

From: Formica, Richard
To: Jadia Bruckner
Cc: Matt Belton; McLaughlin, Chris (HRSA); Tina Rhoades; Rebecca Murdock; Lauren Mauk; HRSA OPTN EXT COB; Mauro, Patrick (HRSA); Germain, Mesmin (HRSA); Sara Moriarty; Sarah Payamps; Aigbe, Aitebureme (Aite) (HRSA); Holloman, Frank (HRSA); Lynch, Raymond (HRSA); Nair, Suma (HRSA); Doby, Brianna (HRSA); Petrone, Stephanie (HRSA); Locke, Jayme (HRSA); John, Hanock (HRSA); Kimberly Uccellini; Mauro, Patrick (HRSA); Aigbe, Aitebureme (Aite) (HRSA); Holloman, Frank (HRSA); Lynch, Raymond (HRSA); Doby, Brianna (HRSA); Locke, Jayme (HRSA); John, Hanock (HRSA)
Subject: [EXTERNAL] Re: COI follow-up-- HRSA-directed investigation plan
Date: Thursday, February 6, 2025 5:18:20 PM

Jadia,
Please ensure I have read only access to all of the documents
Rich
Richard N Formica Jr , MD
Professor of Medicine and Surgery
Director of Transplant Medicine

Sent from my iPhone

On Feb 6, 2025, at 5:15 PM, Jadia Bruckner <[REDACTED]> wrote:

Hello Everyone,

The reconfiguration of the working SharePoint in complete Users will not be able to download attachments

Please let me know if we are approved to release the records to reviewers

I have put together a draft schedule to help keep track of review milestones

- 2/6 Records released to reviewers
- 2/19 Target deadline for record review
- 2/20 Contractor staff compile and theme reviewer feedback
- 2/21 Exit interview with reviewers to align themes
- 2/24-2/25 Report writer owner (2) editing and approval
- 2/26 Final report to Rich for approval
- 2/27 Final report due to HRSA

Thanks,

Jadia

OPTN Restricted

From: Matt Belton
Sent: Thursday, February 6, 2025 3:11 PM
To: Formica, Richard; Christopher J McLaughlin
Cc: Tina Rhoades; Jadia Bruckner; Rebecca Murdock; Lauren Mauk; [REDACTED]; Mauro, Patrick (HRSA); Mesmin Germain; Sara Moriarty; Sarah Payamps; Aigbe, Aitebureme (Aite) (HRSA); Holloman, Frank (HRSA); Lynch, Raymond (HRSA); Suma Nair; Doby, Brianna (HRSA); Stephanie Petrone; Locke, Jayme (HRSA); Hanock John; Kimberly Uccellini
Subject: Re: COI follow-up-- HRSA-directed investigation plan

Good Afternoon Chris,

We are diligently working on the reconfiguration and expect to make all the necessary changes by late afternoon today As soon as the changes are completed and tested, I will send you an update and wait for your approval to distribute to the volunteers

Thanks,
Matt

OPTN Restricted

From: Formica, Richard <[REDACTED]>
Sent: Thursday, February 6, 2025 2:16 PM
To: Christopher J McLaughlin <[REDACTED]>
Cc: Tina Rhoades <[REDACTED]>; Jadia Bruckner <[REDACTED]>; Rebecca Murdock <[REDACTED]>; Lauren Mauk <[REDACTED]>; [REDACTED] <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Mesmin Germain <[REDACTED]>; Sara Moriarty <[REDACTED]>; Sarah Payamps <[REDACTED]>; Matt Belton <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Suma Nair <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Stephanie Petrone <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>; John Hanock <[REDACTED]>; Kimberly Uccellini <[REDACTED]>; [REDACTED] <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Mesmin Germain <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Suma Nair <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Stephanie Petrone <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>; Hanock John <[REDACTED]>
Subject: [EXTERNAL] Re: COI follow-up-- HRSA-directed investigation plan

Just want to point out that we are now 21 days from the expected delivery date That means completing the review and writing the report
Rich
Richard N Formica Jr , MD
Professor of Medicine and Surgery
Director of Transplant Medicine

Sent from my iPhone

On Feb 6, 2025, at 2:11 PM, McLaughlin, Chris (HRSA) <[REDACTED]> wrote:

Hi Tina: HRSA does want to approve distribution after UNOS confirms reconfiguration. Please let us know when to expect communication from UNOS re reconfiguration and we will be monitoring to respond.
Thanks, Chris

Christopher J. McLaughlin
Senior Advisor
FAC-COR-III, OPTN Contract
Division of Transplantation
Health Systems Bureau
[REDACTED]

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From: Tina Rhoades <[REDACTED]>
Sent: Thursday, February 6, 2025 1:38 PM
To: McLaughlin, Chris (HRSA) <[REDACTED]>; Jadia Bruckner <[REDACTED]>; Formica, Richard <[REDACTED]>; Rebecca Murdock <[REDACTED]>
Cc: Lauren Mauk <[REDACTED]>; [REDACTED] <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Germain, Mesmin (HRSA) <[REDACTED]>; Sara Moriarty <[REDACTED]>; [REDACTED] <[REDACTED]>; Sarah Payamps <[REDACTED]>; Matt Belton <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Petrone, Stephanie (HRSA) <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>; John, Hanock (HRSA) <[REDACTED]>; Kimberly Uccellini <[REDACTED]>
Subject: [EXTERNAL] RE: COI follow-up-- HRSA-directed investigation plan

Thank you! For clarification, can we share the materials with the reviewers after the reconfiguration and upon notification to HRSA or will we need an additional approval? I ask to ensure we do not unnecessarily lose any additional review time if we can share upon notification. I appreciate your cooperation as we ensure alignment.

Best,
Tina

OPTN Restricted

From: Christopher J. McLaughlin <[REDACTED]>
Sent: Thursday, February 6, 2025 12:49 PM
To: Tina Rhoades <[REDACTED]>; Jadia Bruckner <[REDACTED]>; Formica, Richard <[REDACTED]>; Rebecca Murdock <[REDACTED]>
Cc: Lauren Mauk <[REDACTED]>; HRSA OPTN EXT COR <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Mesmin Germain <[REDACTED]>; Sara Moriarty <[REDACTED]>; [REDACTED] <[REDACTED]>; Sarah Payamps <[REDACTED]>; Matt Belton <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Petrone, Stephanie (HRSA) <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>; John, Hanock (HRSA) <[REDACTED]>; Kimberly Uccellini <[REDACTED]>
Subject: [EXTERNAL] RE: COI follow-up-- HRSA-directed investigation plan

Tina: thanks for answering our questions. Please move forward to reconfigure the SharePoint site to restrict saving/downloading of the materials to be reviewed for this investigation. Please notify HRSA when this reconfiguration is complete and UNOS is ready to share the materials with reviewers. Thanks, Chris

Christopher J. McLaughlin
Senior Advisor
FAC-COR-III, OPTN Contract
Division of Transplantation
Health Systems Bureau
[REDACTED]

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OPTN Restricted

From: Tina Rhoades <[REDACTED]>
Sent: Wednesday, February 5, 2025 2:24 PM
To: McLaughlin, Chris (HRSA) <[REDACTED]>; Jadia Bruckner <[REDACTED]>; Formica, Richard <[REDACTED]>; Rebecca Murdock <[REDACTED]>
<[REDACTED]>
Cc: Lauren Mauk <[REDACTED]>; HRSA OPTN EXT COR <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Germain, Mesmin (HRSA) <[REDACTED]>; Sara Moriarty <[REDACTED]>; Sarah Payamps <[REDACTED]>; Matt Belton <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Petrone, Stephanie (HRSA) <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>; John, Hanock (HRSA) <[REDACTED]>; Kimberly Uccellini <[REDACTED]>
Subject: [EXTERNAL] RE: COI follow-up-- HRSA-directed investigation plan

Thank you, Chris Our answers are below and we are happy to provide any other information as requested

1 In regard to management of PHI and confidentiality

- 1 Does the wording of the log in agreement / disclaimer contain an acknowledgement that the information is furnished for the purpose of federal oversight and is to be kept confidential by the reviewers?

This is the language posted on the SharePoint site (easy to edit if edits are requested): "Your access to this SharePoint site is limited solely to you This information contains PHI and is made in accordance with 45 C.F.R. § 164.512(d), which permits such disclosures without patient authorization for the purposes of facilitating government health oversight activities Please treat the data and files on this site securely and confidentially, as it contains personal health information"

- 1 Does the sharepoint prevent downloading of furnished materials to personal devices?

Currently, the SharePoint site allows for documents to be saved/downloaded, but we can reconfigure it to not allow saving/downloading by users but will require some time -- we believe we can have it completed and tested by midday tomorrow if we receive word that we should move forward

Thank you,
Tina

OPTN Restricted

From: Christopher J. McLaughlin <[REDACTED]>
Sent: Wednesday, February 5, 2025 1 04 PM
To: Tina Rhoades <[REDACTED]>; Jadia Bruckner <[REDACTED]>; Formica, Richard <[REDACTED]>; Rebecca Murdock <[REDACTED]>
<[REDACTED]>
Cc: Lauren Mauk <[REDACTED]>; HRSA OPTN EXT COR <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Mesmin Germain <[REDACTED]>; Sara Moriarty <[REDACTED]>; Sarah Payamps <[REDACTED]>; Matt Belton <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Petrone, Stephanie (HRSA) <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>; John, Hanock (HRSA) <[REDACTED]>; Kimberly Uccellini <[REDACTED]>
Subject: [EXTERNAL] RE: COI follow-up-- HRSA-directed investigation plan

Hi Tina: my apologies for the confusion on my part The email below from 10:28 is the accurate communication Thanks, Chris

Christopher J. McLaughlin
Senior Advisor
FAC-COR-III, OPTN Contract
Division of Transplantation
Health Systems Bureau
[REDACTED]

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OPTN Restricted

From: Tina Rhoades <[REDACTED]>
Sent: Wednesday, February 5, 2025 12:44 PM
To: McLaughlin, Chris (HRSA) <[REDACTED]>; Jadia Bruckner <[REDACTED]>; Formica, Richard <[REDACTED]>; Rebecca Murdock <[REDACTED]>
<[REDACTED]>
Cc: Lauren Mauk <[REDACTED]>; HRSA OPTN EXT COR <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Germain, Mesmin (HRSA) <[REDACTED]>; Sara Moriarty <[REDACTED]>; Sarah Payamps <[REDACTED]>; Matt Belton <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Petrone, Stephanie (HRSA) <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>; John, Hanock (HRSA) <[REDACTED]>; Kimberly Uccellini <[REDACTED]>
Subject: [EXTERNAL] RE: COI follow-up-- HRSA-directed investigation plan

Hi Chris,
I received two recall notifications but believe that neither applied to this email Please confirm that this is still an active request before we proceed Sorry for the confusion

Appreciatively,
Tina

OPTN Restricted

From: Christopher J. McLaughlin <[REDACTED]>
Sent: Wednesday, February 5, 2025 10:28 AM
To: Tina Rhoades <[REDACTED]>; Jadia Bruckner <[REDACTED]>; Formica, Richard <[REDACTED]>; Rebecca Murdock <[REDACTED]>
Cc: Lauren Mauk <[REDACTED]>; HRSA OPTN EXT COR <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Mesmin Germain <[REDACTED]>; Sara Moriarty <[REDACTED]>; Sarah Payamps <[REDACTED]>; Matt Belton <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Petrone, Stephanie (HRSA) <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>; John, Hanock (HRSA) <[REDACTED]>; Kimberly Uccellini <[REDACTED]>
Subject: [EXTERNAL] COI follow-up-- HRSA-directed investigation plan

Good morning Tina and all:

Please see below for guidance in regard to the OPTN's investigation of KYDA

- 1 In regard to the question of Ms. McRann's disclosure HRSA finds no COI that would preclude her involvement
- 2 In regard to management of PHI and confidentiality
 - 1 Does the wording of the log in agreement / disclaimer contain an acknowledgement that the information is furnished for the purpose of federal oversight and is to be kept confidential by the reviewers?
 - 2 Does the sharepoint prevent downloading of furnished materials to personal devices?
- 3 HRSA approves a 7 day extension to the timeline (from the January 17 email) with the final report now due by COB 2/27

