From: Goldkind, Sara
Sent: Wednesday, March 19, 2014 2:16 PM
To: [redacted]
Subject: RE: CTTI Informed Consent Project - Question not directly associated with project[redactged

[redacted]

I am not aware of FDA guidance (including ICH) or any other online guidances that address documenting the parent/legal guardian to child relationship in the US.

In discussing your query with other folks in my office, the suggestion came up that a sponsor may wish to consider establishing standard operating policies and procedures on such matters that include accounting for country or state specific requirements. Alternatively, sponsors may develop expectations of sites in terms of having such SOPPs. Additionally, sites may have their own SOPPs in this regard that sponsors may want to inquire about and be aware of.

I'm sorry I can't be more informative on this point.

Sincerely,

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From: [redacted]
Sent: Monday, March 17, 2014 2:31 PM
To: Goldkind, Sara
Subject: CTTI Informed Consent Project - Question not directly associated with project

Sara,

Good afternoon. I'm a participant in the CTTI Informed Consent Project and was on the recent call where there was the discussion of ICF content & what was wrong/what could make it better. I work for [redacted] as the global ICF process owner/subject matter expert.

I'm also currently working internally on projects associated with pediatrics and assents. I've been searching online for guidance on documenting the parent/legal guardian to child relationship in the US, but haven't been able to find much guidance (Except from ethics committees & that's not consistent). I was hoping that you could point me in the right direction. Some countries have specific documentation requirements.

In the US, we have relied on ethics committees (and local requirements) to determine the documentation needed to establish the parent/legal guardian to child relationship. Often, the ethics committees only required documentation

when there was a legal guardian relationship (i.e. step child, grandchild, etc…) or some noticeable issue (i.e. different last name). Our ICFs do have a line in the signature block for the parent/legal guardian to indicate relationship in writing (and if the ICF does not contain the line, the site has a process to note the relationship in the site file).

Recently, there have also been issues with what is "acceptable" documentation for the typical parent-child relationships. Is documentation needed to establish any parent/legal guardian to child relationship OR just when the relationship is not easily ascertained? Is this just a notation in the original medical record of who the parent is, a court order, a child custody agreement, birth certificate, etc…? Do copies need to be retained in the study file. Is the birth certificate sufficient to establish that the parent has the "right" to consent for the child? What about in cases of divorce where medical guardianship is only given to one parent (but the birth certificate would not have changed)? What due diligence/documentation would be needed to indicate that the parents weren't divorced?

We want to ensure that the sites are properly documenting the relationship.

Any guidance would be deeply appreciated. Thank you so very much.

regards,
[redacted]