Informed Consent Tracking Through DataFax

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Overview

- Why we collect Informed Consents
- Why DataFax
- Challenges
- Process
- Future directions
Why We Collect Informed Consents
Why We Collect Informed Consents

Mandate to collect and verify

Critical Elements

- Signatures and dates
- Initials
- HIPAA authorization

Social Security Numbers
Why DataFax?
Why DataFax?

Worked okay for small studies....
Why DataFax?

- Large studies: # of participants
- Complex studies: multiple IC per participant
  - Screening, randomization, extended follow up
- Protocol changes requiring re-consent
- Tracking of HIPAA

...Onerous, and time consuming!
Why DataFax?

- Experienced DataFax users
- Tracking capabilities
  - Edit Checks
  - QC Report Process
- Minimal training of project managers
- Accommodate risk-based monitoring
Challenges
Challenges

- Simplifying user interface for project manager
- Keeping protected health information confidential
- Separating IC queries from data queries
Process
1. Utilized appropriate consent form type? ........................................... □
2. Most current version used/signed? ........................................... □
3. Central IRB stamp/date of approval (footer) present? .................. □
4. Embedded blank fields in header of each page filled correctly? ...... □
5. All pages of the Informed Consent Form present? ......................... □
6. Responded to blood collection for future research analysis (Tissue Bank)? □
   6.1 If participant agreed to blood collection, a box in restrictions section was checked? □
7. Correct name entered in the “Agreement to Participate” section of ICF? □
8. Printed name appears on the signature page for: 
   8.1 Participant or LAR? ........................................... □
   8.2 Person Obtaining Consent? ........................................... □
9. Signature and date appears on the signature page for: 
   9.1 Participant or LAR? ........................................... □
   9.2 Person Obtaining Consent? ........................................... □
10. Signature Date of participant or LAR is consistent with Signature Date of Person Obtaining Consent? □
11. If applicable, the LAR’s relationship to the participant has been noted? □
Informed Consent Completeness Log

CSP # 574 - Informed Consent Completeness Log

- Participant ID
- Hospital
- Participant
- Date Participant or LAR Signed Consent
- Month
- Day
- Year
- Site Staff Initials
- CSP Study No.
- Plate #468
- Please Indicate Type of Consent Here

- Main Consent & HIPAA by Participant
- Main Consent & HIPAA by LAR/DPOA
- Confirming Consent & HIPAA
- Other Consent 1
- Other Consent 2
- Other Consent 3

1. Utilized appropriate consent
2. Most current version used
3. Central IRB stamp/date if used
4. Embedded blank fields if used
5. All pages of the informed
6. Responded to feedback
   - 6.1 If participant agrees to a box in restrictions
7. Collect name entered in box
8. Printed name appears on
   - 8.1 Participant or LAR
   - 8.2 Person Obtaining Cons
9. Signature and date appear
   - 9.1 Participant or LAR
   - 9.2 Person Obtaining Cons
10. Signature date of participant
11. If applicable, the LAR's name

Informed Consent Completeness Log
CSP #574 Version 0.00
Protecting PHI

CSP STUDY #574
- Plate 467 (Contains SSN and participant initials)
- Plate 468-469 (ICF Completeness Log)

Informed Consent Database
Study #080

Clinical Study Database
Study #574
Overview

SITE:
- Obtains informed consent from participant
- Completes Informed Consent Completeness Log
- Faxes the log into DataFax

CSP STAFF:
- Data Entry Staff processes faxed log
Overview

CSP STAFF

Project Manager reviews mailed ICF and completes the center-specific side of the ICF log
Query Generation

“Yes” response \(\rightarrow\) no query generated
A “No” response → triggers an edit check that fires only in batch mode
Query Generation

“Hopeless” response → suppresses an edit check
Query Generation

1. Utilized appropriate consent form type? ......................................................... □ Yes □ No □ Hop
2. Most current version used/signed? ............................................................... □ Yes □ No □ Hop
3. Central IRB stamp/date of approval (footer) present? .................................... □ Yes □ No □ Hop
4. Embedded blank fields in header of each page filled correctly? ....................... □
5. All pages of the Informed Consent Form present? ........................................... □ Yes □ No □ Hop

“No” response that requires further clarification
Query Generation

Add tailored messages to generic edit checks

5. Please send signature page ASAP.
<table>
<thead>
<tr>
<th>PATIENT</th>
<th>VISIT, FORM, PAGE PROBLEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>9991234</td>
<td>Consent for Parti 3. Central IRB stamp/dt o = No (Other Problem)</td>
</tr>
<tr>
<td></td>
<td>The Central IRB stamp/date of approval (footer) is not present.</td>
</tr>
<tr>
<td>9991234</td>
<td>Consent for Parti 5.2 Signature page = Missing (Other Problem)</td>
</tr>
<tr>
<td></td>
<td>The signature page is missing. Comment: Please send signature page ASAP.</td>
</tr>
<tr>
<td>9991234</td>
<td>Consent for Parti 6. Responded to blood cc1 = No (Other Problem)</td>
</tr>
<tr>
<td></td>
<td>Participant did not respond to the Tissue Bank question.</td>
</tr>
</tbody>
</table>
Simplifying User Interface

- Disabled CRF image window
- Retrieval tasks
- Queries in batch mode
- Dfwarning pop-up box
- IC Queries added to question/answer section of QCR
Future Directions
iDF 4.3

- Simplified interface
- Help buttons
- Set up tasks specifically for IC plates
Future Directions

Further simplifying?
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