Please confirm receipt HRSA will need to review your answers to Q2a and Q2b and provide subsequent approval to move forward before materials are shared with reviewers

Thanks, Chris McLaughlin

Christopher J. McLaughlin
Senior Advisor
FAC-COR-III, OPTN Contract
Division of Transplantation
Health Systems Bureau
[REDACTED]

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From: "Tina Rhoades" <[REDACTED]>
Date: Monday, February 3, 2025 at 8:19:43 PM
To: "Jadia Bruckner" <[REDACTED]>; "McLaughlin, Chris (HRSA)" <[REDACTED]>; "Formica, Richard" <[REDACTED]>; "Rebecca Murdock" <[REDACTED]>
Cc: "Lauren Mauk" <[REDACTED]>; "HRSA OPTN EXT COR" <[REDACTED]>; "Mauro, Patrick (HRSA)" <[REDACTED]>; "Germain, Mesmin (HRSA)" <[REDACTED]>; "Sara Moriarty" <[REDACTED]>; "Sarah Payamps" <[REDACTED]>; "Matt Belton" <[REDACTED]>; "Aigbe, Aitebureme (Aite) (HRSA)" <[REDACTED]>; "Holloman, Frank (HRSA)" <[REDACTED]>; "Lynch, Raymond (HRSA)" <[REDACTED]>; "Nair, Suma (HRSA)" <[REDACTED]>; "Doby, Brianna (HRSA)" <[REDACTED]>; "Petrone, Stephanie (HRSA)" <[REDACTED]>; "Locke, Jayme (HRSA)" <[REDACTED]>; "John, Hanock (HRSA)" <[REDACTED]>; "Kimberly Uccellini" <[REDACTED]>; "Mauro, Patrick (HRSA)" <[REDACTED]>; "Aigbe, Aitebureme (Aite) (HRSA)" <[REDACTED]>; "Holloman, Frank (HRSA)" <[REDACTED]>; "Lynch, Raymond (HRSA)" <[REDACTED]>; "Doby, Brianna (HRSA)" <[REDACTED]>; "Locke, Jayme (HRSA)" <[REDACTED]>
Subject: [EXTERNAL] RE: HRSA ONLY -- RE: COI follow-up-- HRSA-directed investigation plan

We look forward to further direction. To provide context for our ask for clear direction related to case materials, because this is a HRSA directed special review by the OPTN and not a MPSC review, it does not follow the routine processes we use for MPSC. It is documented in the investigation plan that, per HRSA, this is not to be done under confidential medical peer review criteria and materials were to be provided nonredacted. The materials are available in a secure Sharepoint site that requires an individual assigned log in and contains a disclaimer about the PHI/PII. Since this is outside of the routine processes that we follow, we identified the need to align on this prior to making the materials available to the reviewers unredacted. Additionally, I encourage HRSA and OPTN BOD leadership to review the timeline of this investigation and provide any updates to ensure appropriate time for assigned reviewers.

With appreciation,
Tina

OPTN Restricted

From: Jadia Bruckner <[REDACTED]>
Sent: Monday, February 3, 2025 10:58 AM
To: Christopher J. McLaughlin <[REDACTED]>; Tina Rhoades <[REDACTED]>; Formica, Richard <[REDACTED]>; Rebecca Murdock <[REDACTED]>
Cc: Lauren Mauk <[REDACTED]>; HRSA OPTN EXT COR <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Mesmin Germain <[REDACTED]>; Sara Moriarty <[REDACTED]>; Sarah Payamps <[REDACTED]>; Matt Belton <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Petrone, Stephanie (HRSA) <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>; John, Hanock (HRSA) <[REDACTED]>; Kimberly Uccellini <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>
Subject: Re: HRSA ONLY -- RE: COI follow-up-- HRSA-directed investigation plan

Good Morning, Chris!

Hope you had a nice weekend Reminders:

- Records have not been released to the reviewers Pending PHI decision
- Debbi McRann has not been added to the review panel Pending COI clearance
- HRSA does not have access to the working SharePoint Pending list of approved HRSA staff

I am ready to move forward as soon as I get the go ahead

Thanks!

Jadia

OPTN Restricted

From: Christopher J. McLaughlin <[REDACTED]>
Sent: Friday, January 31, 2025 6:50 PM
To: Tina Rhoades <[REDACTED]>; Jadia Bruckner <[REDACTED]>; Formica, Richard <[REDACTED]>; Rebecca Murdock <[REDACTED]>
Cc: Lauren Mauk <[REDACTED]>; HRSA OPTN EXT COR <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Mesmin Germain <[REDACTED]>; Sara Moriarty <[REDACTED]>; Sarah Payamps <[REDACTED]>; Matt Belton <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Petrone, Stephanie (HRSA) <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>; John, Hanock (HRSA) <[REDACTED]>; Kimberly Uccellini <[REDACTED]>; Patrick (HRSA) <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>
Subject: [EXTERNAL] RE: HRSA ONLY -- RE: COI follow-up-- HRSA-directed investigation plan

HRSA is reviewing I'll get back to you asap --Chris

Christopher J. McLaughlin
Senior Advisor
FAC-COR-III, OPTN Contract
Division of Transplantation
Health Systems Bureau
[REDACTED]

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From: Tina Rhoades <[REDACTED]>
Sent: Friday, January 31, 2025 5:30 PM
To: Jadia Bruckner <[REDACTED]>; Formica, Richard <[REDACTED]>; Rebecca Murdock <[REDACTED]>
Cc: McLaughlin, Chris (HRSA) <[REDACTED]>; Lauren Mauk <[REDACTED]>; HRSA OPTN EXT COR <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Germain, Mesmin (HRSA) <[REDACTED]>; Sara Moriarty <[REDACTED]>; Sarah Payamps <[REDACTED]>; Matt Belton <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Petrone, Stephanie (HRSA) <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>; John, Hanock (HRSA) <[REDACTED]>; Kimberly Uccellini <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>
Subject: [EXTERNAL] RE: HRSA ONLY -- RE: COI follow-up-- HRSA-directed investigation plan

Agree, thank you for confirming this Rich We request confirmation from HRSA on releasing the records in an unredacted format to ensure we are aligned in understanding I am concerned if we do not get this out today we will lose over 2 full days of potential review time on this timeline Please confirm as soon as possible

Thank you,

Tina

OPTN Restricted

From: Jadia Bruckner <[REDACTED]>
Sent: Friday, January 31, 2025 5:07 PM
To: Formica, Richard <[REDACTED]>; Rebecca Murdock <[REDACTED]>
Cc: Christopher J. McLaughlin <[REDACTED]>; Lauren Mauk <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Mesmin Germain <[REDACTED]>; Sara Moriarty <[REDACTED]>; Sarah Payamps <[REDACTED]>; Matt Belton <[REDACTED]>; Tina Rhoades <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Suma Nair <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Stephanie Petrone <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>; John Hanock <[REDACTED]>; Kimberly Uccellini <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>
Subject: Re: HRSA ONLY -- RE: COI follow-up-- HRSA-directed investigation plan

Rich- Thank you for the affirmative.

Update and HRSA confirmation needed to clear Debbi McRann's COI disclosure

"Matt Niles is the VP Chief Clinical Officer for the Kentucky/Ohio program. He was the clinical director of WRTC the OPO that Living Legacy merged with to form Infinite Legacy in January of 2023. Matt left prior to the merge. I wanted to disclose that prior connection so that you could evaluate whether this is a conflict."

"I'm disclosing in the interest of avoiding the appearance of a conflict.
I do not feel it is an actual personal conflict."

Please confirm HRSA's approval and acceptance of the COI disclosure.

Thank you

Jadia

From: Formica, Richard
Sent: Friday, January 31, 2025 4:56 PM
To: Rebecca Murdock
Cc: Jadia Bruckner; Christopher J. McLaughlin; Lauren Mauk; [REDACTED]; Mauro, Patrick (HRSA); Mesmin Germain; Sara Moriarty; Sarah Payamps; Matt Belton; Tina Rhoades; Aigbe, Aitebureme (Aite) (HRSA); Holloman, Frank (HRSA); Lynch, Raymond (HRSA); Suma Nair; Doby, Brianna (HRSA); Stephanie Petrone; Locke, Jayme (HRSA); John Hanock; Kimberly Uccellini; Mauro, Patrick (HRSA); Aigbe, Aitebureme (Aite) (HRSA); Holloman, Frank (HRSA); Lynch, Raymond (HRSA); Doby, Brianna (HRSA); Locke, Jayme (HRSA)
Subject: [EXTERNAL] Re: HRSA ONLY -- RE: COI follow-up-- HRSA-directed investigation plan

Jadia,
I agree with your approach s
Rich
Richard N. Formica Jr, MD
Professor of Medicine and Surgery
Director of Transplant Medicine

Sent from my iPhone

On Jan 31, 2025, at 1:18 PM, Rebecca Murdock <[REDACTED]> wrote:

Apologies for the double email, but wanted to correct the below

Per HRSA direction, the documents reviewed as part of this directed investigation are **not** protected by confidential peer review, though they are protected by other applicable federal law. As such, the message we will provide to reviewers on the SharePoint site is corrected below. I'm recopying the email from Jadia so as not to lose the rest of the content of the email, with the corrected legal disclaimer included.

Original email + corrections:

"Rich and Chris,

Updates:
We have identified one additional reviewer, Luis Mayen. Theresa Daly reached out to let us know that she appreciates being asked but is unable to make the required commitment to participate in this review at this time. We are still awaiting final information from the third proposed replacement. In the interest of the timeline, we will be sending initial assignments to the 8 confirmed reviewers this afternoon upon confirmation from HRSA and Rich Formica, including the requested confirmation below.

As you are aware, the records will be transmitted securely by way of a SharePoint site, maintained by the OPTN Contractor. These records contain PHI, and in accordance with previous guidance from HRSA, will be posted **without redaction**. This disclosure would be made in accordance with 45 C.F.R. § 164.512(d), which permits such disclosures without patient authorization for the purposes of facilitating government health oversight activities. HRSA is asked to treat the data and files that we are transmitting pursuant to this request securely and confidentially **as it contains personal health information**. **Please confirm this approach.** With HRSA approval, similar language will be included in emails to reviewers with the link to the SFTP as well as on the SFTP website itself."

Please let Jadia or me know if there are any questions

Rebecca

Rebecca Murdock
Senior Policy Counsel

[REDACTED]

OPTN Restricted

From: Jadia Bruckner <[REDACTED]>
Sent: Friday, January 31, 2025 2:35 PM
To: Formica, Richard <[REDACTED]>; Christopher J. McLaughlin <[REDACTED]>
Cc: Lauren Mauk <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>
 Mesmin Germain <[REDACTED]>; Sara Moriarty <[REDACTED]>; Sarah Payamps <[REDACTED]>
 Rebecca Murdock <[REDACTED]>; Matt Belton <[REDACTED]>; Tina Rhoades <[REDACTED]>
 Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>
 Lynch, Raymond (HRSA) <[REDACTED]>; Suma Nair <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>
 Stephanie Petrone <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>; John Hanock <[REDACTED]>
 Mauro, Patrick (HRSA) <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>
 Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>
 Locke, Jayme (HRSA) <[REDACTED]>; John Hanock <[REDACTED]>; Kimberly Uccellini <[REDACTED]>
Subject: Re: HRSA ONLY -- RE: COI follow-up-- HRSA-directed investigation plan

Rich and Chris,

Updates:

We have identified one additional reviewer, Luis Mayen. Theresa Daly reached out to let us know that she appreciates being asked but is unable to make the required commitment to participate in this review at this time. We are still awaiting final information from the third proposed replacement. In the interest of the timeline, we will be sending initial assignments to the 8 confirmed reviewers this afternoon upon confirmation from HRSA and Rich Formica, including the requested confirmation below.

As you are aware, the records will be transmitted securely by way of a SharePoint site, maintained by the OPTN Contractor. These records contain PHI, and in accordance with previous guidance from HRSA, will be posted **without redaction**. This disclosure would be made in accordance with 45 C.F.R. § 164.512(d), which permits such disclosures without patient authorization for the purposes of facilitating government health oversight activities. HRSA is asked to treat the data and files that we are transmitting pursuant to this request securely and confidentially, as they contain both personal health information and confidential medial peer review information. **Please confirm this approach.** With HRSA approval, similar language will be included in emails to reviewers with the link to the SFTP as well as on the SFTP website itself.

