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## *Comprehensive Data Resource Lite (CDR-Lite)* User Guide

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11/7/2016

## **Version History**

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## TABLE OF CONTENTS

<b>1</b>	<b>INTRODUCTION.....</b>	<b>1</b>
<b>2</b>	<b>CDR-LITE BASICS.....</b>	<b>2</b>
2.1	CDR-Lite Functionality.....	2
2.2	CDR-Lite Accounts, Roles, and Responsibilities .....	3
2.3	Logging In and Out of the CDR-Lite.....	4
2.3.1	Login Screen Fields .....	5
2.3.2	Login Screen Links.....	5
<b>3</b>	<b>ROLE OF THE BIOSPECIMEN/TISSUE SOURCE SITE IN BASIC DATA ENTRY .....</b>	<b>7</b>
3.1	Process Overview.....	7
3.1.1	The Study Home Page.....	8
3.1.2	The CaseRecord List.....	8
3.1.3	The CandidateRecord List .....	9
3.1.4	Search .....	10
3.2	Case List .....	13
3.3	Candidate List.....	13
3.4	Uploading Files.....	14
3.5	Downloading a File.....	15
3.6	Submitting the Case for Review and Processing.....	15
3.6.1	Process.....	15
3.6.2	Workflow .....	16
3.7	Responding to Irregularities Found in Review: The Query Tracker .....	16
3.8	Adding a New Candidate.....	18
3.9	Adding a Screening Enrollment Form to a Candidate.....	20
3.10	Candidate Consent Form .....	22
3.11	Entering Candidate Demographic Data.....	25
3.12	Entering Candidate Health History Form .....	28

3.12.1	Creating the Health History Record.....	28
3.12.2	Adding General Medical History.....	30
3.12.3	Adding General Medications History.....	31
3.13	Entering Candidate Social History Form.....	32
3.14	Adding Candidate Case Records.....	33
3.15	Adding a Blood Collection and Processing Form .....	36
3.16	Adding a Surgery Anesthesia Form .....	40
3.17	Adding a Tissue Gross Evaluation Form .....	43
3.18	Adding a Tissue Receipt and Dissection Form.....	46
3.19	Adding Specimens by Adding a Tissue Preservation Form.....	48
3.20	Adding a Tissue Processing-Embedding Form.....	50
3.21	Adding Slides by Adding a Slide Sectioning Form.....	53
3.22	Adding a Slide Prep and Staining Form .....	55
3.23	Adding a Surgical Pathology Form.....	57
3.24	Adding a Clinical Data Entry Form.....	58
<b>4</b>	<b>PATHOLOGY RESOURCE CENTER ROLE .....</b>	<b>64</b>
4.1	Pathology Case Summary Report .....	64
<b>5</b>	<b>DATA MANAGEMENT ROLE .....</b>	<b>68</b>
5.1	Setting/Clearing the DM Role Flag.....	68
5.2	Understanding the Data Management Home Page.....	69
5.3	Using the Query Tracker Tool .....	70
5.4	Creating a New Query.....	70
5.5	Viewing a Query.....	72
5.6	Closing a Query .....	72
5.7	Using the User Login History Tool.....	74
5.8	Using the Vocabulary Tool .....	74
<b>6</b>	<b>LIMITED DATA SET ROLE.....</b>	<b>79</b>
6.1	Setting and Clearing the LDS Role Flag .....	79

<b>7 ADMINISTRATIVE ROLE .....</b>	<b>80</b>
7.1Process for Creating a New Study in the CDR-Lite.....	80
7.2Adding a New Study Record.....	80
7.3Adding an Organization .....	81
7.4Associating a Study and Tissue Types with a BSS .....	85
7.5Administering Users.....	86
7.6Administering Application Settings.....	91
7.7Modifying Tissue List to Include New Types of Specimens .....	92
7.8Modifying the List of Organizations.....	93

## Table of Figures

Figure 1: The CDR-Lite in the Context of the GTEx Study .....	3
Figure 2: CDR-Lite Login .....	5
Figure 3: Basic Data Entry Page Flow .....	7
Figure 4: Example Study Home Page .....	8
Figure 5: Example CaseRecord List .....	9
Figure 6: Example CandidateRecord List.....	9
Figure 7: Search Home Screen .....	10
Figure 8: Uploaded Files Line of Case Record Details Screen .....	14
Figure 9: Screen for Upload PDF or ZIP File Selection.....	15
Figure 10: Upload Files List Row on the Case Record Details Screen .....	15
Figure 11: Example of an Attempt to Submit a Form with Missing Required Fields .....	16
Figure 12: Query List .....	17
Figure 13: Example Home Screen with a Query Pending .....	17
Figure 14: Query List with Case Details for a Query .....	18
Figure 15: Adding a Candidate from the Study Home Page .....	18
Figure 16: Create CandidateRecord Form.....	19
Figure 17: Example View Candidate Record Details .....	19
Figure 18: Study Home Page with One Candidate in List.....	20
Figure 19: Create Candidate Screening Enrollment Form .....	20
Figure 20: Example Edit Candidate Screening Enrollment Form .....	21
Figure 21: Updated View Candidate Record Details.....	22
Figure 22: Study Home Page, Where Candidate Needs Consent Added .....	22
Figure 23: Candidate Details with Consent Verification Needed.....	23
Figure 24: Create Candidate Consent Validation Form .....	24
Figure 25: Expanded View Candidate Record Details.....	25
Figure 26: Create Candidate Demographics Form .....	26
Figure 27: Expanded View Candidate Record Details .....	27
Figure 28: Show Demographics for Candidate with Resume Edit Button .....	28
Figure 29: Create Health History Form .....	29
Figure 30: Show Health History Screen.....	30
Figure 31: General Medical History Form .....	30
Figure 32: Create General Medical History Record Fields .....	31
Figure 33: Medications History List for a Candidate.....	32
Figure 34: Additional Fields for Creating an Entry in the Medications History .....	32
Figure 35: Create Social History Screen .....	33
Figure 36: Creating a Case Record for a Candidate .....	34
Figure 37: Show Case Record Details Screen .....	35
Figure 38: Change Case Status Screen .....	36
Figure 39: Editing a Blood Form.....	36
Figure 40: Edit Blood Draw Screen.....	38
Figure 41: Surgery Anesthesia Form .....	41
Figure 42: Create Tissue Gross Evaluation Screen .....	44
Figure 43: Expanded Create Tissue Gross Evaluation Form.....	45
Figure 44: Additional Tissue Gross Evaluation Fields for Tissue Bank .....	46

Figure 45: Creating a Tissue Receipt and Dissection Form .....	47
Figure 46: Creating/Adding Specimens Form .....	49
Figure 47: Save Tissue Processing-Embedding Form for a Case .....	51
Figure 48: Creating a Slide Sectioning Form for a Case .....	54
Figure 49: Ancillary Window for Entering Slide ID and Associated Specimen ID.....	54
Figure 50: Create Slide Prep Form .....	56
Figure 51: Upload Surgical Pathology Form.....	57
Figure 52: Creating a Clinical Data Entry Form for a Case .....	59
Figure 53: Expanded Question 4 for Entering Details of Radiation Therapy .....	60
Figure 54: Expanded Question 5 for Entering Details of Chemotherapy.....	61
Figure 55: Expanded Question 6 for Entering Details of Immunotherapy .....	61
Figure 56: Expanded Question 7 for Hormonal Therapy .....	62
Figure 57: Expanded Question 14 for Karnofsky Score.....	62
Figure 58: Expanded Question 14 for Eastern Cancer Oncology (ECOG) Score.....	63
Figure 59: Enabling PRC Role (Green Arrow) and Message .....	65
Figure 60: Study-Specific (WBL) PRC Home Screen .....	65
Figure 61: Edit PRC Report Screen .....	66
Figure 62: Home Screen, with Green Arrow Indicating Location of DM Flag .....	69
Figure 63: DM Home Screen .....	69
Figure 64: Query List Screen in the Query Tracker .....	70
Figure 65: Create Query Screen .....	71
Figure 66: Show Query After a New Query Creation.....	72
Figure 67: Show Addressed Query; Note Additional Buttons at Bottom .....	73
Figure 68: CDR-Lite User Login History Tool .....	74
Figure 69: CDR-Lite Data Services Vocabulary and Configuration .....	75
Figure 70: BloodDrawType List .....	76
Figure 71: Create BloodDrawType Screen .....	77
Figure 72: Show BloodDrawType After Adding New Type .....	77
Figure 73: Home Screen with Green Arrow Indicating Location of LDS Flag .....	79
Figure 74: Study List Screen with Two Example Studies.....	80
Figure 75: Create Study Screen.....	81
Figure 76: Adding the DM Role in Adding an Organization .....	82
Figure 77: Accessing Administrative Vocabulary Items .....	82
Figure 78: CDR-Lite Data Services Vocabulary and Configuration Showing Organization.....	83
Figure 79: Organization List with New Organization Indicated .....	83
Figure 80: Create Organization Screen .....	84
Figure 81: Show Organization Screen .....	85
Figure 82: Show an Individual Study Screen.....	85
Figure 83: Edit Study Screen .....	86
Figure 84: CDR-Lite Project Home Destination Page .....	87
Figure 85: CDR Back Office.....	87
Figure 86: Spring Security Management Console.....	88
Figure 87: Create User: User Details .....	89
Figure 88: Create User: Roles.....	90
Figure 89: Determining Which Users Have a Specific Role .....	90
Figure 90: CDR-Lite AppSetting List .....	92

## Table of Tables

Table 1: Roles and Associated Capabilities .....	4
Table 2: Login Screen Important Information.....	6
Table 3: Upper Right Corner Links .....	10
Table 4: Search Operators.....	11
Table 5: Definition of Fields in Case List .....	13
Table 6: Fields in Candidate List.....	14
Table 7: Vocabulary Items and Access Restrictions .....	75
Table 8: Types of Users Required for Each Study .....	86
Table 9: CDR-Lite Basic Applications Settings .....	91

## 1 Introduction

The Comprehensive Data Resource (CDR) meets the challenges of collecting data regarding tissues gathered in the early stages of the biospecimen lifecycle.<sup>1</sup> These data include information about potential candidates; their eligibility criteria and consent; their medical history; surgical procedures used; acquisition; and processing, handling, and storage. As the focus for biospecimen-based studies of cancer has turned to the molecular level, collecting comprehensive annotation during biospecimen acquisition is more important than ever.

**Note:** All data (e.g., study names, institute/site names, comments) used in examples in this document are completely fictitious. The data displayed do not describe any candidate or case and are for demonstration purposes only.

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<sup>1</sup> <http://biospecimens.cancer.gov/researchnetwork/lifecycle.asp>

## 2 CDR-Lite Basics

### 2.1 CDR-Lite Functionality

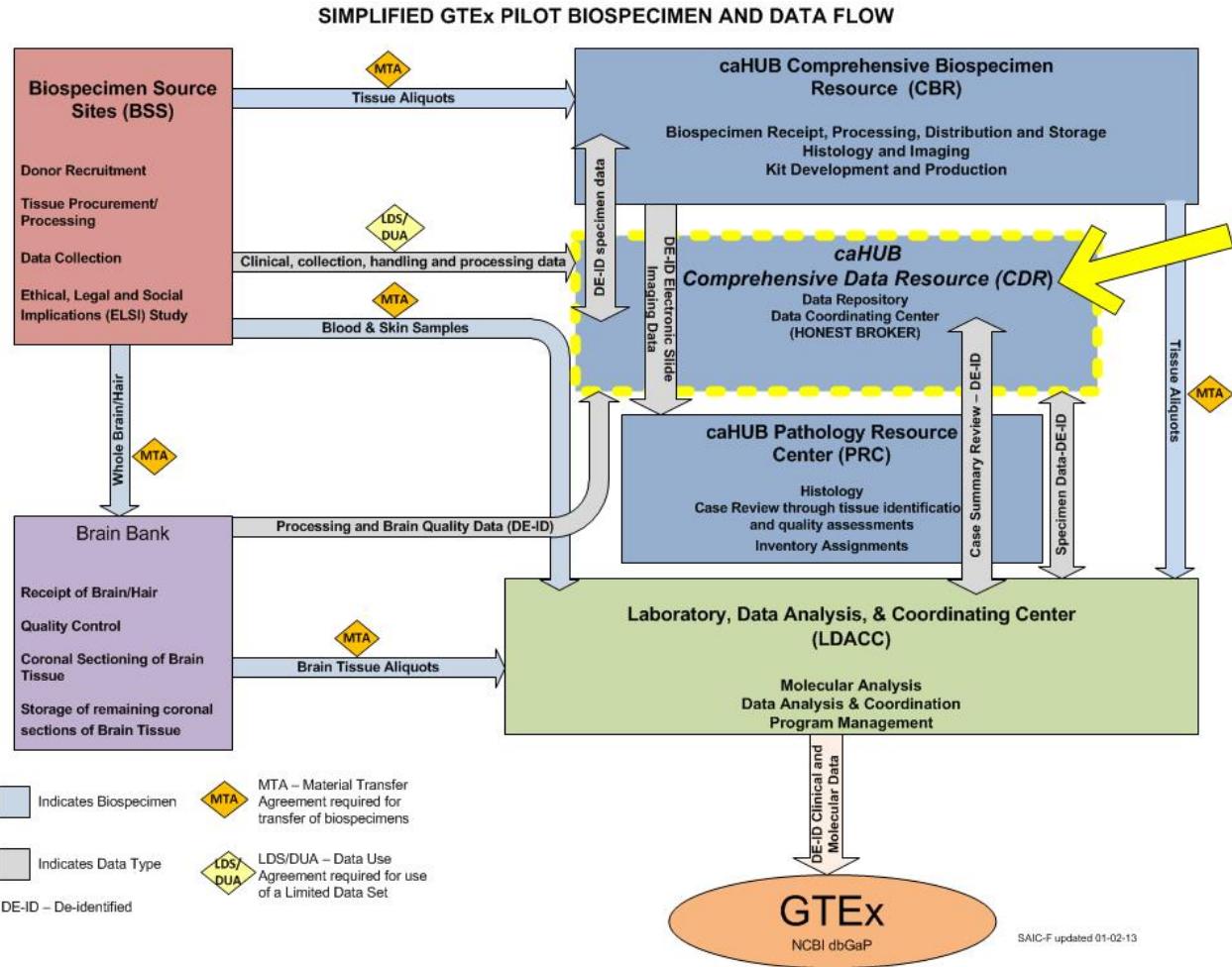
The CDR-Lite is a Web-based application, custom built to support specimen collection, clinical data entry, specimen logistics, and curation and aggregation of study data. Its functionality, which reflect the needs of the supported projects, include the following:

- Allows remote users (e.g., researchers, support staff) to securely enter, revise, and review data about biospecimen collection through a standard (HTTPS) Web interface using a series of electronic forms with a sophisticated role-driven workflow;
- Connects to remote systems via Web service application program interfaces, such as laboratory information management systems, whole-slide imaging systems, and molecular analysis systems;
- Sends automatic email alerts to communicate timely information to project managers and data analysts, letting them know when to start working on something;
- Assists with quality assurance by auditing process flows through data management and pathology teams;
- Controls display of personally identifiable information (PII) based on user entitlements and roles.

Figure 1 is drawn from materials from the Genotype-Tissue Expression (GTEx) program. The CDR-Lite acts as a data hub in three ways:

- Stores information about the geographically diverse collections from the biospecimen source sites (BSS);
- Transfers and processes information through the Comprehensive Biospecimen Resource (CBR);
- Hands off information to both the brain bank and the molecular analysis facility.

The blue lines show the flow of biospecimens, and the gray lines show the flow of information about their collection. When the BSSs collect tissues, they use the forms hosted by the CDR-Lite to describe the case, biospecimens, and other clinical information. As the biospecimens transfer to the CBR, the CDR-Lite receives inventory information on the collected biospecimens (through Web service messages) from the informatics system at the CBR. This instantiates workflows and creates triggers for data managers and pathologists to review cases. Once the tissues are processed, the CBR records subsequent transfer of materials to other specialized labs, including the Laboratory, Data Analysis, and Coordinating Center, for molecular studies. Web services and users enter the results of various tests at these specialized labs into the CDR-Lite, providing comprehensive study information.



**Figure 1: The CDR-Lite in the Context of the GTEx Study**

## 2.2 CDR-Lite Accounts, Roles, and Responsibilities

Table 1 connects three key elements of the CDR-Lite. Individuals have unique accounts, which can be authorized with certain roles. Any account may be assigned one or more roles, which gives that account the associated capabilities.

**Table 1: Roles and Associated Capabilities**

Role	BSS_ROLE	BCR_ROLE	DCC_ROLE	DM_ROLL	QM_ROLE	LDS_ROLE	PRC_ROLE
Only Access Own Org Data	✓	✓	✓				
Read Only		✓	✓	✓	✓	✓	
View LDS	✓					✓	
Create Candidate	✓						
Change Status	Initialized, Data Entry Underway, DE Complete, Remediation			✓			Pathology Review Underway, Pathology Review Complete
View Query List	✓			✓			
New Query				✓			
Memo	✓	Read Only		✓	✓	Read Only	Read Only
Create User				✓			
Create Case	✓						
Case File Upload	✓				✓		
Case File Download	✓			✓	✓	✓	✓
Case File Edit	Files This BSS Uploaded			✓			
General File Upload	✓			✓	✓	✓	✓
General File Download	✓			✓	✓	✓	
General File Edit	Files This BSS Uploaded			✓			

## 2.3 Logging In and Out of the CDR-Lite

When you visit the CDR-Lite website, you will always see the login page first.



**CDR-Lite Data Services Login**

---

Login ID

Password

---

**Important links**

- [Reset or Forgot Password? \(for non-NIH logins only\)](#)
- [Request technical assistance via email](#)  
(A support response will be provided by the end of the next business day, 8am-5pm Eastern)

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**Figure 2: CDR-Lite Login**

**Note:** All users must set their password upon their initial login to the production site. A default password may be set by the CDR System Administrator upon creating the account.

### 2.3.1 Login Screen Fields

Both **login ID** and **password** are case sensitive. Accounts lock automatically after a number of unsuccessful tries. If you are locked out, contact your CDR-Lite administrator and request help with the password change and recovery process.

Click on the word **Logout** at the upper right corner of any CDR-Lite screen to log out.

If the CDR-Lite user does not update the browser session for 30 minutes, then the session automatically logs out, and any unsaved data will be lost. This is to meet NIH security standards.

Upon logout, whether automatic or intentional, the CDR-Lite Login screen appears.

### 2.3.2 Login Screen Links

At the bottom of the screen are links to auxiliary sites, such as a password recovery site, and an email link for requesting help.

**Table 2: Login Screen Important Information**

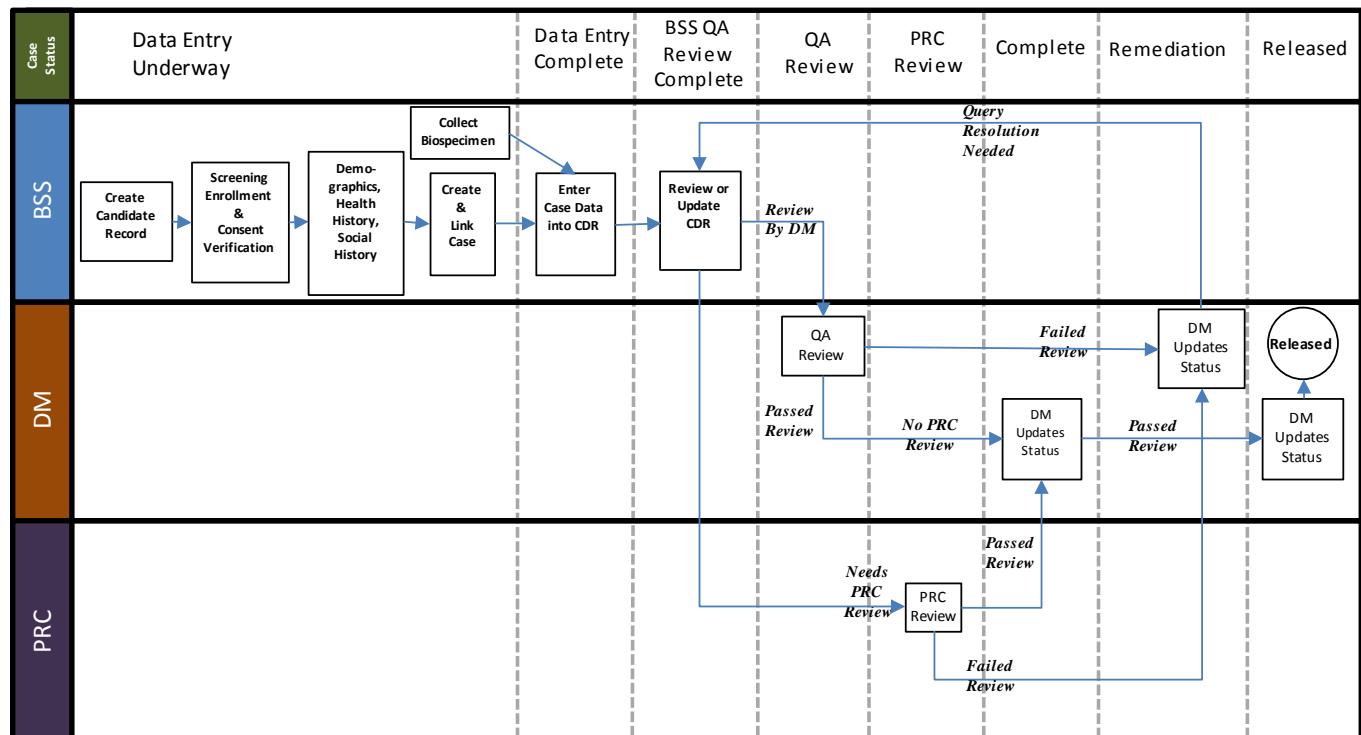
Link/Information	Description
<b>Reset or Forgot Password?</b>	The Reset or <b>Forgot Password</b> link on the home screen brings up a small window for entering the user name. The CDR-Lite sends an email to the email address set when the account was created, allowing the user to complete the password change or recovery process.
<b>Request Help via Email</b>	This link opens the default email client for sending a request for help to a study-specific help mail provider.
<b>CDR-Lite Version Number</b>	At the bottom of the Login screen (and every screen) is the CDR-Lite version number. When describing any problems, remember to include this number.

