



# EDRN's Validation Study Information Management System

Developed for EDRN by the DMCC



Cancer Biomarkers Group  
Division of Cancer Prevention



# VSIMS Enter Page



## Validation Study Information Management System

Welcome to the EDNRN Validation Study Information Management System (VSIMS). VSIMS is a web based system designed to automate the flow of study procedures at the involved laboratories and to facilitate communication and collaboration among scientists and staff. The system includes a specimen tracking system, a data forms processing system, communication tools and protocol management tools.

Information in VSIMS is confidential and intended solely for authorized investigators and staff.

[New User](#) [Forgot Password](#) [Change Password](#) [Upgrade browser](#)

**Enter**

This site is best viewed with browser version IE 5.01 or NS 7.0 or greater.

# VSIMS: Users & Permissions

User Rights	Permission
Administrator rights	Initiate/update new study. Enter, update, and delete information (excluding participant data) of any study. Read any information from any site in any study.
Key staff rights	Enter, update, delete information (excluding participant data) for a specific site, specific study. Read any information from any site within the study.
Working rights	Enter, update, delete information (excluding participant data) for a specific site within the study. Read any information within the site and study
Master visitor rights	Read any information from any site within the study.
Visitor rights	Read any information within the site and study.

# VSIMS Home Page



An infrastructure for supporting validation studies in the EDRN  
Sponsored by National Cancer Institute



Protocol: DCP ( ID: 111 ) User: Jackie Dahlgren ( Site ID: 5 )

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Submit Data ▶

Confirm Eligibility

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## Study Update - DCP:

The EDRN Validation Study entitled "Validation of Serum Markers for the Early Detection of Hepatocellular Carcinoma" will investigate a new diagnostic test called des-gamma carboxyprothrombin (DCP) for liver cancer [Study Overview](#)

## Documents:

[Meeting agenda for November 2-3, 2004](#)

[Conference call \(specimen tracking\) on August 11, 2004](#)

[Conference call on August 10, 2004](#)

[Conference call on July 27, 2004](#)

## Message Board

**The DCP Study is starting on Monday, February 21st, 2005.**

**Version 1.1 of the Protocol, Manual of Operations, and bulletins with the revision histories were posted to the website February 16th, 2005. Sites should submit these modifications to their IRB ASAP.**

# Current Projects using VSIMS

- MSA
- DCP
- Breast Standard Specimen Reference Set
- Prostate Standard Specimen Reference Set

# Submit Data

- This feature captures all the clinical and epidemiologic data required for a study
- Audit trail
- Built-in edit checks
- Easy access to instructions
- Print copies for site's records

# Submit Data Forms

Protocol: DCP (ID: 111) User: Jackie Dahlgren (Site ID: 5)

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Staff Name: Jackie Dahlgren

DCP Role: Master Read Only

▣ **Early Detection Research Network Validation Study & Reference Set** (Baseline Entry)