Thank you,

Jadia

From: Jadia Bruckner
Sent: Thursday, January 30, 2025 2:32 PM
To: Formica, Richard
Cc: Christopher J. McLaughlin; Lauren Mauk; [REDACTED]; Mauro, Patrick (HRSA); Mesmin Germain; Sara Moriarty; Sarah Payamps; Rebecca Murdock; Matt Belton; Tina Rhoades; Aigbe, Aitebureme (Aite) (HRSA); Holloman, Frank (HRSA); Lynch, Raymond (HRSA); Suma Nair; Doby, Brianna (HRSA); Stephanie Petrone; Locke, Jayme (HRSA); John Hanock; Mauro, Patrick (HRSA); Aigbe, Aitebureme (Aite) (HRSA); Holloman, Frank (HRSA); Lynch, Raymond (HRSA); Doby, Brianna (HRSA); Locke, Jayme (HRSA); John Hanock
Subject: Re: HRSA ONLY -- RE: COI follow-up-- HRSA-directed investigation plan

Rich (and all),

Invitations to the three new reviewers are out (this group is cc'd)

I am going to assign a sample of case records to the 7 approved reviewers to keep things moving. That will not prohibit us from pivoting if and when we add reviewers.

Do you have any thoughts on who you would like to ask to be report writing contributor? SOP/Process & Protocol reviewer/s?

Reminder of records to be reviewed:

- 360 Donor and patients (multiple files in each-chart, process deviations, hospital feedback, huddle records)
- 35 SOP/Protocol/Policies
- 60 Donor huddle records (without donor files)

Tentative Panel:

Name	OPTN Role	Organization	Region	
Kyle Herber	MPSC	Live On Nebraska	8	Accepted
Kristine Browning	MPSC; living donor	LifeGift Organ Donation	4	Accepted
Chad Denlinger	MPSC	Indiana University Health	10	Accepted
Zoe Stewart Lewis	MPSC	University Hospitals of Cleveland	10	Accepted, Writer
Patrick Northup	BOD Director	NYU Langone Health	9	Accepted
Glen Kelley	BOD Director; transplant recipient	President, Second Chance for Life Foundation	3	Accepted, Writer
Steve Potter	Vice Chair of Operations & Safety Committee	MedStar Georgetown Transplant Institute	2	Accepted
Luis Mayen	MPSC	Donor Network West	5	Asked
Theresa Daly	OPO	LifeLink, FL	3	Asked
Deborah McRann	MPSC	Infinite Legacy	2	Asked

Can make myself available for a phone call anytime that works for you,

Jadia

From: Formica, Richard
Sent: Thursday, January 30, 2025 9:45 AM
To: Jadia Bruckner
Cc: Christopher J McLaughlin; Lauren Mauk; [REDACTED]; Mauro, Patrick (HRSA); Mesmin Germain; Sara Moriarty; Sarah Payamps; Rebecca Murdock; Matt Belton; Tina Rhoades; Aigbe, Aitebureme (Aite) (HRSA); Holloman, Frank (HRSA); Lynch, Raymond (HRSA); Suma Nair; Doby, Brianna (HRSA); Stephanie Petrone; Locke, Jayme (HRSA); John Hanock; Mauro, Patrick (HRSA); Aigbe, Aitebureme (Aite) (HRSA); Holloman, Frank (HRSA); Lynch, Raymond (HRSA); Doby, Brianna (HRSA); Locke, Jayme (HRSA); John Hanock
Subject: [EXTERNAL] Re: HRSA ONLY -- RE: COI follow-up-- HRSA-directed investigation plan

Jadia,
Let's invite,
Luis,
Theresa,
And Deborah
That gives us diversity of regional representation Please send the invites today as time is short
Thanks,
Rich
Richard N Formica Jr, MD
Professor of Medicine and Surgery
Director of Transplant Medicine

Sent from my iPhone

On Jan 30, 2025, at 7:41 AM, Jadia Bruckner <[REDACTED]> wrote:

Good Morning Rich,

Agreed on the importance of having OPO representation for this review and have identified potential reviewers for consideration who did not sign the AOPO letter

Potential Replacement Reviewers:

Name	Organization	Region	Current OPTN Service	Prior Service
Luis Mayen	Donor Network West	5	MPSC	OSC (two terms), work groups
Theresa Daly	LifeLink, FL	3	OPO	Board, MPSC, OSC, POC, workgroups
Chad Ezzell	Louisiana OPO	3	MPSC	OPO, workgroups
Christy Keahy	Legacy of Hope	3	MPSC	Prior MPSC term, OPO, OSC, workgroups
Deborah McRann	Infinite Legacy	2	MPSC	Peds, Pancreas, VCA, workgroups

The posted version of the AOPO letter contained images of signatures, making the search tool unreliable However, we used the original document as a reference and created an attached list of names as a searchable resource to support this process While this is not the source document, we took extra steps to ensure accuracy to the best of our ability

Given HRSA's tight deadline, we have a few options to meet their timeline Would you be available for a 30-minute call today to discuss the next steps? Let me know a time that works for you, and I will send an invite to all parties to attend if they are available

Thank you,

Jadia

OPTN Restricted

From: Formica, Richard
Sent: Wednesday, January 29, 2025 5:52 PM
To: Jadia Bruckner
Cc: Christopher J McLaughlin; Lauren Mauk; [REDACTED]; Mauro, Patrick (HRSA); Mesmin Germain; Sara Moriarty; Sarah Payamps; Rebecca Murdock; Matt Belton; Tina Rhoades; Aigbe, Aitebureme (Aite) (HRSA); Holloman, Frank (HRSA); Lynch, Raymond (HRSA); Suma Nair; Doby, Brianna (HRSA); Stephanie Petrone; Locke, Jayme (HRSA); John Hanock; [REDACTED]; Mauro, Patrick (HRSA); Aigbe, Aitebureme (Aite) (HRSA); Holloman, Frank (HRSA); Lynch, Raymond (HRSA); Suma Nair; Doby, Brianna (HRSA); Stephanie Petrone; Locke, Jayme (HRSA); Hanock John
Subject: [EXTERNAL] Re: HRSA ONLY -- RE: COI follow-up-- HRSA-directed investigation plan

Hi Jadia,
To do this review properly we need OPO people Can you provide me a list of those who signed the letter and a list of suggested replacements?

Thanks,
Rich
Richard N Formica Jr, MD
Professor of Medicine and Surgery
Director of Transplant Medicine

Sent from my iPhone

On Jan 29, 2025, at 12:26 PM, Jadia Bruckner <[REDACTED]> wrote:

Dear HRSA Team,

We wanted to provide an update regarding the KYDA review process and recent developments

Rick Hasz has been informed that he is excused from this review following his additional disclosure

During our review, 3 additional reviewers (OPO professionals) were identified as conflicted for having signed the AOPO Open Letter on Misinformation. Following HRSA's previous guidance, these 3 individuals will also be removed from the list of participants. With removing these 4 individuals, only 7 reviewers remain. We recommend replacing all excused individuals (4) due to the volume of materials that will need to be reviewed. At this point in time, the approximate record counts are as follows:

- 360 Donor and patients (multiple files in each-chart, process deviations, hospital feedback, huddle records)
- 35 SOP/Protocol/Policies
- 60 Donor huddle records (without donor files)

Please confirm the approach of seeking replacements for all 4 reviewers and that staff should look to Rich Formica for recommendations as to replacements. After replacements are recommended, those individuals will also need to be reviewed and contacted for potential COIs (self-disclosed or otherwise identified). Staff will provide an update to HRSA and Rich at the conclusion of that review for final approval.

Below is an outline of our previously agreed upon timeline, but using business days vs dates. Specific dates will be provided once reviewers are confirmed to prevent unnecessary rework of the timeline.

Task	Days Allocated for Task	Total Business Days
Reviewer Reach Out	1	1
Confirm Reviewers and No Additional COI	2	3
Provide Instruction and Release Records	1	4
Deadline to Complete Reviews	10	14
Exit Conference (4-Day Range)	4	18
Report Writing	5	23
Draft Report Due	3	26
Final Report Due	4	30

Reminder: Please send a list of authorized individuals you would like to have access to the SharePoint site housing the material for the reviewers.

Please let us know of any questions, or if you would like to set up a call to talk through this plan.

Thank you

Jadia

OPTN Restricted

From: Christopher J. McLaughlin

Sent: Monday, January 27, 2025 3:36 PM

To: Lauren Mauk; Jadia Bruckner; HRSA OPTN EXT COR; Mauro, Patrick (HRSA); Mesmin Germain; Sara Moriarty; Sarah Payamps; Rebecca Murdock; Formica, Richard; Matt Belton; Tina Rhoades

Cc: Aigbe, Aitebureme (Aite) (HRSA); Holloman, Frank (HRSA); Lynch, Raymond (HRSA); Nair, Suma (HRSA); Doby, Brianna (HRSA); Petrone, Stephanie (HRSA); Locke, Jayme (HRSA); John, Hanock (HRSA)

Subject: [EXTERNAL] FW: HRSA ONLY -- RE: COI follow-up-- HRSA-directed investigation plan

Hi Lauren and all: Please see below in **red text** the HRSA responses to your requests.

- Rich Formica to recommend an additional reviewer/report writer to replace Rick. **Agree—if deemed necessary.**
- Agreement on 2 business days to contact additional recommended reviewer for acceptance and request to disclose any potential COI. **Agree.**
- Rich Formica and HRSA to review the timeline based on the current status of the investigation and provide updated direction. Since materials have not yet been disseminated, HRSA would like to stay on the existing schedule. One option would be to move forward without another reviewer. If this does not seem feasible, and another reviewer is deemed necessary, please confirm this path with HRSA. If a new reviewer is necessary, HRSA would prefer that they complete reviews by the 2/8-2/9 to allow the investigation to move forward as planned.
 - Reviewer Reach out 1/17
 - Additional information from KYDA due 1/17
 - Confirm reviewers and no additional COI by 1/21
 - Provide instruction and release records 1/21
 - Deadline to complete reviews 2/4
 - Exit conference, based on availability between 2/4-7 (4 business day options)
 - Report Writing 2/10-2/14
 - Draft report due 2/14
 - **Final report due 2/20**
- Approval for UNOS staff to notify Rick Hasz that he has been excused due to his additional disclosure. **Agree.**

Please let me know if you have any questions.

Thanks, Chris

Christopher J. McLaughlin

Senior Advisor
FAC-COR-III, OPTN Contract
Division of Transplantation
Health Systems Bureau
[REDACTED]

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[<image006.png>](#)

[<image007.png>](#)

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OPTN Restricted

From: Christopher J McLaughlin <[REDACTED]>
Sent: Monday, January 27, 2025 9:38 AM
To: Jadia Bruckner <[REDACTED]>; Lauren Mauk <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Sara Moriarty <[REDACTED]>; Rebecca Murdock <[REDACTED]>; Formica, Richard <[REDACTED]>; Sarah Payamps <[REDACTED]>; Matt Belton <[REDACTED]>; Tina Rhoades <[REDACTED]>
Cc: Aigbe, Atebureme (Aite) (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Petrone, Stephanie (HRSA) <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>; John, Hanock (HRSA) <[REDACTED]>
Subject: [EXTERNAL] COI follow-up-- HRSA-directed investigation plan
Importance: High

Good morning Jadia, Lauren, and all: HRSA has reviewed the self-identified COIs from the reviewers and requests that a replacement for Rick Hasz be identified. Please confirm receipt of this notification, and please keep us informed of your process for identifying another reviewer. Thanks for your ongoing help with this investigation. Sincerely, Chris

Christopher J. McLaughlin
Senior Advisor
FAC-COR-III, OPTN Contract
Division of Transplantation
Health Systems Bureau
[REDACTED]

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Sign up for email updates!