### 3 Role of the Biospecimen/Tissue Source Site in Basic Data Entry

The biospecimen/tissue source sites collect biological materials for use in studies. Researchers at those sites use the CDR-Lite to record information about specimens on a series of web-based forms. This information gives later researchers insight into the collection, processing, handling, preservation, and storage of each specimen. Without this detailed information, the specimens lose their individual history. A comprehensive individual specimen history is critical for researchers as they work to interpret results obtained from analysis of the collected specimens.

This section gives an overview of the process for collecting and entering data and the details of each form involved.

#### 3.1 Process Overview



**Figure 3: Basic Data Entry Page Flow**

Figure 3 shows the process of entering data into the CDR-Lite as it relates to the case status. The first column or stage is “Data Entry Underway”. The user adds a new candidate by using the Study Home Page (Figure 4). The Show Case Record Details screen shows the case status and allows the user to set the values appropriately.

The BSS performs the basic data entry by filling out a series of web-based forms. After logging in, the user sees the home page for the appropriate study. That user first creates a candidate and later adds information about the candidate’s eligibility. Additional forms add details about collection and processing of study-specific specimens. When data entry on the candidate is complete, then BSS Quality Assurance locally reviews the data entry. After the BSS Quality Assurance reviews the candidate, the candidate is submitted for review by the data management (DM) team at the study level. The reviewed candidate may have issues. If there are issues, DM starts a query for each of those issues. The BSS must respond to each query in a timely manner. With the resolution of all queries, the DM team changes the status of the case

to “Complete,” and the case can go on for further analysis. The DM team directs any additional remediation that is necessary. When no further remediation is needed, the case is released.

### 3.1.1 The Study Home Page

[Home](#) | [Search](#) | [Add a Candidate](#)

Welcome, testeruuu | [Logout](#)  
 Org: UUU University  
 Help  
 Session expires in: **28:28**

**BPS Home**

**BPS Case List**

QT	Case ID	Primary Organ	BSS	Candidate ID	Specimens	Case Status	Date Created
0	BPS-UUU-7253	Lung	UUU	UUU-C2113086-C	25	Data Entry Complete	12/28/2015 15:31
0	BPS-UUU-7252	Lung	UUU	UUU-25C0BC90-C	25	Data Entry Complete	12/28/2015 12:55
0	BPS-UUU-7251	Kidney	UUU	UUU-481B2F7C-C	25	Data Entry Complete	12/28/2015 12:53
0	BPS-UUU-7250	Kidney	UUU	UUU-34FF925F-C	20	Data Entry Complete	12/28/2015 12:44
0	BPS-UUU-7249	Colon	UUU	UUU-E12754D8-C	22	Data Entry Complete	12/28/2015 12:40
0	BPS-UUU-7248	Colon	UUU	UUU-0F4AC6CE-C	26	Data Entry Complete	12/28/2015 12:35
0	BPS-UUU-7247	Colon	UUU	UUU-A52B4E38-C	20	Data Entry Complete	12/28/2015 12:29
0	BPS-UUU-7246	Kidney	UUU	UUU-53F3609D-C	28	Data Entry Complete	12/28/2015 12:11
0	BPS-UUU-7245	Colon	UUU	UUU-EBA4C95B-C	21	Data Entry Complete	12/28/2015 12:06
0	BPS-UUU-7244	Lung	UUU	UUU-8B04959A-C	20	Data Entry Complete	12/28/2015 12:00

Most recently created on top

[View all Cases >>](#)

**Candidate List**

QT	Candidate ID	BSS	Study	Case ID	Subject Screening	Eligible?	Consented?	Date Created
0	UUU-C2113086-C	UUU	Biospecimen Preservation Study	BPS-UUU-7253	Completed (View)	Yes	Yes	12/28/2015 15:30
0	UUU-25C0BC90-C	UUU	Biospecimen Preservation Study	BPS-UUU-7252	Completed (View)	Yes	Yes	12/28/2015 12:55
0	UUU-481B2F7C-C	UUU	Biospecimen Preservation Study	BPS-UUU-7251	Completed (View)	Yes	Yes	12/28/2015 12:53
0	UUU-34FF925F-C	UUU	Biospecimen Preservation Study	BPS-UUU-7250	Completed (View)	Yes	Yes	12/28/2015 12:44
0	UUU-E12754D8-C	UUU	Biospecimen Preservation Study	BPS-UUU-7249	Completed (View)	Yes	Yes	12/28/2015 12:40
0	UUU-0F4AC6CE-C	UUU	Biospecimen Preservation Study	BPS-UUU-7248	Completed (View)	Yes	Yes	12/28/2015 12:35
0	UUU-A52B4E38-C	UUU	Biospecimen Preservation Study	BPS-UUU-7247	Completed (View)	Yes	Yes	12/28/2015 12:29
0	UUU-53F3609D-C	UUU	Biospecimen Preservation Study	BPS-UUU-7246	Completed (View)	Yes	Yes	12/28/2015 12:10
0	UUU-EBA4C95B-C	UUU	Biospecimen Preservation Study	BPS-UUU-7245	Completed (View)	Yes	Yes	12/28/2015 12:06
0	UUU-8B04959A-C	UUU	Biospecimen Preservation Study	BPS-UUU-7244	Completed (View)	Yes	Yes	12/28/2015 12:00

Most recently created on top

[View all Candidates >>](#)

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**Figure 4: Example Study Home Page**

The study home page, shown in Figure 4, is the first page you will see after logging in to the CDR-Lite. Click on the Home icon in the upper left of the screen to go to this page at any time. The home screen displays information for the most recent 10 cases and candidates. Use the **View all Candidates** and **View all Cases** links to browse the full lists of candidates and cases.

### 3.1.2 The CaseRecord List

After using the **View all Cases** link in the study home page, the CaseRecord List displays the last few cases entered in this study. The cases are listed by date of start for the entry, beginning with the most recent entry. Table 5 shows the columns in the Study Case List. At the bottom of the table is a link, **View all Cases >>**. Click on this link to go to the CaseRecord List screen (Figure 5), which lists every case by Case ID. If you have the ROLE\_BSS flag set, only cases associated with your BSS will show. Clicking on the Case ID or Candidate ID changes the screen, showing the appropriate details. Query tracker information is not available on the CaseRecord list screen.

Case ID	Primary Organ	BSS	Candidate ID	Specimens	Case Status	Date Created
f	Kidney	BSS2	<a href="#">BSS2-411F0274-C</a>	0	Data Entry Underway	2016-02-10 14:25:47 EST
Steve1	Kidney	BSS2	<a href="#">BSS2-CF4156BE-C</a>	0	Data Entry Underway	2016-02-10 14:18:45 EST
TestingLocalPathReport1	Colon	BSS 1	<a href="#">BSS 1-6C808229-C</a>	1	Data Entry Underway	2016-01-21 15:29:16 EST
abcd-12345	Kidney	BSS2	<a href="#">BSS2-F39DE33F-C</a>	4	Data Entry Underway	2016-01-04 16:37:37 EST

| Total: 4

CDR-Lite v1.0-M8

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Figure 5: Example CaseRecord List

### 3.1.3 The CandidateRecord List

Figure 6 shows a sample CandidateRecord List screen. The meaning of the column headers is explained in Table 6. If you have the ROLE\_BSS flag set, only candidates associated with your BSS will show. Click on the Case ID, Candidate ID, **View**, or **Start** to go to a screen showing details. Query tracker information is not available on this screen.

Candidate ID	BSS	Study	Case ID	Subject Screening	Eligible?	Consented?	Date Created
<a href="#">BSS2-411F0274-C</a>	BSS2	Brent1	f	<a href="#">Completed (View)</a>	<a href="#">Yes</a>	<a href="#">Yes</a>	2016-02-10 14:25:11 EST
<a href="#">BSS2-CF4156BE-C</a>	BSS2	Brent1	Steve1	<a href="#">Completed (View)</a>	<a href="#">Yes</a>	<a href="#">Yes</a>	2016-02-10 14:17:51 EST
<a href="#">BSS 1-9A4CEE2A-C</a>	BSS 1	Brent1		<a href="#">Not Started (Start)</a>	<a href="#">No</a>	<a href="#">No</a>	2016-02-09 12:15:04 EST
<a href="#">BSS 1-6C808229-C</a>	BSS 1	Brent1	TestingLocalPathReport1	<a href="#">Completed (View)</a>	<a href="#">Yes</a>	<a href="#">Yes</a>	2016-01-07 11:01:14 EST
<a href="#">BSS2-F39DE33F-C</a>	BSS2	Brent1	abcd-12345	<a href="#">Completed (View)</a>	<a href="#">Yes</a>	<a href="#">Yes</a>	2015-12-30 14:05:11 EST

| Total: 5

CDR-Lite v1.0-M8

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Figure 6: Example CandidateRecord List

### Important Home Screen Links

Several links are available at the top of the study home page. These links are described elsewhere in this guide. They are as follows:

- [Home \(Section 3.1.1\)](#)
- [Search \(Section 3.1.4\)](#)
- [Add a Candidate \(Section 3.8\)](#)

## Upper Right Screen Links

Table 3 describes the useful information and links that appear in the upper right corner of the home screen and all CDR-Lite screens.

**Table 3: Upper Right Corner Links**

Information Item	Description
<b>Login Name and Organization</b>	Each individual Login ID and organization name appear here. If the account is for a BSS, only candidates and cases associated with that BSS are visible.
<b>Help (Email)</b>	The Help link transfers users to a page for creating an email for the CDR-Lite Admin.
<b>“Session expires” Time</b>	Because the National Cancer Institute mandates automatic logout for sessions with 30 minutes of inactivity, this feature is extremely useful, indicating the number of minutes and seconds until logout. To reset the time available, simply save any form or change from one CDR-Lite page to another. This text field turns red when less than 5 minutes remain before automatic logout.
<b>Search</b>	Section 3.1.4 discusses the search function in detail.

### 3.1.4 Search

The CDR-Lite has a powerful search capability. Click the **Search** link, typically found next to the Home icon, on any screen to bring up the Search home screen and set up a search.

The screenshot shows the 'Search Data' interface. At the top, there is a 'Home' icon and a 'Search Data' title. Below the title is a 'Enter Search Criteria:' input field and a 'Go' button. A 'Hints' section is expanded, containing two subsections: 'All Field Search' and 'Specific Field Search'. The 'All Field Search' section lists various search operators and fields such as Case ID, Candidate ID, BSS, and Demographics. The 'Specific Field Search' section provides syntax examples for fields like CaseRecord, CandidateRecord, BSS, CaseStatus, CaseCollectionType, SpecimenRecord, Demographics, PrcSpecimen, AcquisitionType, Date range search, and Number range search.

**Figure 7: Search Home Screen**

A search can be for any character string in any candidate or case information and, of course, any of the text strings appearing on the home screen and the View All views. For example, to find case BPV-000004, simply enter that text in the Enter Search Criteria field and click on **Go**.

Keyword search supports a variety of search operators. Table 4: Search Operators summarizes the search operators and their anticipated results.

**Table 4: Search Operators**

Simple Search Operators	Example	Results
<b>Double quotes (" ")</b> will return specimens that contain the exact phrase quoted, in any of the fields.	<b>"Research Institute"</b>	Comments anywhere containing the exact phrase "Research Institute" It is case sensitive. <b>Note:</b> Some fields may include spaces, so searches require double quotes to get the proper meaning.
An <b>asterisk (*)</b> is a wild-card search operator that can replace any number of characters in a search term.  An asterisk in the beginning, middle, or end of a search term.  In quoted strings, asterisks are not wild cards.	<b>caseID:GTEX-100*5</b>	A range of GTEx cases
A <b>question mark (?)</b> is a wild-card search operator replacing a single character in the search term.  Question marks as wild cards are valid in the beginning, middle, or end of a search term. Using multiple question marks within a single search term, each will match one character. Question marks in quoted strings are not wild cards.	<b>BSSName:ABC???</b>	Information related to a BSS whose name is six characters long and starts with "ABC"
A <b>tilde (~)</b> is a search operator that will return terms that are spelled similarly to the term that prefaces it.  It should follow a single-word search term.	<b>BSSName:Nat~</b>	Specimens containing the terms "National" or "Nationwide" in the PRC Comments field

Simple Search Operators	Example	Results
Using <b>parentheses</b> to group queries allows you to combine search operators.	<b>"2 pieces"</b> AND ( <b>internal OR external</b> )	Specimens containing the phrase "2 pieces" and either "internal" or "external"
Prefacing a search phrase with <b>BSSName:</b> limits the query for the search phrase to the BSSName field. Generally, this matches multiple cases.  Other search terms: caseId candidateId BSSName BSSCode statusName statusCode statusDescription collectionTypeName collectionTypeCode tissueName tissueCode	<b>BSSName:</b> "Specimens R Us"	All specimens from BSSs with the name "Specimens R Us"
<b>Compound Searches</b>		
<p>You can use the following notations to combine any set of the above single searches, making your search more focused. The examples all use single words for clarity, but any of the above is acceptable.</p>		
Including <b>AND</b> or <b>+</b> between search phrases will return records containing both search phrases.  When entering more than one search term, this search operator applies as the default.  If the operator is in a quoted string, it is not an operator.	<b>muscle AND skeletal</b> or <b>muscle + skeletal</b> or <b>muscle skeletal</b>	Comments anywhere containing both "muscle" and "skeletal"
Including <b>OR</b> between search phrases will return images that contain either search term or both.	<b>BSSName:(AAA OR BBB)</b>	BSS whose names are "AAA," "BBB," or both

Simple Search Operators	Example	Results
<p>Including <b>NOT</b> or <b>-</b> (minus) between search terms will return records that do not contain the term that follows the operator.</p> <p>This operator requires a search term that returns results. The dash by itself has no meaning. Also, it must appear between terms; a search like <b>"- brain"</b> will not work.</p> <p>Operators in a quoted string are not treated as operators.</p>	<b>cortex NOT brain</b>	Comments anywhere containing “cortex” but not “brain”

## 3.2 Case List

The **Case List** on the home screen gives access to all cases whose subjects have not withdrawn or denied consent.

**Table 5: Definition of Fields in Case List**

Case List Field	Definition
<b>QT</b>	Short for “query tracker.” If no queries are pending for this case (meaning there are no problems being questioned by DM), the number zero (“ <b>0</b> ”) shows in green. Otherwise, the count of queries pending shows in red (e.g., “ <b>5</b> ”). Clicking on this non-zero number moves the screen to the Query List for Case Details.
<b>Case ID</b>	Unique ID assigned to each case
<b>Primary Organ</b>	Source of the tissue collected from the candidate
<b>BSS</b>	Abbreviation for the BSS associated with the candidate
<b>Candidate ID</b>	Specifies the Candidate ID linked to this case
<b>Specimen Count</b>	The number of specimens collected for this case
<b>Case Status</b>	The status of the case in the information processing sequence – “Data Entry Underway”, “Data Entry Complete,” “BSS QA Review Complete”, and so forth.
<b>Date Created</b>	Indicates the date and time of case record creation

## 3.3 Candidate List

The Candidate List on the home screen gives users access to all visible candidates in the system. Candidates linked to a case are displayed in *italics*. If your account has ROLE\_BSS, only candidates created by your BSS will show.

Five fields make up the Candidate List. You can sort the list in ascending or descending order by BSS, Study, or Date Created. Table 6 shows the Candidate List fields.

**Table 6: Fields in Candidate List**

Candidate List Field	Definition
QT	Short for “query tracker.” If no queries are pending for this candidate, the number zero (“0”) shows in green. Otherwise, the count of queries pending shows in red (e.g., “5”). Clicking on this non-zero number moves the screen to the Query List for Candidate Details.
<b>Candidate ID</b>	Unique identification number of each candidate
<b>BSS</b>	Abbreviation for the BSS associated with the candidate
<b>Study</b>	Study under which the tissue specimens were collected
<b>Case ID</b>	Indicates whether the candidate is linked to one of the cases collected in the Bio4D system and, if so, the case ID number
<b>Subject Screening Form</b>	Indicates the status of data entry for this form: “Not Started,” “In Progress,” or “Completed”
<b>Subject Consent Form</b>	Indicates the status of data entry for this form: “Not Started,” “In Progress,” or “Completed”
<b>Eligible?</b>	Indicates whether the patient has met the eligibility criteria for this study, based on the Subject Consent Form
<b>Consented?</b>	Indicates whether the patient has given consent, based on the Subject Consent Form
<b>Date Created</b>	Indicates the date and time this candidate record was created

### 3.4 Uploading Files

While a case is marked “Data Entry Underway,” you can upload PDFs, Zip files, or Word documents (.doc or .docx) of tissue collection and processing forms to the CDR-Lite.

**Note:** Make sure that no Personally Identifiable Information (PII) is included in uploaded files. This applies to the filename as well as the entire contents of each file.

To add a file to the CDR-Lite, click on the **Upload** button on the Case Record Details screen beneath the Uploaded Files row, as shown in Figure 8.

The screenshot shows a portion of a software interface. At the top, there is a field labeled "Date Created:" with the value "2012-09-05 14:49". Below this is a section titled "Uploaded Files:". Underneath the title, there is a blue rectangular button with a white "Upload" label and a small orange cloud icon. The rest of the screen is mostly blank white space.

**Figure 8: Uploaded Files Line of Case Record Details Screen**

The Upload file screen appears, as shown in Figure 9.

The screenshot shows a web-based form titled "Upload a pdf or zip file". At the top left is a "Home" link. The main area has three input fields: "Case Id" containing "BPV-000006", "Choose File" with a "Browse..." button, and "Comments" with an up/down arrow. At the bottom are two buttons: "Upload" and "Cancel".

**Figure 9: Screen for Upload PDF or ZIP File Selection**

Complete the following steps:

1. Click on **Browse...** to browse to the file (.pdf, .zip, .doc, or .docx) to upload.
2. Optional: Add comments about the file.
3. Click on the **Upload** button.

After the upload is complete, the Uploaded Files row of the Case Record Details screen will update (see Figure 10), showing newly uploaded files. The **Upload** button is also available for adding additional files related to the case.

The screenshot shows a table titled "Uploaded Files:" with three columns: "File Name", "Date Uploaded", and "Comments". A single row is listed: "CDRDS\_users\_guide-1348692298000.pdf" uploaded on "9/26/12 4:44:58 PM". To the right of the table are "Download" and "Remove" buttons. At the bottom left is an "Upload" button.

**Figure 10: Upload Files List Row on the Case Record Details Screen**

### 3.5 Downloading a File

To download a copy of a file from the CDR-Lite to your local machine, find the file for download and click the corresponding **Download** link on the Uploaded Files row of the Case Record Details screen, as shown in Figure 10.

### 3.6 Submitting the Case for Review and Processing

After data entry is completed for a case, and before the DM or Pathology Resource Center (PRC) can begin their work on the case, the case status must be updated **twice**. The first update signifies that the required forms are complete. The second update signifies that any quality review at the BSS is complete, and the BSS is comfortable with the data quality. The need for an independent quality review depends on the experimental protocols in use for the study.

If the DM or PRC reviews indicate issues requiring BSS remediation, then the case status is set to **Remediation**, and the query tracker is used in resolving the issues.

#### 3.6.1 Process

The process for submitting the case is as follows:

1. Go to the Case Record Details screen, and click the **(Change)** link next to "Case Status." The Change Case Status screen appears.
2. Change the status to "Data Entry Complete," indicating that all case data have been entered.
3. Change the status to "BSS QA Review Complete," indicating that the BSS affirms that the case data are correct and consistent.
4. As appropriate, click **Save** to change the status.

When the status is “**BSS QA Review Complete**,” all update buttons disappear from screens, and data review and processing begin on the case. No further data entry can occur unless a later reviewer changes the case status to “**Remediation**.”

The Case Record List screen and home screen reflect the change in status.

### **3.6.2 Workflow**

When entering data into a new form, you will see a **Save** button at the bottom of the page. You may enter a portion of the data, save the form, and resume data entry later. During this time, the form status is “In Progress”. If the CDR-Lite detects errors, the errors are displayed in red, as in Figure 11.

The screenshot shows a web-based form titled "Edit PR-0006-F30\_BPV Colon Surgery/Anesthesia Form for Case BPV-000000". At the top, there is a "Home" link. Below the title, a message says "PR-0006-F30\_BPV Colon Surgery/Anesthesia Form for Case BPV-000000 created". A large red box highlights a list of validation errors:

- ① Surgery date is required.
- ① Please choose at least one Pre-operative IV Sedation drug and enter the dosage and time for the drug administered
- ① Please choose at least one Pre-operative IV Opiates drug and enter the dosage and time for the drug administered
- ① Please choose at least one Pre-operative IV Antiemetics drug and enter the dosage and time for the drug administered
- ① Please choose at least one Pre-operative IV Anti-acids drug and enter the dosage and time for the drug administered
- ① Time Anesthesia Induction began is required
- ① Please choose at least one Local Anesthesia Agents drug and enter the dosage and time for the drug administered
- ① Please choose at least one Regional (Spinal/Epidural) Anesthesia Agents drug and enter the dosage and time for the drug administered
- ① Please choose at least one IV Anesthesia Agents drug and enter the dosage and time for the drug administered
- ① Please choose at least one IV Narcotic/Opiate Agents drug and enter the dosage and time for the drug administered
- ① Please choose at least one IV Muscle Relaxants drug and enter the dosage and time for the drug administered
- ① Please choose at least one Inhalation Anesthesia Agents drug and enter the dosage and time for the drug administered
- ① Please enter details for at least one of the other medications administered during surgery.
- ① Time of First Incision is required
- ① Surgical Procedure is required
- ① Time of First Clamp is required
- ① Time of Organ Resection is required
- ① Please answer question #24 regarding the temperature details
- ① Carbon Dioxide level (CO2) recorded at time closest to organ resection is required
- ① Time when the specimen left Operating Room is required

**Figure 11: Example of an Attempt to Submit a Form with Missing Required Fields**

After you save a form that is complete and has no errors, the **Submit** button will appear. If the form passes validation and submits, the form status on the Case Details screen will appear as “Complete.”

After submission, you can edit any form by clicking **(View)** on the Case Record Details screen and then clicking **Resume Editing** at the bottom of the form. After editing a form, you must revalidate it by clicking **Submit**. When you submit a new version, the Date Submitted column on the Case Record Details screen will update with the new date and time.

