From: OC GCP Questions
To: [redacted]
Subject: Question about Minors and Proof of Guardianship
Date: Friday, July 31, 2015 7:44:46 AM

Good morning --

FDA's regulations and FDA guidance documents are silent on this point. FDA's regulations define children as "persons who have not attained the legal age for consent to treatments or procedures involved in clinical investigations, under the applicable law of the jurisdiction in which the clinical investigation will be conducted." (See 21 CFR 50.3(o)).

The documentation of a guardianship is dependent on the applicable law of the jurisdiction in which the study will be conducted necessitating familiarity with the applicable law(s).

The FDA definitions below that address minor and children. (21 CFR 50.3 (l-s) --

(l) Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(m) Family member means any one of the following legally competent persons: Spouse; parents; children (including adopted children); brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship.

(n) Assent means a child's affirmative agreement to participate in a clinical investigation. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(o) Children means persons who have not attained the legal age for consent to treatments or procedures involved in clinical investigations, under the applicable law of the jurisdiction in which the clinical investigation will be conducted.

(p) Parent means a child's biological or adoptive parent.

(q) Ward means a child who is placed in the legal custody of the State or other agency, institution, or entity, consistent with applicable Federal, State, or local law.

(r) Permission means the agreement of parent(s) or guardian to the participation of their child or ward in a clinical investigation.

(s) Guardian means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

Please see the link below to the final rule on Additional Safeguard for Children in Clinical investigations for FDA-regulated products.

http://www.gpo.gov/fdsys/pkg/FR-2013-02-26/pdf/2013-04387.pdf

An additional reference which you may find helpful is An additional reference which you may find helpful is Appendix B (State Regulation of Medical Research with children and Adolescents: An Overview and Analysis by Amy T. Campbell) found in the Institute of Medicine Report on Ethical Conduct of Clinical Research Involving Children, The National Academies Press, Washington, DC..
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The Ethical Conduct of Clinical Research Involving Children

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards

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From: [redacted]
Sent: Thursday, July 30, 2015 5:02 PM
To: OC GCP Questions
Subject: Question about Minors and Proof of Guardianship

For clinical trials that involve minors, what proof of guardianship forms(birth certificate, etc.) do you like to see verified?

Thank you,

[redacted]