EDRN's Validation Study Information Management System

Developed for EDRN by the DMCC

FRED HUTCHINSON CANCER RESEARCH CENTER
A LIFE OF SCIENCE

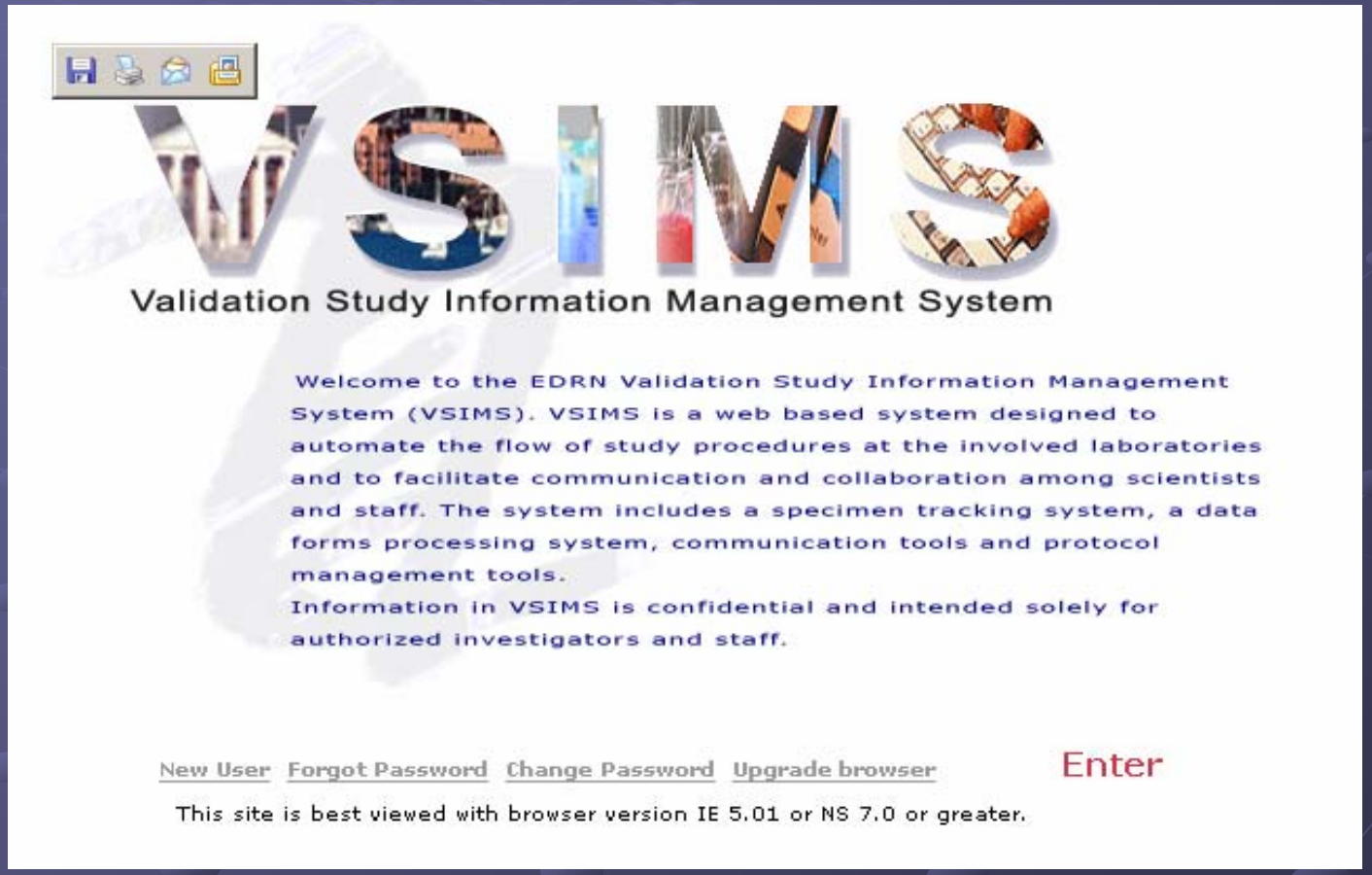
NASA

JPL
Jet Propulsion Laboratory
California Institute
of Technology

NATIONAL CANCER INSTITUTE
Cancer Biomarkers Group
Division of Cancer Prevention

Early Detection Research Network

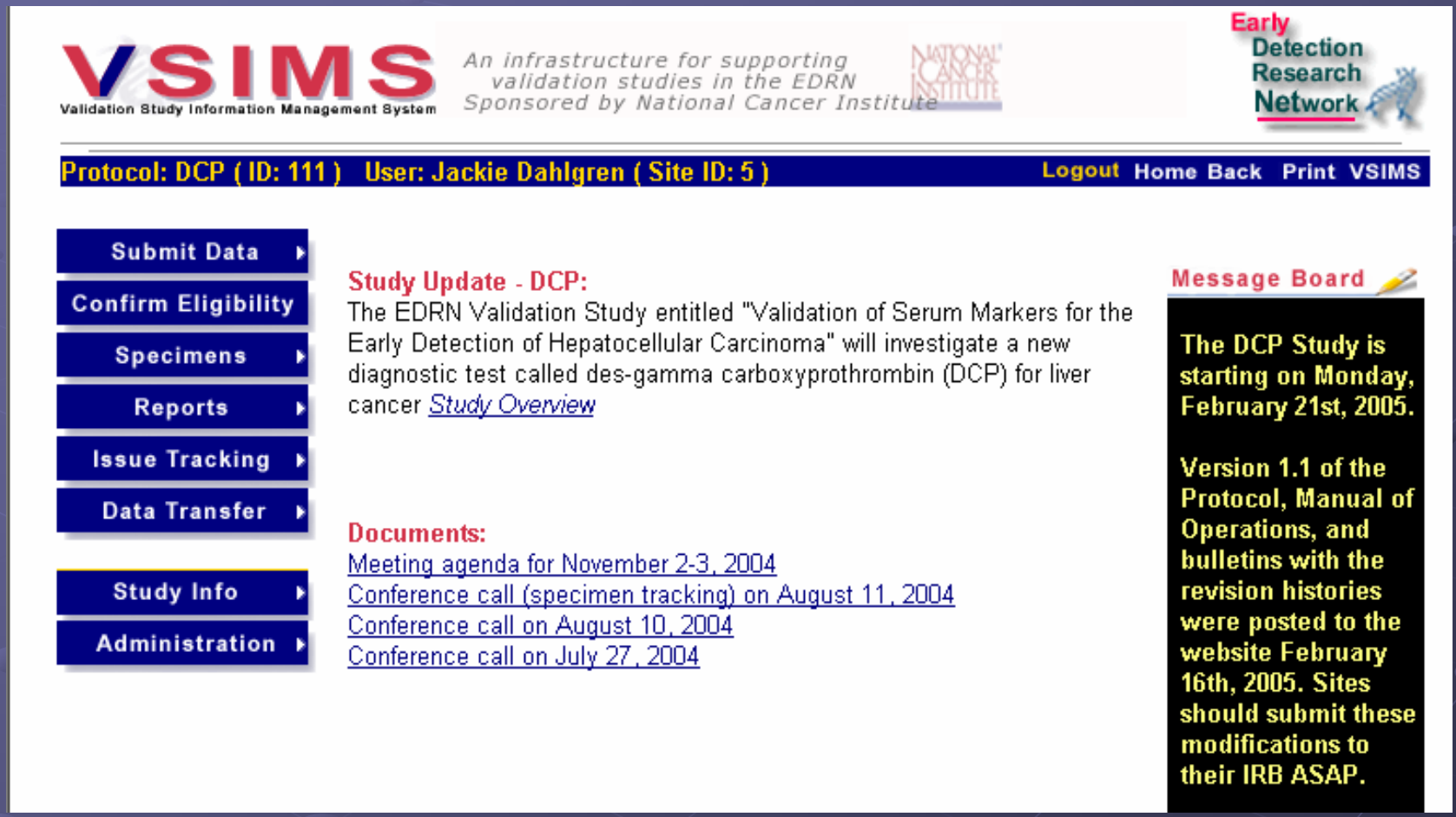