## **3.7 Responding to Irregularities Found in Review: The Query Tracker**

After the BSS user submits a form, the DM team reviews the form for consistency with appropriate standard operating procedures (SOPs). If an issue arises during review, the DM team creates a new query describing the issue. The home page then shows a query tracker (QT) count in red.

Clicking on that QT count brings up the Query List screen, as shown in Figure 12. The far right column contains a magnifying glass icon. Clicking on that icon brings up the Show Query screen, detailing the issue. The data entry team (e.g., the BSS user) evaluates the description and takes appropriate action (perhaps by modifying values in question). After making changes, the data entry team adds a response to the query and submits the query for further review by the DM team. This cycle of DM review followed by data entry response continues until the issue is resolved. At that time, the DM team changes the query status to “Closed,” and the QT count goes down.

**Figure 12: Query List**

The process is as follows. **Note:** For this example, case “Steve1” has one query. However, a case could have multiple queries pending at once.

1. Go to the home screen (see Figure 13). Note the Case List has a red 1 in the QT column for Case ID Steve1.

**Figure 13: Example Home Screen with a Query Pending**

2. Click on the red number in the row with Case ID Steve1. This brings up the case-specific Query List for Steve1, with the query details, as shown in Figure 14.

The screenshot shows the CDR-Lite interface. At the top, there's a header bar with the CDR logo and navigation links like 'Logout', 'Org: Data Coordinating Center', 'Privileges: DM | PRC | LDS', and 'Help'. Below the header, a 'Query List' section displays a table of queries. One row is visible, representing a query for 'Kidney' with ID '4'. The table includes columns for ID, Issue type, Description, Organization, IS, Query type, Date opened, Opened by, Due Date, Date closed, Closed by, Initial Site Response to Query Open Date Duration, Query Open Date to Query Close Date Duration, and View (which contains a magnifying glass icon). A total count of '1' is shown below the table. At the bottom, there are logos for National Cancer Institute, Leidos Biomedical Research, Inc., NIH, and USA.gov.

**Figure 14: Query List with Case Details for a Query**

- Click on the magnifying glass icon in the View column to show the full set of case details (Figure 37).

### 3.8 Adding a New Candidate

A candidate is a potential participant in a study. Candidates become associated with a case once they have been screened, have consented, and have been determined to be eligible. Eligibility criteria are unique to each study and are beyond the scope of this document.

Use the following process to add a candidate:

- After identifying a candidate for entry into the CDR-Lite, go to the home screen, then click **Add a Candidate** (see Figure 15).

The screenshot shows the CDR-Lite Study Home Page. At the top, there's a header bar with the CDR logo and navigation links like 'Logout', 'Org: Data Coordinating Center', 'Privileges: DM | PRC | LDS', and 'Help'. Below the header, a 'WBL Home' section displays two tables: 'WBL Case List' and 'Candidate List'. The 'WBL Case List' table has columns for QT, Case ID, Primary Organ, BSS, Candidate ID, Specimens, Case Status, and Date Created. The 'Candidate List' table has columns for QT, Candidate ID, BSS, Study, Case ID, Subject Screening, Eligible?, Consented?, and Date Created. Red arrows point to the 'Add a Candidate' button in the top navigation bar and the 'View all Candidates >>' link at the bottom right of the 'Candidate List' table. At the bottom, there are logos for National Cancer Institute, Leidos Biomedical Research, Inc., NIH, and USA.gov.

**Figure 15: Adding a Candidate from the Study Home Page**

- The Create CandidateRecord form appears, as shown in Figure 16.

Welcome, brent1 | Logout  
Org: Data Coordinating Center  
Privileges: DM | PRC | LDS  
Help  
Session expires in: 29:15

BSS: BSS2

Comments: \*  
New Candidate for the WBL study.  
\*No PHI allowed in this field

Study: WBL

**Create**

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NATIONAL CANCER INSTITUTE leidos NIH USA.gov

Figure 16: Create CandidateRecord Form

3. Select your BSS.
4. The Study field pre-populates with the name of the study.
5. When you are finished, click on the **Create** or **Save** (if a previously created candidate) button. The screen updates, showing the candidate record, as shown in Figure 17. The following points are important:
  - i. The candidate has a unique identifier.
  - ii. The screen indicates that the Screening Enrollment form and Consent Verification form have not been completed; those forms must be completed before the candidate can proceed in the study.

Welcome, brent1 | Logout  
Org: Data Coordinating Center  
Privileges: DM | PRC | LDS  
Help  
Session expires in: 29:42

**CDR Comprehensive Data Resource**

**View Candidate Record Details for BSS2-F39DE33F-C**

Candidate record BSS2-F39DE33F-C created

Candidate Id	BSS2-F39DE33F-C ( <a href="#">Edit</a> )
Study	Brent1
Bss	BSS2 (BSS2)
Date Created	2015-12-30 14:05:11 EST
Screening Enrollment Form:	<a href="#">Not Started (Start)</a>
Consent Verification Form:	<a href="#">Not Started (Start)</a>
Is Consented	False
Is Eligible	False
Comments	New Candidate for the WBL study.

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NATIONAL CANCER INSTITUTE leidos NIH USA.gov

Figure 17: Example View Candidate Record Details

6. To exit without creating a new candidate, either use the back arrow on the browser or click on the Home icon.

**Note:** A new candidate (one whose record was just created) has not consented, been determined eligible, nor been linked to a case.

### 3.9 Adding a Screening Enrollment Form to a Candidate

The Screening Enrollment form is for entering general information about the candidate. Use the following process to add the form:

1. After entering information on the candidate, go to the home screen and click on the Candidate ID (Figure 18).

The screenshot shows the CDR Study Home Page. At the top, there is a header with the CDR logo and a welcome message for user 'brent1'. Below the header is a navigation bar with links for 'Home', 'Search', and 'Add a Candidate'. The main content area is titled 'WBL Home' and contains two tables: 'WBL Case List' and 'Candidate List'. The 'WBL Case List' table has columns for QT, Case ID, Primary Organ, BSS, Candidate ID, Specimens, Case Status, and Date Created. It displays a single row with 'No cases exist'. The 'Candidate List' table has columns for QT, Candidate ID, BSS, Study, Case ID, Subject Screening, Eligible?, Consented?, and Date Created. It displays a single row for candidate 'BSS2-F39DE33F-C' with the study 'Brent1', subject screening status 'Not Started (Start)', and both 'Eligible?' and 'Consented?' set to 'No'. At the bottom of the page, there are logos for National Cancer Institute, Leidos Biomedical Research, Inc., NIH, and USA.gov, along with the text 'CDR-Lite v1.0-M8'.

**Figure 18: Study Home Page with One Candidate in List**

2. The Candidate List contains a field titled "Subject Screening" that has an entry "Not Started (Start)." Click on **Start** to go to the Candidate Screening Enrollment form (Figure 19).

The screenshot shows the 'Create Candidate Screening Enrollment Form' page. At the top, there is a header with the CDR logo and a welcome message for user 'brent1'. Below the header is a navigation bar with links for 'Home' and 'Candidate Screening Enrollment Form List'. The main content area is titled 'Create Candidate Screening Enrollment Form' and contains a section for 'Candidate Details'. It shows the Candidate ID 'BSS2-F39DE33F-C' and BSS 'BSS2'. There are four numbered questions: 1. Name of person who performed Screening (text input field), 2. Does the Candidate meet all eligibility criteria defined within the Study Protocol? (radio buttons for Yes and No), 3. Comments (text area), and 4. Screening Date (date input field with calendar icon and clear button). At the bottom, there are 'Save' and 'Cancel' buttons.

**Figure 19: Create Candidate Screening Enrollment Form**

3. Fill in the following required fields:
  - i. Name of person who performed Screening: Enter the name.
  - ii. Does the Candidate meet all eligibility criteria defined within the Study Protocol? Click on Yes or No, as appropriate.
  - iii. Comments: Record any insights from the screener.
  - iv. Screening Date: Use the calendar tool to select the date.
4. Save the information in the fields by clicking on the **Save** button. This records the entries and validates the form. If the form passes automatic validation, the **Submit** button appears (Figure 20). To exit without recording the entries, click the **Cancel** button, use the browser's back button, or click on the Home icon.

The screenshot shows the 'Edit Candidate Screening Enrollment Form' page. At the top, there is a header with the CDR logo and a navigation bar with links like 'Home', 'Logout', 'Org: Data Coordinating Center', 'Privileges: DM | PRC | LDS', 'Help', and a session expiration notice ('Session expires in: 28:11'). Below the header, the title 'Edit Candidate Screening Enrollment Form' is displayed, followed by a message indicating a 'Screening Enrollment form for Candidate BSS2-F39DE33F-C created'. The main content area is titled 'Candidate Details' and contains four numbered input fields: 1. Name of person who performed Screening (text input: 'Porch Screener'), 2. Does the Candidate meet all eligibility criteria defined within the Study Protocol? (radio buttons: 'Yes' (selected) and 'No'), 3. Comments (text area), and 4. Screening Date (date input: '12/21/2015', calendar icon, and 'Clear' button). At the bottom of the form are two buttons: 'Save' and 'Submit'.

**Figure 20: Example Edit Candidate Screening Enrollment Form**

5. If you need to make corrections, change the appropriate fields before clicking on the **Save** button. The form status remains “In Progress” until the form is successfully submitted. Click on the **Submit** button once all fields are correct. The CDR-Lite will then go back to the Candidate Details screen, which will display the updated status (Figure 21).



Welcome, brent1 | Logout  
Org: Data Coordinating Center  
Privileges: DM | PRC | LDS  
Help  
Session expires in: 29:54

[Home](#)

### View Candidate Record Details for BSS2-F39DE33F-C

Screening Enrollment form for Candidate BSS2-F39DE33F-C submitted

Candidate Id	BSS2-F39DE33F-C ( <a href="#">Edit</a> )
Study	Brent1
Bss	BSS2 (BSS2)
Date Created	2015-12-30 14:05:11 EST
Screening Enrollment Form:	<a href="#">Completed (View)</a>
Consent Verification Form:	<a href="#">Not Started (Start)</a>
Is Consented	False
Is Eligible	True
Comments	New Candidate for the WBL study.

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**Figure 21: Updated View Candidate Record Details**

### 3.10 Candidate Consent Form

After you add or edit a new candidate, you must enter the consent information on the Candidate Consent Form. The CDR-Lite tracks all candidates regardless of consent status. Items 1 through 11 on the form determine eligibility, and the remaining items contain important information that does not affect eligibility.

Use the following process to complete the form. Complete only the top portion before saving the form. Questions 13 and 15 require comments if answered “Yes.”

- From the study home page, find the candidate to be consented (see Figure 22).

**CDR Comprehensive Data Resource**

Welcome, brent1 | Logout  
Org: Data Coordinating Center  
Privileges: DM | PRC | LDS  
Help  
Session expires in: 29:47

[Home](#) [Search](#) [Add a Candidate](#)

**WBL Home**

WBL Case List	QT	Case ID	Primary Organ	BSS	Candidate ID	Specimens	Case Status	Date Created
No cases exist								

Most recently created on top [View all Cases >>](#)

Candidate List	QT	Candidate ID	BSS	Study	Case ID	Subject Screening	Eligible?	Consented?	Date Created
	0	BSS2-F39DE33F-C	BSS2	Brent1		<a href="#">Completed (View)</a>	<a href="#">Yes</a>	<a href="#">No</a>	12/30/2015 14:05

Most recently created on top [View all Candidates >>](#)

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**Figure 22: Study Home Page, Where Candidate Needs Consent Added**

- Click on the Candidate ID to go to the View Candidate Record Details screen (Figure 23).



Welcome, brent1 | Logout  
 Org: Data Coordinating Center  
 Privileges: DM | PRC | LDS  
 Help  
 Session expires in: 29:45

[Home](#)

### View Candidate Record Details for BSS2-F39DE33F-C

Candidate Id	BSS2-F39DE33F-C ( <a href="#">Edit</a> )
Study	Brent1
Bss	BSS2 (BSS2)
Date Created	2015-12-30 14:05:11 EST
Screening Enrollment Form:	<a href="#">Completed (View)</a>
Consent Verification Form:	<a href="#">Not Started (Start)</a>
Is Consented	False
Is Eligible	True
Comments	New Candidate for the WBL study.

CDR-Lite v1.0-M8



**Figure 23: Candidate Details with Consent Verification Needed**

3. In the field labeled “Consent Verification Form,” click on the highlighted word **Start** to go to the Create Candidate Consent Verification Form (Figure 24). Fill in the following fields:
  - i. Site Protocol Number: Enter the unique identifier given to the protocol at this BSS for the study.
  - ii. Person Obtaining Consent: Enter the name of the person at the BSS obtaining consent.
  - iii. Relationship to donor: Choose “self,” “spouse,” “parent,” “sibling,” or “other (specify)” to indicate the consenting person’s relationship to the donor.
  - iv. Does the candidate meet all eligibility criteria within the Study Protocol? Select “Yes” or “No.”
  - v. Was Consent Obtained? Select “Yes” or “No.”
  - vi. Institutional version of Informed Consent Document: Enter the version of the informed consent document that was in force when the candidate consented; the version may change during the course of a long study.
  - vii. IRB Approval Date: Choose the date that the institutional review board (IRB) approved the study protocol.
  - viii. IRB Expiration Date: Choose the date that the IRB approval expires.
  - ix. Willingness to be contacted for Other Studies: Select “Yes” or “No.”
  - x. Specify Limitations if any: Enter any limits on consent that the participant stipulated.
  - xi. Comments: Enter any notes from the person obtaining consent; this field is optional.

# CDR Comprehensive Data Resource

Welcome, brent1 | Logout  
 Org: Data Coordinating Center  
 Privileges: DM | PRC | LDS  
 Help  
 Session expires in: 29:05

[Home](#) [Print](#)

## Create Candidate Consent Verification Form

### Candidate Details

Candidate ID: BSS2-F39DE33F-C BSS: BSS2

1. Site Protocol Number
2. Person obtaining consent
3. Relationship to donor
4. Does candidate meet all eligibility criteria within the study Protocol
5. Was Consent Obtained
10. Institutional version of Informed Consent Document
11. IRB Approval Date
12. IRB Expiration Date
13. Willingness to be contacted for Other Studies
14. Specify Limitations if any

<input type="text"/>	<input type="text"/>	<input type="text"/>	
<input type="radio"/> Yes	<input type="radio"/> No	<input type="radio"/> Yes	<input type="radio"/> No
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="button" value="Clear"/>	<input type="button" value="Clear"/>	<input type="radio"/> Yes	<input type="radio"/> No
<input type="text"/>		<input type="text"/>	
<input type="text"/>		<input type="text"/>	

15. Comments

[Save](#)

CDR-Lite v1.0-M8



**Figure 24: Create Candidate Consent Validation Form**

4. When the form is complete, click on the **Save** button.
5. The screen will show an edit window for the Consent Validation Form. Review the values for the fields and modify them as necessary. When you are finished, click on the **Save** button again.
6. When the form is complete and accurate, click on the **Submit** button. The CDR-Lite will return to the Candidate Details screen. If the subject has consented, additional fields will become visible.

Home

**View Candidate Record Details for BSS2-F39DE33F-C**

Consent Verification Form for Candidate BSS2-F39DE33F-C submitted

Candidate Id	BSS2-F39DE33F-C <a href="#">(Edit)</a>
Study	Brent1
Bss	BSS2 (BSS2)
Date Created	2015-12-30 14:05:11 EST
Screening Enrollment Form:	<a href="#">Completed (View)</a>
Consent Verification Form:	<a href="#">Completed (View)</a>
Is Consented	True
Is Eligible	True
Demographics Form:	<a href="#">Not Started (Start)</a>
Health History Form:	<a href="#">Not Started (Start)</a>
Social History Form:	<a href="#">Not Started (Start)</a>
Case List	<ul style="list-style-type: none"> <li>▪ <a href="#">Add CaseRecord</a></li> </ul>
Comments	New Candidate for the WBL study.

**Figure 25: Expanded View Candidate Record Details Form**

### 3.11 Entering Candidate Demographic Data

The Demographics form records basic information about a candidate, such as height, weight, race, and ethnicity. All candidates must have an associated Demographics form. Research has demonstrated that a variety of factors—such as the overall health of the patient, food and beverages consumed prior to biospecimen collection, the patient's medication status, and the time of day at which the biospecimen is collected—may affect levels of analytes.

Use the following process to enter demographic data:

1. Go to the View Candidate Record Details form (Figure 25).
2. Find the item Demographics form, and click on the word **Start**, in blue. The CDR-Lite will show the Demographics form (Figure 26). The Demographics and other web-based forms appear only after both Screening and Consent forms are entered.

# CDR Comprehensive Data Resource

Welcome, brent1 | Logout  
Org: Data Coordinating Center  
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Help  
Session expires in: 29:39

[Home](#) [Print](#)

## Create Candidate Demographics form

### Candidate Details

Candidate ID: BSS2-F39DE33F-C    BSS: BSS2

1. Date Of Birth

 [Clear](#)

2. Gender

Male  Female  Other

3. Height(in)

(inches)

4. Weight(lbs)

(lbs)

5. BMI

0

6. Race(choose all that apply)

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or other Pacific Islander
- White
- Unknown

7. Ethnicity

- Hispanic or Latino
- Not-Hispanic or Latino
- Not reported
- Unknown

[Save](#)

CDR-Lite v1.0-M8



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**Figure 26: Create Candidate Demographics Form**

3. Enter the data as follows:

- i. Date of Birth: Note that this is PII. Use the calendar tool to select the candidate's birth date.
  - ii. Gender: Select "Male," "Female," or "Other." If you select "Other," specify the gender information in the text field that appears.
  - iii. Height: Enter the candidate's height in inches.
  - iv. Weight: Enter the candidate's current weight in pounds.
  - v. BMI: This field automatically calculates the candidate's body mass index.
  - vi. Race: This field allows for multiple responses. Select all that apply.
  - vii. Ethnicity: This field allows for multiple responses. Select all that apply.
4. After completing all fields, click on the **Save** button. The CDR-Lite will automatically check for completeness. Any problems found show in a red box at the top of the screen, and the questions are boxed in red. The user must fix these problems before being allowed to continue.

5. Click on the **Submit** button. This certifies that the data are complete and ready for DM review. The screen will shift back to the View Candidate Record, as shown in Figure 27. Note how the Demographics Form field has changed to Completed.

The screenshot shows the CDR-Lite application interface. At the top, there is a header with the CDR logo and the text "Comprehensive Data Resource". On the right side of the header, there is a user session information block. Below the header, the main content area is titled "View Candidate Record Details for BSS2-F39DE33F-C". A message indicates that a "Consent Verification Form for Candidate BSS2-F39DE33F-C submitted". The main content is a table listing various fields and their values:

Candidate Id	BSS2-F39DE33F-C ( <a href="#">Edit</a> )
Study	Brent1
Bss	BSS2 (BSS2)
Date Created	2015-12-30 14:05:11 EST
Screening Enrollment Form:	<a href="#">Completed (View)</a>
Consent Verification Form:	<a href="#">Completed (View)</a>
Is Consented	True
Is Eligible	True
Demographics Form:	<a href="#">Not Started (Start)</a>
Health History Form:	<a href="#">Not Started (Start)</a>
Social History Form:	<a href="#">Not Started (Start)</a>
Case List	<a href="#">Add CaseRecord</a>
Comments	New Candidate for the WBL study.

**Figure 27: Expanded View Candidate Record Details**

To make changes in the completed Demographics form, click on **View**, which shows the record information (see Figure 28), and then click on the **Resume Edit** button. After making those changes, click on the **Save** or **Submit** button to record the changes.

Welcome, brent1 | [Logout](#)  
Org: Data Coordinating Center  
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[Help](#)  
Session expires in: 29:50

[Home](#) [Print](#)

## Show Demographics for Candidate

### Candidate Details

Candidate ID: BSS2-F39DE33F-C    BSS: BSS2

1. Date Of Birth	01/05/1998
2. Gender	Female
3. Height (inches)	500
4. Weight (lbs)	150
5. BMI	0.42
6. Race	Unknown
7. Ethnicity	Not reported

[Resume Edit](#)

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**Figure 28: Show Demographics for Candidate with Resume Edit Button**

### 3.12 Entering Candidate Health History Form

Entering health history has several steps. First, create a health history record, containing only the source of the health history and the candidate's cancer history. Next, create the general medical history records. Finally, add the medications history.

The following three sections describe the process for entering health history information.

#### 3.12.1 Creating the Health History Record

1. Go to the View Candidate Record Details form (Figure 25).
2. Find the item Health History Form, and click on the word **Start**, in blue. The CDR-Lite will show the Create Health History form (Figure 29).

The screenshot shows the 'Create Health History' page of the CDR-Lite application. At the top right, there is a user menu with options like 'Logout', 'Org: Data Coordinating Center', 'Privileges: DM | PRC | LDS', 'Help', and a session expiration message 'Session expires in: 27:27'. Below the menu, a 'Home' link is visible. The main content area has a title 'Create Health History'. It contains two input fields: 'Source' (with a dropdown arrow) and 'History Of Cancer' (with a dropdown arrow showing 'No'). A 'Create' button is located below these fields. At the bottom of the page, there is footer information including 'CDR-Lite v1.0-M8', logos for 'National Cancer Institute', 'Leidos Biomedical Research, Inc.', 'NIH National Institutes of Health', and 'USA.gov Government Made Easy', along with a copyright notice '© 2010 Leidos Biomedical Research, Inc.'.

**Figure 29: Create Health History Form**

3. Enter the data as follows:
  - i. Source: Select “Self-Report,” “Medical Record,” or “Family Report” from the pull-down menu to indicate the source of health history information.
  - ii. History of Cancer: Select “Yes,” “No,” or “Unknown” to indicate whether this candidate has ever had cancer before.
4. After answering both questions, click on the **Create** button to store the information. If a field was not completed, then an error message will appear at the top of the screen, and the missing field will have a red line around it.
5. After you successfully create a health history record, the CDR-Lite will display the Show Health History screen (see Figure 30).



