# Tina Rhoades

From: Jadia Bruckner

Sent: Wednesday, February 19, 2025 2:38 PM

To: Formica, Richard; Christopher J. McLaughlin

Cc: Tina Rhoades; 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); Lauren Mauk; Mauro, Patrick (HRSA); HRSA

OPTN EXT COR; Rebecca Murdock; Caroline Hales

Subject: Re: [Secure] Reviewers: HRSA Directed Investigation

Thank you for the update—I appreciate your perspective and also share gratitude for the time and effort of our volunteers.

I'm happy to schedule based on your availability (poll responses below-Glen is not available at all on Friday). Please let me know if you'd like me to proceed with scheduling.

Morning (8-9 AM)	Kristine, Rich
Afternoon (12-1 PM)	Rich
Evening (4-5 PM)	Kristine, Kyle

Thank you!

#### **OPTN Restricted**

From:

Sent: Wednesday, February 19, 2025 2:12 PM

To: Formica, Richard; Christopher J. McLaughlin; Jadia Bruckner

Cc: Tina Rhoades; 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);

Lauren Mauk; Mauro, Patrick (HRSA); HRSA OPTN EXT COR; Rebecca Murdock; Caroline Hales

Subject: [EXTERNAL] RE: [Secure] Reviewers: HRSA Directed Investigation

#### Hi Jadia,

I started this conversation with Suma yesterday. I think we have gone to the well too many times and it is dry. Moreover, we "created" (in quotes because I acknowledge the perceived conflict caused by signing the letter refute statements made at E&C although I disagree that it is an actual conflict) by eliminating nearly 1100 potential volunteers to help with the review. I have been logging on when I can, and looking through files, and reading the comments. I feel that we have a more than representative sample from which to draw conclusions about the overall performance of this OPO. Suma implied that there may be specific files that HRSA is concerned about. Because the board leadership has the ability to look at these from all angles, I told Suma we would informally look at them and render and opinion that HRSA could then use to choose to resolve that file or ask for someone else to review. Otherwise, I am out of ideas. I think we need to remember that OPTN does all of its work through volunteers. We have published the monetary value of that work. I think in the current environment the volunteers are feeling both taken for

granted and taken advantage of. I just got off the phone with a committee chair and vice chair who are concerned their whole committee is going to step down. I am meeting with the committee to try to assuage their feelings and keep things going. I will be on the Friday call, or are your counting me as one of the respondents?

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From: Jadia Bruckner			
Sent: Wednesday, Februa	rv 19. 2025 6:37:07 PM		
To: Formica, Richard	Christopher J. McLa	ughlin <	<b>&gt;</b>
Cc: Tina Rhoades <	>; Aigbe, Aitebureme (Aite)		Holloman, Frank
(HRSA)	Lynch, Raymond (HRSA)	; Nair, Suma	(HRSA)
Doby, Brianna (HRSA)	Petrone, Stephanie (HRSA)		Locke, Jayme (HRSA)
John,	Hanock (HRSA)	/lauk	Mauro, Patricl
(HRSA)	HRSA OPTN EXT COR	Rebec	ca Murdock
	Caroline Hales		
Subject: Re: [Secure] Revie	ewers: HRSA Directed Investigation	120	

Good afternoon from a snowy Richmond,

Smaller group email with Rich and HRSA:

Today marks the final dedicated day for record review. Here's where we stand:

- One reviewer has not been engaged, and one writer has completed all reviews but has committed to serving as an author.
- 41 patient and donor records remain unassigned.
- Only two reviewers are available for the scheduled call on Friday.
- Of the three reviewers who responded to the poll, only one indicated they would be able to complete their record review.

To accommodate different schedules and capture a broader range of input, I have cleared my schedule to offer extended office hours on Monday. My hope is that this will provide more flexibility for reviewers to share their insights.

Despite these challenges, we remain committed to delivering the OPTN Board presentation and final report on time with the information available.

Are there any updates from yesterday's COR call? Please let me know if there is a specific direction you would like me to take moving forward.

