

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Question regarding clinical trials  
**Date:** Tuesday, November 25, 2014 11:22:32 AM

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Good morning –

Sponsors generally use the age of 18 for enrollment and exclusion/inclusion criteria because it does not involve the pediatric population or need for assent or legally authorized representative (LAR) for the informed consent. The age of 18 is not required by FDA regulations nor is it a “hard and fast” rule.

I hope this helps,

Kind regards,

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Senior Health Policy Analyst  
Office of Good Clinical Practice  
Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

**From:** GYXUM/XQ  
**Sent:** Sunday, November 23, 2014 12:42 AM  
**To:** OC GCP Questions  
**Subject:** Question regarding clinical trials

To Whom It May Concern,

I am reaching out to you hoping you will be willing to answer a general question for me regarding clinical trials. I realize there are variances from program to program, but in this case I am looking for a "rule of thumb" answer.

When looking at an investigational program, I often see an age minimum of 18 yrs. old. Is this a hard and fast FDA clinical rule, or is there a means by which a researcher and parent of a child under the age of 18 may request a waiver or exception given appropriate conditions and admit a participant under the age of 18. This question assumes of course that the researcher properly comply with informed consent procedures and that the parents / legal guardian understand the situation and are of sound mind and judgement to properly evaluate and weigh the potential benefits and harms.

Thank you for your time and consideration in answering this question. If there are resources online that address this topic, please refer me to them so that I do not take up valuable time that can be addressed with research. I have spent several hours looking for information, and may simply have missed it.

Respectfully,  
[redacted]