Welcome, brent1 | [Logout](#)  
 Org: Data Coordinating Center  
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[Help](#)  
 Session expires in: 28:33

[Home](#)

## Show Health History

[Health History 2 created](#)

Candidate Record

BSS2-F39DE33F-C

Source

Medical Record

History Of Cancer

Unknown

Date Created

01/04/2016

[Show General Medical History](#)

[Show Medications History](#)

[Edit](#)

[Submit](#)

[Display Full Report](#)

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**Figure 30: Show Health History Screen**

### 3.12.2 Adding General Medical History

- Click on the text in blue, **Show General Medical History**, on the Show Health History screen. This brings up the General Medical History Candidate Details form, shown in Figure 31.

**Figure 31: General Medical History Form**

- Click on the **Add** button. An additional portion of the screen for recording an instance of disease history will appear (Figure 32). Complete the following fields:
  - Disease Name: Enter the name of the individual disease.
  - Month Year of First Diagnosis: Select, from the pull-down menus, when the diagnosis was made.
  - Treatment: Select Yes, No, or Unknown to indicate whether the disease was treated.
  - Month Year of Last Treatment: Select, from the pull-down menus, the date of the last treatment for this disease.

- v. Source: Select Self-Reported, Medical History, or Family Report to indicate the source of this disease history record.

The screenshot shows the CDR Comprehensive Data Resource software interface. At the top, there is a header bar with the CDR logo, the text "Comprehensive Data Resource", and a user session status: "Welcome, brent1 | Logout", "Org: Data Coordinating Center", "Privileges: DM | PRC | LDS", "Help", and "Session expires in: 29:52". Below the header, a navigation menu includes "Home" and "show Health History". The main title is "General Medical History for candidate BSS2-F39DE33F-C". Under "Candidate Details", it shows "Candidate ID: BSS2-F39DE33F-C" and "BSS: BSS2". A table displays one row of data: ID 2, Disease Name "aaa", Month Year Of First Diagnosis "01/2014", Treatment "No", and Month Year Of Last Treatment "06/2015". Below this, a section titled "Create General Medical History" contains fields for "Disease Name", "Month Year Of First Diagnosis", "Treatment", "Month Year Of Last Treatment", and "Source". A "Create" button is located at the bottom left of this section. At the bottom of the page, there is footer text "CDR-Lite v1.0-M8" and logos for the National Cancer Institute, Leidos Biomedical Research, Inc., NIH, National Institutes of Health, and USA.gov.

**Figure 32: Create General Medical History Record Fields**

3. After completing all fields, click on the **Create** button to store the information.
4. Repeat to enter all disease history.
5. Once you have entered all disease history, click the Show Health History icon near the top of the display.

### 3.12.3 Adding General Medications History

1. Click on the text in blue, **Show Medications History**, on the Show Health History screen to bring up the Medications History list, shown in Figure 33.

Welcome, brent1 | Logout  
Org: Data Coordinating Center  
Privileges: DM | PRC | LDS  
Help  
Session expires in: 29:08

ID	Medication Name	Date of Last Administration	Source	Date Created

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**Figure 33: Medications History List for a Candidate**

- For each medication listed in the health records, click on the **Add** button, fill out the fields revealed on the Medications History form, and click on the **Create** button (see Figure 34).

Welcome, brent1 | Logout  
Org: Data Coordinating Center  
Privileges: DM | PRC | LDS  
Help  
Session expires in: 21:23

ID	Medication Name	Date of Last Administration	Source	Date Created

**Create Medication History**

Medication Name:

Date of Last Administration:

Source:

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**Figure 34: Additional Fields for Creating an Entry in the Medications History**

- After entering all medications, click on the Show Health History icon near the top of the screen. This will bring up the Show Health History screen. After entering all medical history, click on the **Submit** button, submitting this information for review. The View Candidate Record Details screen will appear. If the submission was successful, a note will display under the screen title.

### 3.13 Entering Candidate Social History Form

The Create Social History form records information about smoking and alcohol exposure. Use the following process to complete the form:

- On the View Candidate Record Details screen, find the line "Social History Form," and click on the word in blue, **Start**.
- This brings up the Create Social History screen for a particular candidate, shown in Figure 35.

# CDR Comprehensive Data Resource

Welcome, brent1 | [Logout](#)  
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[Help](#)  
 Session expires in: 29:01

[Home](#)

## Create Social History

### Candidate Details

Candidate ID: BSS2-F39DE33F-C    BSS: BSS2

#### Alcohol History

**1. Alcohol consumption:**

- Lifelong non-drinker
- Alcohol consumption up to 2 drinks per day
- Alcohol consumption more than 2 drinks per day
- Consumed alcohol in the past, but currently a non-drinker
- Alcohol consumption history not available

#### Tobacco smoking history

**3. Tobacco smoking history:**

- Lifelong non-smoker: Less than 100 cigarettes smoked in lifetime
- Current smoker: Includes daily and non-daily smokers
- Current reformed smoker for more than 15 years
- Current reformed smoker for less than 15 years
- Smoking history not available

**8. Was the Participant exposed to secondhand smoke?**

- No
- Yes
- Not Available

[Save](#)

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**Figure 35: Create Social History Screen**

3. Each question allows only a single response. Answer each question, and then click on the **Save** button.
4. The CDR-Lite will confirm that all questions have a response. If so, the **Save** button at the bottom will be replaced by two buttons, **Update** and **Submit**. If you need to change the information, alter the values and click **Update**. If the information is complete, click **Submit**. The CDR-Lite will display the View Candidate Record Details screen.

### 3.14 Adding Candidate Case Records

When a candidate is found eligible, he or she may be accepted into a study. Upon acceptance, the candidate becomes associated with a case. The case record includes all information detailing tissue collection, processing, and storage.

Use the following process to add a candidate case record:

1. On the View Candidate Record Details screen (Figure 17), find the Case List item. Click on the blue text to the right, **Add Case Record**. The CDR-Lite will display the Create Case Record screen, shown in Figure 36.

The screenshot shows the 'Create Case Record' interface. At the top left is the 'CDR Comprehensive Data Resource' logo. On the right is a user session header: 'Welcome, brent1 | Logout', 'Org: Data Coordinating Center', 'Privileges: DM | PRC | LDS', 'Help', and 'Session expires in: 29:31'. Below the header is a navigation bar with a 'Home' icon and link. The main form has several input fields: 'BSS' (set to 'Candidate Record'), 'Case Id' (empty), 'Case Status' (set to 'Data Entry Underway'), 'Primary Tissue Type' (a dropdown menu showing '-Select one-'), and 'Study' (set to 'WBL'). At the bottom are 'Create' and 'Cancel' buttons. The footer contains logos for the National Cancer Institute, Leidos Biomedical Research, Inc., NIH, and USA.gov, along with the text 'CDR-Lite v1.0-M8'.

**Figure 36: Creating a Case Record for a Candidate**

2. Complete the fields as follows:
  - i. Case ID: Enter the unique identifier given to this case.
  - ii. Case Status: This field is automatically generated as Data Entry Underway. To update it, use the Show Case Record Details screen, shown in Figure 37.
  - iii. Primary Tissue Type: Select one type from the list of tissues involved in this study.
  - iv. Study: This field automatically displays the name of the current study.
3. Click on the **Create** button. The CDR-Lite will display the Show Case Record Details screen for the case number just entered. When the case is successfully recorded, a note will appear under the title, as shown in Figure 37.



Welcome, brent1 | [Logout](#)  
 Org: Data Coordinating Center  
 Privileges: DM | PRC | LDS  
[Help](#)  
 Session expires in: 27:47

[Home](#)

### Show Case Record Details for abcd-12345

[Case record abcd-12345 created](#)

Case Id	abcd-12345 ( <a href="#">Edit</a> )	
Collection Type	Surgical	
Case Status	Data Entry Underway ( <a href="#">Change</a> )	
Study	Brent1	
BSS	<b>BSS2</b>	
Primary Organ	Kidney	
Candidate Record ID	<b>BSS2-F39DE33F-C</b>	
Date Created	2016-01-04 16:37:37 EST	
Last Updated	2016-01-04 16:37:37 EST	
Uploaded Files:	<a href="#"></a>	
<a href="#"></a> Upload		
CRF Status:		
Form	Status	Date Submitted
Blood Collection and Processing Form	<b>Not Started (Start)</b>	
Surgery Anesthesia Form	<b>Not Started (Start)</b>	
Tissue Gross Evaluation Form	<b>Not Started (Start)</b>	
Tissue Receipt and Dissection Form	<b>Not Started (Start)</b>	
Tissue Preservation Form (Add specimens)	<b>Not Started (Add Specimens)</b>	
Tissue Processing-Embedding Form	<b>Not Started (Start)</b>	
Slide Sectioning Form (Add slides)	<b>Not Started (Start)</b>	
Slide Prep and staining Form	<b>Not Started (Start)</b>	
Surgical Pathology Form	<b>Not Uploaded</b> <a href="#"></a>	
Clinical Data Entry Form	<b>Not Started (Start)</b>	

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**Figure 37: Show Case Record Details Screen**

4. Click on the blue text (**Change**) in the Case Status line to bring up the Change Case Status screen, shown in Figure 38. Select the new status of the case from the pull-down menu, and click **Update**. The CDR-Lite will return to the updated Show Case Record Details page. Figure 3 shows a typical progression of Case Status values.

**Figure 38: Change Case Status Screen**

5. You must complete each form in the core record form's Status. Sections 3.15 through 3.24 describe these forms and the fields.

### 3.15 Adding a Blood Collection and Processing Form

The Blood Form collects information on blood draws. Separate blood draw forms cover the details of each blood draw. To add a form, take the following steps:

1. On the Show Case Record Details screen (Figure 37), find the Blood Collection and Processing Form. Click on the blue text, **Start**, to go to the Edit Blood Form screen, shown in Figure 39.

**Figure 39: Editing a Blood Form**

2. The following fields populate automatically with information previously entered:
  - i. Case ID: Unique ID given to the case associated with this Blood form. Click the ID to navigate to the Show Case Record Details screen (Figure 37).
  - ii. Primary Organ: Organ in the study associated with this case

- iii. BSS: Biospecimen source site associated with this collection
- 3. Complete the one optional field as follows:
  - i. Comment: Enter any free text necessary for describing details across all draws.
- 4. Click on the **Add Blood Draw** button. The CDR-Lite will go to the Edit Blood Draw form used to record details of each draw. Because of the large number of fields in this form, Figure 40 shows a slightly scaled-down version of the entire form.

# CDR Comprehensive Data Resource

[Home](#) [Blood Form](#)

Welcome, brent1 | [Logout](#)  
 Org: Data Coordinating Center  
 Privileges: DM | PRC | LDS  
[Help](#)  
 Session expires in: 26:21

## Edit Blood Draw

### Blood Collection Instruction

1. The minimum requirement was met for blood collection as per the SOP:  Yes  No

2. Blood draw type:

3. Date and time blood was drawn:  [Clear](#)

4. Blood draw was performed by:

5. Name of person performed blood draw:

6. Were there any issues or difficulties with the blood draw?  Yes  No

7. Blood Collection Comments:

### Blood Processing Overview

8. Date and time blood received in the lab:  [Clear](#)

9. Blood tube(s) received in lab by:

10. Temperature in lab when blood was received:  °C

11. Humidity in lab when tube(s) were received:  %

### 12. Blood Collection Tube Details

Collection Tube Specimen Barcode ID	Specimen Tube Type	Processed for	Volume Collected (ml)	Action
<a href="#">Add</a>				

13. Time blood processing began:  [Clear](#)

14. Time blood processing completed:  [Clear](#)

### 15. Blood fraction aliquot details

#### 15a. Blood fraction cryovial aliquot information

Blood Collection Tube Source, Barcode ID	Aliquot Barcode ID:	Aliquot Type:	Aliquot Volume (ml)	Scanned ID: Record when Aliquot Frozen	Time Aliquot Frozen	Scanned ID: Record when Aliquot Transferred to Freezer	Time Aliquot Transferred to Freezer	Action

15b. Aliquots were processed by:

15c. Frozen aliquot transfer completed by:

### Note Deviations from SOP, Processing or Storage Issues

16. Blood Processing was performed in accordance with specified SOP:  Yes  No

17. Blood Processing Comments:

18. Was Clotting observed in a collection tube?  Yes  No

19. Was presence of Gross Hemolysis observed?  Yes  No

20. Storage Issues:

[Save](#) [Delete](#)

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Figure 40: Edit Blood Draw Screen

5. Complete the fields as follows:

- i. The minimum requirement was met for blood collection as per the SOP: Select “Yes” or “No”; this field is required. The exact volume varies between studies and is specified in the study-specific SOP for this draw.
- ii. Blood draw type: Select “Pre-operative” or “Post-operative.” These options are controlled by the BloodDrawType list in the vocabulary.
- iii. Date and time blood was drawn: Click on the calendar icon and select the date and time.
- iv. Blood draw was performed by: Use the pull-down menu to select the role of the individual performing the sampling.
- v. Name of person performed blood draw: Enter the name of the individual performing the sampling.
- vi. Were there any issues or difficulties with the blood draw? Select “Yes” or “No”; this field is required.
- vii. Blood Collection Comments: Describe anything specific about this individual draw.
- viii. Date and time blood received in the lab: Click on the calendar icon and select the date and time.
- ix. Blood tube(s) received in lab by: Enter the name of the person receiving the tubes.
- x. Temperature in lab when blood was received: Enter the ambient air temperature in the room where the lab is located.
- xi. Humidity in lab when tube(s) were received: Enter the ambient air relative humidity in the room where the lab is located.
- xii. Blood Collection Tube Details: For each tube in the collection, add a line. Click on the **Add** button to display a sub-screen for entering the following information for each tube used.
  - a. Collection Tube Specimen Barcode ID: Enter the unique barcode on the collection tube used.
  - b. Specimen Tube Type: Select from a list of potential collection tube types. The list is controlled by the BloodTubeType list in the vocabulary.
  - c. Processed for: Select from a list of potential targets, such as DNA, RNA, and Plasma. The list is controlled by the BloodCollectionReason list in the vocabulary.
  - d. Volume Collected: Enter the number of milliliters of product collected in this tube.When you have entered all tubes, click on the **Save** button.
- xiii. Time blood processing began: Click on the calendar icon to select the date and time.
- xiv. Time blood processing completed: Click on the calendar icon to select the date and time.
- xv. Blood fraction aliquot details:
  - a. Blood fraction cryovial aliquot information: After entering tubes for question 12, click on the **Add** button to open a sub-screen for recording additional information about frozen specimens:
    1. Blood Collection Tube Source, Barcode ID: Select tube IDs from a prepopulated pull-down menu.
    2. Aliquot Barcode ID: Enter the ID associated with a single portion of the sample.
    3. Aliquot Type: Select the blood product type from the pull-down menu.
    4. Aliquot Volume (ml): Enter the volume of this particular part of the overall sample.
    5. Scanned ID: Record when Aliquot Frozen: Record the tube ID at the time of freezing.
    6. Scanned ID: Record when Aliquot Transferred to Freezer: Record the tube ID at the time of transfer to freezer storage.
    7. Time Aliquot Transferred to Freezer: Enter the time of material transfer to freezer storage.
  - b. Aliquots were processed by: Enter the name of the individual performing the processing.

- c. Frozen aliquot transfer completed by: Enter the name of the individual moving the aliquots to the freezer storage.
  - xvi. Blood Processing was performed in accordance with specified SOP: Select “Yes” or “No”; this field is required.
  - xvii. Blood Processing Comments: Enter any notes specific to processing.
  - xviii. Was Clotting observed in a collection tube? Select “Yes” or “No”; this field is required.
  - xix. Was presence of Gross Hemolysis observed? Select “Yes” or “No”; this field is required.
  - xx. Storage Issues: Describe any problems or incidents in storage.
6. When you are done, click on the **Save** button. Any problems will display at the top of the screen.
  7. When all problems are resolved, click on the **Save** button. A message stating “Draw ## Updated” will appear at the top of the form.
  8. To enter additional draws, click on the Blood Form icon near the top of the form, and repeat the process.

### **3.16 Adding a Surgery Anesthesia Form**

The Surgery Anesthesia form records pre-analytic variable information about the collection event. This information is critical in understanding the context of the tissue collection. To add the form, use the following process:

1. On the Show Case Record Detail screen (Figure 33), find the Surgery Anesthesia Form. Click on the blue text to the right, **Start**, to go to the Create Surgery Anesthesia Form screen, shown in Figure 41.
2. The following fields populate automatically with information previously entered:
  - i. Case ID: Unique ID given to the case associated with this blood form. Clicking the ID navigates the CDR-Lite to the Show Case Record Details screen, shown in Figure 37.
  - ii. Primary Organ: Organ in the study associated with this case
  - iii. BSS: Biospecimen source site associated with this collection

 <b>Comprehensive Data Resource</b>		Welcome, brent   Logout DRC Data Coordinating Center Data Coordinating Unit (DCU)   LDS Help Session expires on: 29/15
<b>Edit Surgery Anesthesia Form</b> <span style="background-color: #e0f2e0; border: 1px solid black; padding: 2px;">Surgery Anesthesia Form for abcd-12345 created</span>		
<b>Case Details</b> Case ID: abcd-12345 Primary Organ: Kidney BSS: 5552		
Pre-operative medications administration: Record medications administered in the holding area prior to participant entering the operating room. If additional space is required record any additional pre-operative medications administered in #6 below.		
1. Date of surgery: <input type="text"/> <input type="button" value="Clear"/>		
2. Pre-operative IV Sedation administered: <input type="radio"/> Yes <input type="radio"/> No		
3. Pre-operative IV Opiates administered: <input type="radio"/> Yes <input type="radio"/> No		
4. Pre-operative IV Antiemetics administered: <input type="radio"/> Yes <input type="radio"/> No		
5. Pre-operative IV Antacid administered: <input type="radio"/> Yes <input type="radio"/> No		
6. Other Pre-operative IV Medications administered: <input type="radio"/> Yes <input type="radio"/> No		
Type of anesthesia administered: Please record ONLY ANESTHESIA agents administered PRIOR TO REMOVAL OF ORGAN. If additional space is required record any additional anesthesia agents administered in #13 below.		
7. Local anesthesia agents administered: <input type="radio"/> Yes <input type="radio"/> No		
8. Regional (Spinal/Epidural) anesthesia agents administered: <input type="radio"/> Yes <input type="radio"/> No		
9. IV anesthesia agents administered: <input type="radio"/> Yes <input type="radio"/> No		
10. IV Narcotic/Opiate agents administered: <input type="radio"/> Yes <input type="radio"/> No		
11. IV Muscle Relaxants administered: <input type="radio"/> Yes <input type="radio"/> No		
12. Inhalation anesthesia agents administered: <input type="radio"/> Yes <input type="radio"/> No		
13. Additional anesthesia agents used: <input type="radio"/> Yes <input type="radio"/> No		
Surgery information: Indicate whether any of the following medications were administered during surgery.		
14. Other medications administered during surgery prior to removal of the organ: Was insulin administered during surgery? <input type="radio"/> Yes <input type="radio"/> No Were Steroids administered during surgery? <input type="radio"/> Yes <input type="radio"/> No Were antibiotics administered during surgery? <input type="radio"/> Yes <input type="radio"/> No Were other medications administered during surgery? <input type="radio"/> Yes <input type="radio"/> No		
<b>Surgical procedure details</b>		
15. Time of first incision: <input type="text"/>		
16. Surgical procedure: <input type="text"/>		
Surgical method: <input type="text"/>		
17. Time of first clamp: <input type="text"/>		
18. Time of second clamp: <input type="text"/>		
19. Time of organ resection: <input type="text"/>		
20. In Vivo Intra-operative Ischemic Period (minutes): <input type="text"/>		
21. Describe Blood Pressure excursions from time of anesthesia induction to 15 minutes post induction <input type="text"/>		
22. Describe Blood Pressure excursions from 15 minutes post anesthesia induction to organ excision: <input type="text"/>		
23. Temperature: First Participant temperature recorded in OR: <input type="text"/> °C <input type="button" value="▼"/> Time of first temperature: <input type="text"/> Second Participant temperature recorded in OR: <input type="text"/> °C <input type="button" value="▼"/> Time of second temperature: <input type="text"/>		
24. Describe Epochs of Oxygen (O2) desaturation of <92% for >5 minutes prior to organ excision: <input type="text"/>		
25. Carbon Dioxide level (CO2) recorded at time closest and prior to organ excision: <input type="text"/> mmHg <input type="button" value="▼"/>		
Intraoperative blood product administration: 26a. Albumin Units: <input type="text"/> ml 26b. Packed Red Blood Cells: <input type="text"/> Units 26c. Platelets: <input type="text"/> ml 26d. Fresh Frozen Plasma: <input type="text"/> Units		
Participant fluid output: 27. Blood loss: <input type="text"/> ml At what point was blood loss recorded? Select one: <input type="text"/>		
28. Urine volume collected: <input type="text"/> ml At what point was urine output recorded? Select one: <input type="text"/>		
Additional information 29. Duration of fasting prior to surgery: <input type="text"/> hours		
30. Describe pre-operative bowel preparation prior to surgery: <input type="text"/>		

**Figure 41: Surgery Anesthesia Form**

3. Complete the fields as follows:
  - i. Date of Surgery: Use the calendar tool to select the date the biospecimens were collected.
  - ii. Pre-operative IV Sedation administered: Select “Yes” or “No”; this field is required.
  - iii. Pre-operative IV Opiates administered: Select “Yes” or “No”; this field is required.
  - iv. Pre-operative IV Antiemetics administered: Select “Yes” or “No”; this field is required.
  - v. Pre-operative IV Antacid administered: Select “Yes” or “No”; this field is required.
  - vi. Other pre-operative IV Medications administered: Select “Yes” or “No”; this field is required.
  - vii. Local anesthesia agents administered: Select “Yes” or “No”; this field is required.
  - viii. Regional (Spinal/Epidural) anesthesia agents administered: Select “Yes” or “No”; this field is required.
  - ix. IV anesthesia agents administered: Select “Yes” or “No”; this field is required.
  - x. IV Narcotic/Opiate agents administered: Select “Yes” or “No”; this field is required.
  - xi. IV Muscle Relaxants administered: Select “Yes” or “No”; this field is required.
  - xii. Inhalation anesthesia agents administered: Select “Yes” or “No”; this field is required.
  - xiii. Additional anesthesia agents used: Select “Yes” or “No”; this field is required.
  - xiv. Other medications administered during surgery prior to removal of the organ:
    - a. Was Insulin administered during surgery? Select “Yes” or “No”; this field is required.
    - b. Were Steroids administered during surgery? Select “Yes” or “No”; this field is required.
    - c. Were antibiotics administered during surgery? Select “Yes” or “No”; this field is required.
    - d. Were other medications administered during surgery? Select “Yes” or “No”; this field is required.
  - xv. Time of first incision: Enter the hour and minute, using a 24-hour clock.
  - xvi. Surgical procedure: Choose the appropriate procedure from the drop-down list; this field is required.  
Surgical method: Choose the appropriate methodology from the drop-down list of standard methodologies. If it is not in the list, select “Other” and enter the methodology in the text box that appears.
  - xvii. Time of first clamp: Enter the hour and minute that blood flow was restricted to the organ, using a 24-hour clock; this field is required.
  - xviii. Time of second clamp: Enter the hour and minute that the second clamp restricted blood to the organ, using a 24-hour clock; this field is required.
  - xix. Time of organ resection: Enter the hour and minute of the organ resection, using a 24-hour clock; this field is required.
  - xx. In Vivo Intra-Operative Ischemic Period (minutes): Enter the duration in minutes; this field is required.
  - xxi. Describe Blood Pressure excursions from time of anesthesia induction to 15-minute post induction: Comment on blood pressure observations.
  - xxii. Describe Blood Pressure excursions from 15 minutes’ post-anesthesia induction to organ excision: Comment on blood pressure observations.
  - xxiii. Temperature:
    - a. First Participant temperature recorded in OR: Enter the body temperature; this field is required. A pull-down menu allows the data entry in either Celsius or Fahrenheit. Set the pull-down to °F or °C before recording the temperature.
    - b. Time of first temperature: Enter the hour and minute, using a 24-hour clock.
    - c. Second Participant temperature recorded in OR: Enter the body; this field is required. A pull-down menu allows the data entry in either Celsius or Fahrenheit. Set the pull-down to °F or °C before recording the temperature.
    - d. Time of second temperature: Enter the hour and minute, using a 24-hour clock.
  - xxiv. Describe Epochs of Oxygen ( $O_2$ ) desaturation of <92% for >5 minutes prior to organ excision: Note any  $O_2$  desaturations.