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From: Jadia Bruckner <[REDACTED]>
Sent: Tuesday, January 21, 2025 3:34 PM
To: Lauren Mauk <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; HRSA OPTN EXT COR <[REDACTED]>; Sara Moriarty <[REDACTED]>; McLaughlin, Chris (HRSA) <[REDACTED]>; Rebecca Murdock <[REDACTED]>; Formica, Richard <[REDACTED]>; Sarah Payamps <[REDACTED]>; Matt Belton <[REDACTED]>; Tina Rhoades <[REDACTED]>
Cc: Aigbe, Atebureme (Aite) (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Petrone, Stephanie (HRSA) <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>; John, Hanock (HRSA) <[REDACTED]>
Subject: [EXTERNAL] Re: REVISIONS REQUESTED: HRSA-directed investigation plan

Good afternoon HRSA colleagues,

Please find below key updates regarding the KYDA directive and next steps for the review process:

KYDA Jan 2025 Files

- All KYDA-provided files related to this directive can be found in the HRSA SFTP under the folder: "**1.2025 inquiry**", within the directive SFTP: "**10.18.24 HRSA Directed Investigation_Revised Permissions.**"
- Please note that KYDA has password-protected the files. The password is located in the footnote of their letter, available in the SFTP: "**NFH - HRSA Addtl Requests (01-17-2025).**"
- If assistance is needed with the password, I am happy to provide it via secure email

Reviewer Responses

To facilitate the review process and address secure email concerns, I have compiled all reviewer responses for your review. Please confirm HRSA's approval and acceptance of the COI disclosures by **noon on January 22**. Once confirmed, I will proceed with granting reviewers access to SharePoint and assigning their respective reviews.

Reviewer	COI Response
Glen Kelley	I do not have any conflicts of interest as it relates to this investigation.
Kristine Browning	I do not have any conflicts to disclose and am happy to serve.
Chad Denlinger	The only potential conflicts I have with reviewing this case should already be apparent to HRSA. I live and work in the neighboring state of Indiana and I occasionally travel to the OPO for organ recovery operations.
Dorrie Dils	I am replying that aside from being an employee of an OPO, serving as AOPO President, and being a member of the INVEST board, I have no other conflicts to identify.
Steve Potter	I have no conflict of interest.
Jennifer Murielt	I have no conflict of interest as defined below. Please let me know the next steps and anything else I can do to support. Thank you.
Zoe Stewart Lewis	No conflicts of interest.
Kyle Herber	It's great to hear from you. I do not have any known or perceived conflicts of interest with KYDA.
Colleen McCarthy	I do not have any conflicts to disclose and accept this assignment.
Patrick Northup	No conflicts based on the information given in the email.
Rick Hasz	I would be happy to participate in this important review. As a way of disclosure, the Gift of Life Institute, (our education consulting and training institute for which I'm also the President) has done some work with KODA in the recent past by providing individual team member authorization training in 2020, 2021, 2022. The Institute also provided KODA a customized authorization training for staff in 2023. I was not personally involved in any of these trainings and they did not "provide personal or financial gain related to the outcomes of matters affecting the OPTN."

Reviewer SharePoint Access

Please provide a list of any HRSA staff members who require access to the reviewers' working SharePoint. As a reminder, the data contains a significant amount of PHI and PII.

Should you have any questions or require further details, please do not hesitate to reach out.

Jadia Bruckner
Patient Safety Manager

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Saving lives together



700 North 4th Street, Richmond, VA 23219

www.unos.org

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<image011.gif>

OPTN Restricted

From: Lauren Mauk
Sent: Friday, January 17, 2025 3:52 PM
To: Mauro, Patrick (HRSA); HRSA OPTN EXT COR; Sara Moriarty; Christopher J. McLaughlin; Rebecca Murdock; Formica, Richard; Sarah Payamps; Matt Belton; Tina Rhoades
Cc: Aigbe, Aitebureme (Aite) (HRSA); Holloman, Frank (HRSA); Lynch, Raymond (HRSA); Nair, Suma (HRSA); Doby, Brianna (HRSA); Petrone, Stephanie (HRSA); Locke, Jayme (HRSA); John, Hanock (HRSA); Jadia Bruckner

Subject: RE: REVISIONS REQUESTED: HRSA-directed investigation plan

Good afternoon HRSA colleagues,

Providing an update on the investigation

We were just informed by counsel for the program that they are actively compiling and organizing the documents per the most recent request, but it is taking longer than expected given the nature and size of some of the files. They expect to be done later this evening. In the event KYDA does not provide the materials by COB today, UNOS staff will be able to upload them into SFTP for HRSA upon return to office on Tuesday.

In addition, the OPTN President has requested an extension to the timeline for the reviewers. Based on his request, the following timeline is proposed. Please confirm if this timeline is acceptable to you.

- Reviewer Reach out 1/17
- Additional information from KYDA due 1/17
- Confirm reviewers and no additional COI by 1/21
- Provide instruction and release records 1/21
- Deadline to complete reviews 2/4
- Exit conference, based on availability between 2/4-7 (4 business day options)
- Report Writing 2/10-2/14
- Draft report due 2/14
- Final report due 2/20

Thank you,

Lauren Parker Mauk

Assistant Director - Contract Operations
OPTN Project Director

[REDACTED]
[REDACTED]

OPTN Restricted

From: Mauro, Patrick (HRSA) <[REDACTED]>
Sent: Monday, January 13, 2025 1:42 PM
To: Lauren Mauk <[REDACTED]>; HRSA OPTN EXT COR <[REDACTED]>; Sara Moriarty <[REDACTED]>; Christopher J. McLaughlin <[REDACTED]>; Rebecca Murdock <[REDACTED]>; Formica, Richard <[REDACTED]>; Sarah Payamps <[REDACTED]>; Matt Belton <[REDACTED]>; Tina Rhoades <[REDACTED]>
Cc: Aigbe, Atebureme (Aite) (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Petrone, Stephanie (HRSA) <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>; John, Hanock (HRSA) <[REDACTED]>
Subject: [EXTERNAL] RE: REVISIONS REQUESTED: HRSA-directed investigation plan

Hi Lauren,

The distribution plan is also acceptable. Thanks!

Best,
Patrick Mauro
HRSA/HSB

OPTN Restricted

From: Mauro, Patrick (HRSA)
Sent: Monday, January 13, 2025 1:39 PM
To: Lauren Mauk <[REDACTED]>; HRSA OPTN EXT COR <[REDACTED]>; Sara Moriarty <[REDACTED]>; McLaughlin, Chris (HRSA) <[REDACTED]>; Rebecca Murdock <[REDACTED]>; Formica, Richard <[REDACTED]>; Sarah Payamps <[REDACTED]>; Matt Belton <[REDACTED]>; Tina Rhoades <[REDACTED]>
Cc: Aigbe, Atebureme (Aite) (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Petrone, Stephanie (HRSA) <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>; John, Hanock (HRSA) <[REDACTED]>
Subject: RE: REVISIONS REQUESTED: HRSA-directed investigation plan

Hi Lauren,

We can agree to an extension until 4 pm Eastern on Friday 1/17. I'll need to follow up with the question regarding material distribution.

Best,
Patrick Mauro
HRSA/HSB

From: Lauren Mauk <[REDACTED]>
Sent: Monday, January 13, 2025 1:19 PM
To: HRSA OPTN EXT COR <[REDACTED]>; Sara Moriarty <[REDACTED]>; McLaughlin, Chris (HRSA) <[REDACTED]>; Rebecca Murdock <[REDACTED]>; Formica, Richard <[REDACTED]>; Sarah Payamps <[REDACTED]>; Matt Belton <[REDACTED]>; Tina Rhoades <[REDACTED]>
Cc: Aigbe, Atebureme (Aite) (HRSA) <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>

[REDACTED] Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>;
Petrone, Stephanie (HRSA) <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>;
John, Hanock (HRSA) <[REDACTED]>
Subject: [EXTERNAL] Re: REVISIONS REQUESTED: HRSA-directed investigation plan

Good afternoon HRSA colleagues,

Following back up on the outstanding questions for this investigation in the email below With the tight turnaround for the institution we are looking to give them a response and the team a path forward on review

Thank you,
Lauren Parker Mauk

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From: Lauren Mauk
Sent: Friday, January 10, 2025 2:36:26 PM
To: 'HRSA OPTN EXT COR' <[REDACTED]>; Sara Moriarty <[REDACTED]>; Christopher J. McLaughlin; Rebecca Murdock <[REDACTED]>; Formica, Richard; Sarah Payamps <[REDACTED]>; Matt Belton <[REDACTED]>; Tina Rhoades <[REDACTED]>
Cc: Aigbe, Ardebureme (Aite) (HRSA); Mauro, Patrick (HRSA); Holloman, Frank (HRSA); Lynch, Raymond (HRSA); Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA); Petrone, Stephanie (HRSA) <[REDACTED]>; Locke, Jayme (HRSA); John, Hanock (HRSA) <[REDACTED]>
Subject: RE: REVISIONS REQUESTED: HRSA-directed investigation plan

Good afternoon HRSA colleagues,

I have two follow-up questions for this request

- 1 We reached out to KYDA to request the data you are seeking within 5 business days They responded and asked if they could have an extension until COB January 21st given the time it will take to identify and collect the records which will require a manual search In addition, their offices are also currently closed due to inclement weather Would HRSA be okay with an extension? KYDA did note they can deliver earlier if they are able to complete their collection before January 21st
- 2 In the Investigation Plan it was proposed that OPTN reviewers would be organized to assess information by topic Based on the number of materials being asked to review, we would like to know if HRSA would be okay with distributing the volume of materials to all reviewers with the ask that they review their assigned content for all three focus areas (patient safety, quality assurance, and operational compliance) Please advise

Thank you,
Lauren Parker Mauk
Assistant Director Contract Operations
OPTN Project Director

[REDACTED]

From: HRSA OPTN EXT COR <[REDACTED]>
Sent: Friday, January 10, 2025 12:28 PM
To: Sara Moriarty <[REDACTED]>; Christopher J. McLaughlin <[REDACTED]>; Lauren Mauk <[REDACTED]>; Rebecca Murdock <[REDACTED]>; Formica, Richard <[REDACTED]>; Sarah Payamps <[REDACTED]>; Matt Belton <[REDACTED]>; Tina Rhoades <[REDACTED]>; HRSA OPTN EXT COR <[REDACTED]>
Cc: Aigbe, Ardebureme (Aite) (HRSA) <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Petrone, Stephanie (HRSA) <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>; John, Hanock (HRSA) <[REDACTED]>
Subject: [EXTERNAL] RE: REVISIONS REQUESTED: HRSA-directed investigation plan

Will do

Thanks,

Mesmin Germain
Mesmin Germain
Division of Transplantation
Health Systems Bureau
[REDACTED]

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OPTN Restricted

From: Sara Moriarty <[REDACTED]>
Sent: Thursday, January 9, 2025 11:35 AM
To: McLaughlin, Chris (HRSA) <[REDACTED]>; Lauren Mauk <[REDACTED]>;
Rebecca Murdock <[REDACTED]>; Formica, Richard <[REDACTED]>; Sarah
Payamps <[REDACTED]>; Matt Belton <[REDACTED]>; HRSA OPTN EXT COR
<[REDACTED]>; Tina Rhoades <[REDACTED]>
Cc: Germain, Mesmin (HRSA) <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA)
<[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Holloman, Frank (HRSA)
<[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA)
<[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Goodrich-Doctor, Adrienne (HRSA)
<[REDACTED]>; Petrone, Stephanie (HRSA) <[REDACTED]>; Locke, Jayme
<[REDACTED]>; John, Hanock (HRSA) <[REDACTED]>
Subject: [EXTERNAL] RE: REVISIONS REQUESTED: HRSA-directed investigation plan

Hi Chris, confirming receipt

We are adding Tina Rhoades to this thread as well, and ask that HRSA please include her in any future communications about this topic

Thanks,

Sara

OPTN Restricted

From: Christopher J. McLaughlin <[REDACTED]>
Sent: Wednesday, January 8, 2025 5:11 PM
To: Lauren Mauk <[REDACTED]>; Rebecca Murdock <[REDACTED]>;
Formica, Richard <[REDACTED]>; Sarah Payamps <[REDACTED]>; Sara
Moriarty <[REDACTED]>; Matt Belton <[REDACTED]>; HRSA OPTN EXT COR
<[REDACTED]>
Cc: Mesmin Germain <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>;
Mauro, Patrick (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch,
Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna
<[REDACTED]>; Adrienne Goodrich-Doctor <[REDACTED]>; Petrone,
Stephanie (HRSA) <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>; John, Hanock
<[REDACTED]>
Subject: [EXTERNAL] RE: REVISIONS REQUESTED: HRSA-directed investigation plan
Importance: High

