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| **From:** | Zhu, Yao-Yao |
| **To:** | "Amanda Parrish, Ph.D." |
| **Cc:** | Davidson, Mark; Haudenschild, Changting; Irony, Ilan; Gavin, Denise K |
| **Subject:** | RE: BLA 125407 Question about Consent Forms |
| **Date:** | Friday, June 22, 2012 2:01:29 PM |

Dear Amanda,

Please see following regarding donor consent forms of your BLA. Please let me know any questions.

**Carolinas Cord Blood Bank:** In preparation for our large BLA amendment later this month, I wanted to inquire keeping the section on Consent Forms (3.2.R.3) up to date. In our original BLA, we submitted copies of all consent forms for each current collection site. Moving forward, we plan to continue to consent each potential donor with a local, IRB-approved consent. However, we would like to propose that this section is eventually removed from our application- if acceptable to the Agency. If that information is not needed, the alternative of keeping that section constantly up to date with each new, IRB-approved version of the consent (which may be modified at varying times throughout the year) seems a bit cumbersome. However, I was hoping that you could provide some guidance on what might be acceptable to the Agency.

**FDA Response:** As part of our BLA review, we have reviewed the donor consent forms in your BLA application (3.2.R.3). You do not need to submit the revised versions for review. If the BLA is approved, then cord blood collected after approval would no longer be an investigational product. FDA does not require use of a consent form for donation of cord blood under a license. Federal, state, or local authorities may have guidelines or requirements regarding donor informed consent that you would need to take into consideration.

Yao-Yao Zhu, MD, PhD
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**From:** Amanda Parrish, Ph.D. [mailto:amanda.b.parrish@duke.edu]
**Sent:** Thursday, May 17, 2012 1:57 PM
**To:** Zhu, Yao-Yao
**Cc:** Davidson, Mark
**Subject:** RE: BLA 125407 Question about Consent Forms

Yao-Yao,

Thank-you for following up internally regarding this issue.

Amanda

Amanda B. Parrish, PhD, RAC
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**From:** Zhu, Yao-Yao [mailto:Yao-Yao.Zhu@fda.hhs.gov]
**Sent:** Thursday, May 17, 2012 1:50 PM
**To:** Amanda Parrish, Ph.D.
**Cc:** Davidson, Mark
**Subject:** RE: BLA 125407 Question about Consent Forms

Amanda,

I need to discuss it internally before giving you a definitive answer about exclusion of the donor consent information.

Yao-Yao

Yao-Yao Zhu, MD, PhD
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**From:** Amanda Parrish, Ph.D. [mailto:amanda.b.parrish@duke.edu]
**Sent:** Thursday, May 17, 2012 1:43 PM
**To:** Zhu, Yao-Yao
**Cc:** Davidson, Mark
**Subject:** BLA 125407 Question about Consent Forms

Dr. Zhu,

In preparation for our large BLA amendment later this month, I wanted to inquire keeping the section on Consent Forms (3.2.R.3) up to date. In our original BLA, we submitted copies of all consent forms for each current collection site. Moving forward, we plan to continue to consent each potential donor with a local, IRB approved consent. However, we would like to propose that this section is eventually removed from our application- if acceptable to the Agency. If that information is not needed, the alternative of keeping that section constantly up to date with each new, IRB approved version of the consent (which may be modified at varying times throughout the year) seems a bit cumbersome. However, I was hoping that you could provide some guidance on what might be acceptable to the Agency.

I had inquired with our primary product reviewer, Denise Gavin, about this issue, and she directed me to you.

Thanks-

Amanda

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