Thank you,

Jadia

From:

Sent: Saturday, February 15, 2025 12:35 PM

To: gp.kelley; Formica, Richard; Christopher J. McLaughlin; Potter, Steven; Jadia Bruckner; Tina Rhoades
Cc: Denlinger, Chadrick E; Kyle Herber; Stewart Lewis, Zoe A.; Luis Mayen; Debbi
McRann; 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); Lauren
Mauk; Mauro, Patrick (HRSA); HRSA OPTN EXT COR; Rebecca Murdock; Caroline Hales

Subject: [EXTERNAL] RE: [Secure] Reviewers: HRSA Directed Investigation

# Hi Jadia,

rich

Chris and I will discuss the plan on Tuesday. At this point in time, I want to acknowledge the large volume of work everyone has done. I know that each case can take up to an hour and that you all have jobs that need to be done in addition to your volunteerism. I also realize these reviews are emotionally taxing to read, making this a very heavy lift. Thank you everyone. If we all meet at WTC, drinks will be on me. best,

# OPTN Restricted

From: Tina Rhoades Sent: Saturday, February 15, 2025 2:51:34 PM To: gp.kelley Formica, Richard Christopher J. McLaughlin Potter, Steven Jadia Bruckner Cc: Denlinger, Chadrick E Kyle Herber Stewart Lewis, Zoe A. Luis Mayen Debbi McRann Aigbe, Aitebureme (Aite) (HRSA) Holloman, Frank (HRSA) Lynch, Raymond (HRSA) Nair, Doby, Brianna (HRSA) Suma (HRSA) Petrone, Stephanie (HRSA) Locke, Jayme (HRSA) John, Hanock (HRSA) Lauren Mauk Mauro, Patrick (HRSA) HRSA OPTN EXT COR Caroline Hales Rebecca Murdock

# Good morning,

Thank you for the clarifying question. The report is still a required deliverable. Per HRSA's direction, the timeline has been adjusted to incorporate a presentation to the OPTN Board of Directors on February 27<sup>th</sup> which will allow the Board the opportunity to provide input to the final report. Please see the adjusted timeline below. We welcome any additional questions and appreciate your time and dedication, always.

- 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 (exact time tbd)
- 2/24-2/25 Report writer owner (2) editing and approval

Subject: RE: [Secure] Reviewers: HRSA Directed Investigation

- 2/27 Presentation to OPTN Board of Directors
- 3/3 Final report to Rich Formica for approval

3/4 Final report due to HRSA

Thank you, Tina

**OPTN Restricted** 

From:				
Sent: Friday, February 14	, 2025 5:15 PM			
To: Formica, Richard	Christophe	er J. McLaughlin		Formica, Richard
	Christopher J. McLaughlin		Potter, Steven	
	Jadia Bruckner			
Cc: Denlinger, Chadrick E	gp.kelle	ey ·		Kyle
Herber	Stewart Lewis, Zo	e A.		Luis Mayen
	Debbi McRann	Aigbe, Aite	ebureme (Aite) (H	RSA)
Holl	oman, Frank (HRSA)	Lynch, Raym	ond (HRSA)	Nair,
Suma (HRSA)	Doby, Brianna (HRSA)	Petro	ne, Stephanie (HR	SA)
Le	ocke, Jayme (HRSA)	John, Hanock (HR	SA)	Lauren Mauk
	Mauro, Patrick (HRSA)	HRSA OPT	N EXT COR	185
	Rebecca Murdock ·		Caroline Hales	
	Tina Rhoades			
Subject: [EXTERNAL] RE:	[Secure] Reviewers: HRSA Directed I	nvestigation		

Jadia,

Thank you for the status update. A quick point of clarification, previously there was a report to be written and I believe I was one of the assigned writers. Is that no longer in the process stream?

I'll continue to move through the records as best I can over these remaining days.

Thank you,

Glen

From: Jadia Bruckner				
Sent: Friday, February 14,	2025 9:57:26 PM			
To: Formica, Richard	Christopher	J. McLaughlin		Formica, Richard
	Christopher J. McLaughlin		Potter, Steven	
Cc: Denlinger, Chadrick E	gp.kelley	/ <		
	Kyle Herber	<	S	tewart Lewis, Zoe A
	Luis Mayen ·	Debbi	McRann	
	Aigbe, Aitebureme (Aite) (HRS	A) -	Holloman, Fra	nk (HRSA)
Ly	nch, Raymond (HRSA)	Nair, Suma	(HRSA)	Doby,
Brianna (HRSA)	Petrone, Stephanie (HRSA	) -	Locke, Jayme	(HRSA)
John, I	Hanock (HRSA)	Lauren Mauk		Mauro, Patrick
(HRSA)	HRSA OPTN EXT COR		Rebecca Murdock	
	Caroline Hales	Fina	Rhoades ·	
Subject: Re: [Secure] Revie	wers: HRSA Directed Investigation			

Happy Valentines Day,

I want to provide an update on our progress as we approach the final days of review.

