

New Process for Donor Center Lot Release

Panel Presentation

Meet the Panel



Casey Beardslee

Session Moderator

Stephanie Thompson

Quality Regulatory Specialist Auditor

Laurie Schmitt

Supervisor, Quality Management

Karen Hidding

Donor Services Liaison

Lori Gaus

Quality Control Specialist

Disclosures

The following faculty and planning committee staff have no financial disclosures:

Name	Institution
Casey Beardslee	NMDP/Be The Match
Stephanie Thompson	NMDP/Be The Match
Lori Gaus	NMDP/Be The Match
Karen Hidding	NMDP/Be The Match
Laurie Schmitt	NMDP/Be The Match

Now Showing

Objectives

Panel Interview

Case Studies

Q&A

Learning objectives

At the conclusion of this session, attendees will be able to:

- Define the impact of NMDP/Be The Match moving toward centralizing the lot release process
- Share historical findings with DC 001 lot release
- Prepare contracted centers for implementation of lot release within the coming year

Question

What is your favorite Game Show

A. The Price is Right

B. Jeopardy

C. Who Wants to Be a Millionaire

D. Wheel of Fortune

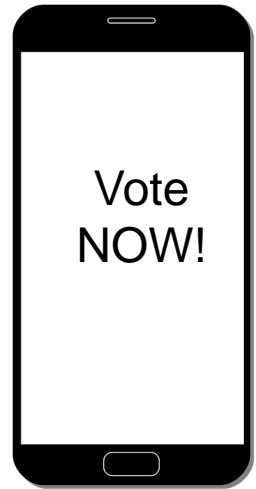


Vote
NOW!

Warm up Polling question

How many people registered for this session today?

- A. 492
- B. 19
- C. Actual correct answer
- D. Everyone





Panel Interview



- Stephanie Thompson
 - Quality Regulatory Specialist Auditor

21 CFR 1271.265(c)

*(c) Availability for distribution. (1) **Before** making an HCT/P available for **distribution**, you must **review manufacturing and tracking records** pertaining to the HCT/P, and, on the basis of that record review, you must **verify** and **document** that the **release criteria** have been met.*

A responsible person must document and date the determination that an HCT/P is available for distribution.

“Elements of Eligibility”



