
Informed Consent Tracking Through DataFax

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Palo Alto Health Care System



VA Cooperative Studies Program



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

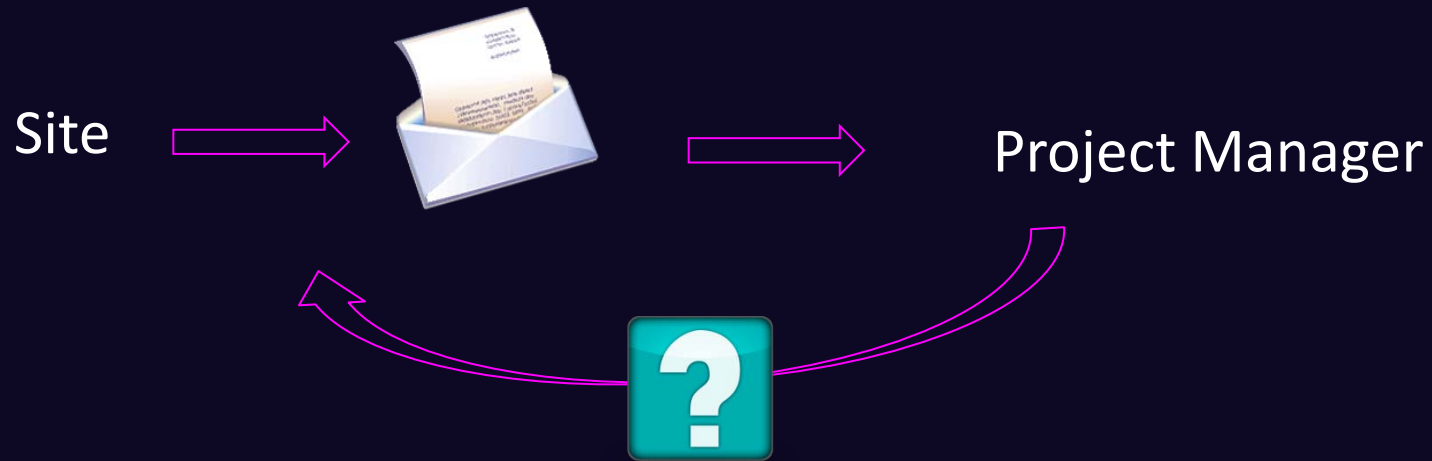
Critical Elements

- 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

Informed Consent Completeness Log

CSP # 574 : Informed Consent Completeness Log

Plate #468

Participant-ID
Hospital: [][][][] Participant: [][][][]

CSP Study No. 0574

Date Participant or LAR Signed Consent
Month: [][] Day: [][] Year: [][][][]

Site Staff Initials F: [][] M: [][] L: [][]

Please Indicate Type of Consent Here

<input type="checkbox"/> Main Consent & HIPAA by Participant	<input type="checkbox"/> Other Consent 1
<input type="checkbox"/> Main Consent & HIPAA by LAR/DPOA	<input type="checkbox"/> Other Consent 2
<input type="checkbox"/> Confirming Consent & HIPAA	<input type="checkbox"/> Other Consent 3

- Utilized appropriate consent form
- Most current version used
- Central IRB stamp/date of approval
- Embedded blank fields in form
- All pages of the Informed Consent form
- Responded to blood collection
 - If participant agrees to blood collection, a box in restrictions
- Correct name entered in form
- Printed name appears on form
 - Participant or LAR?
 - Person Obtaining Consent?
- Signature and date appear on form
 - Participant or LAR?
 - Person Obtaining Consent?
- Signature Date of participant or Person Obtaining Consent
- If applicable, the LAR's restrictions

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Please Indicate Type of Consent Here

<input type="checkbox"/> Main Consent & HIPAA by Participant	<input type="checkbox"/> Other Consent 1
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<input type="checkbox"/> Confirming Consent & HIPAA	<input type="checkbox"/> Other Consent 3

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

Query Generation

1. Utilized appropriate consent form type?	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Hop	
2. Most current version used/signed?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Hop	Missing? Hopeless?
3. Central IRB stamp/date of approval (footer) present?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Hop	<input type="checkbox"/> <input checked="" type="checkbox"/>
4. Embedded blank fields in header of each page filled correctly?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Hop	Signature Page Missing? Hopeless? <input checked="" type="checkbox"/> <input type="checkbox"/>
5. All pages of the Informed Consent Form present?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Hop	<input checked="" type="checkbox"/> <input type="checkbox"/>



“Yes” response → no query generated

Query Generation

1. Utilized appropriate consent form type?	<input checked="" type="checkbox"/>	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Hop	Missing Pages Tissue Page Missing? Hopeless? <input type="checkbox"/> <input checked="" type="checkbox"/> Signature Page Missing? Hopeless? <input checked="" type="checkbox"/> <input type="checkbox"/>
2. Most current version used/signed?	<input checked="" type="checkbox"/>	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Hop	
3. Central IRB stamp/date of approval (footer) present?	<input checked="" type="checkbox"/>	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Hop	
4. Embedded blank fields in header of each page filled correctly?	<input checked="" type="checkbox"/>				
5. All pages of the Informed Consent Form present?	<input checked="" type="checkbox"/>	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No		

A “No” response → triggers an edit check that fires only in batch mode

Query Generation

1. Utilized appropriate consent form type?	<input checked="" type="checkbox"/>	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Hop	Missing Pages Tissue Page Missing? Hopeless? <input type="checkbox"/> <input checked="" type="checkbox"/> Signature Page Missing? Hopeless? <input checked="" type="checkbox"/> <input type="checkbox"/>
2. Most current version used/signed?	<input checked="" type="checkbox"/>	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Hop	
3. Central IRB stamp/date of approval (footer) present?	<input checked="" type="checkbox"/>	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Hop	
4. Embedded blank fields in header of each page filled correctly?	<input checked="" type="checkbox"/>				
5. All pages of the Informed Consent Form present?	<input checked="" type="checkbox"/>	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No		

“Hopeless” response → suppresses an edit check

Query Generation

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

Missing Pages

Tissue Page
Missing? Hopeless?

Signature Page
Missing? Hopeless?

“No” response that requires further clarification

Query Generation

of Person Obtaining Consent? Yes No Incorrect? Hopeless?

11. If applicable, the LAR's relationship to the participant has been noted? Yes No N/A *peless* Incorrect? Hopeless?

Other: Incorrect? Hopeless?

CSP Comments?

Add tailored messages to generic edit checks

QC Report: Q&A Section

PATIENT VISIT, FORM, PAGE PROBLEM

9991234 Consent for Part 3. Central IRB stamp/dt o = No (Other Problem)
The Central IRB stamp/date of approval (footer) is not present.

9991234 Consent for Part 5.2 Signature page = Missing (Other Problem)
The signature page is missing. Comment: Please send signature page ASAP.

9991234 Consent for Part 6. Responded to blood col = No (Other Problem)
Participant did not respond to the Tissue Bank question.

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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- Andrés Busette
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Thank You