- xxv. Carbon Dioxide level (CO<sub>2</sub>) recorded at time closest and prior to organ excision: Enter the measure and units of CO<sub>2</sub> recorded in the patient during surgery.
- xxvi. Intraoperative blood product administration:
  - a. Albumin Units: Enter the milliliters of albumin administered during the procedure.
  - b. Packed Red Blood Cells: Enter the number of units of packed red blood cells administered during the procedure.
  - c. Platelets: Enter the milliliters of platelets administered during the procedure.
  - d. Fresh Frozen Plasma: Enter the number of units of fresh frozen plasma administered during the procedure.
- xxvii. Blood loss: Enter the number of milliliters of blood the patient lost during the procedure. At what point was blood loss recorded? Select one: Select from the pull-down menu of epochs in the procedure when the patient lost blood.
- xxviii. Urine Volume Collected: Enter the number of milliliters of urine collected from the patient during the procedure. At what point was urine output recorded? Select one: Select from the pull-down menu of epochs in the procedure when the patient's urine output was recorded.
- xxix. Duration of fasting prior to surgery: Enter, in hours, how long the patient went without food.
- xxx. Describe pre-operative bowel preparation prior to surgery: Describe bowel preparation, if any.

4. Click on the **Save** button. If the form was successfully added, a note will appear under the title. Otherwise, error messages display in red. Any problems need correcting before data entry can continue.
5. Click on **Home** to go back to the study home page.

### **3.17 Adding a Tissue Gross Evaluation Form**

The BSS local pathology lab provides the gross evaluation of the biospecimens' collection. This includes immediate and interim processing. Use the following process to add a Tissue Gross Evaluation form:

1. On the View Candidate Record Details screen (Figure 17), find the Tissue Gross Evaluation Form item. Click on the blue text to the right, **Start**, to go to the Create Tissue Gross Evaluation screen, shown in Figure 42.

**Figure 42: Create Tissue Gross Evaluation Screen**

2. The following information displays under the Case Details line:
  - i. Case ID: Unique identifier given to this case; click on this to go to the Display Case screen
  - ii. Primary Organ: Organ under evaluation
  - iii. BSS: Biospecimen source site procuring this tissue
3. This screen contains only one field:
  - i. Tissue received in Gross Room from OR? Select “Yes” or “No”; this field is required.
4. If the tissue was received in the gross room, the Create Tissue Gross Evaluation form will expand to the form shown in Figure 43, which includes the following fields:
  - i. Date and time Specimen arrived in pathology gross room from OR: Use the calendar tool to select the date and time; this field is required.
  - ii. Specimen was received in gross room by: Enter the name of the person who received the tissue in the pathology gross room.
  - iii. SOP governing transport of tissue from OR to pathology gross room: Enter the ID of the SOP governing tissue handling during transport; this field is required.
  - iv. Transport of tissue was performed per Surgical Tissue Collection and Preservation SOP: Select “Yes” or “No” to indicate whether collection and preservation followed the study-specific SOP. This field is required. If you select “No,” you must enter notes in the comment field that appears.
  - v. Temperature of pathology gross room when specimen arrived from OR: Enter the air temperature, in degrees Celsius, in the pathology gross room. If only available in Fahrenheit, set the pull-down to °F before recording the temperature.
  - vi. Humidity of pathology gross room when specimen arrived from OR: Enter the relative humidity in the pathology gross room.
  - vii. Gross evaluation of resected tissue was performed by: Enter the name of the pathologist performing the gross evaluation; this field is required.
  - viii. Dimensions of resection: Enter the size, in three dimensions, of the tissue sample.
  - ix. Weight of resection: Enter the mass, in grams, of the tissue specimen.
  - x. Gross appearance of disease was observed in resected tissue: Select “Yes” or “No”; this field is required.
  - xi. Comments: Describe the overall gross appearance of the tissue.
  - xii. Gross diagnosis of resected tissue: Enter high-level text evaluating the tissue; this field is required.

- xiii. Photograph(s) of tissue was/were taken in pathology gross room? Select “Yes” or “No”; this field is required. If you select “Yes,” an option to upload the files with the tissue photographs will appear.
- xiv. Pathology ink used? Select “Yes” or “No”; this field is required. If you select “Yes,” enter the type of ink used in the text box that appears.
- xv. Tumor tissue was released to the tissue bank? Select “Yes” or “No”; this field is required. If the answer is “Yes,” fill in the additional fields shown in Figure 44.

The screenshot shows the 'Create Tissue Gross Evaluation' form. At the top right, there is a user session header: 'Welcome, brent1 | Logout', 'Org: Data Coordinating Center', 'Privileges: DM | PRC | LDS', 'Help', and 'Session expires in: 27:50'. Below the header, the page title is 'Create Tissue Gross Evaluation'. The form is divided into several sections:

- Case Details:** Shows Case ID: abcd-12345, Primary Organ: Kidney, BSS: BSS2.
- Receipt of Tissue in Pathology Gross Room:**
  - Tissue received in Gross Room from OR? (radio buttons: Yes, No)
  - 1. Date and time Specimen arrived in pathology gross room from OR: (text input field with calendar icon, 'Clear' button)
  - 2. Specimen was received in gross room by: (text input field)
  - 3. SOP governing transport of tissue from OR to pathology gross room: (text input field)
  - 4. Transport of tissue was performed per Surgical Tissue Collection and Preservation SOP: (radio buttons: Yes, No)
  - 5. Temperature of pathology gross room when specimen arrived from OR: (text input field with dropdown menu for °C)
  - 6. Humidity of pathology gross room when specimen arrived from OR: (text input field with dropdown menu for %)
- Gross Evaluation of Resected Tissue:**
  - 7. Gross evaluation of resected tissue was performed by: (text input field)
  - 8. Dimensions of resection: (text input field with separator for cm x cm x cm)
  - 9. Weight of resection: (text input field with separator for Grams)
  - 10. Gross appearance of disease was observed in resected tissue: (radio buttons: Yes, No)
  - 11. Comments: (text area)
  - 12. Gross diagnosis of resected tissue: (text input field)
  - 13. Photograph(s) of tissue was/were taken in pathology gross room? (radio buttons: Yes, No)
  - 14. Pathology ink used? (radio buttons: Yes, No)
- Gross Evaluation of Tumor Tissue:**
  - 15. Tumor tissue was released to the tissue bank? (radio buttons: Yes, No)

At the bottom left is a 'Create' button. The footer contains the text 'CDR-Lite v1.0-M8' and logos for the National Cancer Institute, Leidos Biomedical Research, Inc., NIH, and USA.gov.

**Figure 43: Expanded Create Tissue Gross Evaluation Form**

- xvi. Tissue Bank ID: Identify the tissue bank storing the tissue; this field is required.
- xvii. Dimensions of tissue: Enter the size of the tumor tissue in centimeters; this field is required.
- xviii. Percentage of gross area of necrosis of material sent to tissue bank: Enter the percentage of tissue area showing necrosis; this field is required.
- xix. Percentage of tumor content of material sent to tissue bank: Enter the percentage of the “tumor” tissue containing actual tumor material; this field is required.

- xx. Gross appearance of material sent to tissue bank: Enter commentary on the transported material.
- xi. Do the dimensions of each experimental piece meet the criteria specified within the BPS Surgical Tissue Collection and Preservation Procedure? Select “Yes” or “No”; this field is required. If you select “No,” a text field will appear for entering notes on why the experimental piece did not meet the criteria.
- xii. Normal adjacent tissue was released to the tissue bank in addition to tumor tissue? Select “Yes” or “No”; this field is required. If the answer is “Yes,” an additional set of fields will appear for gathering the normal adjacent tissue size, in centimeters.
- xiii. Time specimen was transferred from the pathology gross room to the tissue bank: Enter the time, in 24-hour clock values, that the material was transferred to the tissue bank.

Gross Evaluation of Tumor Tissue		
15. Tumor tissue was released to the tissue bank?	<input checked="" type="radio"/> Yes	<input type="radio"/> No
16. Tissue Bank ID:	<input type="text"/>	
17. Dimensions of tissue:	<input type="text"/> cm x	<input type="text"/> cm x
	<input type="text"/> cm	
18. Percentage of gross area of necrosis of material sent to tissue bank:	<input type="text"/> %	
19. Percentage of tumor content of material sent to tissue bank:	<input type="text"/> %	
20. Gross appearance of material sent to tissue bank:	<input type="radio"/> Metastatic <input type="radio"/> Tumor <input type="radio"/> Tumor Center <input type="radio"/> Tumor Edge	
21. Do the dimensions of each experimental piece meet the criteria specified within the BPS Surgical Tissue Collection and Preservation Procedure?	<input checked="" type="radio"/> Yes	<input type="radio"/> No
Normal Adjacent Tissue Information (if applicable)		
22. Normal adjacent tissue was released to the tissue bank in addition to tumor tissue?	<input type="radio"/> Yes	<input checked="" type="radio"/> No
Transfer of Tissue to Tissue Bank		
24. Time specimen was transferred from the pathology gross room to the tissue bank:	<input type="text"/>	

**Figure 44: Additional Tissue Gross Evaluation Fields for Tissue Bank**

- Click on the **Create** or **Save** button. If the tissue was not received in the pathology gross room, you must enter an explanation before clicking **Save**.

### 3.18 Adding a Tissue Receipt and Dissection Form

Well-characterized and validated assays are important to all research. Assays need thorough documentation to ensure that they remain reproducible over time.

Use the following process to add a Tissue Receipt and Dissection form:

- On the View Candidate Record Details screen (Figure 17), find the Tissue Receipt and Dissection Form item. Click on the blue text to the right, **Start**, to go to the Create Tissue Receipt and Dissection screen, shown in Figure 45.
- The following fields populate automatically with information previously entered:
  - Case ID: Unique ID given to the case associated with this blood form. Click the ID to navigate to the Show Case Record Details screen (Figure 37).
  - Primary Organ: Organ in the study associated with this case
  - BSS: Biospecimen source site associated with this collection



[Home](#)

### Create Tissue Receipt and Dissection Form

#### Case Details

Case ID: abcd-12345 Primary Organ: Kidney BSS: BSS2

Receipt and dissection of surgical tissue are expected to conform to your surgical tissue collection and processing SOP. Please specify any deviation(s) from the SOP in the Comments fields at the bottom of each section.

1. SOP governing receipt and dissection of surgical tissue in the Tissue Bank
2. Date and time tissue specimens were received in Tissue Bank from the Pathology Gross Room
3. Tissue specimens were received in Tissue Bank from the Pathology Gross Room by: (name)
4. Comments/issues with tissue receipt or deviation(s) from SOP

Tumor Tissue Specimen Dissection Information. Note any deviation(s) from your SOP in the Comments field at the bottom of this section.

5. Dissection of gross tissue specimen was performed by
  6. Time dissection of gross tissue specimen began
  7. Time dissection of gross tissue specimen ended
  8. Gross appearance of tissue specimen as determined in Pathology Gross Room
  9. Source of tumor tissue
  10. Tissue collection procedure
- Required Study Tissue
11. Fixative Type
  12. Fixative Formula
  13. Fixative pH
  14. Manufacturer of fixative
  15. Fixative Lot Num
  16. Date Fixative Lot Num Expired
  17. Fixative Product Num
  18. Is fixative a commercial product or prepared in-house
  19. Comments/issues with tissue fixation or deviation(s) from SOP

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**Figure 45: Creating a Tissue Receipt and Dissection Form**

3. Complete the fields as follows:
  - i. SOP Governing receipt and dissection of surgical tissue in the Tissue Bank: Enter the unique identifier for the SOP in effect when processing this tissue.
  - ii. Date and time tissue specimens were received in Tissue Bank from the Pathology Gross Room: Select the date and time using the calendar tool; this field is required.
  - iii. Tissue specimens were received in Tissue Bank from the Pathology Gross Room by: (name): Enter the name of the individual receiving tissue at the Tissue Bank.

- iv. Comments/issues with tissue receipt or deviation(s) from SOP: Enter any notes about the tissue upon receipt.
  - v. Dissection of gross tissue specimen was performed by: Enter the name of the individual who performed the dissection.
  - vi. Time dissection of gross tissue specimen began: Enter the hour and minute the dissection began, using a 24-hour clock; this field is required.
  - vii. Time dissection of gross tissue specimen ended: Enter the hour and minute the dissection was complete, using a 24-hour clock; this field is required.
  - viii. Gross appearance of tissue specimen as determined in Pathology Gross Room: Use the pull-down menu to specify whether the tissue was tumor or “Other.” If you select “Other,” describe the gross tissue appearance in the text field that appears.
  - ix. Source of tumor tissue: Describe where the tissue was located: primary or metastatic.
  - x. Tissue collection procedure: Select “Surgical,” “Core biopsy,” “Needle biopsy,” or “Other” from the pull-down menu. If you select “Other,” describe the procedure used in the text field that appears.
  - xi. Fixative Type: Select “Buffered-formalin,” “Ethanol,” “PAXgene tissue,” or “Other” from the pull-down menu. If you select “Other,” describe the fixative type in the text field that appears. The list in the pull-down menu is controlled by the Fixative list in the vocabulary.
  - xii. Fixative Formula: Describe the buffer for the fixative.
  - xiii. Fixative pH: Describe the pH for the fixative.
  - xiv. Manufacturer of fixative: Enter the name of the manufacturer of the fixative.
  - xv. Fixative Lot Num: Enter the manufacturer’s lot number for the fixative.
  - xvi. Date Fixative Lot Num Expired: Use the calendar tool to select the expiration date; this field is required.
  - xvii. Fixative Product Num: Record the product number of the fixative.
  - xviii. Is fixative a commercial product or prepared in-house: Select “Commercial,” “In-House,” or “Other” from the pull-down menu. If you select “Other,” describe the type of fixative preparation in the text field that appears.
  - xix. Comments/issues with tissue fixation or deviation(s) from SOP: Record comments, such as any deviations from the SOP.
4. Click on the **Save** button. The CDR-Lite will display the Show Case Record Details for the case number just entered. If the form was created successfully, a note will appear under the title. If there are problems, they are shown at the top of the page. All problems need correcting before the form may be saved.

### **3.19 Adding Specimens by Adding a Tissue Preservation Form**

Every attempt at optimizing the handling of biospecimens should minimize molecular changes that can result from processing activities. This includes not only the temperature and timing of biospecimen processing but also such considerations as the size and volume of the biospecimen that will be stored for future use. This form records the details about tissue handling during preservation.

To add a Tissue Preservation form, take the following steps:

1. On the Show Case Record Details screen (Figure 37), find the line item Tissue Preservation form (add Specimens). Click on the blue text to the right, **Add Specimen Record**. This takes the browser to the Create Specimen Record screen (Figure 46).
2. The following fields populate automatically with information previously entered:
  - i. Case ID: Unique ID given to the case associated with this blood form. Click the ID to navigate to the Show Case Record Details screen (Figure 37).
  - ii. Primary Organ: Organ in the study associated with this case
  - iii. BSS: Biospecimen source site associated with this collection

Welcome, brent1 | Logout  
Org: Data Coordinating Center  
Privileges: DM | PRCI | LDS  
Help  
Session expires in: 29:45

**Create Specimen Record**

**Case Details**

Case ID: abcd-12345 Primary Organ: Kidney BSS: BSS2

1. Gross Id:

2. Specimen Id:

3. Tissue Type:

4. Tissue Location:

5. Fixative:

6. Container Type:

7. Preservation Time:

8. Processing Person:

9. Storage Person:

10. Storage Temp:  
 Ambient  
 4 Degrees  
 -20 Degrees  
 -80 Degrees

11. Storage Time:

12. Tissue Size:

13. Tissue Size Units:

14. Comments:

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**Figure 46: Creating/Adding Specimens Form**

3. Complete the fields as follows:
  - i. Gross Id: Enter the ID of the gross specimen from which this aliquot was taken.
  - ii. Specimen Id: Enter the unique identifier for this particular specimen.
  - iii. Tissue Type: Select a type from the list of tissues involved in this study. The list is controlled by the Tissue Type list in the vocabulary.
  - iv. Tissue Location: Describe the location of the specimen (e.g., left, right, middle).
  - v. Fixative: Select a fixative from the list of fixatives involved in this study. The list is controlled by the Fixative list in the vocabulary.
  - vi. Container Type: Select a type from the list of containers involved in this study. The list is controlled by the Container Type list in the vocabulary.
  - vii. Preservation Time: Use the calendar tool to select the date and time preservation began.
  - viii. Processing Person: Enter the name of the individual performing the processing.
  - ix. Storage Person: Enter the name of the individual placing the specimen in storage.

- x. Storage Temp: Select one of the available items, showing the ambient temperature in the specimen storage.
  - xi. Storage Time: Use the calendar tool to select the date and time the specimen began storage.
  - xii. Tissue Size: Enter the specimen size.
  - xiii. Tissue Size Units: Enter the units (e.g., cm, ml) used in the specimen size.
  - xiv. Comments: Record any observations about the specimen, preservation, or storage.
4. Click on the **Create** button. The CDR-Lite will check the entries. If a problem is found, an error message will appear in red at the top of the screen. After correcting the problem, click on the **Save** button at the bottom of the form. When no further problems are found, click on the **Submit** button, which alerts the DM team that this record is ready for review. After clicking **Submit**, you will see the Show Case Record Details screen for this record.