- HHSQ / Zika

- Physical Examination

- IDMs

- Donor Center Review of Medical Records

- **Statement of Urgent Medical Need & Attachments**

21 CFR 1271.265(c) continue

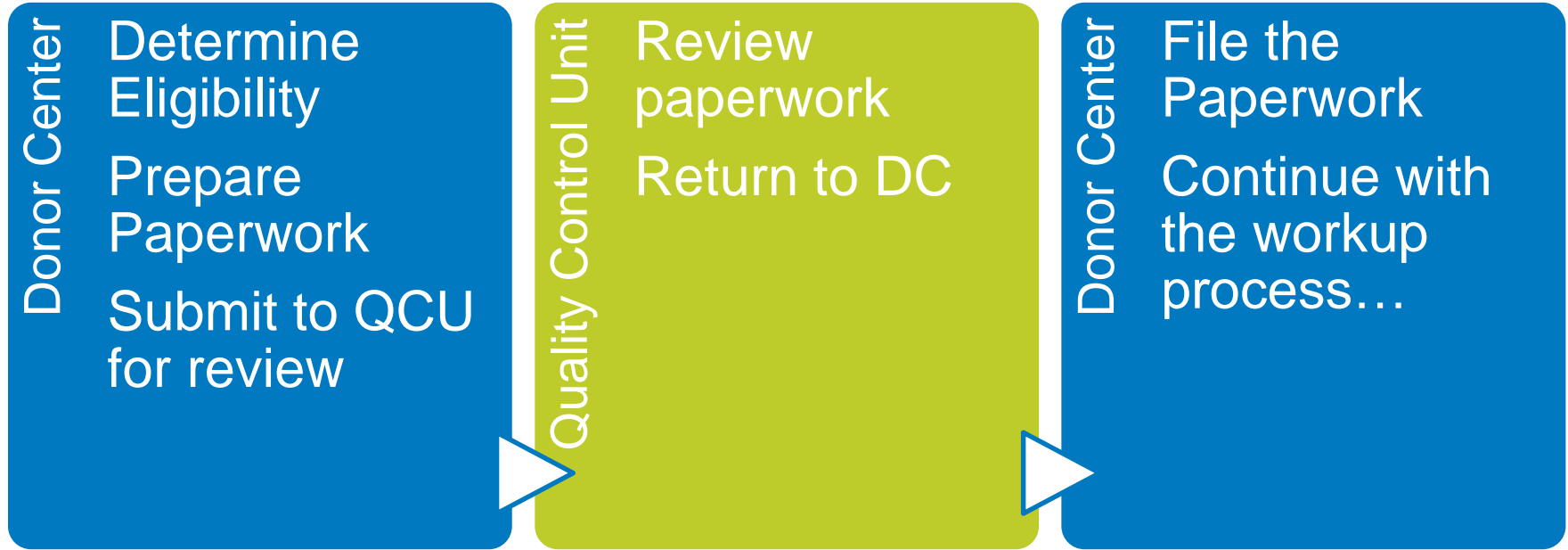
- (c) Availability for distribution. (1)
Before making an HCT/P available for distribution, you must review manufacturing and tracking records pertaining to the HCT/P, and, on the basis of that record review, you must verify and document that the release criteria have been met. A responsible person must document and date the determination that an HCT/P is available for distribution.
- Declaration of Eligibility-Adult Donor
- Quality Control Specialists Review