Review Days Remaining: 5 (3 business days)

#### Record Review Counts:

- Donor & Patient Records: 67 reviewed / 295 not reviewed (29 unassigned)
- Process & Protocol: 16 reviewed / 18 not reviewed
- Huddle Records: 15 reviewed / 44 not reviewed (6 unassigned)

We recognize the significant workload remaining and appreciate the reviewer's continued effort in moving this forward.

# Record Review Reassignment:

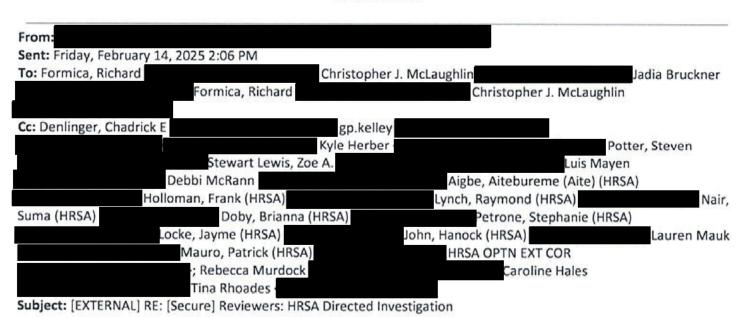
Thank you, Steve, for your thoroughness and feedback. I am yet again humbled by how much time OPTN volunteers give. I will assign a second OPO reviewer to the record you identified. However, the question remains on how to handle the remaining unassigned documents. Chris and Rich-Please advise on how you would like me to proceed.

#### Board Presentation:

The contractor will develop a presentation for Rich to review and edit by February 26. If 100% of the reviews are not complete by then, we will submit the presentation with the information available from completed reviews.

Here to support!

Jadia



# Chris,

I have completed review of all the documents assigned me.

For one document (ID and synopsis of concern previously sent to the team) I would appreciate one of my OPO colleagues reviewing that one record as well. Other than that one record, my review yielded no process or communication concerns or any other concerns. It looks like the Member under review is doing a challenging job as well as can be expected and is, at the very least, doing that job in a sufficient manner. More subjectively, I would aver that they are performing an extremely difficult job in a more than sufficient, and at times absolutely commendable manner.

Additionally, I would be happy to volunteer my assessment of this process now or post-hoc if you or anyone on your team is interested in feedback at all.

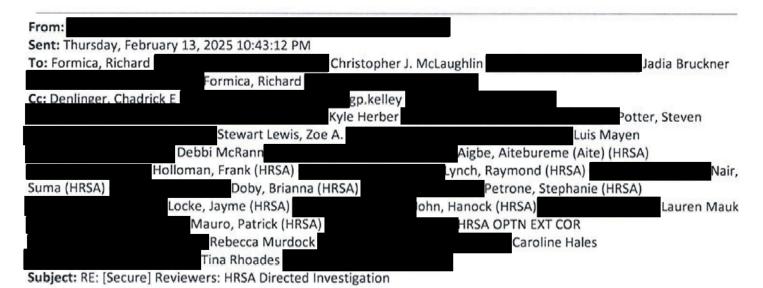
Thank you for the opportunity to serve. Have a great day.