### **3.20 Adding a Tissue Processing-Embedding Form**

SOPs specific to the biospecimen type and the biomolecules under analysis dictate handling of individual types of biospecimens. This form records the handling of tissues during processing and embedding, as appropriate to the study. To complete the form, take the following steps:

1. On the View Case Record Details screen (Figure 37), find the Tissue Processing-Embedding Form item. Click on the blue text to the right, **Start**, to go to the Save Tissue Processing-Embedding Form, shown in Figure 47.
2. The following fields populate automatically with information previously entered:
  - i. Case ID: Unique ID given to the case associated with this blood form. Click the ID to navigate to the Show Case Record Details screen (Figure 37).
  - ii. Primary Organ: Organ in the study associated with this case
  - iii. BSS: Biospecimen source site associated with this collection



[Home](#) [Print](#)

### Save Tissue Processing-Embedding Form for Case abcd-12345

#### Case Details

Case ID: abcd-12345 Primary Organ: Kidney BSS: BSS2

1. SOP governing processing of formalin-fixed Tissue:	<input type="text"/>
2. Make and model of tissue processor:	<input type="radio"/> Leica Peloris Rapid Tissue Processor <input type="radio"/> Other, Specify
3. Was processor maintenance provided as per the manufacturer recommendation:	<input type="radio"/> Yes <input type="radio"/> No - Specify
4. Type of alcohol:	<input type="radio"/> Absolute Ethanol (100%) <input type="radio"/> Other, Specify
5. Type of clearing agent:	<input type="radio"/> Xylene <input type="radio"/> Other, Specify
Were the following done as per the formalin-fixed tissue processing SOP?	
6. Alcohol stage duration:	<input type="radio"/> Yes <input type="radio"/> No - Specify
7. Duration of dehydration process:	<input type="radio"/> Yes <input type="radio"/> No - Specify
8. Temperature of dehydration:	<input type="radio"/> Yes <input type="radio"/> No - Specify
9. Number of stages/replicates:	<input type="radio"/> Yes <input type="radio"/> No - Specify
10. Duration in clearing agent:	<input type="radio"/> Yes <input type="radio"/> No - Specify
11. Temperature of clearing agent:	<input type="radio"/> Yes <input type="radio"/> No - Specify
12. Paraffin impregnation method:	<input type="radio"/> Yes <input type="radio"/> No - Specify
13. Temperature of paraffin:	<input type="radio"/> Yes <input type="radio"/> No - Specify
14. Provide any comments related to processing of formalin-fixed tissues:	<input type="text"/>

#### Embedding

15. SOP governing embedding of tissue:	<input type="text"/>
16. Type of paraffin:	<input type="text"/>
17. Manufacturer of paraffin:	<input type="radio"/> Fisher <input type="radio"/> Other, Specify
18. Paraffin product #:	<input type="text"/>
19. Paraffin lot #:	<input type="text"/>
20. Temperature of paraffin dispensed for embedding:	<input type="text"/> °C
21. Type of paraffin used in embedding:	<input type="radio"/> Fresh Paraffin <input type="radio"/> Other, Specify
22. Age of paraffin:	<input type="text"/> day(s)
23. Total time the freshly poured blocks were cooled:	<input type="text"/> minute(s)

#### FFPE Block Storage

24. SOP governing handling, tracking and storage of FFPE tissue block:	<input type="text"/>
25. Were the FFPE blocks stored as per SOP:	<input type="radio"/> Yes <input type="radio"/> No - Specify

26. Provide any additional comments related to paraffin embedding of formalin-fixed tissue:

[Save](#) [Cancel](#)

Figure 47: Save Tissue Processing-Embedding Form for a Case

3. Complete the fields as follows:

- i. SOP governing processing of formalin-fixed Tissue: Enter the unique identifier given to the SOP governing the processing and embedding of formalin-fixed, paraffin-embedded (FFPE) tissue.
- ii. Make and model of tissue processor: Select an approved processor or "Other" from the list. If you select "Other," enter the make and model in the text field that appears.
- iii. Was processor maintenance provided as per the manufacturer recommendation: Select "Yes" or "No." If you select "No," enter the maintenance specifics in the text field that appears.
- iv. Type of alcohol: Select an approved alcohol for cleaning/processing or "Other" from the list. If you select "Other," enter the type of alcohol in the text field that appears.
- v. Type of clearing agent: Select an approved cleaning agent (e.g., Xylene) or "Other." If you select "Other," enter the type of cleaning agent in the text field that appears.
- vi. Alcohol stage duration: Select "Yes" or "No" to indicate whether the time in the alcohol stage was as per the formalin-fixed tissue processing SOP. If you select "No," enter the variation specifics in the text field that appears.
- vii. Duration of dehydration process: Select "Yes" or "No" to indicate whether the time in the dehydration process was as per the formalin-fixed tissue processing SOP. If you select "No," enter the variation in the text field that appears.
- viii. Temperature of dehydration: Select "Yes" or "No" to indicate whether the temperature during the dehydration process was as per the formalin-fixed tissue processing SOP. If you select "No," enter the temperature variation in the text field that appears.
- ix. Number of stages/replicates: Select "Yes" or "No" to indicate whether the number of repeats in the cleaning/dehydration process was as per the formalin-fixed tissue processing SOP. If you select "No," enter the number of replicates in the text field that appears.
- x. Duration in clearing agent: Select "Yes" or "No" to indicate whether the total amount of time spent in repeats in the cleaning/dehydration process was as per the formalin-fixed tissue processing SOP. If you select "No," enter the duration in the text field that appears.
- xi. Temperature of clearing agent: Select "Yes" or "No" to indicate whether the temperature of the cleaning agent was as per the formalin-fixed tissue processing SOP. If you select "No," enter the temperature and units in the text field that appears.
- xii. Paraffin impregnation method: Select "Yes" or "No" to indicate whether the impregnation methodology for paraffin was as per the formalin-fixed tissue processing SOP. If you select "No," enter the variations in the text field that appears.
- xiii. Temperature of paraffin: Select "Yes" or "No" to indicate whether the temperature of the paraffin was as per the formalin-fixed tissue processing SOP. If you select "No," enter the observed temperature of the paraffin in the text field that appears.
- xiv. Provide any comments related to processing of formalin-fixed tissues: Enter any comments or observations about the FFPE process for this sample.
- xv. SOP governing embedding of tissue: Enter the unique identifier given to the procedure governing the embedding.
- xvi. Type of paraffin: Record the name of the specific paraffin used in embedding the tissue.
- xvii. Manufacturer of paraffin: Select the manufacturer of the paraffin product used for embedding the tissue or "Other." If you select "Other," enter the manufacturer's name in the Specify box that appears.
- xviii. Paraffin product #: Enter the individual product number, typically found on the label or packing materials.
- xix. Paraffin lot #: Enter the individual production lot number, typically found on the label or packing materials.
- xx. Temperature of paraffin dispensed for embedding: Record the temperature of the paraffin (as an integer) when the lab performed the embedding. Use the pull-down menu to select the temperature units (Fahrenheit or Celsius).

- xxi. Type of paraffin used in embedding: Select “Fresh” or “Other.” Choosing “Other” brings up a text entry box for recording the details of the paraffin type.
  - xxii. Age of paraffin: Enter the number of days that the paraffin has been in use; this field is required.
  - xxiii. Total time the freshly poured blocks were cooled: Enter the number of minutes that the blocks cooled after pouring.
  - xxiv. SOP governing handling, tracking and storage of FFPE tissue block: Enter the ID of the SOP, including the version, under which the FFPE tissue blocks were stored.
  - xxv. Were the FFPE blocks stored as per SOP: Select “Yes” or “Other.” Choosing “Other” brings up a text entry box for recording details of the storage of FFPE blocks.
  - xxvi. Provide any additional comments related to paraffin embedding of formalin-fixed tissue: Enter notes or observations about the process of FFPE preparation or storage.
4. Click on the **Save** button. The CDR-Lite will check the entries. If a problem is found, an error message will appear in red at the top of the screen. After correcting the problem, click on the **Save** button at the bottom of the form. When no further problems are found, click on the **Submit** button, which alerts the DM team that this record is ready for review. After clicking **Submit**, you will see the Show Case Record Details for this case.

### **3.21 Adding Slides by Adding a Slide Sectioning Form**

This form records the general histological techniques used in the production of slides from collected tissue. The process for completing the form is as follows:

1. On the View Candidate Record Details screen (Figure 17), find the Slide Sectioning Form (Add slides). Click on the blue text to the right, **Start**, to go to the Save Slide Sectioning Form for Case, shown in Figure 48.
2. The following fields populate automatically with information previously entered:
  - i. Case ID: Unique ID given to the case associated with this blood form. Click the ID to navigate to the Show Case Record Details screen (Figure 37).
  - ii. Primary Organ: Organ in the study associated with this case
  - iii. BSS: Biospecimen source site associated with this collection



Welcome, brent1 | Logout  
Org: Data Coordinating Center  
Privileges: DM | PRC | LDS  
Help  
Session expires in: 29:36

[Home](#) [Print](#)

### Save Slide Sectioning Form for Case abcd-12345

#### Case Details

Case ID: abcd-12345 Primary Organ: Kidney BSS: BSS2

#### FFPE Sectioning

Slide Prep technician name:

#### Slides Created

Slide ID(s)	Specimen	Action
<a href="#">Add</a>		

**FFPE Sectioning Details**

1. Slide Prep SOP:
2. Microtome:
3. Microtome blade type:
4. Microtome blade age:
5. Preparation of block face for sectioning:
6. Section thickness:
7. Slide charge:
8. Water bath temp:
9. Microtome maintenance:
10. Waterbath maintenance:
11. Any additional comments related to preparation of FFPE tissue sections:

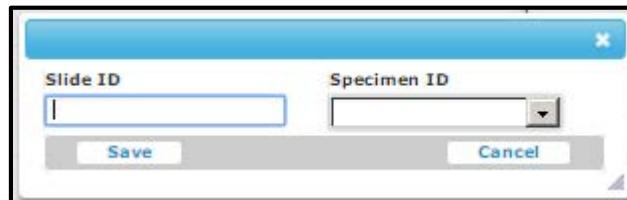
[Save](#) [Cancel](#)

CDR-Lite v1.0-MB



**Figure 48: Creating a Slide Sectioning Form for a Case**

3. For each slide created, click on the **Add** button in the Slides Created box. This will bring up an ancillary window for entering one Slide ID and associated Specimen ID, shown in Figure 49.



**Figure 49: Ancillary Window for Entering Slide ID and Associated Specimen ID**

Typically, the slide ID comes from pre-labeled slides or a label, in accordance with a study's SOP. The Specimen ID field is a pull-down menu with the IDs of the specimens for the current case. Enter these two values and click on the **Save** button.

4. Complete the fields as follows:
  - i. Slide Prep SOP: Enter the version number of the slide preparation SOP in effect.
  - ii. Microtome: Select the manufacturer of the microtome used for embedding the tissue or "Other." If you select "Other," enter the manufacturer's name in the text field that appears.
  - iii. Microtome blade type: Select the type of blade in the microtome used in producing the tissue slide. If you select "Other," enter the type of blade in the text field that appears.
  - iv. Microtome blade age: Select the age of the blade in the microtome used in producing the tissue slide. If you select "Other," enter a description of the blade's age in the text field that appears.
  - v. Preparation of block face for sectioning: Select "20 Minutes on Ice" or "Other" to describe the block preparation for the microtome. If you select "Other," enter the preparation in the text field that appears.
  - vi. Section thickness: Select "4-5 micrometers" or "Other" to describe the section produced by the microtome. If you select "Other," enter the section thickness in the text field that appears.
  - vii. Slide charge: Select a description of the charge associated with the slide glass surface. If not "Charged" (for Silanized slides) or "Uncharged" (for neutral slides), select "Other" and enter the charge details in the text field that appears.
  - viii. Water bath temp: Select "43 + -2 Degree C" or "Other" to describe the temperature of the water bath. If you select "Other," enter the water bath temperature in the text field that appears.
  - ix. Microtome maintenance: Select "Daily" or "Other" to describe the routine maintenance period for the microtome. If you select "Other," enter the deviations from routine maintenance in the text field that appears.
  - x. Waterbath maintenance: Select "Daily" or "Other" to describe the routine maintenance period for the water bath. If you select "Other," enter the deviations from routine maintenance in the text field that appears.
  - xi. Any additional comments related to preparation of FFPE tissue sections: Enter any additional observations related to this set of slide preparations.
5. Click on the **Save** button. The CDR-Lite will check the entries. If a problem is found, an error message will appear in red at the top of the screen. After correcting the problem, click **Save** at the bottom of the form. When no further problems are found, click the **Submit** button at the bottom of the form. Submitting the form signals the DM team that this record is ready for review. Click on the case ID (at the top of the screen, under Case Details) to resume data entry.

### **3.22 Adding a Slide Prep and Staining Form**

Most pathology reviews require slide preparation. Details of slide preparation are described in the study SOPs. This form records the major steps in preparation. Use the following process to complete the form:

1. On the View Candidate Record Details screen (Figure 17), find the Case List item. Click on the blue text to the right, **Add Case Record**, to go to the Create Slide Prep screen, shown in Figure 50.
2. The following fields populate automatically with information previously entered:
  - i. Case ID: Unique ID given to the case associated with this blood form. Click the blue text to navigate to the Show Case Record Details screen (Figure 37).
  - ii. Primary Organ: Organ in the study associated with this case

- iii. BSS: Biospecimen source site associated with this collection

The screenshot shows the 'Create Slide Prep' page. At the top, there's a header with the CDR logo and navigation links for Home and Print. On the right, there's a user session info bar. Below the header, the page title 'Create Slide Prep' is displayed. Underneath, a section titled 'Case Details' shows 'Case ID: abcd-12345', 'Primary Organ: Kidney', and 'BSS: BSS'. The main form area is titled 'H&E Staining' and contains a numbered list from 1 to 8, each with a dropdown menu. A ninth item is a text input field. Below this is a large text area for additional comments. At the bottom left is a 'Create' button, and at the bottom right are several logos: National Cancer Institute, Leidos Biomedical Research, Inc., NIH, USA.gov, and Government User Easy.

**Figure 50: Create Slide Prep Form**

3. Complete the fields as follows:
- Slide List: Check all slides described in this form. The list encompasses slides previously entered via a Slide Sectioning form (Section 3.21).
  - H&E time in oven: Select “20 minutes” or “Other” to describe the period for heating the slide in the oven for H&E staining. If you select “Other,” record the duration in the text field that appears.
  - H&E oven temp: Select “60° C” or “Other” to describe the temperature in the oven for H&E staining. If you select “Other,” record the temperature and scale in the text field that appears.
  - H&E de-paraffin method: Select “Manual,” “Automated Stainer,” or “Other” to describe the method used to de-paraffin before H&E staining. If you select “Other,” record the de-paraffin methodology in the text field that appears.
  - H&E stain method: Select “Manual,” or “Automated Stainer,” or “Other” to describe the method used for H&E staining. If you select “Other,” record the staining methodology in the text field that appears.
  - H&E clearing method: Select “Manual,” “Automated Stainer,” or “Other” to describe the method used for clearing. If you select “Other,” record the clearing methodology in the text field that appears.

- vii. H&E cover slipping: Select “Manual” or “Other” to describe the method used for applying the slide cover. If you select “Other,” record the cover slipping methodology in the text field that appears.
  - viii. H&E equipment maintenance: Select “Daily,” “Weekly,” “Bi-Monthly,” “Per SOP,” or “Other” to describe the maintenance periods used for the H&E equipment. If you select “Other,” record the frequency of equipment maintenance in the text field that appears.
  - ix. Additional comments related to preparation of FFPE Hematoxylin and Eosin stained slides: Record any notes or observations about the H&E staining for the slides covered by this form.
4. Click on the **Create** button. The CDR-Lite will automatically review the form contents for completeness and accuracy. If irregularities are found, they appear in red at the top of the form. Edit the form appropriately, and click on **Create** or **Save**. After you have corrected all problems, a **Submit** button will appear at the bottom of the screen; click on this button to request DM review of the entries. After submission, the screen shows a read-only version of the form and gives an option to **Resume Editing**. To continue to the next step, click on the blue **CDR-Lite** logo at the top of the page. The CDR-Lite will display the Show Case Record Details for the case number just entered. When the case has been added, a note will appear under the title.

### **3.23 Adding a Surgical Pathology Form**

This section is unlike the other core record forms (CRFs). The Surgical Pathology Form is a form uploaded from a scanned image or a file (such as a Word document, PDF, or text). There can be only one file for the Surgical Pathology Form at a time, although the file may contain multiple pages.

If no file is currently loaded, then the status is **Not Started**, and an up-arrow icon shows. If a file is currently loaded, then the status is **Uploaded**, and two icons show: a down arrow and a trash can. The down arrow starts the file download (from the CDR-Lite to the local machine). The trash can deletes the file currently uploaded, making room for a subsequent file upload.

To upload a file, take the following steps:

1. On the Show Case Record Details screen (Figure 37), find the Surgical Pathology Form. Click on the up-arrow icon to go to the file upload screen, shown in Figure 51.

The screenshot shows the CDR-Lite interface for uploading a surgical pathology form. At the top, the CDR logo and 'Comprehensive Data Resource' are visible. The top right corner displays a welcome message for 'brent1', session details ('Session expires in: 29:54'), and navigation links ('Logout', 'Org: Data Coordinating Center', 'Privileges: DM | PRC | LDS', 'Help'). Below the header, a sub-header reads 'Upload Surgical Pathology Form for Case Steve1'. A form field for 'Case ID' contains 'Steve1'. A 'File:' input field contains the text 'Choose File | No file chosen'. Below these fields are 'Upload' and 'Cancel' buttons. At the bottom of the form, the text 'CDR-Lite v1.0-M9' is displayed, along with logos for National Cancer Institute, Leidos Biomedical Research, Inc., NIH, National Institutes of Health, and USA.gov.

**Figure 51: Upload Surgical Pathology Form**

2. Click on the **Choose File** button to browse to a file on the local machine.

3. Click on the **Upload** button to copy the selected file to the CDR-Lite, or click on the **Cancel** button to abort the upload.

To remove a file, first find the Surgical Pathology Form on the Show Case Record Details screen (Figure 37). Click on the trash can icon. The CDR-Lite will ask for confirmation that this file should be deleted; answer yes.

### **3.24 Adding a Clinical Data Entry Form**

The Clinical Data Entry form records information about the cancer and disease ancestry information related to the case. To complete the form, take the following steps:

1. On the Show Candidate Record Details screen (Figure 17), find the Case List item. Click on the blue text to the right, **Add Case Record**, to go to the Create Clinical Data Entry Form screen, shown in Figure 52.
2. The following fields populate automatically with information previously entered:
  - i. Case ID: Unique ID given to the case associated with this blood form. Click the blue text to navigate to the Show Case Record Details screen, shown in Figure 37.
  - ii. Primary Organ: Organ in the study associated with this case
  - iii. BSS: Biospecimen source site associated with this collection

# CDR Comprehensive Data Resource

Welcome, brent1 | [Logout](#)  
 Org: Data Coordinating Center  
 Privileges: DM | PRC | LDS  
[Help](#)  
 Session expires in: 29:41

[Home](#)

## Create Clinical Data Entry Form

### Case Details

Case ID: abcd-12345 Primary Organ: Kidney BSS: B552

#### History of Cancer in Participant or blood relatives

1. Does the Participant have a history of prior malignancy?  Yes  No  Unknown
2. Participant's blood relatives who have had a history of Cancer:

Blood Relative	Type of Cancer
<input type="checkbox"/> Aunt	
<input type="checkbox"/> Brother	
<input type="checkbox"/> Daughter	
<input type="checkbox"/> Father	
<input type="checkbox"/> Mother	
<input type="checkbox"/> Sister	
<input type="checkbox"/> Son	
<input type="checkbox"/> Uncle	
<input type="checkbox"/> Grandmother	
<input type="checkbox"/> Grandfather	
<input type="checkbox"/> Nephew	
<input type="checkbox"/> Niece	
<input type="checkbox"/> Other - Specify	
<input type="checkbox"/> None	

3. Does the Participant have an immunosuppressive issue (HIV, organ transplant, steroid use, etc.)?  Yes  No  Unknown

4. Has the Participant received radiation therapy prior to surgery?  Yes  No  Unknown

5. Has the Participant received chemotherapy prior to surgery?  Yes  No  Unknown

6. Has the Participant received immunotherapy prior to surgery?  Yes  No  Unknown

7. Has the Participant received hormonal therapy prior to surgery?  Yes  No  Unknown

#### Infectious Diseases

8. Has the Participant been diagnosed with Hepatitis B?  Yes  No  Unknown

9. Has the Participant been diagnosed with Hepatitis C?  Yes  No  Unknown

10. Has the Participant been diagnosed with HIV?  Yes  No  Unknown

11. Does the Participant have a history of repeatedly reactive screening assays for HIV-1 or HIV-2 antibodies regardless of the results of supplemental assays?  Yes  No  Unknown

12. Other infectious diseases:

#### Clinical tumor stage group (AJCC 7th Edition)

13. Clinical tumor stage group (AJCC 7th Edition):

#### Record Karnofsky Score OR Eastern Cancer Oncology (ECOG) Score

14. Performance Status Scale recorded:

- Karnofsky Score
- Eastern Cancer Oncology Group
- Not recorded

16. Comments:

[Create](#)

CDR-Lite v1.0-MB



**leidos**  
Leidos Biomedical Research, Inc.



National Institutes of Health



USA.gov  
Government Made Easy

Figure 52: Creating a Clinical Data Entry Form for a Case

3. Complete the fields as follows:
- i. Does the Participant have a history of prior malignancy? Select “Yes,” “No,” or “Unknown”; this field is required.
  - ii. Participant's blood relatives who have had a history of Cancer: This field is required. Click on the check box next to the relationships of blood relatives with a history of cancer. Record the type of cancer in the text box that appears. If two or more relatives with the same relationship have had cancer, enter one on the appropriate relationship line and the second under “Other – Specify.” If no relatives have had cancer, check the final box, “None.” If “None” is selected, no other boxes may be checked.
  - iii. Does the Participant have an immunosuppressive issue (HIV, organ transplant, steroid use, etc.)? This field is required. Select “Yes,” “No,” or “Unknown.” If you select “Yes,” a series of check boxes will appear: “HIV,” “Organ transplant,” “Chronic systemic steroid use,” and “Other – Specify.” Select all that apply. If you select “Other,” record the immunosuppressive issue in the text field that appears.
  - iv. Has the Participant received radiation therapy prior to surgery? This field is required. Select “Yes,” “No,” or “Unknown.” If you select “Yes,” a blank table will appear, along with an **Add** button. Click the **Add** button to expand the form, as shown in Figure 53. Describe the details of the radiation therapy in the large text box. The calendar pull-down allows for entry of the date of the completion of radiation therapy; if you do not know the exact date, enter the number of years since the therapy. Clicking on the **Save** button adds a line to the table. If, after entering radiation therapy prior to surgery, you need to change the entry, use the **Delete** button in the right column, and enter the correct data in a new record.

4. Has the Participant received radiation therapy prior to surgery?

Yes  No  Unknown

Description	Date of radiation therapy or Time since receiving radiation therapy (Yrs)	Delete
Describe radiation therapy the Participant received prior to surgery:		

When radiation therapy was received: ?

Or

Figure 53: Expanded Question 4 for Entering Details of Radiation Therapy

- v. Has the Participant received chemotherapy prior to surgery? This field is required. Select “Yes,” “No,” or “Unknown.” If you select “Yes,” a blank table will appear, along with an **Add** button. Click the **Add** button to expand the form, as shown in Figure 54. Use the large text box to describe the details of chemotherapy. The calendar pull-down allows for entry of the date of completion of chemotherapy; if you do not know the exact date, enter the number of years since the therapy. Clicking on the **Save** button adds a line to the table. If, after entering chemotherapy prior to surgery, you need to change the entry, use the **Delete** button in the right column, and enter the correct data in a new record.

5. Has the Participant received chemotherapy prior to surgery?		<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
Description	Date of Chemotherapy or Time since receiving date of chemotherapy (Yrs)	Delete
Describe chemotherapy the Participant received prior to surgery:	<div style="border: 1px solid #ccc; height: 100px; width: 100%;"></div>	
When chemotherapy was received: <span style="color: blue;">i</span>	<input type="text"/> <input type="button" value="Clear"/> Or <input type="text"/> Time since when chemotherapy was received (in Years): <input type="text"/>	
<input type="button" value="Save"/> <input type="button" value="Cancel"/>		

**Figure 54: Expanded Question 5 for Entering Details of Chemotherapy**

- vi. Has the Participant received immunotherapy prior to surgery? This field is required. Select “Yes,” “No,” or “Unknown.” If you select “Yes,” a blank table will appear, along with an **Add** button. Click the **Add** button to expand the form, as shown in Figure 55. Use the large text box to describe the details of the immunotherapy. The calendar pull-down allows for entry of the date of the completion of immunotherapy; if you do not know the exact date, enter the number of years since the therapy. Clicking on the **Save** button adds a line to the table. If, after entering immunotherapy prior to surgery, you need to change the entry, use the **Delete** button in the right column, and enter the correct data in a new record.