Panel Interview

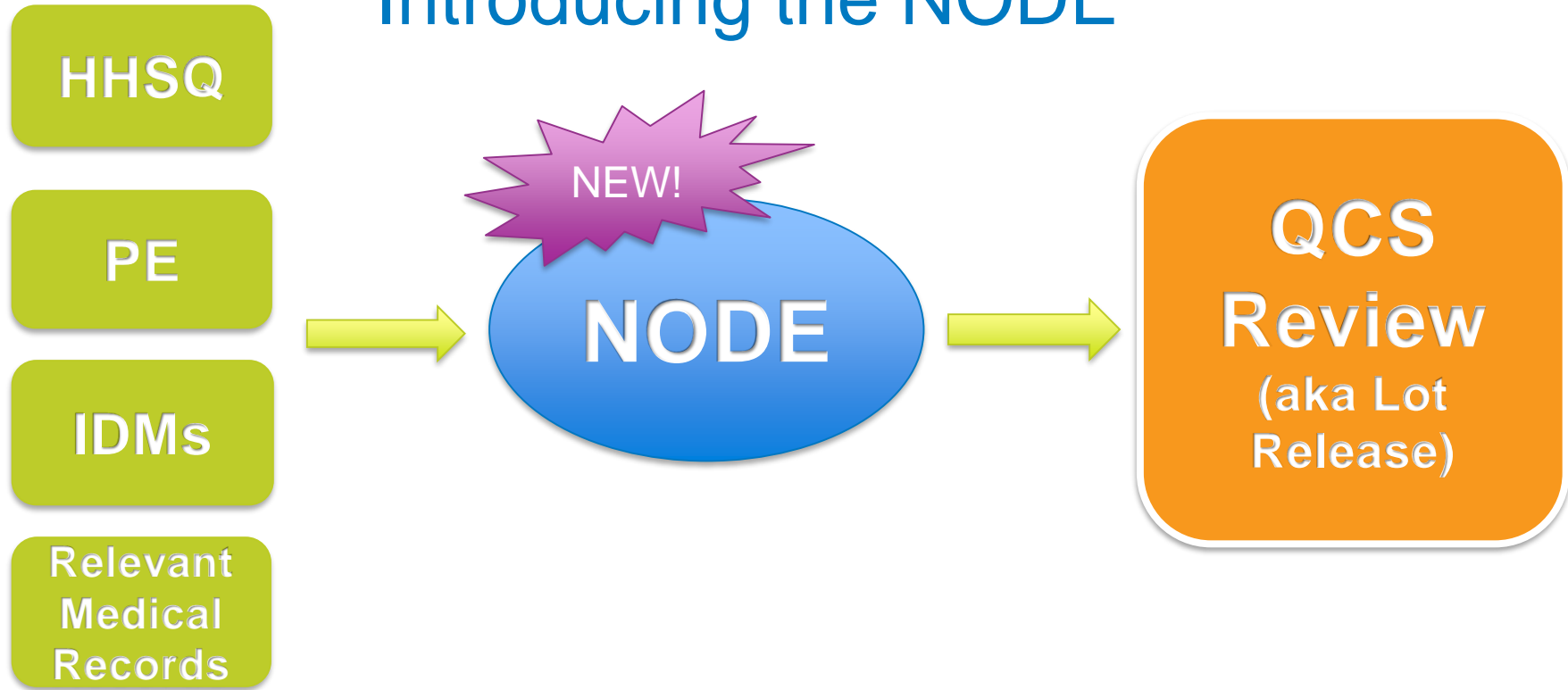


- Laurie Schmitt
 - Supervisor, Quality Management

High Level Overview



Introducing the NODE



Notification of Donor Eligibility

HHSQ

PE

IDMs

**Relevant
Medical
Records**

**Determine Eligibility
Status**

Sign Off

I think the process is quite easy!

I like it!

The lot release pilot has been a breath of fresh air!

Staff will be pleased with the new streamlined process.