VSIMS Enter Page



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



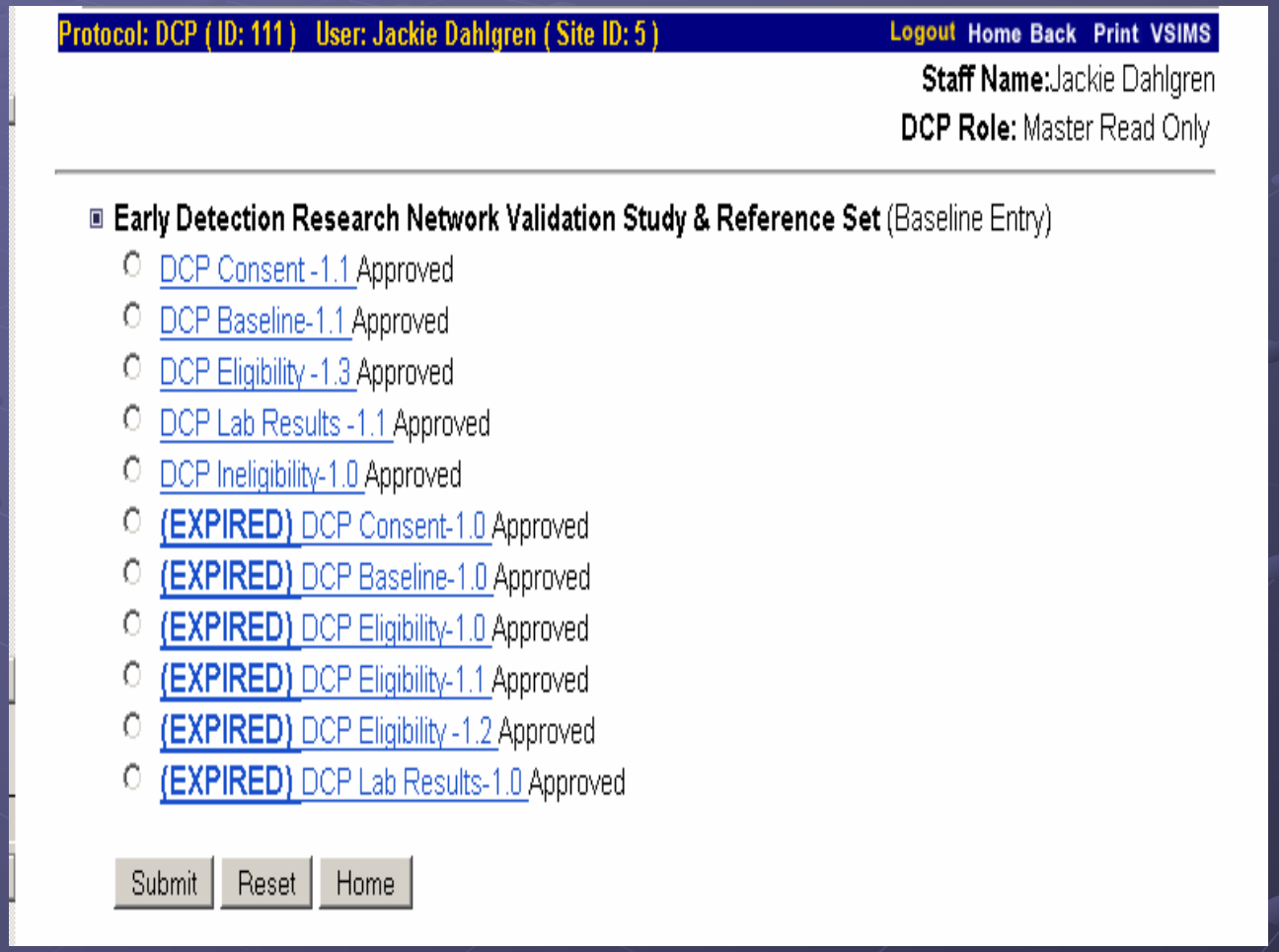
Current Projects using VSIMS

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

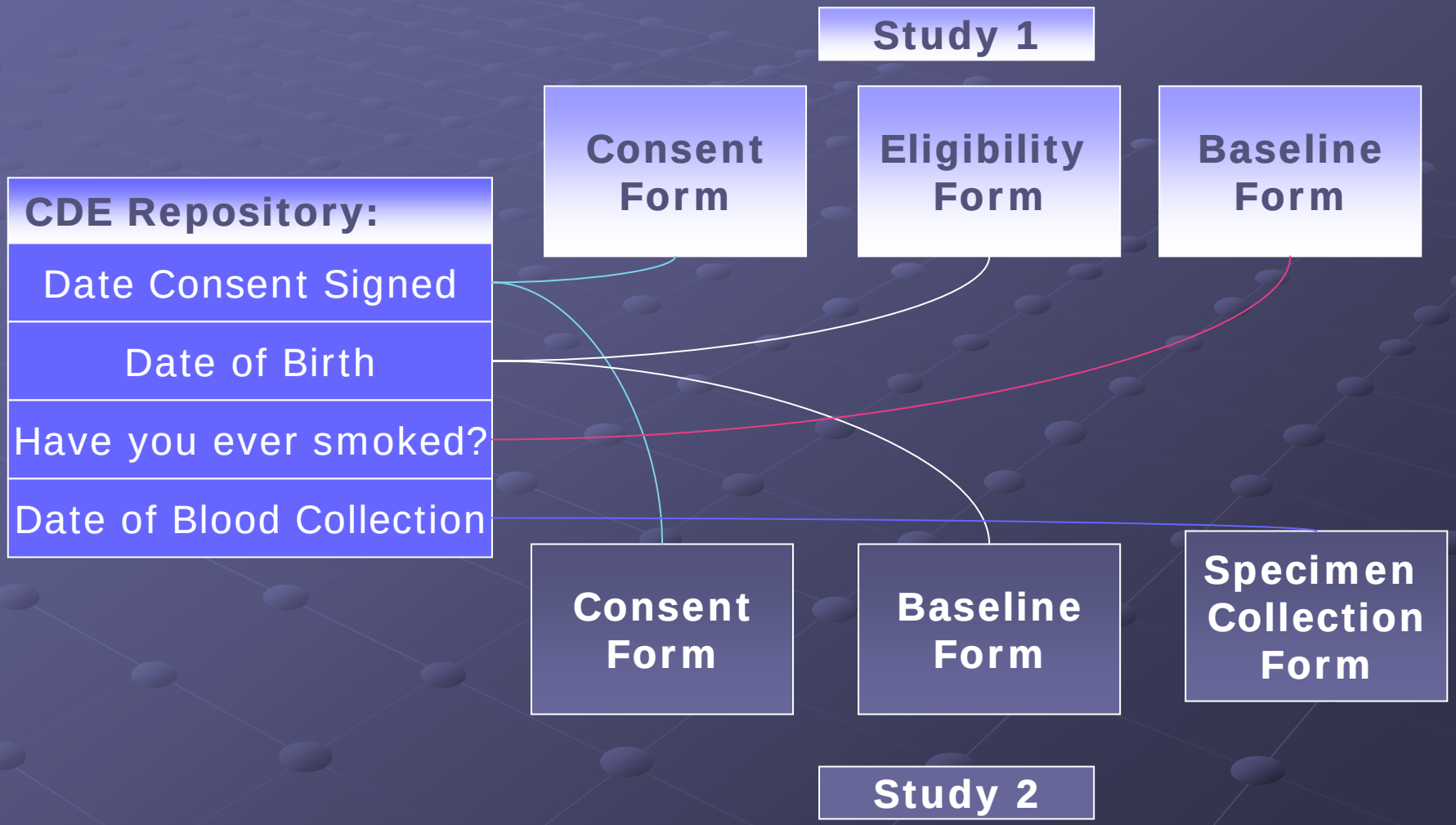
Submit Data

- 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

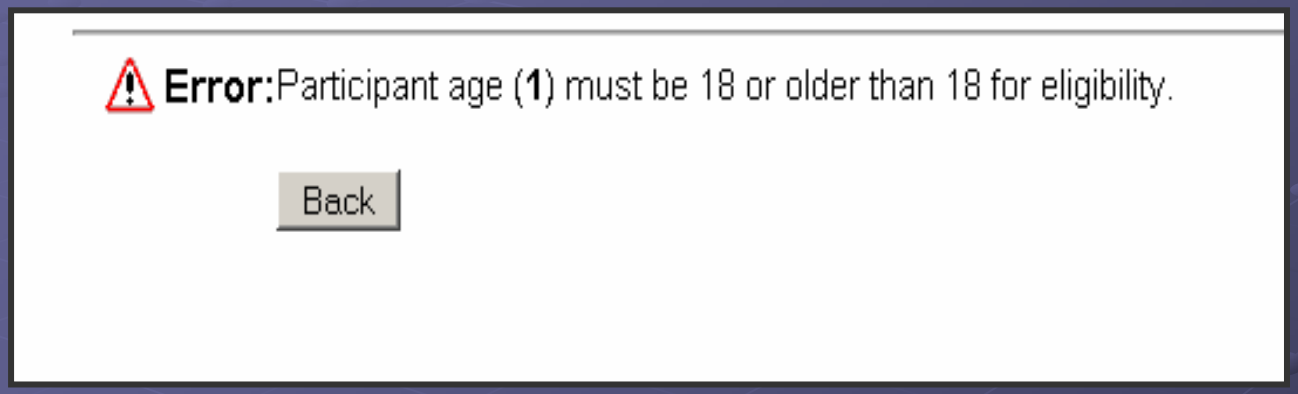
Submit Data Forms



CDE Use


Study 1
Consent Form
Eligibility Form
Baseline Form
CDE Repository:
Date Consent Signed
Date of Birth
Have you ever smoked?
Date of Blood Collection
Consent Form
Baseline Form
Specimen Collection Form
Study 2

Built in Edit Check



View Instruction of Specific CDE

Definitional Attribute

Document Text:	Race (What is your race? Check all that apply.)
Definition:	Major living subspecies of man differentiated by genetic and physical characteristics.

Representation Attributes

Representation Form:	Code
Data Type:	Character
Format:	N/A
Maximum Size:	4
Minimum Size:	4

Permissible Value:

List 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
		A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indidan subcontinent	
7	Native Hawaiian or other Pacific Islander	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		