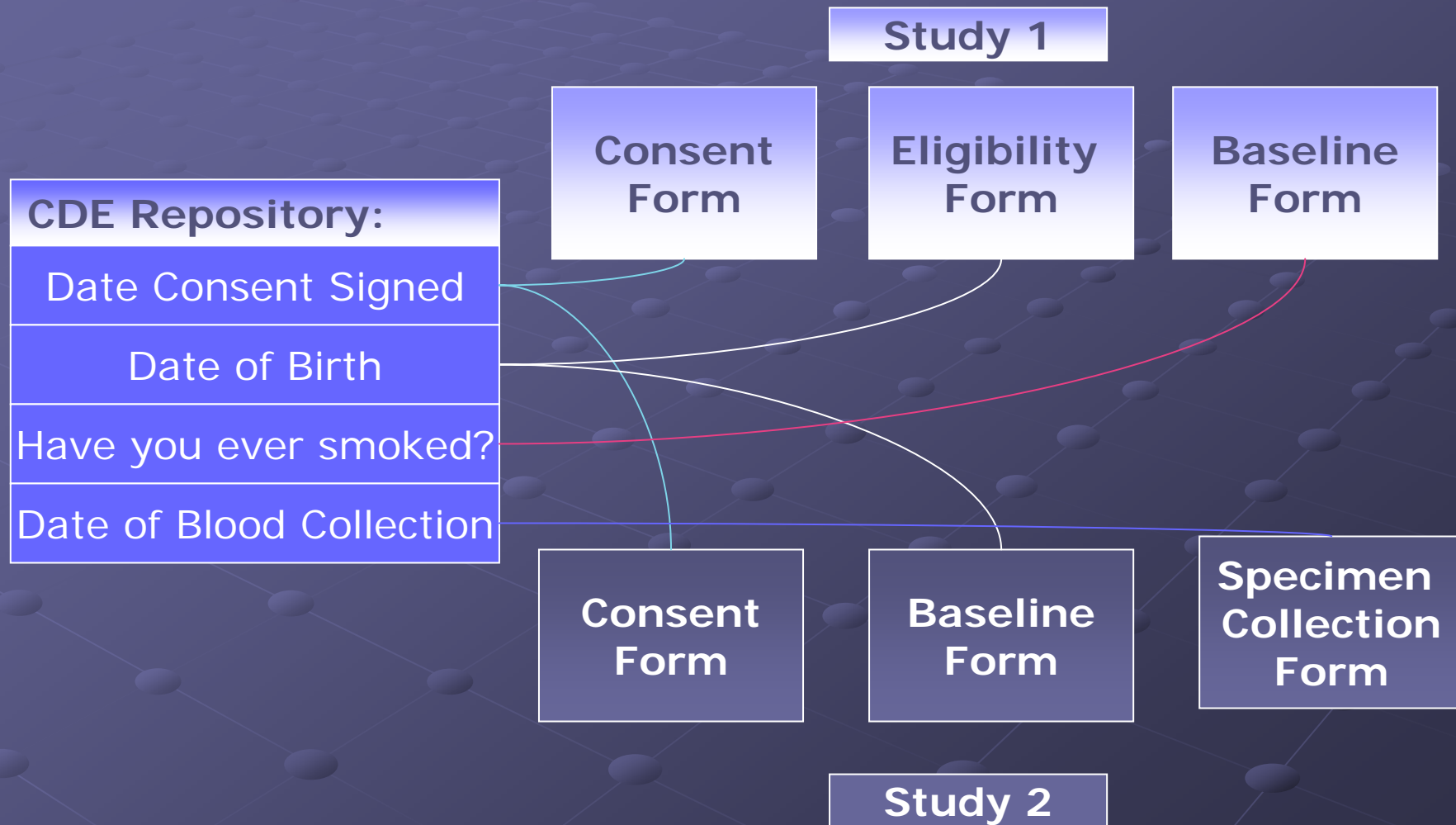
- [DCP Consent-1.1](#) Approved
- [DCP Baseline-1.1](#) Approved
- [DCP Eligibility-1.3](#) Approved
- [DCP Lab Results-1.1](#) Approved
- [DCP Ineligibility-1.0](#) Approved
- [\(EXPIRED\) DCP Consent-1.0](#) Approved
- [\(EXPIRED\) DCP Baseline-1.0](#) Approved
- [\(EXPIRED\) DCP Eligibility-1.0](#) Approved
- [\(EXPIRED\) DCP Eligibility-1.1](#) Approved
- [\(EXPIRED\) DCP Eligibility-1.2](#) Approved
- [\(EXPIRED\) DCP Lab Results-1.0](#) Approved

Submit

Reset


Home

# CDE Use





# Built in Edit Check

 **Error:** Participant age (1) must be 18 or older than 18 for eligibility.

Back

# View Instruction of Specific CDE

Definitional Attribute				
<b>Document Text:</b> Race (What is your race? Check all that apply.)				
<b>Definition:</b> Major living subspecies of man differentiated by genetic and physical characteristics.				
Representation Attributes				
<b>Representation Form:</b> Code				
<b>Data Type:</b> Character				
<b>Format:</b> N/A				
<b>Maximum Size:</b> 4				
<b>Minimum Size:</b> 4				
Permissible Value:ID	List Value	Comments	Source	
1	White	A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.	NCI Metathesaurus	
2	Black or African-American	A person having origins in any of the black racial groups of Africa.	NCI Metathesaurus	
3	American Indian or Alaska Native	A person having origins in any of the original peoples of North Central, or South America, and who maintains tribal affiliations or community attachment	NCI Metathesaurus	
7	Native Hawaiian or other Pacific Islander	A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.	NCI Metathesaurus	
97	Other, specify:			
99	Unknown/refused			
<b>Note:</b> Permissible Values listed above are specified for all related forms.				
<b>Maximum Value:</b> 99				
<b>Minimum Value:</b> 1				
<b>Unit:</b> N/A				
Administrative Attribute				
<b>Instruction:</b> Choose more than one race if participant is of mixed race. Select all that apply.				

