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:

<table>
<thead>
<tr>
<th>Name</th>
<th>Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Casey Beardslee</td>
<td>NMDP/Be The Match</td>
</tr>
<tr>
<td>Stephanie Thompson</td>
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<td>Lori Gaus</td>
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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

**Donor Center**
- Determine Eligibility
- Prepare Paperwork
- Submit to QCU for review

**Quality Control Unit**
- Review paperwork
- Return to DC

**Donor Center**
- File the Paperwork
- Continue with the workup process…
Introducing the NODE

HHSQ

PE

IDMs

Relevant Medical Records

QCS Review (aka Lot Release)

NEW!
Notification of Donor Eligibility

HHSQ

PE

IDMs

Relevant Medical Records

Determine Eligibility Status

Sign Off
I think the process is quite easy!

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

I like it!

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

Donor Center
- Determine Eligibility
- Prepare Paperwork
- Submit to QCU for review

Quality Control Unit
- Review paperwork
- Return to DC

Donor Center
- Store to Paperwork
- Continue with the 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

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

Replaces: F00806 rev 1
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

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

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.

Tattoo on 10/21/2017

John Smith, MD

Signature

Printed Name/Title

Date

11-06-2017
### Scenario 2: Set Up

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>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?</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>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?</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>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?</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>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?</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>51. In the past 12 months, have you been held in a jail, prison, juvenile detention, or lockup for more than 72 continuous hours?</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>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?</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>53. MALE DONORS ONLY: In the past 5 years, have you had sex, even once, with another male?</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>54. In the past 5 years, have you taken money, drugs, or other payment in exchange for sex?</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>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?</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>56. Since 1977, were you born in or have you lived in Africa?</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>56A. Was it Benin, Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Kenya, Niger, Nigeria, Senegal, Togo, or Zambia?</td>
<td>☑</td>
<td></td>
</tr>
<tr>
<td>56B. Did you receive a blood transfusion or medical treatment with a blood product while there?</td>
<td>☑</td>
<td></td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>✗</td>
<td></td>
</tr>
<tr>
<td>Verified with donor on 11-04-2017</td>
<td></td>
<td></td>
</tr>
<tr>
<td>For 11-04-2017</td>
<td></td>
<td></td>
</tr>
<tr>
<td>44. In the past 12 months, have you had an ear, skin, or body piercing using shared instruments or needles?</td>
<td></td>
<td>✗</td>
</tr>
</tbody>
</table>
Scenario 3: Set Up

<table>
<thead>
<tr>
<th>Sunday</th>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
<th>Saturday</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
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<td>6</td>
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<td>27</td>
<td>28</td>
</tr>
</tbody>
</table>

What is the donor’s eligibility determination?

- **MNC(A) Request**
- **IDM’s Drawn**
- **Collection Date**
- **TODAY!**

COUNCIL MEETING: Sharing Our Passion For Life
Scenario 3: Question

• MNC(A) had IDMs drawn on 11\textsuperscript{th}, collection is on the 25\textsuperscript{th}. 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

<table>
<thead>
<tr>
<th>Sunday</th>
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- **MNC(A) Request**
- **IDM’s Drawn**
- **Collection Date**
- **TODAY!**
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 5: Set Up

### Donor Center Review of Medical Records

<table>
<thead>
<tr>
<th>Record Type (i.e., IDMs, HHSQ, PE, etc)</th>
<th>Creation or Blood Draw Date (mm/dd/yyyy)</th>
<th>Relevant Communicable Disease or Xenotransplant Risk</th>
<th>Risk Expiration Date</th>
<th>Date Record Reviewed &amp; Reviewer Initials (mm/dd/yyyy)</th>
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</thead>
<tbody>
<tr>
<td>CT HHSQ</td>
<td>09/01/2017</td>
<td></td>
<td>NA</td>
<td>10/31/2017</td>
</tr>
<tr>
<td>Zika</td>
<td>09/01/2017</td>
<td></td>
<td>NA</td>
<td>10/31/2017</td>
</tr>
<tr>
<td>Form 24</td>
<td>09/07/2017</td>
<td></td>
<td>NA</td>
<td>10/31/2017</td>
</tr>
</tbody>
</table>
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

Vote NOW!
Scenario 5: Wrap Up

Donor Center Review of Medical Records

<table>
<thead>
<tr>
<th>NMDP or Cooperative Registry Donor Identification: 1234-5578-9</th>
</tr>
</thead>
<tbody>
<tr>
<td>NMDP Recipient ID: 987-654-3</td>
</tr>
</tbody>
</table>

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

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<td>10/31/2017</td>
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<tr>
<td>Form 24</td>
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<td>NA</td>
<td>NA</td>
<td>10/31/2017</td>
</tr>
<tr>
<td>SL Nitte</td>
<td>09/01/2017-09/25/2017</td>
<td>NA</td>
<td>NA</td>
<td>11/05/2017</td>
</tr>
</tbody>
</table>

COUNCIL MEETING: Sharing Our Passion For Life
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