Lauren and all: HRSA agrees with the request for additional time

In addition, HRSA requests the additional information be collected from KYDA and provided to HRSA within 5 business days

- 1 Please obtain from KYDA all patient records, between the date of last HRSA request (October 18, 2024) and January 1, 2025, relating to patient cases in which a patient was followed by KYDA for DCD-potential organ procurement that terminated with an extubation of the patient without a cardiac time of death (CTOD). This is sometimes referred to as a "non-converted DCD" and reporting data for the non-recovery of organs by an OPO is required at 42 CFR 486.328(a)(5)
- 2 Please obtain from KYDA all patient records, between the date of last HRSA request (October 18, 2024) and January 1, 2025, relating to the occurrence and content of any pre-withdrawal calls (also often known as a "huddle") to discuss withdrawal procedure, medications or comfort care, pronouncement, roles and prohibitions-of-roles for hospital, OPO, and center/procuring staff as required at OPTN Policy 2.15.F. This request includes patients followed for potential DCD procurement that were not terminally extubated, but for which a pre-withdrawal call or huddle was initiated and/or completed

Please let me know if you have any questions –Chris

Christopher J. McLaughlin
Senior Advisor
FAC-COR-III, OPTN Contract
Division of Transplantation
Health Systems Bureau
[REDACTED]

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OPTN Restricted

From: Lauren Mauk <[REDACTED]>
Sent: Tuesday, January 7, 2025 11:05 AM
To: McLaughlin, Chris (HRSA) <[REDACTED]>; Rebecca Murdock <[REDACTED]>; Formica, Richard <[REDACTED]>; Sarah Payamps <[REDACTED]>; Sara Moriarty <[REDACTED]>; Matt Belton <[REDACTED]>; HRSA OPTN EXT COR <[REDACTED]>
Cc: Germain, Mesmin (HRSA) <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Goodrich-Doctor, Adrienne (HRSA) <[REDACTED]>; Petrone, Stephanie (HRSA) <[REDACTED]>; Locke, Jayme <[REDACTED]>; John, Hanock (HRSA) <[REDACTED]>
Subject: [EXTERNAL] RE: REVISIONS REQUESTED: HRSA-directed investigation plan

Good morning Chris,

I followed up with the team on this request and based on volunteer needs plus the time needed to complete reviews, compile results, and create a report they are asking if they could have an updated completion date for this investigation to mid-February (2/14/2025) Would that be feasible?

Thank you,

Lauren Parker Mauk
Assistant Director Contract Operations
OPTN Project Director

[REDACTED]

OPTN Restricted

From: Lauren Mauk
Sent: Friday, January 3, 2025 3:22 PM
To: 'Christopher J. McLaughlin'; Rebecca Murdock <[REDACTED]>; Formica, Richard <[REDACTED]>; Sarah Payamps <[REDACTED]>; Sara Moriarty <[REDACTED]>; Matt Belton <[REDACTED]>
Cc: Mesmin Germain; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Adrienne Goodrich-Doctor; Petrone, Stephanie (HRSA) <[REDACTED]>; jlocke <[REDACTED]>; John, Hanock (HRSA) <[REDACTED]>
Subject: RE: REVISIONS REQUESTED: HRSA-directed investigation plan

Good afternoon Chris,

Acknowledging receipt of your message I will ensure the team gets your message and confirm the timeline with them

Thank you,

Lauren Parker Mauk
Assistant Director Contract Operations
OPTN Project Director

[REDACTED]

From: Christopher J. McLaughlin <[REDACTED]>
Sent: Friday, January 3, 2025 10:51 AM
To: Rebecca Murdock <[REDACTED]>; Lauren Mauk <[REDACTED]>; Formica, Richard <[REDACTED]>; Sarah Payamps <[REDACTED]>; Sara Moriarty <[REDACTED]>; Matt Belton <[REDACTED]>
Cc: Mesmin Germain; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Adrienne Goodrich-Doctor <[REDACTED]>; Petrone, Stephanie (HRSA) <[REDACTED]>; jlocke <[REDACTED]>; John, Hanock (HRSA) <[REDACTED]>
Subject: [EXTERNAL] RE: REVISIONS REQUESTED: HRSA-directed investigation plan
Importance: High

Rebecca, Lauren and all: HRSA agrees with the updated investigation plan We ask that UNOS complete this investigation by Jan 31, 2025 Please confirm and let us know if there are any concerns about this timeframe

Sincerely, Chris

Christopher J. McLaughlin
Senior Advisor
FAC-COR-III, OPTN Contract
Division of Transplantation
Health Systems Bureau
[REDACTED]

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From: Rebecca Murdock <[REDACTED]>
Sent: Wednesday, December 18, 2024 4:06 PM
To: McLaughlin, Chris (HRSA) <[REDACTED]>; Lauren Mauk <[REDACTED]>;
Formica, Richard <[REDACTED]>; Sarah Payamps <[REDACTED]>; Sara
Moriarty <[REDACTED]>; Matt Belton <[REDACTED]>
Cc: Germain, Mesmin (HRSA) <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA)
Mauro, Patrick (HRSA) <[REDACTED]>; Holloman, Frank (HRSA)
[REDACTED] <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA)
Doby, Brianna (HRSA) <[REDACTED]>; Goodrich-Doctor, Adrienne (HRSA)
[REDACTED] <[REDACTED]>; Petrone, Stephanie (HRSA) <[REDACTED]>; Locke, Jayme
(HRSA) <[REDACTED]>; John, Hanock (HRSA) <[REDACTED]>
Subject: [EXTERNAL] RE: REVISIONS REQUESTED: HRSA-directed investigation plan

Hello all,

Please find an updated investigation plan for HRSA review. Updates to the plan include:

1. The community member who signed the letter has been removed from the list of proposed participants
2. Any UNOS staff who signed the letter will not participate in the investigation and will not have access to any materials related to the investigation

We are scheduled to meet tomorrow (Thursday) at 3:30. If you have specific questions about the proposed plan that you would like to discuss tomorrow, please let us know so we can prepare. If you need more time to review the plan prior to our discussion tomorrow and would prefer to reschedule, please let us know that as well.

Thanks,

Rebecca

Rebecca Murdock
Senior Policy Counsel

OPTN Restricted

From: Christopher J. McLaughlin <[REDACTED]>
Sent: Friday, December 6, 2024 6:21 PM
To: Lauren Mauk <[REDACTED]>; Formica, Richard <[REDACTED]>; Maureen
McBride <[REDACTED]>; Sarah Payamps <[REDACTED]>; Sara Moriarty
[REDACTED] <[REDACTED]>; Rebecca Murdock <[REDACTED]>; Matt Belton
[REDACTED] <[REDACTED]>
Cc: Mesmin Germain <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>;
Mauro, Patrick (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch,
Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna
(HRSA) <[REDACTED]>; Adrienne Goodrich-Doctor <[REDACTED]>; Petrone,
Stephanie (HRSA) <[REDACTED]>; Locke, Jayme (HRSA) <[REDACTED]>; John, Hanock
(HRSA) <[REDACTED]>
Subject: [EXTERNAL] RE: REVISIONS REQUESTED: HRSA-directed investigation plan
Importance: High

Lauren, Rich, and all:

We have feedback on the proposed process to assess conflicts for the investigation and are requesting the following changes:

1. HRSA does not agree with including community members who signed the letter participating in the investigation. Please remove the identified individual from the list of participants and propose a replacement.
2. HRSA also believes that any UNOS staff who signed the letter should not participate, although we understand that such a position may make it difficult for UNOS to support the OPTN in this effort. So, to allow the work to move forward, HRSA agrees to follow the proposed process to assess UNOS staff conflicts with the following revisions:

- 1 For all UNOS staff members who signed the letter, we will need to receive a description of their proposed role in the investigation along with their disclosure
- 2 HRSA will review these disclosures independently of the OPTN President's review, and HRSA's determination of perceived conflicts is not limited to direct personal and/or financial interests
- 3 HRSA will meet with the OPTN President to discuss our findings, but if after discussion HRSA's position remains that a UNOS staff member has a perceived conflict, that staff member will not be allowed to participate

Please let me know if you have any concerns about these changes. Please update the process to reflect these changes and send back to HRSA for review

We look forward to your continued attention to preventing and mitigating potential conflicts of interest in this investigation

Sincerely, Chris

Christopher J. McLaughlin
Senior Advisor
FAC-COR-III, OPTN Contract
Division of Transplantation
Health Systems Bureau
[REDACTED]

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From: Lauren Mauk [REDACTED] >
Sent: Monday, November 25, 2024 4:58 PM
To: McLaughlin, Chris (HRSA) <[REDACTED]>; Formica, Richard <[REDACTED]>; Maureen McBride <[REDACTED]>; Sarah Payamps <[REDACTED]>; Sara Moriarty <[REDACTED]>; Rebecca Murdock <[REDACTED]>; Matt Belton <[REDACTED]>
Cc: Germain, Mesmin (HRSA) <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Goodrich-Doctor, Adrienne (HRSA) <[REDACTED]>; Petrone, Stephanie (HRSA) <[REDACTED]>
Subject: [EXTERNAL] RE: REVISIONS REQUESTED: HRSA-directed investigation plan

Good afternoon Chris,

The revised investigation plan for KYSA is attached. Rich and all, please let us know if you have any feedback

Notes:

- Substantive changes in response to HRSA's Nov 20 email are preceded by "Update."
- You will also see some minor changes for clarity if you compare to the previous version
-

Thank you,

Lauren Parker Mauk
Assistant Director, Contract Operations
OPTN Project Director
[REDACTED]

OPTN Restricted

From: Christopher J. McLaughlin [REDACTED]
Sent: Wednesday, November 20, 2024 3:26 PM
To: Formica, Richard <[REDACTED]>; Liz Robbins <[REDACTED]>; Maureen McBride <[REDACTED]>; Lauren Mauk <[REDACTED]>; Sarah Payamps <[REDACTED]>; Sara Moriarty <[REDACTED]>; Jacqui O'Keefe <[REDACTED]>
Cc: Mesmin Germain <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna <[REDACTED]>

(HRSA) <[REDACTED]>; Adrienne Goodrich-Doctor <[REDACTED]> Petrone,
Stephanie (HRSA) <[REDACTED]>
Subject: [EXTERNAL] REVISIONS REQUESTED: HRSA-directed investigation plan
Importance: High

Dear Rich, Liz, Maureen, and Lauren: Thank you for providing a plan for the HRSA-directed investigation of OPTN member KYDA. HRSA is requesting two revisions to the plan.

First, HRSA wishes to revise our initial direction that the investigation should include a review of KYDA's operations regarding the alleged incident. The OPTN with support from the OPTN contractor should not plan to further investigate the case of the patient identified in the alleged incident. HRSA requests that the plan be revised to focus on the data submitted by KYDA on all other patients with potential to become DCD organ donors.

Second, HRSA has become aware of an open community letter available at <https://aopo.org/wp-content/uploads/Donation-Transplant-Community-Open-Letter-on-Misinformation-1.pdf> that claims the alleged incident is "unsubstantiated" and represents misinformation. Approximately 26 members of UNOS staff and corporate leadership have signed this letter, in addition to many professionals in the donation and procurement field. The purpose of the HRSA-directed investigation is to objectively review evidence to determine if there is any substance to the concerns raised about the member's processes and procedures. Unfortunately, the fact that OPTN contractor staff and leadership have signed this letter creates a perception of conflicted interest for these individuals (and perhaps the organization) and compromises the ability of the OPTN contractor to support the OPTN in its investigation. HRSA is requesting that the plan be revised to document how the OPTN will manage any potential conflicts of interest in its review of KYDA activities and be revised to include specific activities that the OPTN contractor proposes to take to mitigate perceptions of conflicted interest caused by employee signatures on the letter so that the OPTN contractor can effectively support the OPTN in this investigation.

Please confirm receipt of this request for revision, and please provide HRSA with a revised plan by 5pm on Monday, November 25, 2024. Please let me know if you have concerns or questions.