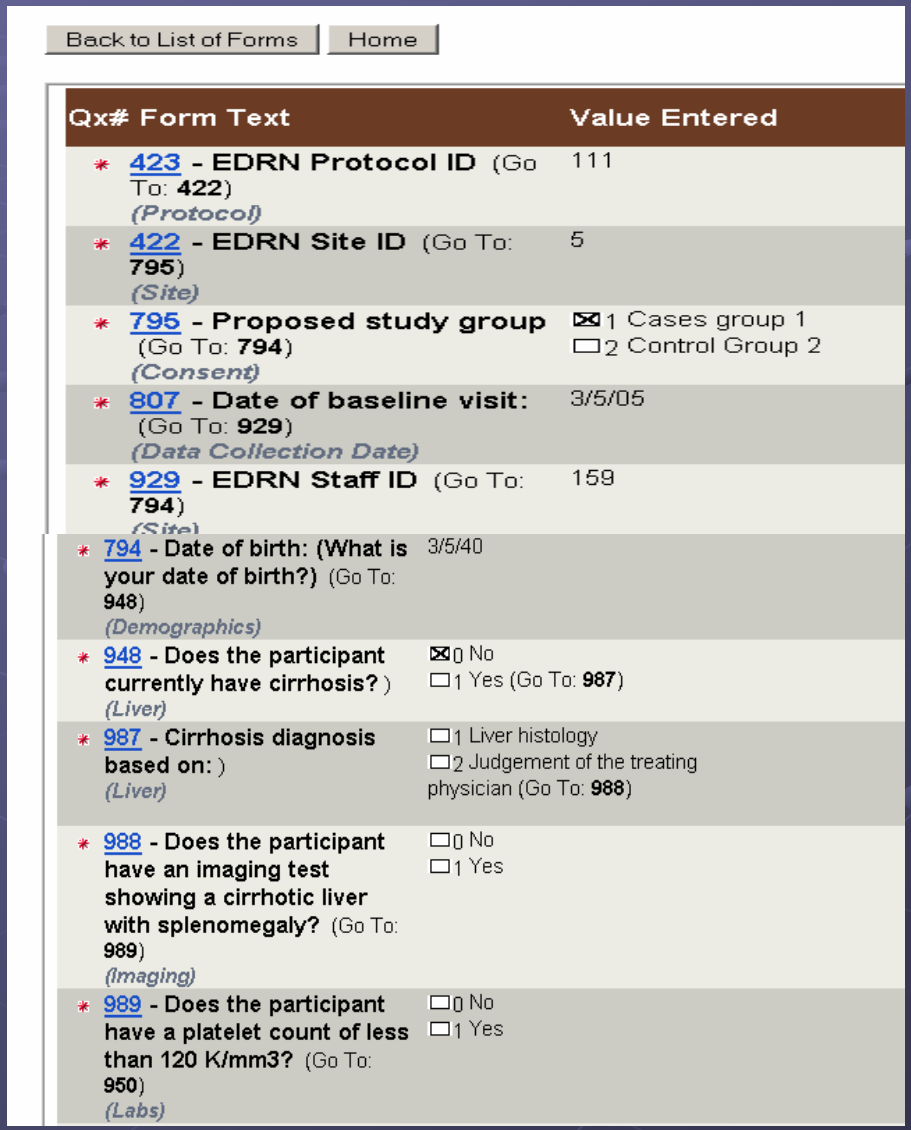
Note: Permissible Values listed above are specifed for all related forms.

Maximum Value:	99
Minimum Value:	1
Unit:	N/A

Administrative Attribute

Instruction:	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
* 423 - EDRN Protocol ID (Go To: 422) *(Protocol)*	111
* 422 - EDRN Site ID (Go To: 795) *(Site)*	5
* 795 - Proposed study group (Go To: 794) *(Consent)*	☒ 1 Cases group 1 ☐ 2 Control Group 2
* 807 - Date of baseline visit: (Go To: 929) *(Data Collection Date)*	3/5/05
* 929 - EDRN Staff ID (Go To: 794) *(Site)*	159
* 794 - Date of birth: (What is your date of birth?) (Go To: 948) *(Demographics)*	3/5/40
* 948 - Does the participant currently have cirrhosis?) *(Liver)*	☒ 0 No ☐ 1 Yes (Go To: 987)
* 987 - Cirrhosis diagnosis based on:) *(Liver)*	☐ 1 Liver histology ☐ 2 Judgement of the treating physician (Go To: 988)
* 988 - Does the participant have an imaging test showing a cirrhotic liver with splenomegaly? (Go To: 989) *(Imaging)*	☐ 0 No ☐ 1 Yes
* 989 - Does the participant have a platelet count of less than 120 K/mm3? (Go To: 950) *(Labs)*	☐ 0 No ☐ 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