# Confirmation Page

[Back to List of Forms](#) [Home](#)

Qx#	Form Text	Value Entered
* <a href="#">423</a>	<b>EDRN Protocol ID</b> (Go To: <a href="#">422</a> ) (Protocol)	111
* <a href="#">422</a>	<b>EDRN Site ID</b> (Go To: <a href="#">795</a> ) (Site)	5
* <a href="#">795</a>	<b>Proposed study group</b> (Go To: <a href="#">794</a> ) (Consent)	<input checked="" type="checkbox"/> 1 Cases group 1 <input type="checkbox"/> 2 Control Group 2
* <a href="#">807</a>	<b>Date of baseline visit:</b> (Go To: <a href="#">929</a> ) (Data Collection Date)	3/5/05
* <a href="#">929</a>	<b>EDRN Staff ID</b> (Go To: <a href="#">794</a> ) (Site)	159
* <a href="#">794</a>	<b>Date of birth: (What is your date of birth?)</b> (Go To: <a href="#">948</a> ) (Demographics)	3/5/40
* <a href="#">948</a>	<b>Does the participant currently have cirrhosis?</b> (Liver)	<input checked="" type="checkbox"/> 0 No <input type="checkbox"/> 1 Yes (Go To: <a href="#">987</a> )
* <a href="#">987</a>	<b>Cirrhosis diagnosis based on:</b> (Liver)	<input type="checkbox"/> 1 Liver histology <input type="checkbox"/> 2 Judgement of the treating physician (Go To: <a href="#">988</a> )
* <a href="#">988</a>	<b>Does the participant have an imaging test showing a cirrhotic liver with splenomegaly?</b> (Go To: <a href="#">989</a> ) (Imaging)	<input type="checkbox"/> 0 No <input type="checkbox"/> 1 Yes
* <a href="#">989</a>	<b>Does the participant have a platelet count of less than 120 K/mm<sup>3</sup>?</b> (Go To: <a href="#">950</a> ) (Labs)	<input type="checkbox"/> 0 No <input type="checkbox"/> 1 Yes

# Confirm Eligibility

- Confirm eligibility of potential participants and assign them to a study arm
- Ineligible Notes display if participant does not meet the eligibility requirements
- Participant Status: Confirmed, Pending or Ineligible

# Specimen Tracking System

- Tracks Original Specimen and Associated Children Specimens
- 2-D Barcoding
- Possible Specimen Tracking Data Elements:
  - Specimen ID
  - Participant ID
  - Specimen collection date
  - Participant visit code (e.g. baseline, follow-up)
  - Specimen source (e.g., blood, urine, bone marrow)
  - Specimen stored (e.g., serum, DNA)
  - How specimen processed
  - Quantity
  - Quantity unit ( e.g., ml )
  - Lab specimen stored
  - Building
  - Room
  - Refrigerator
  - Box
  - Column
  - Row
  - Specimen status (e.g., good, used, defective and reason)

# Specimen Tracking System

- Assay laboratories are blinded to participant information by using a Pair ID number or Specimen ID number that doesn't link back to Participant ID
- All specimens collected in standardized fashion
- Cases and Controls are paired according to matching criteria defined in protocol
- Pull Lists are created and Algorithm Batch Lists are designed for processing lab

# Enter New Specimen

## Enter/Update

- ▶ [Original Specimen](#)
- ▶ [Child Specimen](#)
- ▶ [Specimen Update](#)
- ▶ [Processing Questions](#)

**Original Specimens** are the specimens that obtain directly from a participant for an EDRN Validation Study or existing specimens that are being provided for an EDRN Validation Study.

Please only enter/scan required [Specimen IDs](#) or [Participant IDs](#) that have been distributed by DMCC.

The fields with \* sign are required.

Original Specimen ID *	<input type="text"/>		
Participant ID *	<input type="text"/>		
Specimen Collection Date *	<input type="text"/>		mm/dd/yyyy
Specimen Source *	Blood <input type="button" value="v"/>		
Current Specimen Type *	<input type="text"/>	<input type="button" value="v"/>	
Lab Specimen Stored *	<input type="text"/>	<input type="button" value="v"/>	
Specimen Status *	<input type="text"/>	<input type="button" value="v"/>	
Reason of Defective	<input type="text"/>	<input type="button" value="v"/>	
Other Reason of Defective	<input type="text"/>		
			<input type="button" value="Submit"/>

# Assay Results

Specimen ID *	<input type="text"/>	
Lab Specimen Processed *	<input type="text"/>	
Date of Assay *	<input type="text"/>	mm/dd/yyyy
<b>Locus Values</b>		
D4S243 Informative	<input type="text"/>	
D4S243 Test 1	<input type="text"/>	
D4S243 Test 2	<input type="text"/>	
FGA Informative	<input type="text"/>	
FGA Test 1	<input type="text"/>	
FGA Test 2	<input type="text"/>	
D9S747 Informative	<input type="text"/>	
D9S747 Test 1	<input type="text"/>	
D9S747 Test 2	<input type="text"/>	
D17S254 Informative	<input type="text"/>	