Panel Interview

- Karen Hidding
Donor Services Liaison



Panel Interview

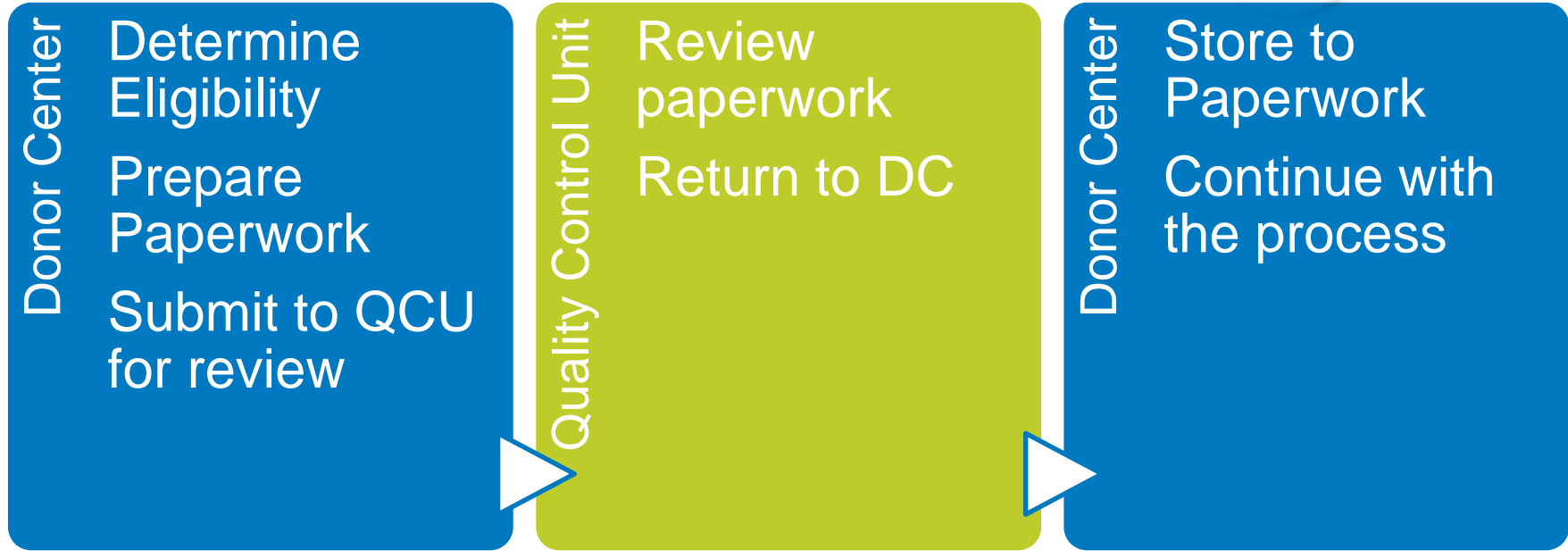


- Lori Gaus
Quality Control
Specialist

Quality Control Specialist Team



High Level Process



Summary of Requirements

Documents Reviewed

- HHSQ and Zika Assessment
- DC Review of Medical Records
- Addendum to PE, if applicable
- IDMs
- DOE
- DEHR (future state NODE)
- SUMN (future state DUMN), if applicable

Review Requirements

- Completeness and accuracy
- Version control
- Appropriate error correction

Scenario 1: Set up

1

2

3

4

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↓
THANK YOU.

The Examining Medical Professional actions are complete with Section 3 signature.

SECTION 4

Completed by *DONOR CENTER MEDICAL DIRECTOR* or designee

Based upon the preceding documented examination for physical evidence or risk for communicable disease,
I have determined that this person:

MARK ONE:

- A. Does not exhibit physical evidence or risk for communicable diseases. → A. ☐
- B. Does exhibit physical evidence or risk for communicable diseases. → B. ☐

If B has been selected in either Sec 1 or 2, it is expected that B would be marked in Sec 4. If B is marked, explain findings.

Printed Name/Title

Signature

Date

Document Number: F00806 rev. 2 (2013)

Replaces: F00806 rev 1

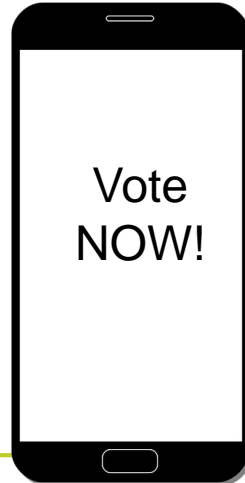
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Scenario 1: Question

What do you feel is the appropriate action with this form?

- A. Pass
- B. I'd like to skip this question
- C. Return for correction or more information
- D. I don't know



Scenario 1: Wrap Up

SECTION 4		Completed by DONOR CENTER MEDICAL DIRECTOR or designee
Based upon the preceding documented examination for physical evidence or risk for communicable disease, I have determined that this person:		
		MARK ONE:
A. <u>Does not</u> exhibit physical evidence or risk for communicable diseases.	→	A. <input type="checkbox"/>
B. <u>Does</u> exhibit physical evidence or risk for communicable diseases.	→	B. <input checked="" type="checkbox"/>
<i>If B has been selected in either Sec 1 or 2, it is expected that B would be marked in Sec 4. If B is marked, explain findings.</i>		
Tattoo on 10/21/2017		
John Smith, MD		11-06-2017
Printed Name/Title	Signature	Date