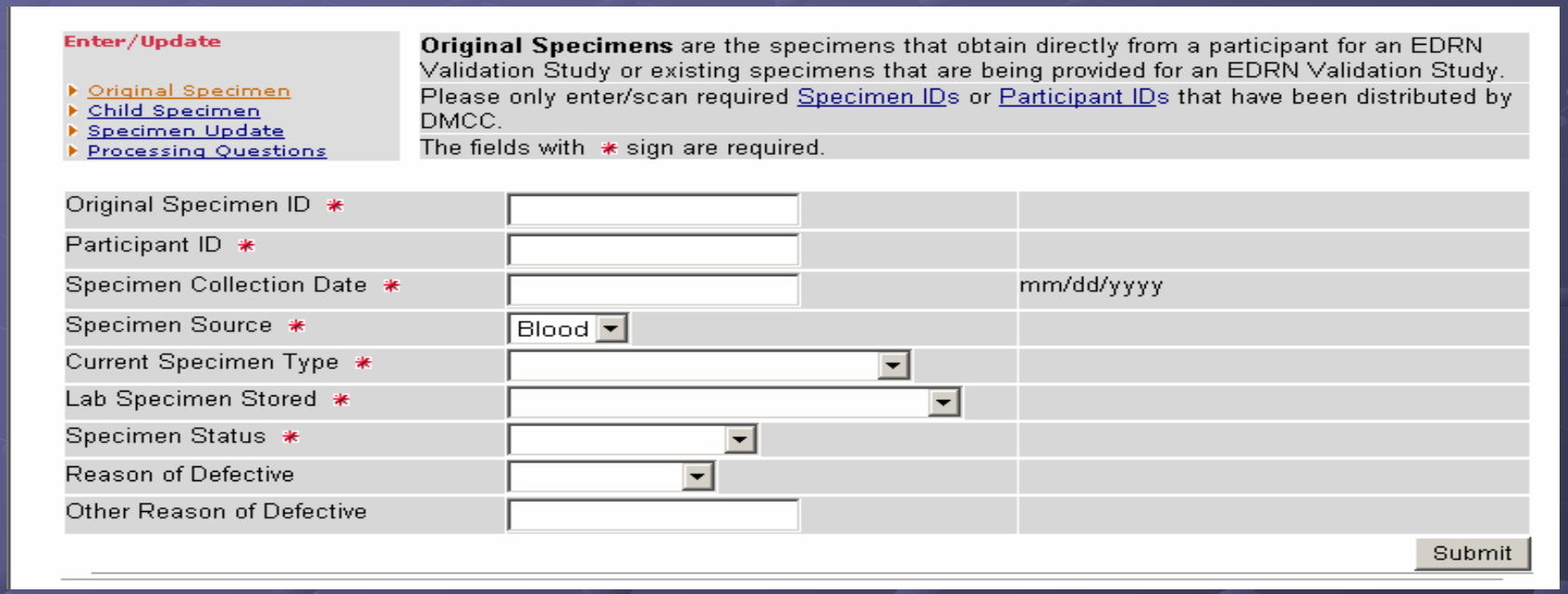
Specimen Tracking System

- 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)