Sincerely, Chris

Christopher J. McLaughlin
Senior Advisor
FAC-COR-III, OPTN Contract
Division of Transplantation
Health Systems Bureau
[REDACTED]

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From: Liz Robbins <[REDACTED]>
Sent: Monday, November 4, 2024 4:31 PM
To: Formica, Richard <[REDACTED]>; McLaughlin, Chris (HRSA) <[REDACTED]>
Cc: Jacquie O'Keefe <[REDACTED]>; Jadia Bruckner <[REDACTED]>; Betsy Warmick <[REDACTED]>; Krissy Laurie <[REDACTED]>; Matt Belton <[REDACTED]>; Robert Patterson <[REDACTED]>; Emily Womble <[REDACTED]>; Maureen McBride <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Rochelle, Kala (HRSA) <[REDACTED]>; Nair, Arjun (HRSA) <[REDACTED]>; Levi, Marilyn (HRSA) <[REDACTED]>; Dunne, Shannon (HRSA) <[REDACTED]>; Goodrich-Doctor, Adrienne (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Germain, Mesmin (HRSA) <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Lauren Mauk <[REDACTED]>; Sarah Payamp <[REDACTED]>; Sara Moriarty <[REDACTED]>; Caroline Hales <[REDACTED]>; Formica, Richard <[REDACTED]>; Anna Messmer <[REDACTED]>; Morgan Jupe <[REDACTED]>; Susie Sprinson <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>
Subject: [EXTERNAL] RE: HRSA-directed investigation

Good Afternoon, Chris,

The proposed investigation plan for KYDA, as discussed on Friday, is attached. Dr. Formica has had a chance to review this before we submitted to you. We look forward to discussing with you.

Thanks,
Liz

OPTN Restricted

From: Liz Robbins <[REDACTED]>
Sent: Friday, November 1, 2024 8:02 AM
To: Formica, Richard <[REDACTED]>; Christopher J McLaughlin <[REDACTED]>
Jadia Bruckner <[REDACTED]>
Cc: Jacquie O'Keefe <[REDACTED]>; Betsy Warnick <[REDACTED]>; Krissy Laurie <[REDACTED]>; Matt Belton <[REDACTED]>; Robert Patterson <[REDACTED]>; Emily Womble <[REDACTED]>; Maureen McBride <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Rochelle, Kala (HRSA) <[REDACTED]>; Naik, Arjun (HRSA) <[REDACTED]>; Marilyn Levi <[REDACTED]>; Shannon Dunne <[REDACTED]>; Adrienne Goodrich-Doctor <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Mesmin Germain <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Lauren Mauk <[REDACTED]>; Sarah Payamps <[REDACTED]>; Sara Moriarty <[REDACTED]>; Caroline Hales <[REDACTED]>; Formica, Richard <[REDACTED]>; Anna Messmer <[REDACTED]>; Morgan Jupe <[REDACTED]>; Susie Sprinson <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>
Subject: Re: HRSA-directed investigation

Hi Chris,

Acknowledging receipt UNOS very much intends to continue to assist the investigation so I hope that was not unclear. However, some of the questions HRSA seeks answers to are only answerable by those who work at OPOs and hospitals every day. Because HRSA did not believe the prior work was "sufficient" we think Dr. Formica's plan of bringing additional, Board level non-MPSC volunteers into the fold for additional insight is a great idea. As always, we will maintain the confidentiality of all materials according to our standard practices. If HRSA thinks we need to do something different, please advise.

Rich, we are happy to help schedule a meeting to make sure everyone is on the same page.

Thanks,
Liz

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From: Formica, Richard <[REDACTED]>
Sent: Thursday, October 31, 2024 7:05:13 PM
To: Christopher J McLaughlin <[REDACTED]>; Liz Robbins <[REDACTED]>; Jadia Bruckner <[REDACTED]>
Cc: Jacquie O'Keefe <[REDACTED]>; Betsy Warnick <[REDACTED]>; Krissy Laurie <[REDACTED]>; Matt Belton <[REDACTED]>; Robert Patterson <[REDACTED]>; Emily Womble <[REDACTED]>; Maureen McBride <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Rochelle, Kala (HRSA) <[REDACTED]>; Naik, Arjun (HRSA) <[REDACTED]>; Marilyn Levi <[REDACTED]>; Shannon Dunne <[REDACTED]>; Adrienne Goodrich-Doctor <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Mesmin Germain <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Lauren Mauk <[REDACTED]>; Sarah Payamps <[REDACTED]>; Sara Moriarty <[REDACTED]>; Caroline Hales <[REDACTED]>; Formica, Richard <[REDACTED]>; Lynch, Raymond <[REDACTED]>
Subject: [EXTERNAL] Re: HRSA-directed investigation

Chris et al,

Acknowledging receipt on behalf of the OPTN, The OPTN President requests the contractor's assistance on this very sensitive topic. The OPTN President also confesses confusion based upon this back and forth and the coded nature of these emails. He requests a meeting of himself, the appropriate contractor staff, and the appropriate HRSA staff to ensure this very important investigation is done correctly.
Best,
rich

--
Richard N. Formica Jr., MD
Professor of Medicine and Surgery
Director of Transplant Medicine
Boardman 124
330 Cedar Street
New Haven, CT 06520

Assistant: Susan Morales - [REDACTED]

OPTN Restricted

From: McLaughlin, Chris (HRSA) <[REDACTED]>
Date: Thursday, October 31, 2024 at 6:34 PM
To: Liz Robbins <[REDACTED]>; Jadia Bruckner <[REDACTED]>; Formica, Richard <[REDACTED]>
Cc: Jacquie O'Keefe <[REDACTED]>; Betsy Warnick <[REDACTED]>; Krissy Laurie <[REDACTED]>; Matt Belton <[REDACTED]>; Robert Patterson <[REDACTED]>; Emily Womble <[REDACTED]>; Maureen McBride <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Rochelle, Kala (HRSA) <[REDACTED]>; Naik, Arjun (HRSA) <[REDACTED]>; Levi, Marilyn (HRSA) <[REDACTED]>; Dunne, Shannon (HRSA) <[REDACTED]>; Goodrich-Doctor, Adrienne (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Germain, Mesmin (HRSA) <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Lauren Mauk <[REDACTED]>; Sarah Payamps <[REDACTED]>; Sara Moriarty <[REDACTED]>; Jacquie O'Keefe <[REDACTED]>; Caroline Hales <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>
Subject: RE: HRSA-directed investigation
Liz, Jadia, and Rich:

HRSA agrees to the proposed deadline extension to November 22. As we stated in our 10/18

communication, HRSA's expectation is that the OPTN contractor would provide necessary effort and support for the investigation activities and requested report, as per contract task 3.6.8. HRSA made the determination to direct an investigation based on the insufficiency of the initial investigation performed by OPTN committees. HRSA understands that the 10/18 request includes additional effort and review by the OPTN and OPTN contractor.

HRSA's direction does not restrict the board's ability to request assistance from the OPTN contractor with performing analysis. Given the time sensitivity of work related to this directed investigation, the Board leadership can make these requests of the OPTN contractor (UNOS) staff directly with a cc to the HRSA COR and staff (Chris McLaughlin, Brianna Doby, Ray Lynch, Mesmin Germain, Patrick Mauro). HRSA encourages OPTN leadership to request assistance from the OPTN contractor to complete the requested investigation, analysis, and report. We hope this is a helpful clarification.

Finally, we wish to note that with the involvement of federal and state authorities in separate investigations of this alleged incident, it is imperative that the OPTN and contractor take appropriate care with highly sensitive information including PIII and PHI. Access and confidentiality for these records must be managed at all times. And, given the potential for conflicting or competing interests, HRSA notes that should the OPTN leadership choose to move forward with volunteer reviewers instead of UNOS staff, those potential COIs must be adequately disclosed, described, and managed.

Please let us know how the OPTN and contractor decide to proceed. Please also let me know if you have any questions.

Sincerely, Chris

Christopher J. McLaughlin
Senior Advisor
FAC-COR-III, OPTN Contract
Division of Transplantation
Health Systems Bureau
[REDACTED]

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From: Liz Robbins <[REDACTED]>
Sent: Wednesday, October 30, 2024 1:36 PM
To: Jadia Bruckner <[REDACTED]>; McLaughlin, Chris (HRSA) <[REDACTED]>
Cc: Jacqui O'Keefe <[REDACTED]>; Betsy Warnick <[REDACTED]>; Krissy Laurie <[REDACTED]>; Matt Belton <[REDACTED]>; Robert Patterson <[REDACTED]>; Emily Womble <[REDACTED]>; Formica, Richard <[REDACTED]>; Maureen McBride <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Rochelle, Kala (HRSA) <[REDACTED]>; Naik, Arjun (HRSA) <[REDACTED]>; Levi, Marilyn (HRSA) <[REDACTED]>; Dunne, Shannon (HRSA) <[REDACTED]>; Goodrich-Doctor, Adrienne (HRSA) <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Germain, Mesmin (HRSA) <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Lauren Mauk <[REDACTED]>; Sarah Payamps <[REDACTED]>; Sara Moriarty <[REDACTED]>; Jacqui O'Keefe <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Caroline Hales <[REDACTED]>
Subject: [EXTERNAL] RE: HRSA-directed investigation

Hi Chris,

I am writing to confirm next steps with you regarding the HHS-directed investigation of KYDA. As you know, UNOS has uploaded all requested OPTN match run and donor data to the SFTP folder. We have also requested all data and information from KYDA, and have been uploading the documents to the SFTP as they are received. KYDA has until today (October 30) to finalize their document production.

In the October 18 email, HRSA requested:

After the OPTN obtains all documents and data requested by HRSA in this letter, HRSA directs the OPTN to review all requested documents and data, focusing on

- (1) KYDA's operations regarding the alleged incident, and
- (2) KYDA's operations regarding patients with potential to become DCD organ donors

Once the OPTN has completed the review as described, HRSA requests that the OPTN prepare a full report containing the assessment of the OPTN reviewers related to KYDA patient safety, quality assurance, and operational compliance with requirements in OPTN Bylaws, Policies, and Obligations for patients with potential to become DCD organ donors. HRSA requests that the OPTN transmit this report to HRSA no later than November 1, 2024.

November 1 is not a feasible deadline, as KYDA has until today to upload all the documents. Additionally, we have asked OPTN President Rich Formica how he would like the OPTN to conduct this analysis, as the direction was to the OPTN and not to UNOS staff to do the analysis. Rich has provided UNOS with a list of OPTN volunteers from the OPTN Board and the OPTN MPSC with expertise in OPO operations and/or

NRP (as well as a patient) to perform the analysis and provide HRSA with the requested report. Because of the quantity of information and the late date at which KYDA was able to provide their documents, the OPTN is requesting an extended deadline to allow for meaningful analysis and coordination of the OPTN volunteers. UNOS staff will support the volunteers through document delivery, coordination of virtual meetings (if necessary), and compiling or summarizing their analysis. The earliest feasible date we anticipate being able to submit the report is November 22.