6. Has the Participant received immunotherapy prior to surgery?		<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown
Description	Date of immunotherapy or Time since immunotherapy (Yrs)	Delete
Describe immunotherapy the Participant received prior to surgery:	<div style="border: 1px solid #ccc; height: 100px; width: 100%;"></div>	
When immunotherapy was received: <span style="color: blue;">i</span>	<input type="text"/> <input type="button" value="Clear"/> Or <input type="text"/> Time since when immunotherapy was received (in Years): <input type="text"/>	
<input type="button" value="Save"/> <input type="button" value="Cancel"/>		

**Figure 55: Expanded Question 6 for Entering Details of Immunotherapy**

- vii. Has the Participant received hormonal therapy prior to surgery? This field is required. Select “Yes,” “No,” or “Unknown.” If you select “Yes,” a blank table will appear, along with an **Add** button. Click the **Add** button to expand the form, as shown in Figure 56. Use the large text box to describe the details of the hormonal therapy. The calendar pull-down allows for entry of the date of the completion of hormonal therapy; if you do not know the exact date, enter the number of years since the therapy. Clicking on the **Save** button adds a line to the table. If, after entering hormonal therapy prior to surgery, you need to change the entry, use the **Delete** button in the right column, and enter the correct data in a new record.

7. Has the Participant received hormonal therapy prior to surgery?		
<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <b>Description</b> Describe hormonal therapy the Participant received prior to surgery: <div style="border: 1px solid #ccc; height: 100px; margin-top: 10px;"></div>	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unknown <b>Date of hormonal therapy or Time since receiving date of hormonal therapy (Yrs)</b> <div style="border: 1px solid #ccc; width: 100%; height: 40px; margin-top: 10px;"></div>	
<b>When hormonal therapy was received:</b> <span style="color: blue;">?</span> <input type="button" value="Clear"/> Or <input style="width: 100px;" type="text"/> Time since when hormonal therapy was received (in Years): <input style="width: 50px;" type="text"/>		<input type="button" value="Delete"/>
<input type="button" value="Save"/> <input type="button" value="Cancel"/>		

**Figure 56: Expanded Question 7 for Hormonal Therapy**

- viii. Has the Participant been diagnosed with Hepatitis B? Select “Yes,” “No,” or “Unknown”; this field is required.
- ix. Has the Participant been diagnosed with Hepatitis C? Select “Yes,” “No,” or “Unknown”; this field is required.
- x. Has the Participant been diagnosed with HIV? Select “Yes,” “No,” or “Unknown”; this field is required.
- xi. Does the Participant have a history of repeatedly reactive screening assays for HIV-1 or HIV-2 antibodies regardless of the results of supplemental assays? Select “Yes,” “No,” or “Unknown”; this field is required.
- xii. Other infectious diseases: Note all infectious diseases with which this patient has been diagnosed.
- xiii. Clinical tumor stage group (AJCC 7th Edition): This field is required. Select “Stage 1,” “Stage 2,” “Stage 3,” or “Not Available” from the pull-down menu to enter the progress stage of the tumor.
- xiv. Performance Status Scale recorded: This field is required. Select one of the performance scales: “Karnofsky Score,” “Eastern Cancer Oncology Group,” or “Not Recorded.” If you select “Karnofsky Score,” the form will expand, allowing you to select the patient status, as shown in Figure 57.

Record Karnofsky Score OR Eastern Cancer Oncology (ECOG) Score	
<b>14. Performance Status Scale recorded:</b> <input checked="" type="radio"/> Karnofsky Score <input type="radio"/> Eastern Cancer Oncology Group <input type="radio"/> Not recorded  <b>Karnofsky Score:</b> <input type="radio"/> 100: asymptomatic <input type="radio"/> 80-90: symptomatic but fully ambulatory <input type="radio"/> 60-70: symptomatic but in bed less than 50% of the day <input type="radio"/> 40-50: symptomatic, in bed more than 50% of the day, but not bed ridden <input type="radio"/> 20-30: bed ridden	
<b>15. Timing of score:</b> <input type="radio"/> Preoperative <input type="radio"/> Pre-adjuvant therapy <input type="radio"/> Post adjuvant therapy <input type="radio"/> Unknown <input checked="" type="radio"/> Other, Specify <div style="border: 1px solid #ccc; width: 100%; height: 40px; margin-top: 10px;"></div>	

**Figure 57: Expanded Question 14 for Karnofsky Score**

If you select “Eastern Cancer Oncology Group,” the form will expand as shown in Figure 58. Select one of the ECOG Functional Performance Status options.

Record Karnofsky Score OR Eastern Cancer Oncology (ECOG) Score

14. Performance Status Scale recorded:

Karnofsky Score  
 Eastern Cancer Oncology Group  
 Not recorded

ECOG Functional Performance Status

0: asymptomatic  
 1: symptomatic but fully ambulatory  
 2: symptomatic but in bed less than 50% of the day  
 3: symptomatic, in bed more than 50% of the day, but not bed ridden  
 4: bed ridden

15. Timing of score:

Preoperative  
 Pre-adjuvant therapy  
 Post adjuvant therapy  
 Unknown  
 Other, Specify

[Text input field]

**Figure 58: Expanded Question 14 for Eastern Cancer Oncology (ECOG) Score**

- xv. Timing of score: This field is not visible unless the answer to question 14 is “Karnofsky Score” or “Eastern Cancer Oncology Group” (see lower half of Figure 57, or Figure 58). If it is visible, select “Preoperative,” “Pre-adjuvant therapy,” “Post adjuvant therapy,” “Unknown,” or “Other, Specify.” If the answer is “Other, Specify,” record the phase of timing in the text field that appears.
- xvi. Comments: Record any notes or observations about the clinical data for this case.
4. Click on the **Create** or **Save** button. The CDR-Lite will automatically review the form for completeness and accuracy. If there are irregularities, they will appear in red at the top of the form. Edit the form appropriately, and click on **Create** or **Save** again. When you have corrected all problems, a **Submit** button will appear at the bottom of the screen. Click this button to request DM review of the entries. After submission, the screen shows a read-only version of the form and gives an option to **Resume Editing**. To continue to the next step, click on the blue CDR-Lite logo at the top of the page to go to the Show Case Record Details for the case number just entered. When the form has been successfully added, a note will appear under the title.

## 4 Pathology Resource Center Role

The PRC reviews the histologic and pathologic properties of the specimens by examining microscope slides or their digital images and reviewing entries recorded earlier by the BSS. When the images are ready for review by the PRC, the CDR-Lite automatically sends an alert to the PRC team stating that images are available. The CDR-Lite records the PRC case assessment in the PRC Review form.

**NOTE:** Cases may be reviewed solely based on the digitally scanned images once they are available to the PRC, or glass slides may be used when images are insufficient for interpreting the case findings completely.

In general, the PRC follows the following procedure. The process varies from study to study.

1. A CDR-Lite alert indicates that images are available.
2. A PRC pathologist begins reviewing the case.
3. Before conducting microscopic examination, the pathologist reviews the clinical and case collection data provided in the forms for the case.
4. The pathologist reviews the images.

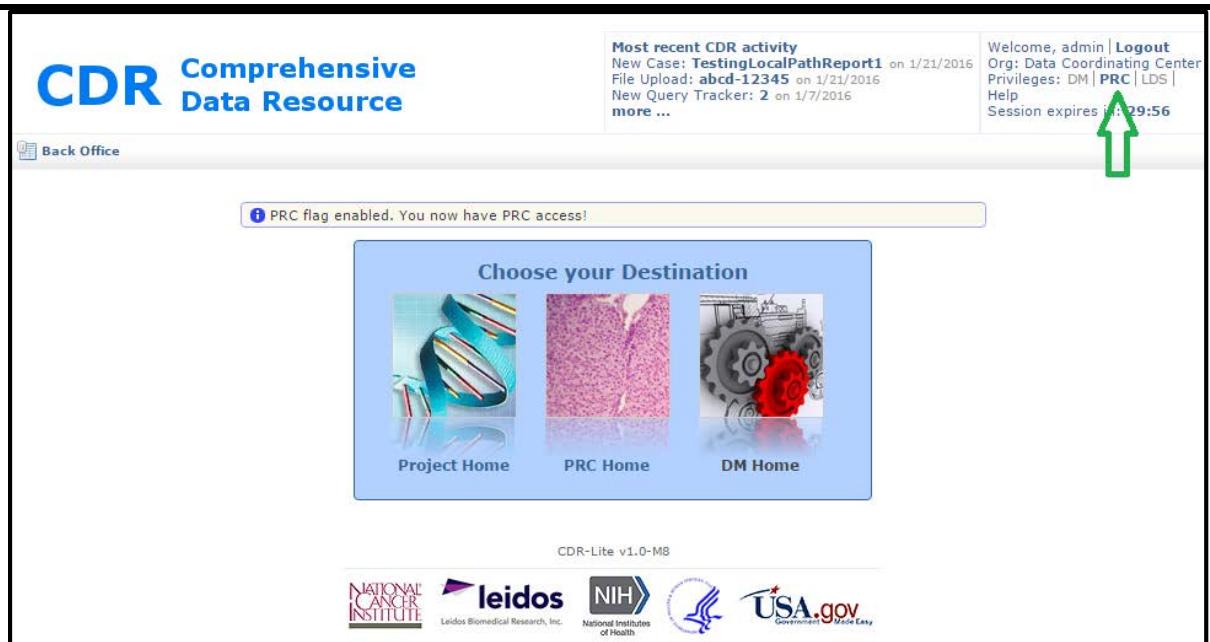
**NOTE:** Pathologists review all tissues to confirm the following:

- I. The presence of the intended morphology, namely the topographic site and, for tumor studies, the histologic type
  - II. The presence and degree of autolysis
  - III. The presence of pathologic findings (e.g., inflammation, hemorrhage, neoplasms)
  - IV. The aliquot amounts, namely tissue pieces as specified in the applicable SOP. Tissue dimensions may be measured and recorded directly on the digital images.
5. Upon identifying any issues, the PRC works with the relevant parties to ensure their complete resolution before assigning a final specimen status. Issues may include the following:
    - Needs for recuts for verification or special stains
    - Mislabeled images or slides
    - Broken slides
    - Extraneous tissues
    - Sampling errors
  6. When the pathology review is successfully completed, the pathologist sends an email to the DM team, telling them the case is ready for final review.

### 4.1 Pathology Case Summary Report

The CDR-Lite Pathology Case Summary Report documents all findings and issues identified in the PRC review in a timely fashion. Use the following process to document the findings and issues:

1. Log in to the CDR-Lite with an account that has or can take on the PRC role.
2. In the upper right corner of the screen, in the “Privileges:” line, click on **PRC**, as shown in Figure 59.



**Figure 59: Enabling PRC Role (Green Arrow) and Message**

3. If the message “PRC flag enabled. You now have PRC access!” does not appear, see the CDR-Lite administrator about having the account adjusted for this role.
4. Click on the **PRC Home** picture or text to go to the PRC home page. To select a study, click on the line with the desired study name. This displays the study-specific PRC Home screen, shown in Figure 60.

The screenshot shows the WBL PRC Home screen. At the top right, there is a user session header with the text "Welcome, admin | Logout", "Org: Data Coordinating Center", "Privileges: DM | PRC | LDS | Help", and "Session expires in: 29:09". Below this, there is a "WBL Case List" table:

Case ID	Primary Organ	Case Status	Specimen ID	Slide Id	PRC Report
TestingLocalPathReport1	Colon	Data Entry Underway	abcdefg-123456789	1289	
abcd-12345	Kidney	Data Entry Underway	abcdefg-123456789	123432	
			specimen 3.1415926	123	

Below the table, there is a message "Most recently created on top" and a link "View all Cases >>". At the bottom, there is a footer with logos for the National Cancer Institute, Leidos Biomedical Research, Inc., NIH, and USA.gov.

**Figure 60: Study-Specific (WBL) PRC Home Screen**

5. Each line in the table shows information on a case-by-case basis; each case is on a separate line. The final column, PRC Report, has one or two icons. Click the pencil-and-paper icon to go to the PRC Report Editor, and click the magnifying glass icon to go to the PRC Report Viewer. If only the magnifying glass shows, there already is a saved PRC Report for this case/specimen/slide ID. Click on the pencil-and-paper icon to go to the Edit PRC Report screen, shown in Figure 61.

The screenshot shows the 'Edit PRC Report' page. At the top, there's a header with the CDR logo and navigation links like 'Home', 'Edit PRC Report', 'Logout', and session information ('Session expires in: 29:32'). Below the header, the main content area is titled 'Case Details'. It contains several input fields: 'Case ID: TestingLocalPathReport1', 'Primary Organ: Colon', 'BSS: BSS 1', 'Slide record: 1289', 'Block ID: abcdefg-123456789', 'Organ origin: Kidney' (selected from a dropdown), 'Tissue category: Normal' (selected from a dropdown), and a large text area for 'Diagnosis/Morphology'. Below these is a section for 'Autolysis rating' with radio buttons for 0, 1, 2, and 3. A large text area for 'Comments' follows. At the bottom left is an 'Update' button. The footer includes the text 'CDR-Lite v1.0-MB' and logos for the National Cancer Institute, Leidos Biomedical Research, Inc., NIH, and USA.gov.

**Figure 61: Edit PRC Report Screen**

6. The following fields populate automatically with data previously entered:
  - i. Case ID: Unique ID given to the case associated with this blood form. Click the blue text to navigate to the Show Case Record Details screen (Figure 37).
  - ii. Primary Organ: Organ in the study associated with this case
  - iii. BSS: Biospecimen source site associated with this collection
  - iv. Slide Record: CDR-Lite slide ID
  - v. Block ID: Specimen ID for the gross tissue from which the slide was cut
7. Complete the following fields:
  - i. Organ origin: Use the pull-down menu to select the organ associated with the block.
  - ii. Tissue category: Use the pull-down menu to specify the category (e.g., "Normal," "Diseased," "Tumor").
  - iii. Diagnosis/Morphology: Describe the PRC evaluation of the diagnosis/morphology.
  - iv. Autolysis rating: This field is optional. Select only one of the four possible values: 0 for None, 1 for Slight, 2 for Moderate, and 3 for Severe.
  - v. Comments: Include the following information for each tissue:
    - The number of tissue pieces
    - The presence of extraneous tissue, such as fat, and its location (internal or external to the target)
    - Relative (%) or actual size of extraneous tissue
    - Pathologic findings (e.g., congestion, hemorrhage, inflammation, fibrosis)
    - Specific entities, such as Hashimoto's thyroiditis or cirrhosis, to facilitate database searches

8. When the PRC Report is completed, the reviewing pathologist approves and submits it. Now click on the **Update** button. The DM team will then review the PRC Report, which is available within the CDR-Lite to all approved parties.

If a PRC Report requires modification, the PRC will make a new instance of the report, assigning an incremental serial version number.

## 5 Data Management Role

Data management ensures that the data in the CDR-Lite are of high quality, without errors, and complete. The quality of the data is central to the whole process; the data serves as the basis for analysis, publications, and future policy implications. Good clinical and biospecimen data that are well organized, easily accessible, and properly cleaned are essential for producing quality products.

A DM review checks for forms with incomplete, incorrect, inaccurate, or irrelevant items in the data set. The CDR-Lite automates some of these data checks (e.g., checking that an age is a positive number); other checks are manual (e.g., checking to see if birth date is consistent with consent). The CDR-Lite performs automatic checks when a user enters information, so the user gets immediate feedback. Detailed DM reviews require more time but are more comprehensive.

When issues show up in the DM review, a conversation occurs through a process called querying. Issues about candidates, cases, or other records are flagged during the DM review. Each flag raises the QT count. QT counts appear in the first column of the study home page; they are green if the count is zero (no issues) or red if it is one or greater (issues are outstanding). When the BSS gets a red QT, it responds as described in Section 3.7. The DM team then reevaluates the issue. When the issue is resolved, the QT count goes down by one. When no more issues remain, the QT count is zero and displays in green.

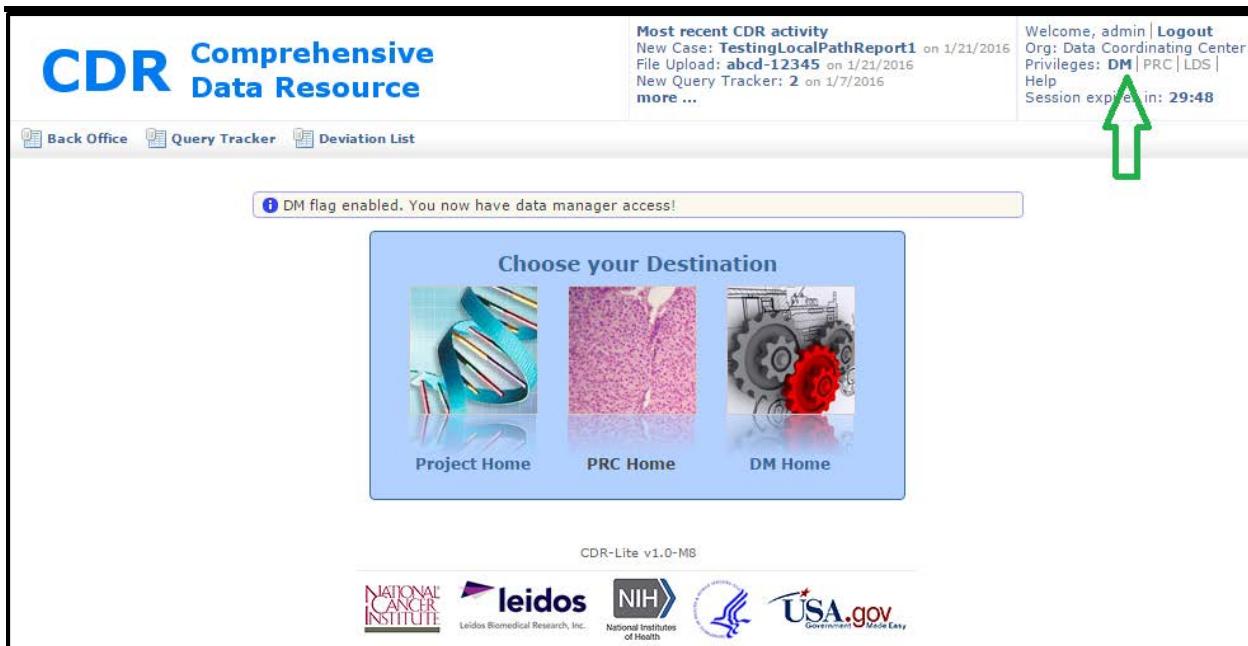
### 5.1 Setting/Clearing the DM Role Flag

The DM role flag toggles access to the Data Manager home and activities found there. Before setting the DM flag, the CDR-Lite Administrator must add the “DM\_ROLE” to the user account. An account with the role is known as “DM enabled.”

Additionally, to use the QT, a user must have the limited data set (LDS) flag set. The CDR-Lite Administrator must add “LDS\_ROLE” to this user account.

Use the following process to set and clear the DM role flag:

1. Log in to the CDR-Lite with a user account that is DM enabled.
2. In the upper right corner of any screen (in Figure 62, the example is of the home screen), click on both the **LDS** and **DM** settings in the “Privileges:” line. This turns on the LDS and DM flags, enabling the viewing and editing of LDS information. A note saying, “DM flag enabled. You now have data manager access!” will appear on the screen.



**Figure 62: Home Screen, with Green Arrow Indicating Location of DM Flag**

3. If this note does not appear, or the LDS and DM text does not display in bold, contact the CDR-Lite administrator about the privileges for your account.
4. To remove DM access, click on the **DM** letters again. The DM letters will no longer be in bold, and the account no longer has access to the DM home page.
5. To go to the DM home page, shown in Figure 63, click on the **DM Home** text or icon.

**Figure 63: DM Home Screen**

## 5.2 Understanding the Data Management Home Page

The Data Management Home page has three tools. The QT is the tool most used in the data cleaning effort. The User Login History is a reporting tool for user logins. The Vocabulary tool allows for setting various values and other functions.

## 5.3 Using the Query Tracker Tool

Queries are the primary mechanism for coordinating data cleaning activities. When questions arise during a DM review of information on a candidate or case, the DM team uses the QT to create a new query. The new query associates with a case record or candidate record by the unique ID. When a query is activated for a candidate or case, the QT count increments. On the study home page, shown in Figure 4, the QT count appears in red. Clicking on the red number for an item brings up its query record.

The following steps outline how to use the QT:

1. Log in to the CDR-Lite with a user account that is DM enabled.
2. In the upper corner of any screen (in Figure 64, the example is the Query List screen), click on the **DM** setting in the “Privileges:” line. A note saying, “DM flag enabled. You have data manager access!” will appear on the screen. Next, click on the **LDS** setting, turning on the LDS flag.
3. Now click on **DM Home**, and select the QT. The CDR-Lite will show the Query List screen, shown in Figure 64, which displays all queries.

ID	Associated With	Case Status	Issue Type	Description	Organization	Query Status	Query Type	Date Opened	Opened By	Due Date	Date Closed	Closed By	Initial Site Response to Query Open Date Duration	Query Open Date to Query Close Date Duration	View
2	abcd-12345	Data Entry Underway	DM Query	asdf	BSS2	Active	Discrepant Data	01/07/2016	asdf	01/01/2016					
1	asdf		DCF	asdf	DCC		Discrepant Data	01/07/2016	asdf	01/01/2016					

**Figure 64: Query List Screen in the Query Tracker**

4. Search for a query to review. Section 3.1.4 explains how to search.

## 5.4 Creating a New Query

Only the data manager can generate a query. Frequently, queries are the result of a data cleansing review of candidate- or case-related information. The process of reviewing is outside the scope of this document, but after finding an issue, use the following steps to create the query:

1. Log in to the CDR-Lite with a user account that is DM enabled.
2. In the upper right corner of any screen (in Figure 65, the example is of the Create Query screen), click on the **DM** setting in the “Privileges:” line. A note saying “DM flag enabled. You have data manager access!” will appear on the screen. Next, click on the **LDS** setting to turn on the LDS flag, enabling the viewing and editing of LDS case information.
3. To create a new query, click on the New Query icon. The CDR-Lite will display the Create Query screen, shown in Figure 65: Create Query Screen.