Scenario 2: Set Up

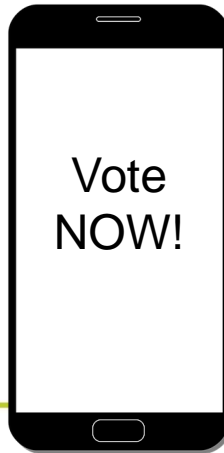
1	41. Have you ever tested positive for HIV?			
	42. Have you, any of your sex partners, ever had a procedure that involved blood transfusion?			
	43. In the past 12 months, have you ever had a blood transfusion? Note if performed in the past 5 years.			
	44. In the past 12 months, have you ever had a blood transfusion?			
	45. In the past 12 months, have you ever had a blood transfusion through an open wound (cut, scratch, or bite) or through your eye or mouth?			
	46. In the past 12 months, have you received Hepatitis B or C vaccine?			
	47. In the past 12 months, have you had sex, even once, with anyone who has used a needle to take drugs, steroids, or anything else not prescribed by a doctor in the past 5 years?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	48. In the past 12 months, have you given money, drugs, or other payment for sex OR have you had sex, even once, with anyone who has taken money, drugs or other payment in exchange for sex in the past 5 years?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	49. In the past 12 months, have you had sex, even once, with anyone who has taken human-derived clotting factors in the past 5 years?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
	50. In the past 12 months, have you had sex, even once, with anyone who has HIV or AIDS or tested positive for the HIV virus?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
51. In the past 12 months, have you been held in a jail, prison, juvenile detention, or lockup for more than 72 continuous hours?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>		
52. FEMALE DONORS ONLY: In the past 12 months, have you had sex with a male who has had sex, even once, with another male in the past 5 years?	If MALE, mark NA <input type="checkbox"/>	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	
53. MALE DONORS ONLY: In the past 5 years, have you had sex, even once, with another male?	If FEMALE, mark NA <input checked="" type="checkbox"/>	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
54. In the past 5 years, have you taken money, drugs, or other payment in exchange for sex?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>		
55. In the past 5 years, have you used a needle, even once, to take drugs, steroids, or anything else not prescribed by a doctor?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>		
56. Since 1977, were you born in or have you lived in Africa? If YES, answer questions #56A & #56B. If NO, do not answer #56A & #56B; go to #57.	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>		
56A. Was it Benin, Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Kenya, Niger, Nigeria, Senegal, Togo, or Zambia?	Yes <input type="checkbox"/>	No <input type="checkbox"/>		
56B. Did you receive a blood transfusion or medical treatment with a blood product while there?	Yes <input type="checkbox"/>	No <input type="checkbox"/>		

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Scenario 2: Question

What do you feel is the appropriate action with this form?

- A. Pass
- B. Tweet a friend for help
- C. Return for correction or more information
- D. I don't know



Scenario 2: Wrap Up

<p>43. In the past 12 months, have you had a tattoo? Provide date of tattoo application and if you have any signs of infection. Note if performed in licensed establishment.</p> <p style="text-align: right;"><i>Verified with donor on 11-04-2017. for 11-04-2017</i></p>	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
<p>44. In the past 12 months, have you had an ear, skin, or body piercing using shared instruments or needles?</p>	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>

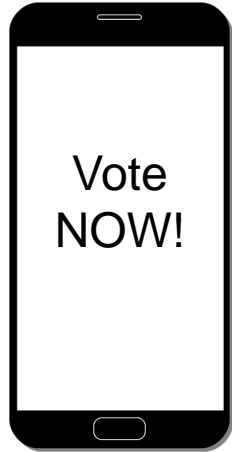
Scenario 3: Set Up

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1	2	3	4 MNC(A) Request	5	6	7
8	9	10	11 <small>Veterans Day</small> IDM's Drawn	12	13 TODAY!	14
15	16	17	18	19	20	21
22	23	24	25 Collection Date	26 <small>Thanksgiving Day</small>	27	28

What is the donor's eligibility determination?

Scenario 3: Question

- MNC(A) had IDMs drawn on 11th, collection is on the 25th. What is the donor's eligibility status?
 - A. I'd like to use the 50/50 option and reduce the answer options by 50%
 - B. Ineligible
 - C. Eligible
 - D. Incomplete



Scenario 3: Wrap up

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1	2	3	4 MNC(A) Request	5	6	7
8	9	10	11 Veterans Day IDM's Drawn	12	13 TODAY!	14
15	16	17	18	19	20	21
22	23	24	25 Collection Date	26 Thanksgiving Day	27	28

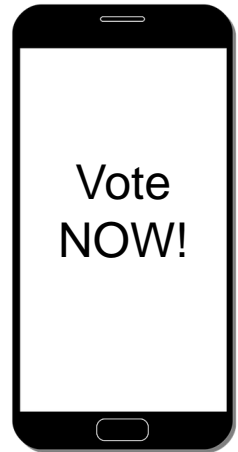
Scenario 4



Scenario 4: Question

What is the most common reason for return for rework for the past month?