Thanks,
Liz

OPTN Restricted

From: Jadia Bruckner <[REDACTED]>
Sent: Friday, October 25, 2024 3:32 PM
To: Christopher J McLaughlin <[REDACTED]>
Cc: Jacqui O'Keefe <[REDACTED]>; Betsy Warnick <[REDACTED]>; Krissy Laurie <[REDACTED]>; Matt Belton <[REDACTED]>; Robert Patterson <[REDACTED]>; Emily Womble <[REDACTED]>; Formica, Richard <[REDACTED]>; Maureen McBride <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Rochelle, Kala (HRSA) <[REDACTED]>; Naik, Arjun (HRSA) <[REDACTED]>; Marilyn Levi <[REDACTED]>; Shannon Dunne <[REDACTED]>; Adrienne Goodrich-Doctor <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Mesmin Germain <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>; Lauren Mauk <[REDACTED]>; Sarah Payamps <[REDACTED]>; Sara Moriarty <[REDACTED]>; Jacquie O'Keefe <[REDACTED]>; Liz Robbins <[REDACTED]>; Lynch, Raymond (HRSA) <[REDACTED]>; Caroline Hales <[REDACTED]>
Subject: RE: HRSA-directed investigation

Good Afternoon,

All documents received to date from KYDA in response to the October 18, 2024 HRSA-directed investigation have been uploaded to the HRSA Responses and Data SFTP folder 10 18 24 HRSA Directed Investigation, subfolders A, B, and C. To navigate, access the same SFTP site, then HRSA Responses and Data, then 10 18 24 HRSA directed investigation. Subfolder D contains OPTN requested information. All match runs involving this donor, and all DonorNet and TIEDI records have been uploaded. Please note, in the test section of the DonorNet chart (AU1488) there is a list of radiographical images that were uploaded by the OPO. Transplant centers are able to view the images through DonorNet by clicking the orange hyperlink under descriptions. Due to the large size of the images (over 300MB each) and the need for the specific viewer program, these images cannot easily be downloaded and exported for view outside of the DonorNet application. If you do need to see each individual image study, we will need to work with you all to figure out how they can be transmitted. Lastly, we are waiting for one more record to be retrieved by our IT staff. The record is a DonorNet attachment identified as having been deleted by a user and subsequently re-uploaded, and we are working on calling it back up because HRSA asked for all deleted documents. This will be uploaded in subfolder D once we can retrieve it. Additionally, included you will find KYDA's response letter (10 23 24 HRSA Investigation Response) and a crosswalk (KYDA_HRSA Directive 2) created by OPTN contractor staff to aid in clarifying items submitted and folder location, as well as items that will be submitted on the granted extension deadline of October 30, 2024. As we continue to receive files from KYDA through their extended deadline, we will upload them to these folders. UNOS has and will continue to transmit all files in the format received from KYDA.

Thank you,

Jadia Bruckner
Patient Safety Manager

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<image009.gif>

<image010.gif>

<image011.gif>

OPTN Restricted

From: Christopher J McLaughlin <[REDACTED]>
Sent: Thursday, October 24, 2024 11:57 AM
To: Jadia Bruckner <[REDACTED]>
Cc: Jacqui O'Keefe <[REDACTED]>; Betsy Warnick <[REDACTED]>; Krissy Laurie <[REDACTED]>; Matt Belton <[REDACTED]>; Robert Patterson <[REDACTED]>; Emily Womble <[REDACTED]>; Formica, Richard <[REDACTED]>; Maureen McBride <[REDACTED]>; Nair, Suma (HRSA) <[REDACTED]>; Doby, Brianna (HRSA) <[REDACTED]>; Rochelle, Kala (HRSA) <[REDACTED]>; Naik, Arjun (HRSA) <[REDACTED]>; Marilyn Levi <[REDACTED]>; Shannon Dunne <[REDACTED]>; Adrienne Goodrich-Doctor <[REDACTED]>; Holloman, Frank (HRSA) <[REDACTED]>; Mauro, Patrick (HRSA) <[REDACTED]>; Mesmin Germain <[REDACTED]>; Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>

Lauren Mauk <[REDACTED]>; Sarah Payamps <[REDACTED]> Sara Moriarty
<[REDACTED]>; Jacqui O'Keefe <[REDACTED]> Liz Robbins
<[REDACTED]> Lynch, Raymond (HRSA) <[REDACTED]>
Subject: [EXTERNAL] RE: HRSA-directed investigation

Jadia and all: HRSA approves the requested extension Thanks, Chris

Christopher J. McLaughlin
Senior Advisor
FAC-COR-III, OPTN Contract
Division of Transplantation
Health Systems Bureau
[REDACTED]

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OPTN Restricted

From: Jadia Bruckner <[REDACTED]>
Sent: Tuesday, October 22, 2024 2:44 PM
To: McLaughlin, Chris (HRSA) <[REDACTED]>
Cc: Jacqui O'Keefe <[REDACTED]>; Betsy Warnick <[REDACTED]>; Krissy
Laurie <[REDACTED]> Matt Belton <[REDACTED]> Robert Patterson <[REDACTED]>
Emily Womble <[REDACTED]> Formica, Richard <[REDACTED]>
Maureen McBride <[REDACTED]> Nair, Suma (HRSA) <[REDACTED]>
Doby, Brianna (HRSA) <[REDACTED]> Rochelle, Kala (HRSA) <[REDACTED]>
Naik, Arjun (HRSA) <[REDACTED]> Levi, Marilyn (HRSA) <[REDACTED]>
Dunne, Shannon (HRSA) <[REDACTED]> Goodrich-Doctor, Adrienne
(HRSA) <[REDACTED]> Holloman, Frank (HRSA) <[REDACTED]> Mauro,
Patrick (HRSA) <[REDACTED]> Germain, Mesmin (HRSA) <[REDACTED]> Aigbe,
Aitebureme (Aite) (HRSA) <[REDACTED]> Lauren Mauk <[REDACTED]> Sara
Payamps <[REDACTED]> Sara Moriarty <[REDACTED]> Jacqui O'Keefe
<[REDACTED]> Liz Robbins <[REDACTED]> Lynch, Raymond (HRSA) <[REDACTED]>
Subject: [EXTERNAL] RE: HRSA-directed investigation

Good Afternoon,

Please see the below message and request from KYDA:

“Thank you for the clarification Based on your response, we will need to pull case records for over 170 patients (approximately 35,000 pages of documents) during this timeframe Due the work on the other requests in the original letter, KYDA respectfully requests an extension on the third bulleted section (items numbered 1-6) of the initial letter to October 30, 2024 The other requested information (items 1-6 in the first bulleted section and 1-2 in the second bulleted section) will be produced by the original deadline ”

Is HRSA agreeable to the deadline extension request?

Thank you,
Jadia

OPTN Restricted

From: Jadia Bruckner
Sent: Tuesday, October 22, 2024 8:42 AM
To: 'Christopher J. McLaughlin' <[REDACTED]>
Cc: Jacqui O'Keefe <[REDACTED]> Betsy Warnick <[REDACTED]> Krissy
Laurie <[REDACTED]> Matt Belton <[REDACTED]> Robert Patterson <[REDACTED]>
Emily Womble <[REDACTED]> Formica, Richard <[REDACTED]>
Maureen McBride <[REDACTED]> Nair, Suma (HRSA) <[REDACTED]>
Doby, Brianna (HRSA) <[REDACTED]> Rochelle, Kala (HRSA) <[REDACTED]>
Naik, Arjun (HRSA) <[REDACTED]> Marilyn Levi <[REDACTED]>
Shannon Dunne <[REDACTED]> Adrienne Goodrich-Doctor <[REDACTED]>
Holloman, Frank (HRSA) <[REDACTED]> Mauro, Patrick (HRSA) <[REDACTED]>
Mesmin Germain <[REDACTED]> Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]>
Lauren Mauk <[REDACTED]> Sarah Payamps <[REDACTED]> Sara Moriarty
<[REDACTED]> Jacqui O'Keefe <[REDACTED]> Liz Robbins
<[REDACTED]> Lynch, Raymond (HRSA) <[REDACTED]>
Subject: RE: HRSA-directed investigation

Thank you, Chris I will relay to KYDA

Hope you have a good day

Thanks,

Jadia

From: Christopher J McLaughlin <[REDACTED]>
Sent: Monday, October 21, 2024 5:50 PM
To: Jadia Bruckner <[REDACTED]>
Cc: Jacquie O'Keefe <[REDACTED]> > Betsy Warnick <[REDACTED]> > Krissy Laurie <[REDACTED]> > Matt Belton <[REDACTED]> > Robert Patterson <[REDACTED]> > Emily Womble <[REDACTED]> > Formica, Richard <[REDACTED]> > Maureen McBride <[REDACTED]> > Nair, Suma (HRSA) <[REDACTED]> > Doby, Brianna (HRSA) <[REDACTED]> > Rochelle, Kala (HRSA) <[REDACTED]> > Naik, Arjun (HRSA) <[REDACTED]> > Marilyn Levi <[REDACTED]> > Shannon Dunne <[REDACTED]> > Adrienne Goodrich-Doctor <[REDACTED]> > Holloman, Frank (HRSA) <[REDACTED]> > Mauro, Patrick (HRSA) <[REDACTED]> > Mesmin Germain <[REDACTED]> > Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]> > Lauren Mauk <[REDACTED]> > Sarah Payamps <[REDACTED]> > Sara Moriarty <[REDACTED]> > Jacquie O'Keefe <[REDACTED]> > Liz Robbins <[REDACTED]> > Lynch, Raymond (HRSA) <[REDACTED]>
Subject: [EXTERNAL] RE: HRSA-directed investigation

Good evening Jadia:

Clarification for KYDA and contractor:

KYDA does not track case rates, and therefore they would like clarification on what HRSA is seeking in the description of services. They are wondering if, because they do not have case rates, does this request for description of services still apply.

HRSA is seeking the financial arrangements between Baptist Health Richmond and KYDA for reimbursement. Whether that is a percentage of bill basis, or per service basis, the financial agreements between KYDA and Baptist Health Richmond are requested in addition to the associated description of services covered by those financial agreements.

KYDA is preparing all cases that went to OR, extubated, but did not pass. They would like clarification on the donors that were not ruled out, do not have a cardiac time of death, and/or were extubated elsewhere (not in the OR) in the hospital. KYDA stated they may not have access to this data because these situations are outside of their purview.

HRSA seeks information for item (3) for all patients with which the OPO interacted for potential DCD procurement.

If a patient was evaluated and authorized for potential DCD procurement, KYDA has a record of those interactions and documents a final disposition of that patient record. If the patient did not progress to attempted DCD procurement, the terminal point in the KYDA record would describe the nature of that disposition (cardiac arrest, family withdrawal of authorization, etc.). If the KYDA patient record was then linked by a death record review (providing CTOD) this should be noted (see: 42 CFR482.45(a)(5)). HRSA notes that for patients referred to the OPO whose organs are not procured, a subset of those patients continue to be followed by the OPO for potential eye and tissue procurement. This would be another way in which the KYDA level record would reflect a disposition for non-converted DCD potential patients.

Let me know if you need further clarification Thanks, Chris

Christopher J. McLaughlin
Senior Advisor
FAC-COR-III, OPTN Contract
Division of Transplantation
Health Systems Bureau
[REDACTED]

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From: Jadia Bruckner <[REDACTED]>
Sent: Monday, October 21, 2024 1:49 PM
To: McLaughlin, Chris (HRSA) <[REDACTED]>
Cc: Jacquie O'Keefe <[REDACTED]> > Betsy Warnick <[REDACTED]> > Krissy Laurie <[REDACTED]> > Matt Belton <[REDACTED]> > Robert Patterson <[REDACTED]> > Emily Womble <[REDACTED]> > Formica, Richard <[REDACTED]> > Maureen McBride <[REDACTED]> > Nair, Suma (HRSA) <[REDACTED]> > Doby, Brianna (HRSA) <[REDACTED]> > Rochelle, Kala (HRSA) <[REDACTED]> > Naik, Arjun (HRSA) <[REDACTED]> > Levi, Marilyn (HRSA) <[REDACTED]> > Dunne, Shannon (HRSA) <[REDACTED]> > Goodrich-Doctor, Adrienne <[REDACTED]> > Holloman, Frank (HRSA) <[REDACTED]> > Mauro, Patrick (HRSA) <[REDACTED]> > Germain, Mesmin (HRSA) <[REDACTED]> > Aigbe, Aitebureme (Aite) (HRSA) <[REDACTED]> > Lauren Mauk <[REDACTED]> > Sarah Payamps <[REDACTED]> > Sara Moriarty <[REDACTED]> > Jacquie O'Keefe <[REDACTED]> > Liz Robbins <[REDACTED]>

Subject: [EXTERNAL] RE: HRSA-directed investigation

Good Afternoon,

KYDA contacted OPTN contractor staff seeking clarity on the following items listed in the HRSA directed investigation:

"2. The OPO-hospital case rates and description(s) of services for patients who have potential to become DCD organ donors at Baptist Health Richmond:

a that was in effect on October 29, 2021, and
b that is currently in effect "

KYDA does not track case rates, and therefore they would like clarification on what HRSA is seeking in the description of services. They are wondering if, because they do not have case rates, does this request for description of services still apply.

"3. All records relating to the occurrence and content of any pre-withdrawal calls (also often known as a "huddle") to discuss withdrawal procedure, medications or comfort care, pronouncement, roles and prohibitions-of-roles for hospital, OPO, and center/procuring staff as required at OPTN Policy 2.15.F." KYDA is preparing all cases that went to OR, extubated, but did not pass. They would like clarification on the donors that were not ruled out, do not have a cardiac time of death, and/or were extubated elsewhere (not in the OR) in the hospital. KYDA stated they may not have access to this data because these situations are outside of their purview.