# Reports

## (Real-time Study Specific Reports)

- Participant Reports
  - Enrollment
  - Adherence
  - Completeness
- Audit Trail
- Specimen Reports
  - Defective List
  - Specimens Collected
  - Status of Assay Results
  - Pull Lists

# Example of Enrollment Report

## Enrollment Reports

Report Generated on 2/12/2007 at 8:59:49 AM

### Final Group Status

Site Name	Cases				Cases
	Liver Ca	Diseased	Controls Cirrhosis	Controls & Sub Total	Controls Site Total
143-University of Michigan	<u>68</u>	<u>1</u>	<u>81</u>	<u>(82)</u>	<u>150</u>
144-Mount Sinai Hospital	<u>109</u>	<u>1</u>	<u>72</u>	<u>(73)</u>	<u>182</u>
145-Mayo Clinic	<u>43</u>	<u>1</u>	<u>26</u>	<u>(27)</u>	<u>70</u>
146-Saint Louis University	<u>41</u>	0	<u>42</u>	<u>(42)</u>	<u>83</u>
147-Stanford University	<u>55</u>	0	<u>58</u>	<u>(58)</u>	<u>113</u>
148-University of Pennsylvania	<u>29</u>	0	<u>36</u>	<u>(36)</u>	<u>65</u>
275-Mayo Clinic Jacksonville	<u>14</u>	0	<u>12</u>	<u>(12)</u>	<u>26</u>
<b>Total</b>	<b><u>359</u></b>	<b><u>3</u></b>	<b><u>327</u></b>	<b><u>(330)</u></b>	<b><u>689</u></b>

# Issue Tracking

- Tracks all correspondence between the study sites and labs and the coordinating center
- Tracks correspondence within the coordinating center (Project Requests linked back to FDA documentation)
- Tracks Data Clarifications

# Inquiry to Coordinating Center

<b>Protocol: DCP ( ID: 111 ) User: Dahlgren, Jackie ( Site ID: 5 )</b>		<a href="#">Logout</a> <a href="#">Home</a> <a href="#">Back</a> <a href="#">Print</a> <a href="#">VSIMS</a>
<a href="#">Report Problem</a>		<b>Issue Tracking System</b>
<b>Options:</b> <a href="#">⇒Back to Listing</a>	Inquiry to Coordination Center	
The fields with * sign are required.		
<b>Date Opened:</b>	1/29/2007	
<b>Study Site:</b>	St. Louis University (Assoc. Member)-146	
<b>Subject: *</b>	<input type="text"/>	
<b>Participant ID: *</b>	<input type="text"/>	
	Enter "None" if no ID needed.	
<b>Details: *</b>	<input type="text"/>	
<b>Comments:</b>	<input type="text"/>	
<b>Related Attachments:</b>	<input type="button" value="Add Attachment"/>	

# Other Components (Data Transfer)

Protocol: DCP (ID: 111) User: ( Site ID: 5) Logout Home Back Print VSIMS

Menu ▾ Study Data Upload DCP DATA TRANSFER

VSIMS users can use this form to transfer a file to EDRN DMCC via a secure channel.  
The fields with \* sign are required.

Upload File *	<input type="text"/>	Browse...
File Sharing Scope *	<input type="text"/>	▾
Keywords	<input type="text"/>	

If you choose to share the file with an EDRN DMCC member only, please specify from the list:

EDRN DMCC Members	<input type="text"/>	▾
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Secure site maintained by COMPASS, Fred Hutchinson Cancer Research Center ©. Last updated on Mon Jan 29 2007 . Contact: [edrdmcc@fhcrc.org](mailto:edrdmcc@fhcrc.org)

# Other Components


## Study Information

- Protocol
- IRB
- Manual of Operations
- Mailing List Subscriptions
- Directory

# Administrative Functions for DMCC

- User Account Manager
- Protocol Manager
- Protocol Registration
- File Manager
- Mailing List Manager
- Login Report
- ID Number Generator

# FDA Compliance

- Category 5 Custom Built Software
- Electronic data stored in 21 CFR Part 11 compliant manner through validation process and SOPs
  - Master Plan, Risk Assessment, Installation-Operational-Performance Qualifications, URS, FS, Program Development Standards & Code Review, Test Cases & Matrix
-  Currently satisfies FDA requirements:



# Summary

- **Flexibility:** Online data entry screens and physical forms are defined by metadata and automatically generated
- **Consistency:** Common framework results in efficient re-use of Common Data Elements (CDEs)
- **Ease of Implementation:** Data entry screens and physical forms are created by non-technical staff via a user-friendly interface
- **FDA Compliant:** Validation Package and SOPs
- **Traceability:** Full audit trail and versioning

Thank You

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