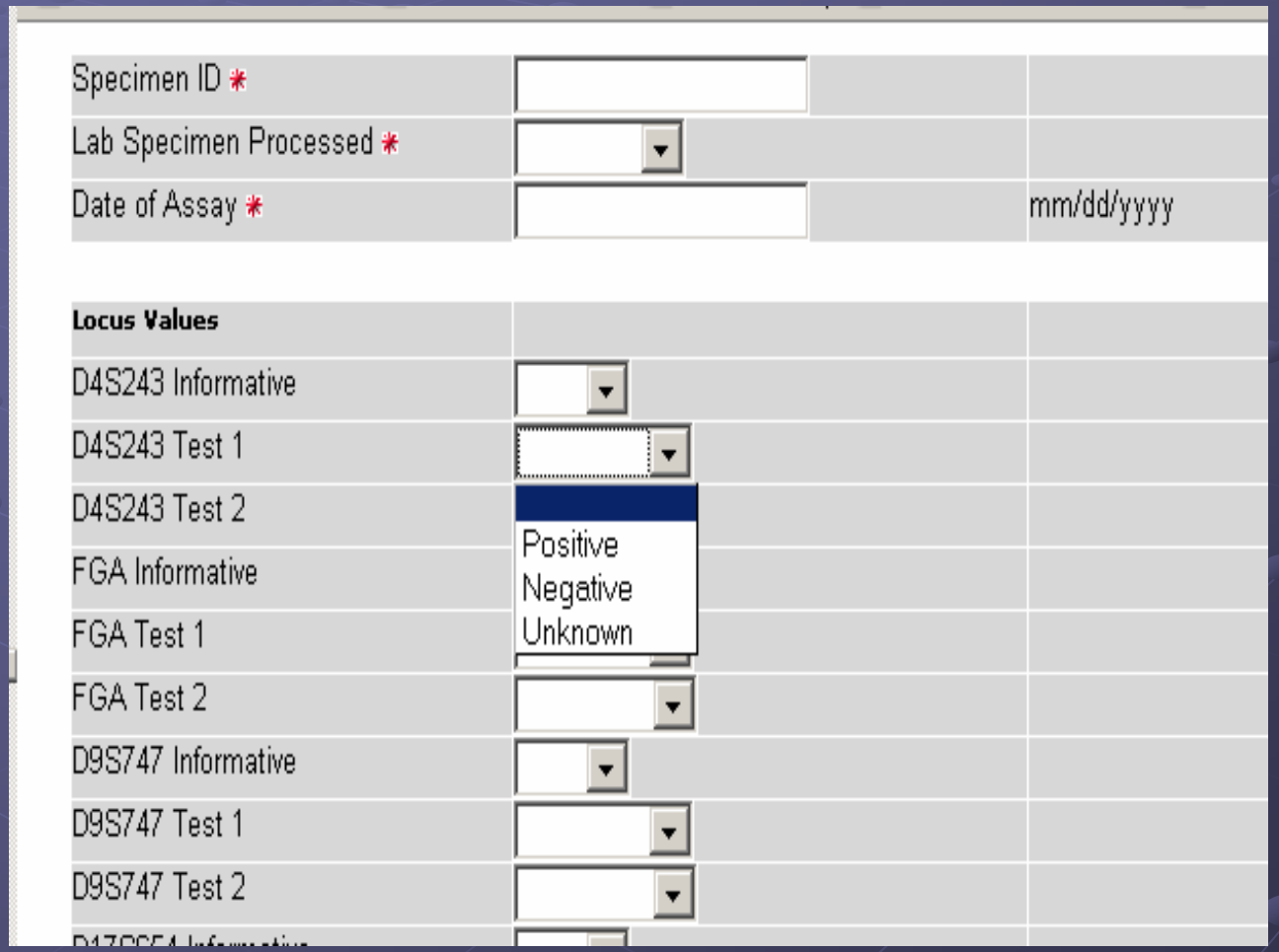
Specimen Tracking System

- 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



Assay Results



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

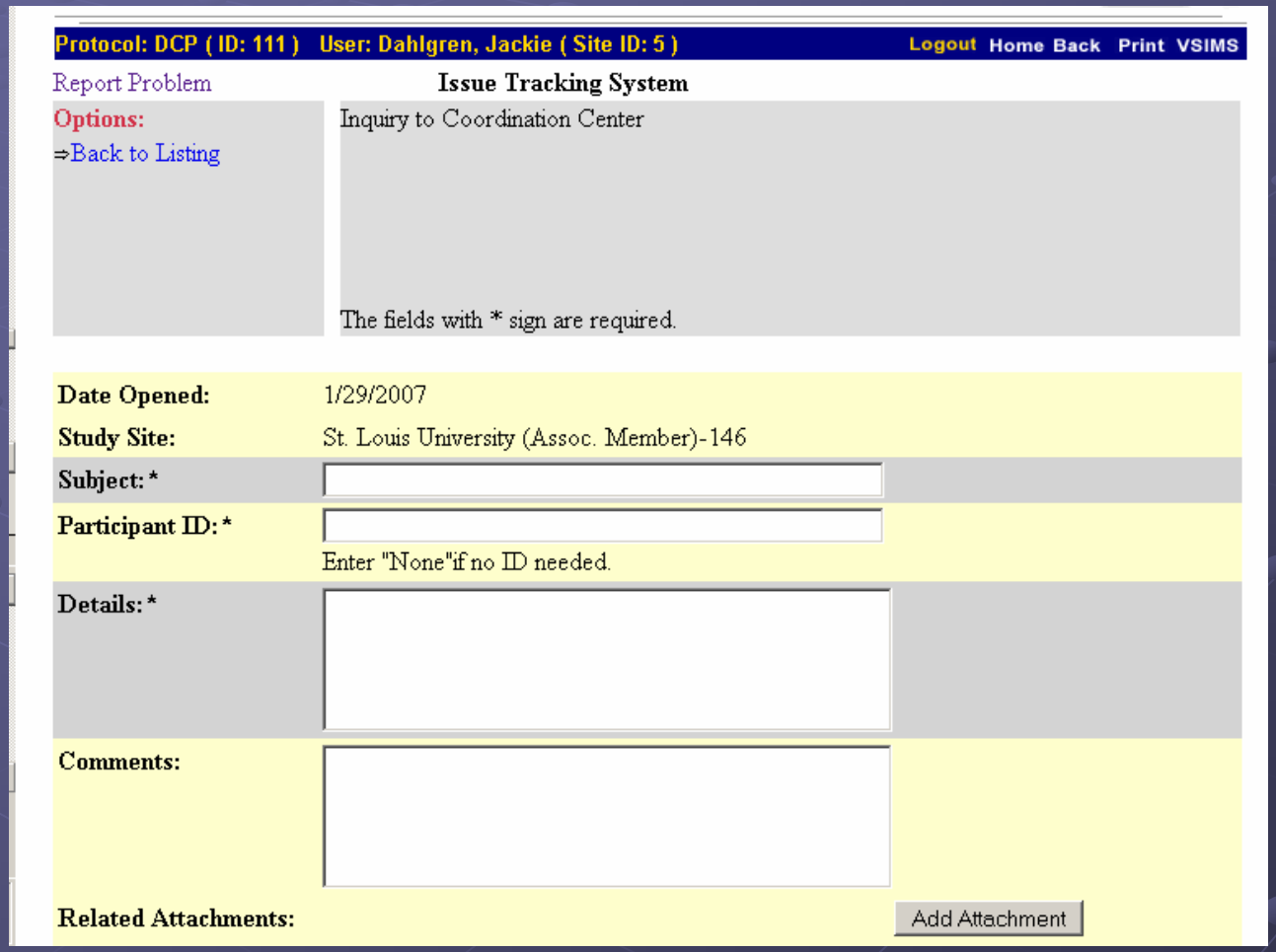
Final Group Status

