

Responsibility Reminder

2010

CHILDREN, GUARDIANS AND LEGALLY AUTHORIZED REPRESENTATIVES

Compass IRB expects the Principal Investigator to understand local laws and special considerations for studies involving children or other populations requiring a guardian or legally authorized representative (LAR).

When Compass IRB reviews your Initial Review Application, the Board will be looking for information regarding whether or not you will be enrolling a vulnerable population and if so, whether or not the vulnerable population requires a guardian, witness or L.A.R. by the prospective subject or legally authorized representative and the information to be communicated to the prospective subject or the legally authorized representative. The Compass IRB application has recently been updated (08 March 2010) and will specifically ask you to detail additional safeguards that the P.I. / site has in place to protect the rights and welfare of your vulnerable populations *and* to also provide information on how the P.I. / site will verify whether or not the category of individuals may require an L.A.R., guardian or witness and whom can act in that capacity in your jurisdiction (according to your local laws).

Compass IRB expects you to review the template ICF provided by your Sponsor and notify us if your local or state laws require any modifications to the language or signature block of the consent documentation.

The Board will be evaluating all the information you provide regarding this matter when reviewing your application and Compass IRB will work diligently to make sure your ICF reflects all the needs of your local laws or site-specific needs.

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For your reference

Additional information on required elements of informed consent and special categories for children/adolescents can be located in the FDA Information Sheet: A Guide to Informed Consent <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm>

If you have additional questions, please visit our FAQ section at www.compassirb.com or feel free to contact us directly.