Survivor: Audit Edition

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Although preparing for and enduring a CIBMTR audit might make you feel like you are on an episode of Survivor…

…the audit team is here to ensure all centers are successful Survivors of the process!
Outline

• Audit Program Overview
• FY14 - 15 Audit Results
• FY15 Corrective Action Summary
• Informed Consent
• Audit and Data Management Training Resources
Audit Overview

Transplant Centers are audited every 4 years, as eligible

TCs are contacted in advance for scheduling

16 recipients are randomly selected since most recent audit

2 auditors come for 3 days for selected case review

Closing meeting with summary review of identified errors

Audit report with corrective active requirements prepared

Training & Development
Audit Milestones

  - NMDP began audit program

  - NMDP & IBMTR combined audit programs; added international sites


- **Cycle 5**: 2014, 2015, 2016
  - Passing critical field error rate drops from 5% to 3%

**Current Audit Cycle**: Cycle 5, Year 3

**Training & Development**
## Audit Results

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Years</th>
<th>Average Critical Field Error Rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cycle 1</td>
<td>1998, 1999, 2000, 2001</td>
<td>5.5%</td>
</tr>
<tr>
<td>Cycle 3</td>
<td>2006, 2007, 2008, 2009</td>
<td>2.5%</td>
</tr>
<tr>
<td>Cycle 4</td>
<td>2010, 2011, 2012, 2013</td>
<td>2.5%</td>
</tr>
<tr>
<td>Cycle 5</td>
<td>2014, 2015, 2016</td>
<td>?</td>
</tr>
</tbody>
</table>

2.1% 2.5%

### Training & Development
FY14-15 Audits (first \( \frac{1}{2} \) of Cycle 5)

**US vs. Non-US Centers Audited**

- **US Centers**: 85%
- **Non-US Centers**: 15%

**105 Centers Audited**

**16 Non-US Centers Audited**

Training & Development
FY14-15 Passing Centers

84 of 105 (80%) centers passed with a critical field error rate $\leq 3\%$

Passing vs. Non-Passing Centers

- Passed (CFER $\leq 3\%$)
- Not Passed

Training & Development
FY14-15 Passing Centers by Location

PASSING CENTERS BY LOCATION

68 of 89 (76%) US centers passed

16 of 16 (100%) Non-US centers passed

Training & Development
FY14-15 Critical Field Error Rates

CENTERS WITH LOWEST CF ERROR RATE

FY2014 – University of Kansas
   St. Luke's Mountain States Tumor Institute

FY2015 - Imperial College London, St. Mary's Hospital

COMBINED AVERAGE CF ERROR RATE*

2.3%

* Median error rate: 2.0%
  (i.e. half of centers were below 2.0%, half were above)
Reporting Areas

- **Disease Status & Assessment**: 52 of 57 centers (91%)
- **HCT Product & Infusion**: 26 of 57 centers (46%)
- **GVHD**: 17 of 57 centers (30%)
- **Disease Classification & Characteristics**: 10 of 57 centers (18%)

FY15

Training & Development
Questions per Reporting Area

FY15

Training & Development
Corrective action is required when:

The critical field error rate **exceeds** 3%;

**Systemic errors** are identified during the audit, even if the critical field error rate is ≤ 3.0%;

Issues are identified with IRB-approved CIBMTR research or repository **consent forms**; and/or

**Missing documentation** identified during the audit are not addressed during the identified follow-up period.
FY14-15 Corrective Action Results

26
Of 105 (25%) had no corrective action

79
of 105 (75%) had required corrective action
Corrective Action Areas

44 of 57 (77%) centers had required corrective action

Was the average # of non-consent corrective action items

FY15

Training & Development
26
Of 44 (59%) centers required consent-specific corrective action

104
Recipients had Consent items requiring corrective action (out of 416 reviewed)

<table>
<thead>
<tr>
<th>Consent Corrective Action</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare professional signature issues</td>
<td>22</td>
</tr>
<tr>
<td>Did not complete identifying options</td>
<td>18</td>
</tr>
<tr>
<td>Out of IRB approval range</td>
<td>15</td>
</tr>
<tr>
<td>Missing dates/time of signatures</td>
<td>11</td>
</tr>
<tr>
<td>Printed subject name blank</td>
<td>9</td>
</tr>
<tr>
<td>Witness name/signature missing</td>
<td>8</td>
</tr>
<tr>
<td>Assent not completed</td>
<td>8</td>
</tr>
<tr>
<td>Subject signature issues</td>
<td>7</td>
</tr>
<tr>
<td>Missing consent</td>
<td>5</td>
</tr>
<tr>
<td>Signed wrong form (Allo vs. Auto, assent)</td>
<td>5</td>
</tr>
<tr>
<td>Translation section issues</td>
<td>3</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
</tr>
<tr>
<td>No consent</td>
<td>1</td>
</tr>
</tbody>
</table>
Informed Consent Review
Ashley Birch, Senior CRA
Live Polling