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

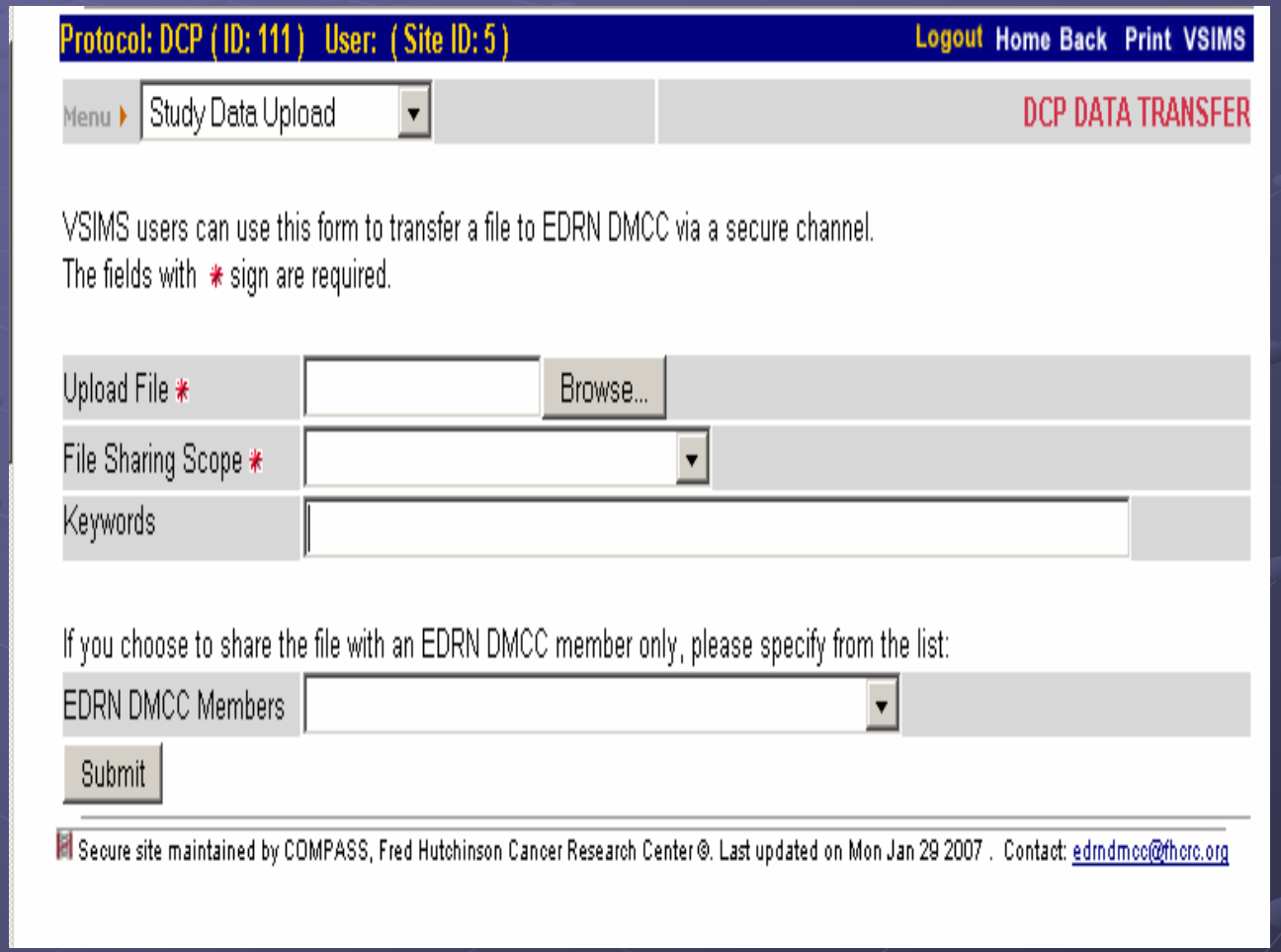
Issue Tracking

- 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



Other Components (Data Transfer)



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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