Best regards,

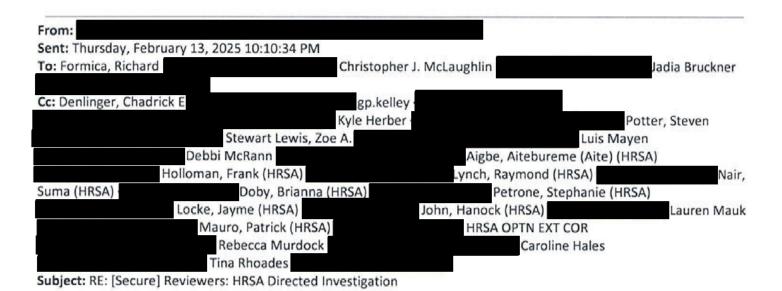
Steve

#### Steven R. Potter, M.D., FACS

Professor of Surgery and Urology
Director, Pancreas Transplantation
Medstar Georgetown Transplant Institute
Georgetown University School of Medicine
Chair, ASTS Surgical Policy Assessment Committee
Vice-Chair, OPTN Operations and Safety Committee
Immediate Past Chair, ASTS Legislative and Regulatory Committee
Certified Abdominal Transplant Surgeon



Hi Jadia and Rich: Although HRSA recognizes the burden being placed on reviewers, the unique aspect of this investigation is that all of these cases are being reviewed to allow the reviewers to come to an informed conclusion on the member's practice based on the evidence provided. It is important to HRSA that all of the records are reviewed. HRSA thanks all of the reviewers for the work on this investigation. Sincerely, Chris

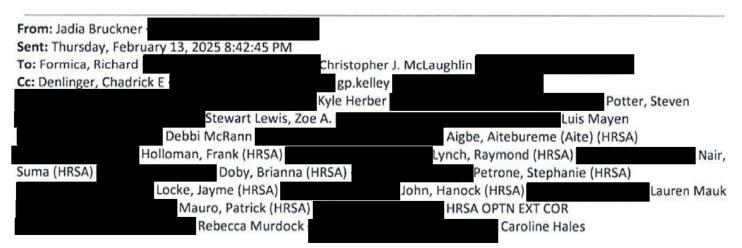


# , Jadia,

I will defer this to Chris. However, I have been looking through some of these records as well and I don't believe we need to have every record reviewed. By and large reviews are coming out the same, and they seem to be suggesting that protocols were followed. The only question I would have for Chris is should we have all cases reviewed because we want to say we were being completely thorough. I think that's a reasonable approach. I just don't know that it's necessary. I'd also point out by looking through these reviews. There's a lot of material that are volunteers are going through And to place more burden on them I think would be unfair.

Just my opinion.

Rich.



Tina Rhoades

Subject: Re: [Secure] Reviewers: HRSA Directed Investigation

# 2/13 Update:

Patrick Northup has communicated that he will not be able to service as a reviewer, "Unfortunately, due to the compressed schedule and unexpected travel I don't think I'm going to be able to dedicate the time to this that I originally thought possible. I'm sorry and apologize. "I have thanked him for letting us know and SharePoint permissions have been updated. Patrick has also been removed from this email thread.

**Please advise** if you would like me to assign the cases among the current review panel, or should they remain unassigned?

Current
Reviewers
Chad
Denlinger
Glen Kelley
Kristine
Browning
Kyle Herbe
Steve Potte
Zoe Stewar
Lewis
Luis Mayen
Debbi
McRann

# Record Review Counts

Donor & Patient Records	47 reviewed/ 315 not reviewed
Process & Protocol	11 reviewed/ 23 not reviewed
Huddle Records	8 reviewed/51 not reviewed

Thanks,

Jadia

#### **OPTN Restricted**

From: Jadia Bruckner

Sent: Tuesday, February 11, 2025 3:31 PM
To: Formica, Richard; Christopher J. McLaughlin

Cc: Denlinger, Chadrick E; gp.kelley; Kyle Herber; Northup, Patrick; Potter, Steven; Stewart

Lewis, Zoe A.; Luis Mayen; Debbi McRann; 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); Lauren Mauk; Mauro, Patrick (HRSA); HRSA OPTN EXT COR; Christopher J. McLaughlin;

Rebecca Murdock; Formica, Richard; Caroline Hales; Tina Rhoades

Subject: Re: [Secure] Reviewers: HRSA Directed Investigation

Hi All.

Providing an update:

There are approximately 8 review days left.

#### Record Review Counts

Donor & Patient Records	14 reviewed/ 348 not reviewed	5 unique reviewers
Process & Protocol	11 reviewed/ 23 not reviewed	1 unique reviewer Rich-would you like to assign a designated reviewer?
Huddle Records 8 reviewed/51 not reviewed 1 unique reviewer		1 unique reviewer

5 total reviewer have engaged with the SharePoint.