Please provide prompt response that will be relayed to KYDA. As a reminder, KYDA has a deadline of Wednesday, October 23 for their portion of the response to allow the OPTN contractor time to prepare and post the documents for HRSA review (deadline October 25th).

Jadia Bruckner
Patient Safety Manager

<image008.png>

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<image009.gif>

<image010.gif>

<image011.gif>

OPTN Restricted

OPTN Restricted

From: Christopher J. McLaughlin
Sent: Friday, October 18, 2024 2:33 PM
To: Formica, Richard >; Maureen McBride >
Cc: Nair, Suma (HRSA) >; Doby, Brianna (HRSA) >; Rochelle, Kala (HRSA) >; Naik, Arjun (HRSA) >; Marilyn Levi >
>; Shannon Dunne >; Adrienne Goodrich-Doctor >
>; Holloman, Frank (HRSA) >; Mauro, Patrick (HRSA) >; Mesmin Germain >; Augbe, Aitebureme (Aite) >
>; Lauren Mauk >; Sarah Payamps >
>; Sara Moriarty >; Jacqui O'Keefe >
>; Liz Robbins >
Subject: [EXTERNAL] HRSA-directed investigation

Dear Rich and Maureen:

The Organ Procurement and Transplantation Network (OPTN) Final Rule authorizes the Secretary of the Department of Health and Human Services (HHS), which authority is delegated to HRSA, to direct the OPTN to investigate potential threats to public health and patient safety. This authority is described at 42 CFR 121.10(b)(3):

"At the request of the Secretary, the OPTN shall conduct special reviews of OPOs and transplant programs, where the Secretary has reason to believe that such entities may not be in compliance with these rules or OPTN policies or may be acting in a manner which poses a risk to the health of patients or to public safety. The OPTN shall conduct these reviews in accordance with such schedules as the Secretary specifies and shall make periodic reports to the Secretary of progress on such reviews and on other reviews conducted under the requirements of this paragraph."

HRSA is directing the OPTN with support from the OPTN contractor to conduct a review for potential risks to patient safety from organ procurement activities performed by OPTN member KYDA, the organ procurement organization (OPO) serving Kentucky and select counties in Ohio, West Virginia, and Indiana. This direction is based on the alleged patient safety incident described in the September 11, 2024 House Energy and Commerce Committee hearing,¹ additional media reporting,² and concerns received from the community, with the goal of ensuring the safety and integrity of the U.S. procurement and transplantation system. The specific issues raised by this incident report that require review are OPO standard operating procedures, quality assurance activities, and safety monitoring for patients identified by KYDA for potential Donation after Circulatory Death (DCD) organ procurement.

¹ See: <https://energycommerce.house.gov/events/oversight-and-investigations-subcommittee-hearing-a-year-removed-oversight-of-securing-the-u-s-organ-procurement-and-transplantation-network-act-implementation>

² See NPR reporting at: <https://www.npr.org/sections/health-news/2024/10/16/nx-s1-5113976/organ-transplantation-mistake-brain-dead-surgery-still-alive>

and Richmond Times-Dispatch reporting at: https://richmond.com/news/local/business/health-care/kentucky-organ-recovery-group-accused-of-pursuing-transplant-before-patient-died/article_0e5b48ee-7062-11ef-9384-43d79b59013d.html

HRSA acknowledges that the OPTN Membership and Professional Standards Committee (MPSC) sent a letter to KYDA requesting information about patient identified as Donor ID AIJ1488 ("patient AIJ1488"), on September 12, 2024; however, upon review of the MPSC's efforts, HRSA determined that the information requested and collected by the MPSC for an investigation into this alleged incident was insufficient

HRSA is directing the OPTN to undertake a review of KYDA's organ procurement process, with particular focus on patients who are evaluated by KYDA for potential Donation after Circulatory Death (DCD) procurement. HRSA acknowledges that the OPTN's investigation, for this phase, includes an initial information request and record reviews, and preparation of a report of the OPTN's assessment. Additional steps, including a directed site visit to the OPO, will be determined after the information HRSA requests through this letter is reviewed by the OPTN and HRSA.

HRSA notes that the OPO information requested in this directed investigation would be routinely collected by OPOs under the Centers for Medicare & Medicaid Services (CMS) Conditions for Coverage (CDC's) described at 42 CFR 486.328, OPTN Policies 2.2, 2.3, 2.4, 2.11, 2.13, 2.14, and 2.15, OPTN Bylaws B.3.A and B.4.E, and 42 U.S.C. 274(b)(2)(E) and (I). HRSA also notes that the hospital information provided about this patient to the OPO is described in CMS's hospital Conditions for Participation at 42 CFR 482.45(a). Further, HHS regulations at 42 CFR 121.11(a)(2) require that OPOs maintain certain transplantation-related records, and that the Secretary has access to facilities and records relating to organ transplantation. HRSA requests that the OPTN obtain this information from KYDA pursuant to this authority, which provides as follows:

Organ procurement organizations and transplant programs —

(i) Maintenance of records. All OPOs and transplant programs shall maintain such records pertaining to each potential donor identified, each organ retrieved, each recipient transplanted and such other transplantation-related matters as the Secretary deems necessary to carry out her/his responsibilities under the Act. The OPO or transplant program shall maintain these records for seven years.

(ii) Access to facilities and records. OPOs and transplant hospitals shall permit the Secretary and the Comptroller General, or their designees, to inspect facilities and records pertaining to any aspect of services performed related to organ donation and transplantation

We further note that the OPTN has the authority to request information from OPTN members to fulfill OPTN compliance monitoring as described at OPTN Article 1.1.E; similarly, OPTN members have an obligation to cooperate and provide requested information for an investigation as described in OPTN membership requirements under OPTN Bylaw Article 1.1.E(3) and Appendix L.5. The OPTN Bylaws also require OPTN members to comply with all requests made by the OPTN under the auspices of a Secretarial Review at OPTN Bylaw L.14.C (emphasis added):

C. Special Secretarial Reviews

*At the request of the Secretary of HHS, the OPTN will conduct special reviews of members when the Secretary has reason to believe that the member may not be in compliance with the OPTN Final Rule or may be acting in a way that poses a risk to patient health or public safety. A Special Review is a review of the member in the manner and within the period specified by the Secretary. This may include, but is not limited to, requests for root cause analysis, corrective action, and due process proceedings completed in the period and as specified by the Secretary. **Members must fully comply with all OPTN requests as part of a Special Review.***

HRSA requests that the OPTN obtain the following information from KYDA regarding patient AIJ1488:

1. All record(s), documentation, and any available copies of medical records for patient AIJ1488 in KYDA's possession, without redactions or deletions. Information in this record is required to complete OPO activities described at OPTN Policy 2.15. a. Please note any deletions of data or documents from the OPO EMR record made during the case process or post hoc.

2. A complete list of all KYDA organ procurement staff members (including coordinators, allocation, perfusionists, administrators on call (AOCs), managers, and medical director) who were on the schedule for each day patient AIJ1488 was on the KYDA referral or case board (a process also typically known as "following the patient" in OPO nomenclature). OPOs are required to provide a "sufficient number of qualified staff" under 42 CFR 486.326 and further specified at 42 CFR 486.326(b). a. For each staff member listed, provide a description of training and qualifications for each staff member. OPOs are required to "ensure that all individuals who provide services and/or supervise services [...] are qualified to provide or supervise the services" under 42 CFR 486.326(a)(1) and further described at 42 CFR 486.328(c).

3. Records of, and transcripts (if available), of all telephone or video calls between or among:

a. KYDA staff including coordinators, allocation, perfusionists, administrators on call (AOCs), managers, and medical directors pertaining to patient AIJ1488.

b. KYDA staff including coordinators, allocation, perfusionists, administrators on call (AOCs), managers, and medical directors with Baptist Health Richmond staff pertaining to patient AIJ1488.

c. KYDA staff including coordinators, allocation, perfusionists, administrators on call (AOCs), managers, and medical directors with family members or legal next of kin for patient AIJ1488.

4. All KYDA exit interviews or notes regarding any staff who departed KYDA in response to the incident.

5. All non-disclosure agreements signed by staff who departed KYDA in response to the incident.

6. All documents relating to any after-action review undertaken by KYDA in response to the incident. OPTN Bylaws require OPOs to complete Quality Assessment activities required under B.3.A.

HRSA requests that the OPTN obtain the following information from KYDA regarding process and protocols in place at Baptist Health Richmond for all patients who have potential to become DCD organ donors:

1. The OPO-hospital agreements with Baptist Health Richmond as required at 42 CFR 486.322:

- a. that was in effect on October 29, 2021, and
- b. that is currently in effect

2. The OPO-hospital case rates and description(s) of services for patients who have potential to become DCD organ donors at Baptist Health Richmond:

- a. that was in effect on October 29, 2021, and
- b. that is currently in effect

HRSA requests that the OPTN obtain the following information from KYDA regarding process and protocols in place at all hospitals in KYDA's Donation Service Area (DSA) for all patients who have

potential to become DCD organ donors:

- 1 All KYDA standard operating procedures (SOPs) regarding location and protocol(s) in effect at any point since the incident date for DCD pathway organ procurement as required at OPTN Policy 2 15 A, 2 15 B, and 2 15 C and OPTN Bylaw B 4 E
- 2 All records relating to patient cases since October 29, 2021 in which a patient was followed by KYDA for DCD-potential organ procurement that terminated with an extubation of the patient without a cardiac time of death (CTOD) This is sometimes referred to as a "non-converted DCD" and reporting data for the non-recovery of organs by an OPO is required at 42 CFR 486.328(a)(5)
- 3 All records relating to the occurrence and content of any pre-withdrawal calls (also often known as a "huddle") to discuss withdrawal procedure, medications or comfort care, pronouncement, roles and prohibitions-of-roles for hospital, OPO, and center/procuring staff as required at OPTN Policy 2 15 F
- 4 Any documented deviations from the protocols required at OPTN Policy 2 15 A and 2 15 B, or huddle required at OPTN Policy 2 15 F, for each listed case
- 5 Any event-specific feedback sought or received from the donor hospital staff and/or hospital leadership following the withdrawal regarding each listed case
- 6 Any event-specific feedback sought or received from the procuring transplant center staff and/or procuring transplant center leadership following the withdrawal regarding each listed case

HRSA requests the following information from the OPTN:

- 1 The complete DonorNet record for patient AIJ1488 without redactions or deletions Please note any deletions of data or documents from the DonorNet record made during the case process or post hoc
 - a A list of all documents uploaded to DonorNet for AIJ1488
 - b Images or PDFs of DonorNet documents page for this DonorNet record to show which documents were visible to users during the organ allocation process (center coordinators, etc) including those marked as removed/error
- 2 All match run(s) associated with AIJ1488 including date and timestamps, and all associated potential transplant recipient (PTR) data

All documents and data requested by HRSA in this letter should be provided by the OPTN to HRSA using the existing Secure File Transfer Protocol (SFTP) mechanism HRSA requests that the OPTN complete the document and data transfer **no later than October 25, 2024.**

After the OPTN obtains all documents and data requested by HRSA in this letter, HRSA directs the OPTN to review all requested documents and data, focusing on

- (1) KYDA's operations regarding the alleged incident, and
- (2) KYDA's operations regarding patients with potential to become DCD organ donors

Once the OPTN has completed the review as described, HRSA requests that the OPTN prepare a full report containing the assessment of the OPTN reviewers related to KYDA patient safety, quality assurance, and operational compliance with requirements in OPTN Bylaws, Policies, and Obligations for patients with potential to become DCD organ donors HRSA requests that the OPTN transmit this report to HRSA **no later than November 1, 2024.**

If HRSA has questions about the report, we may request a meeting with relevant OPTN officials to discuss the report's findings

Thank you for your shared commitment to protecting public health and patient safety Please let me know if the OPTN or contractor has any questions about HRSA's direction to the OPTN as provided in this letter

Sincerely, Chris

Christopher J. McLaughlin
Senior Advisor
FAC-COR-III, OPTN Contract
Division of Transplantation
Health Systems Bureau

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