

Samuel, Lee (CDC/OID/NCEZID)

From: Patterson, Jocelyn (CDC/OID/NCHHSTP)
Sent: Wednesday, March 16, 2016 11:25 AM
To: Youngblood, Laura (CDC/OID/NCEZID)
Cc: Paz-Bailey, Gabriela (CDC/OID/NCHHSTP); Sharp, Tyler M. (CDC/OID/NCEZID); Roberson, Lashonda (CDC/OD/OADS); Samuel, Lee (CDC/OID/NCEZID); NCEZIDHumanStudies (CDC)
Subject: RE: 6848 -- final revisions to address documentation of parental permission

Thank you for incorporating these changes. I approve protocol #6848.

From: Youngblood, Laura (CDC/OID/NCEZID)
Sent: Wednesday, March 16, 2016 10:51 AM
To: Patterson, Jocelyn (CDC/OID/NCHHSTP) <fzp0@cdc.gov>
Cc: Paz-Bailey, Gabriela (CDC/OID/NCHHSTP) <gmb5@cdc.gov>; Sharp, Tyler M. (CDC/OID/NCEZID) <iyp4@cdc.gov>; Roberson, Lashonda (CDC/OD/OADS) <gwk5@cdc.gov>; Samuel, Lee (CDC/OID/NCEZID) <llj3@cdc.gov>; NCEZIDHumanStudies (CDC) <NCEZIDHumanStudies@cdc.gov>
Subject: 6848 -- final revisions to address documentation of parental permission
Importance: High

Thank you for your flexibility, Jocelyn!

The following revisions have been made:

- Title page and footer: version and date have been updated
- Page 22 (Informed consent process): “For all non-emancipated minors ~~14~~ and **16** to 20 years old who wish to participate and are **not** accompanied by their parents, we will request a waiver of documentation for parental permission...”
- Page 22 (Request for waiver of documentation): “...we are requesting to have the parental permission documentation waived **for non-emancipated minors age 16 (legal driving age) to 20 who are not accompanied by a parent.**”
- Page 29, 34 (symptomatic and asymptomatic consent documents): “*If parental permission is sought verbally by telephone, please confirm the following:* Participant is a non-emancipated minor age ~~14~~ **16-20**...”

You'll probably see that these revisions are attributed to me in the tracking; please note that all revisions were discussed with Dr. Paz-Bailey via telephone, and she authorized me to make these revisions on her behalf. I think we got all of the references to waiving parental permission, but please let me know if any were missed.

Many thanks,
Laura

Laura Youngblood, MPH, CIP

Human Subjects Advisor | NCEZID | lyoungblood@cdc.gov | Office: (404) 639-6394 | Mobile: (404) 510-0093

From: Patterson, Jocelyn (CDC/OID/NCHHSTP)
Sent: Wednesday, March 16, 2016 10:09 AM

To: Youngblood, Laura (CDC/OID/NCEZID) <zfk9@cdc.gov>
Cc: Paz-Bailey, Gabriela (CDC/OID/NCHHSTP) <gmb5@cdc.gov>; Sharp, Tyler M. (CDC/OID/NCEZID) <iyp4@cdc.gov>;
Roberson, Lashonda (CDC/OD/OADS) <gwk5@cdc.gov>
Subject: RE: 6848 -- interpretation of expedited review category 2

Yes, that would be great. Once I receive those changes I will approve the protocol.

From: Youngblood, Laura (CDC/OID/NCEZID)
Sent: Wednesday, March 16, 2016 10:08 AM
To: Patterson, Jocelyn (CDC/OID/NCHHSTP) <fzp0@cdc.gov>
Cc: Paz-Bailey, Gabriela (CDC/OID/NCHHSTP) <gmb5@cdc.gov>; Sharp, Tyler M. (CDC/OID/NCEZID) <iyp4@cdc.gov>;
Roberson, Lashonda (CDC/OD/OADS) <gwk5@cdc.gov>
Subject: RE: 6848 -- interpretation of expedited review category 2

Hi Jocelyn,

Thanks for calling me on Monday! I have talked with the investigators, and they have confirmed that for SEDSS, seeking parental permission via telephone really only comes into play for those who are old enough to drive – and for the most part, a parent has always been available to give permission, since SEDSS recruitment occurs while the patient is acutely ill.

The investigators are agreeable to limiting verbal parental permission procedures to only those age 16 and older, as you and I discussed on Monday.

Do you want the investigators to go ahead and revise the protocol accordingly and send back to you (with track changes, and copying LaShonda)?

I'm here until 4:30 today, so feel free to call, if needed.

Thanks,
Laura

Laura Youngblood, MPH, CIP

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From: Patterson, Jocelyn (CDC/OID/NCHHSTP)
Sent: Monday, March 14, 2016 2:34 PM
To: Youngblood, Laura (CDC/OID/NCEZID) <zfk9@cdc.gov>
Subject: RE: 6848 -- interpretation of expedited review category 2

Hi Laura - I've completed my initial review of the responses. Overall, everything looks good. I still have some concerns about number 10. I need to do a little more research into the regulations to make sure I understand. I will follow up with you tomorrow.

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