

DECAMP ECRF Source documentation

Study: 4703(DECAMP 1) and 4704(DECAMP 2)

From: ACRIN Data Management Department

Date: 1AUG2018

RE: ECRF as source data/documentation

Background:

Per our previous discussion during a recent RA call, sites have identified that a lot of time has been spent between transferring data from paper documents to Imedidata ECRF. Sites have identified many issues including lost paper documents, and missing data. This has resulted in incomplete or non-completed ECRFs. To minimize this system of transcription from paper to ECRF, we are notifying the sites of the ability to utilize the ECRF as source documentation for data submission. Incorporating this will promote real-time data entry, accuracy and complete data.

Purpose:

This memo serves as a reminder to sites the ability to utilize ECRFs as source documentation. Completing ECRFs in real-time/during patient visits or study procedure eliminates the process of transcription from paper sources. Sites are to be reminded that the ECRFs can be printed through Imedidata Rave, signed and dated to be used as source documentation. The complete printed document can be stored and filed on site once signed and dated by staff responsible for ECRF submission.

***At the bottom of every ECRF are the blue text icon features that allow the sites to print via a printable version or PDF version.**

Sites are required to sign and date the printable version for the document to be used as a source document. If not signed and dated the document is invalid.

Example:



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Gender of a Person: Male Gender

Enrollment Date: 23 Dec 2014

Inactivate Page

- 2 year Follow up- Biospecimen Collection (1)
- Bronchoscopy
- Blood Collection
- Blood Collection Aliquots Required
- Bronchial Airway Brushings
- Urine Collection (Midstream Clean Catch)
- Nasal Brushing
- Buccal Scraping
- Sputum Samples
- Urine Processing for Metabolomics Study
- Biospecimen Transmittal Required
- Biospecimen Transmittal Required- Bronchial Biopsy Formalin Fixed
- Biospecimen Transmittal Optional
- Biospecimen Transmittal Additional

Biospecimen Collection (1)

Were optional biospecimens sent to the core lab? Yes

If no optional biospecimens were sent to the core lab, leave the table blank. If optional specimens were sent, at least one row of the table must be checked as sent.

Date optional biospecimens sent to core lab

May 17 2017

#	Biospecimen Type	Barcode Sequence #	Check if Specimen Included	Storage Temp	Did any freeze/thaw occur?	If yes to freeze/thaw Total # of Times	If yes to freeze/thaw length of each time ?	Comments
1	Blood Collection- Buffy Coat	13	<input type="checkbox"/>	°C				
2	Blood Collection- Buffy Coat	14	<input type="checkbox"/>	°C				
3	Blood Collection- Buffy Coat	15	<input type="checkbox"/>	°C				
4	Blood Collection- Buffy Coat	16	<input type="checkbox"/>	°C				
5	Blood Collection- Buffy Coat	17	<input type="checkbox"/>	°C				
6	Blood Collection- Buffy Coat	18	<input type="checkbox"/>	°C				
7	Blood Collection- PBMC	27	<input type="checkbox"/>	°C				
8	Blood Collection- PBMC	28	<input type="checkbox"/>	°C				
9	Blood Collection- PBMC	29	<input type="checkbox"/>	°C				
10	Blood Collection- PBMC	30	<input type="checkbox"/>	°C				
11	Blood Collection- PBMC	31	<input type="checkbox"/>	°C				
12	Bronchial Airway Brushings Collection- Tube D	63	<input checked="" type="checkbox"/>	-80 °C	No			
13	Urine Processing for Metabolomics Study	40	<input type="checkbox"/>	°C				
14	Urine Processing for Metabolomics Study	41	<input type="checkbox"/>	°C				
15	Urine Processing for Metabolomics Study	42	<input type="checkbox"/>	°C				
16	Urine Processing for Metabolomics Study	43	<input type="checkbox"/>	°C				
17	Urine Processing for Metabolomics Study	44	<input type="checkbox"/>	°C				

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	Urine Processing for Metabolomics Study	ACRIN-4704	Naval Medical Center San Diego	4704-132	2 year Follow up- Biospecimen Collection (1)	Bios
18	Urine Processing for Metabolomics Study	45	<input type="checkbox"/>	°C		

- 2 year Follow up- Biospecimen Collection
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Total number of Buffy Coat Checks

Total number of PBMC checks

Total number of Urine Processing for Metabolomics Study Checks

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