

FW Teleconference on Thursday_20151112_11.txt

From: Karandish, Safa
Sent: Thursday, November 12, 2015 3:35 PM
To: BeckyH@BloodWorksNW.org
Cc: Niland, Brian; Sista, Ramani V
Subject: FW: Teleconference on Thursday

Dear Dr. Haley:

Thank you for your time earlier this morning. The following is the list of topics that we discussed:

- Form 25-9-179 04- HPC, Cord Blood Final Eligibility Determination (amendment #2): the acceptable time frame for health history screening listed on this form contradicts the criteria (full screening no more than (b) (4) before or after collection) defined in SOPs 1060, 3040, 3050. You stated that the (b) (4) month before and (b) (4) after CBU collection" time frame for health history was added to the form after discussion with NMDP but the form will be revised to reflect the acceptable screening criteria defined in the referenced SOPs. Please submit the revised form.
- Please submit a list of major changes in revised SOPs CBP 8020 and CBP 3010 (amendment #2). You explained that changes were related to verification of holding times and temperature and the minimum acceptance criteria for gestational age.
- According to the response letter dated October 30, 2015, you currently only have 1 collection partner located in Hawaii (3 partners were listed in the original BLA). Please explain who is responsible for training collectors, managing collection supplies, donor screening at the collection sites in Oregon and Washington.
- Please submit information regarding the instructions for performing your validated thawing process at a separate facility including, but not limited to Form 25-9-172, HPC(CB) Product Thaw Instructions, and Form 25-9-189, Thaw Information.
- You also confirmed that: 1) birth mothers who have received antibiotics are not excluded (already provided information to Dr. Joydeep Ghosh), 2) the Cord Blood Summary Sheet referred to on the HPC, Cord shipping Checklist include the list of infectious disease test results.
No additional information is needed.

We will provide you with additional information regarding the process and the required documentation for the facility name change.

Best regards,

Safa

From: Dr. Rebecca Haley [mailto:BeckyH@BloodWorksNW.org]
Sent: Wednesday, November 11, 2015 1:16 PM
To: Karandish, Safa
Cc: Niland, Brian; Tony White
Subject: RE: Teleconference on Thursday

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Please find the conference call information below:

Conf. Line: (b) (4)
Part. Code: (b) (4)

Is it possible to let us know which topics you would like to discuss so we can have the relevant people in the room?

Thanks,
Becky

From: Karandish, Safa [mailto:Safa.Karandish@fda.hhs.gov]
Sent: Tuesday, November 10, 2015 11:28 AM
To: Dr. Rebecca Haley
Cc: Niland, Brian; Tony White
Subject: RE: Teleconference on Thursday

Thanks for getting back to me quickly. Yes, please send us the call-in number.

Best regards,

Safa

From: Dr. Rebecca Haley [mailto:BeckyH@BloodWorksNW.org]
Sent: Tuesday, November 10, 2015 1:42 PM
To: Karandish, Safa
Cc: Niland, Brian; Tony White
Subject: RE: Teleconference on Thursday

Dear Ms Karandish,
Our team is available at 11:00 EST, 08:00 PST on Thursday morning, Nov 12, if that is convenient for you. Would you like for us to send you a call-in number?

Rebecca Haley, MD
Medical Director, Blood Services, Cord Blood Services, NMDP Donor and Apheresis Center

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P 206-689 6301 • (b) (6) FAX 866-261-5228
beckyh@bloodworksnw.org • bloodworksnw.org

Because blood works miracles every day: <http://youtu.be/ujNxqr33VEQ>

From: Karandish, Safa [mailto:Safa.Karandish@fda.hhs.gov]
Sent: Tuesday, November 10, 2015 10:01 AM
To: Dr. Rebecca Haley
Cc: Niland, Brian
Subject: Teleconference on Thursday

Dear Dr. Haley:

We have some questions regarding some of the information that you have submitted in the recent amendment. We are hoping that we can schedule a call for this coming Thursday, Nov 12th, after 11am EST. I appreciate if you could let me know of your availability.

Thank you.

Safa

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