Approximately 4 reviewers have expressed they are currently traveling or have upcoming travel during the review period.

Please let me know what other information I can provide.

Thanks, Jadia

From: Jadia Bruckner

Sent: Friday, February 7, 2025 10:35 AM

To: Denlinger, Chadrick E; gp.kelley; Kyle Herber; Northup, Patrick; Potter, Steven; Stewart

Lewis, Zoe A.; Luis Mayen; Debbi McRann

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); Lauren Mauk; Mauro, Patrick (HRSA); HRSA OPTN EXT COR; Christopher J. McLaughlin; Rebecca Murdock; Formica, Richard; Caroline

Hales; Tina Rhoades

Subject: Re: [Secure] Reviewers: HRSA Directed Investigation

Good Morning,

A how-to video has been added to the FAQ section on SharePoint. Thanks for the suggestion, Glen!

Happy to walk through the site with anyone. Just reach out!

Jadia

From: Jadia Bruckner

Sent: Thursday, February 6, 2025 7:24 PM

To: Denlinger, Chadrick E; gp.kelley; Kyle Herber; Northup, Patrick; Potter, Steven; Stewart

Lewis, Zoe A.; Luis Mayen; Debbi McRann

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); Lauren Mauk; Mauro, Patrick (HRSA); HRSA OPTN EXT COR; Christopher J. McLaughlin; Rebecca Murdock; Formica, Richard; Caroline

Hales; Tina Rhoades

Subject: [Secure] Reviewers: HRSA Directed Investigation

Dear Reviewers.

Thank you all for agreeing to participate in the HRSA-directed investigation into the practices of Network of Hope (KYDA), formerly known as Kentucky Organ Donor Affiliates. This review focuses on patients KYDA identifies for potential donation after circulatory death (DCD).

Apologies for the delay in communication. The review panel required rework due to conflicts of interest.

#### Timeline

We understand the tight timeline and have drafted a schedule to align with the February 27th report deadline.

- · 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

On the SharePoint site, you will find a Home Page with updated information and FAQs to assist with navigating the workspace. 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.

If you have trouble accessing the SharePoint site, please check the attached instructions first. If issues persist, feel free to reach out to me.

#### Instructions to guide review:

As you review the assigned documents, HRSA has asked that you consider the following questions:

- Was there authorization and consent for potential DCD procurement?
- Did KYDA conduct their pre-withdrawal huddle(s)?
  - o If yes, were all the necessary participants involved?
  - Were key aspects such as roles, medications, and device usage clearly discussed and documented?
  - o Did KYDA provide a rationale for any missed pre-withdrawal huddles?
- Did KYDA uphold patient safety protocols from approach through donation?
- Did KYDA follow their own policies and procedures?
  - Were withdrawal procedures followed as specified?
  - o Did KYDA conduct a post-procedure review to ensure adherence to protocols?
  - Were there any deviations from standard procedures, and if so, were these justified and documented?
  - o Did KYDA obtain and document all OPTN-required consents?
  - o Was all required testing completed before procurement?
  - o Did KYDA adhere to all OPTN obligations and timelines throughout the process?

As you review the documents, please record your thoughts, concerns, impressions, etc., in a manner so they can be used in the report writing phase. Your recorded thoughts will be crucial in helping to draft the final report. At the conclusion of document review, a post-review debrief session will be conducted during which you will have an opportunity to share your observations, thoughts, concerns, and recommendations for improvement with other reviewers.

### Working Libraries:

- Donor & Patient Records
  - Multiple files per chart, including process deviations, hospital feedback, and huddle records.
  - Actions Required:
    - Sort on the "Reviewer" column to view your assigned records.
      - Update Review Status
      - Enter Comments: record your observations and concerns to support the report drafting process
- Process & Protocols
  - All reviewers can reference these documents in their review. (these documents maybe assigned a lead reviewer)
- Huddle Records
  - As named and provided by KYDA.
  - Sort on the "Reviewer" column to view your assigned records.
    - Update Review Status

 Enter Comments: record your observations and concerns to support the report drafting process

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 Please let us know if you have any questions. We appreciate your commitment to this critical review.

# Jadia Bruckner

Patient Safety Manager



Saving lives together



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[www.unos.org%20%20%20]www.unos.org





