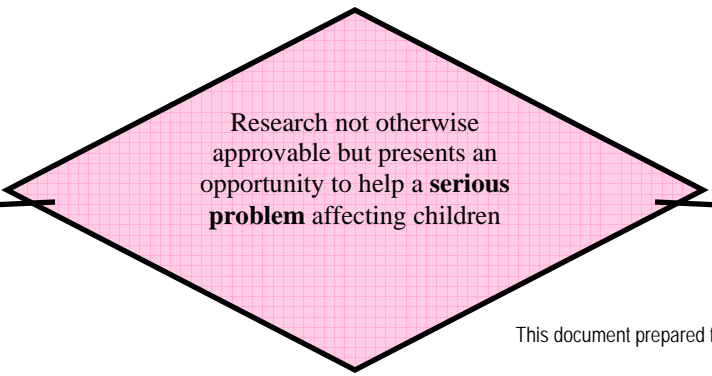
PERMISSION/SIGNATURES	ASSENT OF SUBJECT	PARENTAL PERMISSION WAIVERS THAT MAY BE GRANTED
1 parent/guardian	Usually required for $\geq 7$ unless <b>IRB determines</b> one of the following applies: 1. Capabilities of some or all children is so limited they cannot be consulted. 2. Study offers important benefit unavailable outside of the research.	<b>OHRP</b> —parental permission w/alternate mechanisms <b>FDA</b> —not applicable to FDA regulated research

45 CFR 46.406  
21 CFR 50.53



PERMISSION/SIGNATURES	ASSENT OF SUBJECT	PARENTAL PERMISSION WAIVERS THAT MAY BE GRANTED
2 parents** Wards: Guardian (signs consent document) and Advocate (does not have to sign consent document)****	Usually required for $\geq 7$ unless <b>IRB determines</b> one of the following applies: 1. Capabilities of some or all children is so limited they cannot be consulted. 2. Study offers important benefit unavailable outside of the research.	<b>OHRP</b> —parental permission w/alternate mechanisms <b>FDA</b> —not applicable to FDA regulated research

45 CFR 46.407  
21 CFR 50.54



PERMISSION/SIGNATURES	ASSENT OF SUBJECT	PARENTAL PERMISSION WAIVERS THAT MAY BE GRANTED
2 parents** Wards: Guardian (signs consent document) and Advocate (does not have to sign consent document)****	Usually required for $\geq 7$ unless <b>IRB determines</b> one of the following applies: 1. Capabilities of some or all children is so limited they cannot be consulted. 2. Study offers important benefit unavailable outside of the research.	<b>OHRP</b> —parental permission w/alternate mechanisms <b>FDA</b> —not applicable to FDA regulated research

This document prepared for use by IRBMED in applying federal regulations. See footnotes (right) for references. Contact June Insko, [insco@umich.edu](mailto:insco@umich.edu) if you have questions or comments. Version 7/16/08.

**Footnotes**  
 Information provided in this document is based upon 45 CFR 46 and 21 CFR 50 (Subparts D). To determine when someone under the age of 18 can legally consent to research without parental permission because they could consent for clinical care, see the UM Operations Manual. The IRBMED may impose stricter standards at its discretion.  
 \*HHS secretary approval is required for federally funded studies that fall under 45 CFR 46.407. FDA Commissioner approval is required for studies under FDA jurisdiction approval under 21 CFR 50.54 (regardless of funding). If the study is not federally funded and not under FDA oversight, the UM Office of Vice President for Research must be consulted.  
 \*\*One parent signature will suffice when one parent is deceased, unknown, incompetent . . . or when only one parent has sole legal responsibility for the care and custody of the child.  
 \*\*\*On studies not under FDA oversight, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.  
 \*\*\*\*See 45 CFR 46.409 and 21 CFR 50.56