- A. Missing/incorrect calculated date
- B. Missing required documents
- C. Incorrect transcribed information
- D. Incomplete document




Scenario 4: Wrap up

Number of Defects



Scenario 5: Set Up



BE  THE MATCH

Donor Center Review of Medical Records

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NMDP or Cooperative
Registry Donor Identification: 1234-5678-9

NMDP Recipient ID: 987-654-3

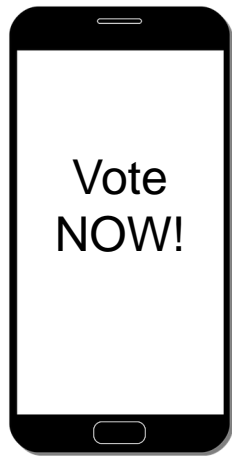
Records Reviewed: Include any IDMs, HHSQs, PE or other historical relevant medical records reviewed.

Record Type (i.e., IDMs, HHSQ, PE, etc)	Creation or Blood Draw Date (mm/dd/yyyy)	Relevant Communicable Disease or Xenotransplant Risk	Risk Expiration Date	Date Record Reviewed & Reviewer Initials (mm/dd/yyyy)
CT HHSQ	09/01/2017	NA <input checked="" type="checkbox"/>	NA <input checked="" type="checkbox"/>	for 10/31/2017
Zika	09/01/2017	NA <input checked="" type="checkbox"/>	NA <input checked="" type="checkbox"/>	for 10/31/2017
Form 24	09/07/2017	NA <input checked="" type="checkbox"/>	NA <input checked="" type="checkbox"/>	for 10/31/2017
		NA <input type="checkbox"/>	NA <input type="checkbox"/>	
		NA <input type="checkbox"/>	NA <input type="checkbox"/>	

Scenario 5: Question

What do you think the outcome of this submission should be?

- A. Return for correction or more information
- B. I always wear red on Saturdays
- C. Pass
- D. I don't know



Scenario 5: Wrap Up



BE THE MATCH

Donor Center Review of Medical Records

Page 1 of 1

NMDP or Cooperative Registry Donor Identification: 1234-5678-9

NMDP Recipient ID: 987-654-3

Records Reviewed: Include any IDMs, HHSQs, PE or other historical relevant medical records reviewed.

Record Type (i.e., IDMs, HHSQ, PE, etc)	Creation or Blood Draw Date (mm/dd/yyyy)	Relevant Communicable Disease or Xenotransplant Risk	Risk Expiration Date	Date Record Reviewed & Reviewer Initials (mm/dd/yyyy)
CT HHSQ	09/01/2017	NA <input checked="" type="checkbox"/>	NA <input checked="" type="checkbox"/>	hr 10/31/2017
Zika	09/01/2017	NA <input checked="" type="checkbox"/>	NA <input checked="" type="checkbox"/>	hr 10/31/2017
Form 24	09/07/2017	NA <input checked="" type="checkbox"/>	NA <input checked="" type="checkbox"/>	hr 10/31/2017
SL Notes	09/01/2017 - 09/25-2017	NA <input checked="" type="checkbox"/>	NA <input checked="" type="checkbox"/>	hr 11/05/2017
		NA <input type="checkbox"/>	NA <input type="checkbox"/>	
		NA <input type="checkbox"/>	NA <input type="checkbox"/>	



Learning objectives

At the conclusion of this session, attendees will be able to:

- Define the impact of NMDP/Be The Match moving toward centralizing the lot release process
- Share historical findings with DC 001 lot release
- Prepare contracted centers for implementation of lot release within the coming year

Evaluation Reminder

Please complete the Council Meeting 2017 evaluation in order to receive continuing education credits and to provide suggestions for future topics.

We appreciate your feedback!



Thank You