• Live polling instructions:
  – Select the LIVE Poll icon on the dashboard
  – Select ‘Survivor: Audit Edition’ and the questions will be displayed
  – Select the question
  – Enter your response, based on options presented and tap submit.
Informed Consent Review

**Allogeneic (unrelated)**
- Research Database
- Research Sample Repository

**Allogenic (related)**
- Research Database
- Research Sample Repository*

**Autologous**
- Research Database

*As of 2/3/16, 79 transplant centers are participating
Informed Consent Review

• Appropriate informed consent document
  – For example: Allogeneic (Adult), Autologous (Minor), etc.
• Signed within IRB-approval period
• Correct version signed
• Signed and dated by recipient (or parent/legal guardian)
• All pages present
Informed Consent Review

• All blanks are completed
  – For example: MRN, printed names, health care provider signature/date, checkboxes, initials, witness (if applicable), etc.

• Sample repository: Signed prior to collection of blood sample

• Database: Signed prior to submission of data

• Assent (if applicable)

• Short form process followed (if applicable)
Informed Consent Review

• International Centers
  – Review process to ensure informed consent was obtained in a manner consistent with the laws and regulations in effect in that country.

• Provide auditor(s) access to regulatory binder
  – Paper or electronic access
Be The Auditor

- Date of HCT: 3/13/2015
- Type of HCT: Allogeneic
- Age of recipient: 14
- Primary language of parent/legal guardian: English
- Primary language of recipient: English
- Research database
  - Consent obtained on 3/2/2015
- Sample repository
  - Consent obtained on 3/2/2015
  - Sample collected on 3/4/2015
Be The Auditor: Question #1

Research Database: Which version of the parent/legal guardian permission form should have been signed?

Option 1: Version 7.1
Option 2: Version 8
## Be The Auditor: Answer #1

<table>
<thead>
<tr>
<th>Approval Type</th>
<th>Version Approved</th>
<th>Approval Date</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuing Review</td>
<td>7.1</td>
<td>10/29/2014</td>
<td>10/28/2015</td>
</tr>
<tr>
<td>Amendment</td>
<td>8.0</td>
<td>2/3/2015</td>
<td>10/28/2015</td>
</tr>
</tbody>
</table>

**Answer: Version 8.0**
Be The Auditor: Question #2

Research Database: Are there any blanks on the assent form?

Option 1: Yes
Option 2: No
Be The Auditor: Answer #2

If you agree to be in this study, sign here:

Minor’s Signature

Print Name of Minor

Date

Age of Minor

Answer: No.
Be The Auditor: Question #3

Sample Repository: Were the correct consent and assent forms used?

Option 1: Yes
Option 2: No, the wrong parent/legal guardian form was used
Option 3: No, the wrong assent form was used
Be The Auditor: Answer #3

Contribution of a Blood Sample to the Research Sample Repository

Minor Allogeneic Recipient Assent Form (7 to 11 years of age)

Answer: No, the wrong assent form was used.
Be The Auditor: Question #4

Sample Repository: Are there any blanks on the parent/legal guardian permission form?

Option 1: Yes
Option 2: No
Answer: Yes, the parent/legal guardian initials are blank on page 4.
How to Avoid Consent Form Errors

• Use of expired forms, wrong version, or incorrect form
  – Review IRB approval dates prior to obtaining consent
  – Check version date to ensure most current consent is used
  – Remove access to expired or outdated versions
  – Clearly label forms
    • For example: Autologous Minor, Allogeneic Adult, Allogeneic Adult Spanish, etc.
How to Avoid Consent Form Errors

• Missing signature/date, assent, or blanks
  – Use flags to highlight checkboxes, initials, signatures, etc.
  – Review consent/assent forms for completeness before subject leaves

• Create checklist and/or internal audit process

• Review SOP for short form consent process

• Educate staff on consent requirements
Training Provided by CIBMTR Audit Team

• On-site training
  – Review of errors and reporting trends
  – Face-to-face discussion and training regarding reporting rules / issues

• Audit Report
  – Summary of findings
  – Identification of problematic reporting areas
  – Discussion of errors for data managers, instructions for reporting, links to manual
  – Corrective Action Requirements
Data Management Training Resources

**FORMS INSTRUCTION MANUAL (as of 1/1/16)**
- 1001 Pages
- 367 Topics
- Additional Sections for Forms Revision coming in 2016

**eLEARNING MODULES (as of 1/1/16)**
- 2 eLearning Modules:
  - Preparative Regimen Form 2006
- Additional data- and audit-focused modules planned

**Planning release of audit website**
&
**Exploring increased access to historic audit documents**
Questions
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Matt Petcoff, Senior CRA
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