**CDR Comprehensive Data Resource**

Most recent CDR activity  
New Case: TestingLocalPathReport1 on 1/21/2016  
File Upload: abcd-12345 on 1/21/2016  
New Query Tracker: 2 on 1/7/2016  
[more ...](#)

Welcome, brent1 | [Logout](#)  
Org: Data Coordinating Center  
Privileges: DM | PRC | LDS  
[Help](#)  
Session expires in: 29:58

[Home](#) [Query List](#) [Print](#)

### Create Query

Organization:

Associated with:  Case Record  Candidate Record  Other

Is this a Data Correction Form (DCF)?  Yes  No

Query type:

Description:

Related form(s):

Due date:

Opened by:

CDR-Lite v1.0-M8

NATIONAL CANCER INSTITUTE leidos Leidos Biomedical Research, Inc. NIH USA.gov

**Figure 65: Create Query Screen**

4. Fill out as many of the fields as necessary to describe the issue:
  - i. Organization: Choose from a pull-down list of all organizations defined in the CDR-Lite. This list reflects the organizations created by the administrator when setting up this study.
  - ii. Associated with: Select one of the items associated with the query: "Case Record," "Candidate Record," or "Other." After selecting the association, enter the ID number in the text field that appears.
  - iii. Is this a Data Correction Form (DCF)? Select "Yes" or "No" to state whether this query is about problems related to static field values provided by the BSS. This field is required.
  - iv. Description: Note which form and field(s) have an issue, and describe the issues.
  - v. Related form(s): Enter the CDR-Lite screens or paper forms that are associated with the issue.
  - vi. Due date: Use the calendar to select the due date. This field is required, and the CDR-Lite will use it to set the completion date.
  - vii. Opened by: Enter the name of the data manager opening this query. This field is required.
5. Click on the **Activate** button at the bottom of the screen. This brings up the Show Query screen, shown in Figure 66. Clicking on the **Save** button records the query for future reference. Click the **Cancel** button to exit without saving the query.

The screenshot shows the 'Show Query' page. At the top, there's a header with the CDR logo and navigation links for Home, Query List, Print, and a message about the most recent CDR activity. The main content area has a sub-header 'Show Query' and a message 'Query 3 created'. Below this, there are several input fields and dropdown menus:

- Organization:** BSS 1
- Associated with:**  Case Record  
 Candidate Record  
 Other
- Candidate Record:** BSS 1-6C808229-C
- Is this a Data Correction Form (DCF)?**  Yes  
 No  
Missing Data
- Query type:**
- Description:** Please review. Candidate affiliated with Trump.
- Related form(s):** Create Candidate
- Due date:** 01/30/2016
- Opened by:** wbl

Below these sections are 'Responses' and 'Attachments' sections, both currently empty. At the bottom of the page, there are logos for National Cancer Institute, Leidos Biomedical Research, Inc., NIH, USA.gov, and Government Made Easy, along with a note about the software version: CDR-Lite v1.0-MB.

Figure 66: Show Query After a New Query Creation

## 5.5 Viewing a Query

Responses to queries use a process of responses and attachments. DM review of a response requires the reviewer to view the existing query. To do so, take the following steps:

1. Log in to the CDR-Lite with a user account that is DM enabled.
2. In the upper right corner of any screen (in Figure 66, the example is the Show Query screen), click on the **DM** setting in the “Privileges:” line. A note saying “DM flag enabled. You have data manager access!” will appear on the screen. Next, click on the **LDS** setting, turning on the LDS flag, to enable the viewing and editing of LDS case information.
3. Click on the View icon in the last column of the Query List (see Figure 64). This brings up the Show Query screen, shown in Figure 66.

## 5.6 Closing a Query

Use the following steps to close a query:

1. Log in to the CDR-Lite with a user account that is DM enabled.
2. In the upper right corner of any screen (in Figure 66, the example is the Query screen), click on the **DM** setting in the “Privileges:” line. A note saying “DM flag enabled. You have data manager access!” will appear on the screen. Next, click on the **LDS** setting to turn on the LDS flag, enabling the viewing and editing of LDS case information.
3. Click on the View icon in the last column of the Query List (see Figure 64). This brings up the Show Query screen, shown in Figure 66.

4. After determining what needs correction, look at the site's response in the Responses section. Determine whether the response addresses the subject of the query (e.g., whether the change was made in the CDR-Lite, an explanation was provided, and existing data were verified).
5. If the site response addresses the query, click on the **Resolve** button at the bottom of the screen. A confirmation dialog box will pop up and ask if the query was resolved. If it was, click **OK**. A message will appear at the top of the screen stating that the query was marked as resolved.
6. If the site response does not satisfactorily address the query, there are two options. The first is to use the Response section to ask for additional information or clarification and then click on the **Reactivate** button, sending the query back to the BSS. If that site cannot offer additional information, use the second option: Mark the query as unresolved by clicking on the **Unresolved** button. The Query List page will display "Not resolved" as the query's status.
7. Verify that the query does not require further action, and then close it by clicking on the **Close** button at the bottom of the Show Query screen.

**Note:** The **RESOLVE** status (button in blue at the bottom of the form, Figure 67) is useful for marking queries for additional action (but not site response) by the DM team.

The screenshot shows the 'Show Query' page for a specific query. At the top, there's a header with the CDR logo and navigation links for Home, Query List, and Print. On the right, there's a sidebar with session information: 'Welcome, admin | Logout', 'Org: Data Coordinating Center', 'Privileges: DM | PRC | LDS', 'Help', and 'Session expires in: 29:24'. The main content area is titled 'Show Query' and contains the following information:

- Date opened:** 01/07/2016    **Query status:** Addressed    **Query ID:** 2
- Organization:** BSS2
- Associated with:**  Case Record     Candidate Record     Other  
**abcd-12345**
- Case Record:**  abcd-12345
- Is this a Data Correction Form (DCF)?**  Yes     No
- Query type:** Discrepant Data
- Description:** asdf
- Related form(s):** asdf
- Due date:** 01/01/2016
- Opened by:** asdf
- Responses**: admin added response 02/10/2016 13:59. Fixed.
- Add** button
- Attachments**: **Upload** button
- Action Buttons**: Edit, Reactivate, Resolve, Unresolve

At the bottom of the page, there's a footer with the text 'CDR-Lite v1.0-M8' and logos for National Cancer Institute, Leidos, NIH, and USA.gov.

**Figure 67: Show Addressed Query; Note Additional Buttons at Bottom**

## 5.7 Using the User Login History Tool

The User Login History tool gives the data manager the ability to look at login times, organizations, and whether users logged out or their sessions timed out. The reports can be limited to any period (default is today), any organization, or any specific user. To use the tool, take the following steps:

1. Go to the DM home page, and click on the User Login History tool. The CDR-Lite will display the basic reporting tool showing all of today's activity, shown in Figure 68.

Username	Organization	Login Date	Session Destroyed	Logout	Session Created	Session Last Accessed	Session Id
admin	DCC	2016-01-28 13:02:54 EST	2016-01-28 14:29:16 EST	False	2016-01-28 13:02:49 EST	2016-01-28 13:59:16 EST	F7958F666007E1658B8C86FF71C74183
brent1	DCC	2016-01-28 13:02:06 EST	2016-01-28 13:02:49 EST	True	2016-01-28 12:50:10 EST	2016-01-28 13:02:41 EST	5D4889D3F768F4B137DEFE99ACC5593D

**Figure 68: CDR-Lite User Login History Tool**

2. The search fields are as follows:
  - i. Enter User Name to search: Use the account user name, not the personal name.
  - ii. Enter Organizational Code to search: This is the code for the organization that was entered when the organization was created in the CDR-Lite. You can enter the Organizational Code or the User Name, but not both.
  - iii. Start: Use the calendar to select the earliest date/time for the report. The default is today at midnight.
  - iv. End: Use the calendar to enter the latest date/time for the report. The default is now.
3. After entering the desired values into the search fields, click on the **Search** button. The list at the bottom of the screen will update, showing the login records that match the search.

## 5.8 Using the Vocabulary Tool

This tool allows data managers to configure certain basic terms used in the various screens (such as selections available from pull-down lists) for a specific study.

Take the following steps to use the Vocabulary tool:

1. Go to the DM home page, and click on **Vocabulary** to display the tool, shown in Figure 69. The screen shows all the vocabulary items that you can customize.


**Comprehensive  
Data Resource**

**Most recent CDR activity**  
New Case: TestingLocalPathReport1 on 1/21/2016  
File Upload: abcd-12345 on 1/21/2016  
New Query Tracker: 2 on 1/7/2016  
[more ...](#)

Welcome, admin | [Logout](#)  
Org: Data Coordinating Center  
Privileges: DM | PRC | LDS |  
Help  
Session expires in: 29:54

[Back Office](#)   [DM Home](#)

### CDR-Lite Data Services Vocabulary and Configuration

Controlled Vocabulary	Description
Activity Type	Define case related activity type codes
Blood Draw Type	Define blood draw types
Blood Collection Reason	Define blood blood collection reasons
Blood Tube Type	Define blood tube types
Blood Aliquot	Define blood aliquots types
Blood Draw Tech	Define blood draw technician codes
BSS List	Biospecimen source sites
Case Attachment Type	Define types of case attachment used in file uploads
Case Collection Type	Case collection types
Case Status	Define case status
Container Type	Define containers used in tissue/Blood collections
Fixatives	Define fixatives used to store tissues specimens
Organization	Define Organizations using CDR-Lite
Query Status	Query status codes
Query Type	Define query types
Storage Temp	Define various storage temperatures used
Study	Define study types
Tissue Type	Define tissue type codes
Tissue Location	Define specific location for tissue types
Tissue Category	Define tissue category

CDR-Lite v1.0-M8







**Figure 69: CDR-Lite Data Services Vocabulary and Configuration**

Table 7 shows the vocabulary items, which roles can modify them, and the forms associated with each item.

**Table 7: Vocabulary Items and Access Restrictions**

Name	Definition	User Roles Having Access	Associated Forms/Pages
Activity Type	Define case-related activity type codes	Admin_Role	CaseRecord List, Case Detail page
Blood Draw Type	Define blood draw types	Admin_Role, DM_Role	Edit Blood Draw
Blood Collection Reason	Define blood collection reasons	Admin_Role, DM_Role	Edit Blood Draw
Blood Tube Type	Define blood tube types	Admin_Role, DM_Role	Edit Blood Draw
Blood Aliquot	Define blood aliquot types	Admin_Role, DM_Role	Edit Blood Draw
Blood Draw Tech	Define blood draw technician codes	Admin_Role, DM_Role	Edit Blood Draw
BSS List	BSS codes; list created by adding an organization and declaring it a BSS	Admin_Role, DM_Role (view only)	Numerous

Name	Definition	User Roles Having Access	Associated Forms/Pages
Case Attachment Type	Define types of case attachment used in file uploads	Admin_Role, DM_Role	
Case Collection Type	Define case collection types	Admin_Role, DM_Role	
Case Status	Define case status	Admin_Role, DM_Role	Create Case Record
Container Type	Define containers used in tissue/blood collections	Admin_Role, DM_Role	Create Specimen Record
Fixatives	Define fixatives used to store tissues specimens	Admin_Role, DM_Role	Create Specimen Record, Create Tissue Receipt and Dissection Form
Organization	Define organizations using the CDR-Lite	Admin_Role, DM_Role	User Login History
Query Status	Define query status codes	Admin_Role, DM_Role	
Query Type	Define query types	Admin_Role, DM_Role	
Storage Temp	Define storage temperatures used	Admin_Role, DM_Role	Create Specimen Record
Study	Define study types	Admin_Role, DM_Role	Home, Numerous
Tissue Type	Define tissue type codes	Admin_Role, DM_Role	Create Specimen Record
Tissue Location	Define specific locations for tissue types	Admin_Role, DM_Role	Create Specimen Record
Tissue Category	Define tissue categories	Admin_Role, DM_Role	Edit PRC Report

2. Click on the item of interest. This example uses “Blood Draw Type,” but all editable vocabulary items work similarly. Clicking on **Blood Draw Type** brings up the BloodDrawType List, shown in Figure 70.

Name	Code	Description
Pre-operative (Pre Anesthesia)	T1	
Post-operative	T2	

Figure 70: BloodDrawType List

3. The two previously defined blood draw types appear in the list, along with a type code. To edit either of those previous entries, click on the name. To add a blood draw type, click on the New BloodDrawType icon. The CDR-Lite will display the Create BloodDrawType screen, shown in Figure 71.

The screenshot shows the 'Create BloodDrawType' page. At the top, there are three input fields: 'Name' (empty), 'Code' (empty), and 'Description' (empty). Below these is a 'Create' button. In the top right corner, there is a status bar with information about recent activity, session details, and navigation links. At the bottom, there are logos for the National Cancer Institute, Leidos, NIH, and USA.gov.

**Figure 71: Create BloodDrawType Screen**

4. Complete the fields as follows:
- Name: Enter the title of the new blood draw type (e.g., "Six-Month Follow-Up"). This field is required.
  - Code: Enter the short code used for tracking this type of blood draw. This field is required.
  - Description: Enter any additional information about this type of blood draw, such as a reference to the SOP containing details.
5. Click on the **Create** button. The CDR-Lite will display the Show BloodDrawType screen with a message that the blood draw type was created, as shown in Figure 72.

The screenshot shows the 'Show BloodDrawType' page. It displays a message: 'BloodDrawType 3 created'. Below this, there is a table with four rows: Id (3), Name (Six-Month Follow-up), Code (T3), and Description (After surgery and collection, return to new normal). At the bottom of the table are 'Edit' and 'Delete' buttons. The top right corner shows the same status bar as Figure 71. The bottom features the same logos as Figure 71.

**Figure 72: Show BloodDrawType After Adding New Type**

6. If all is acceptable, click on the Home icon to return to the DM home page, click on the BloodDrawType List icon to see the updated list, or click on the New BloodDrawType icon to add another draw.

A similar process works for each of the editable items in the vocabulary. Once changed, the modified lists become available on the associated forms.

## 6 Limited Data Set Role

The LDS is a limited set of identifiable patient information as defined in the privacy regulations issued under the Health Insurance Portability and Accountability Act, better known as HIPAA. The CDR-Lite uses a LDS role flag (sometimes just called the “LDS Role”) to distinguish whether a user may view or modify LDS fields. Unlike the other roles in the CDR-Lite, the LDS role flag controls access to LDS information for all users, regardless of other role settings.

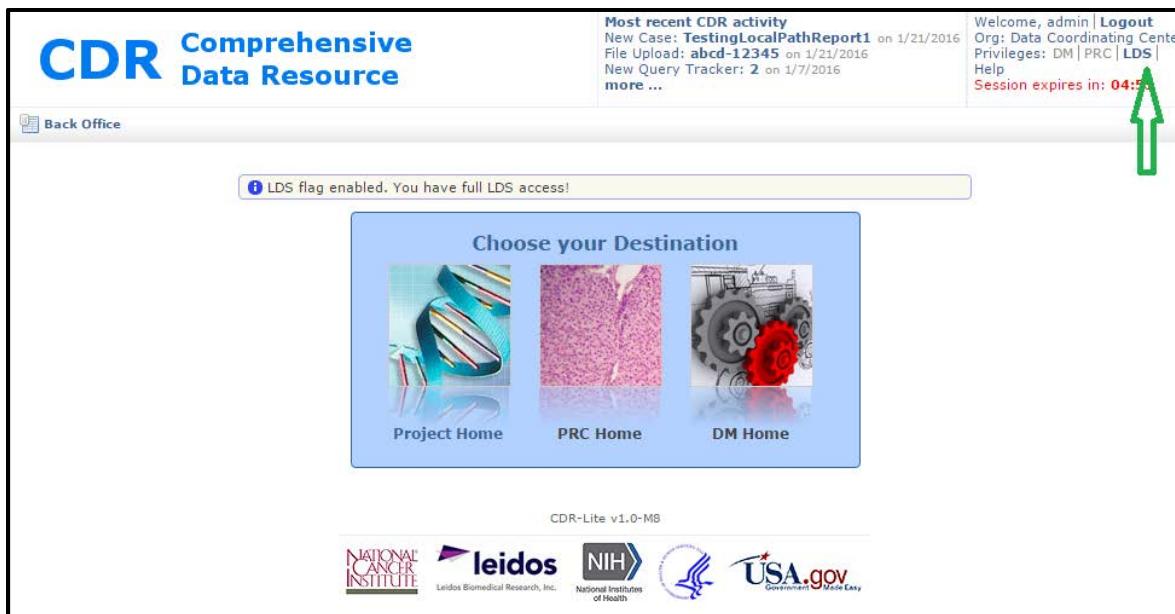
When a user attempts to view a record that contains a field with LDS information but does not have the LDS role flag set, that field displays with the message **REDACTED (No LDS privilege)** in red.

One restriction on the use of the LDS role flag is that it must be set *before* adding any other roles.

### 6.1 Setting and Clearing the LDS Role Flag

The LDS role flag toggles protection of PII and PHI field contents. Before setting the LDS flag, the CDR-Lite Administrator must add the “LDS\_ROLE” to the user account. Use the following process to set and clear the flag:

1. Log in to the CDR-Lite with a user account that is LDS enabled.
2. In the upper right corner of any screen (in Figure 73, the example is of the home screen), click on the **LDS** setting in the “Privileges:” line. This turns on the LDS flag, enabling the viewing and editing of LDS information. A note saying “LDS flag enabled. You have full LDS access!” will appear on the screen.



**Figure 73: Home Screen with Green Arrow Indicating Location of LDS Flag**

3. If this note does not appear, or the LDS text does not display in bold, contact the CDR-Lite administrator about the privileges for this account.
4. To remove LDS access, click on the **LDS** setting again. The “LDS” text will no longer be bold, and all LDS fields will be redacted.

## 7 Administrative Role

The Administrative role gives a user access to many of the CDR-Lite's software internals for activities such as setting up a new study, adding a new organization, and creating new users. The following sections describe the methods for performing most administrative actions.

### 7.1 Process for Creating a New Study in the CDR-Lite

This is the approved process for creating a new, configured study. Note that the following order is critical, because there are dependencies between the steps:

1. Log in to the CDR-Lite as an administrator.
2. Modify the tissue list to cover the tissues in the study (see Section 7.7).
3. Modify the organization list to reflect the organizations participating in this study (see Section 7.8).
4. Create the study (see Section 7.2).
5. Associate any organizations that are BSSs with the study (see Section 7.4). There must be at least one.
6. Create users (see Section 7.5).
7. Update the Application Settings as needed for this study (see Section 7.6).

### 7.2 Adding a New Study Record

This is the approved process for creating a new study:

1. Log in to the CDR-Lite as an administrator.
2. Add the DM role (see Section 7.5).
3. Click on the DM Home icon.
4. Click on **Vocabulary**.
5. Click on the **Study controlled vocabulary** item. This will bring up the Study List screen shown in Figure 74.

The screenshot shows the CDR-Lite application interface. At the top, there is a header bar with the CDR logo and the text "Comprehensive Data Resource". On the right side of the header, there are links for "Logout", "Org: Data Coordinating Center", "Privileges: DM | PRC | LDS", "Help", and "Session expires in: 29:47". Below the header, there is a navigation bar with "Home" and "New Study" buttons. The main content area is titled "Study List". It contains a table with three columns: "Name", "Code", and "Description". There are two rows in the table: one for "Brent2" (Code: ABC D, Description: Test Study with space in code.) and one for "Brent1" (Code: WBL, Description: Example Study). At the bottom of the screen, there is a footer with logos for National Cancer Institute, Leidos Biomedical Research, Inc., NIH, and USA.gov, along with the text "CDR-Lite v1.0-M8".

**Figure 74: Study List Screen with Two Example Studies**

6. Click on the New Study icon. This will bring up the Create Study screen shown in Figure 75.

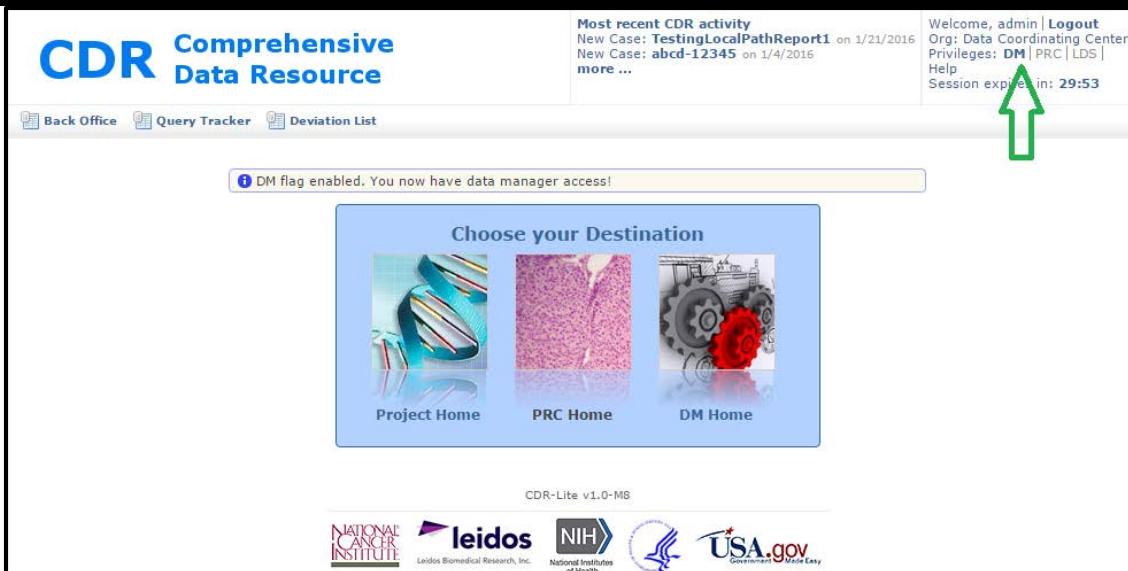
Figure 75: Create Study Screen

7. Fill in the required fields as follows:
  - i. Name: Enter the proper (long) name of the study. Study names should be unique.
  - ii. Code: Enter the prefix used in creating unique identifiers for items related to this study. This prefix should be unique across all studies maintained by this instance of the CDR-Lite. By convention, study codes should have no spaces and be uppercase only.
  - iii. Description: Describe the study.
8. Click on the **Create** button. This will bring up the Study List screen with the new study added.
9. To proceed *without* creating a study, use the back arrow on the browser, or click on the Study List icon.

### 7.3 Adding an Organization

Use the following process to add an organization:

1. Log in as an administrator, and toggle the flag for DM privilege by clicking on **DM** in the "Privileges:" line, shown in Figure 76.



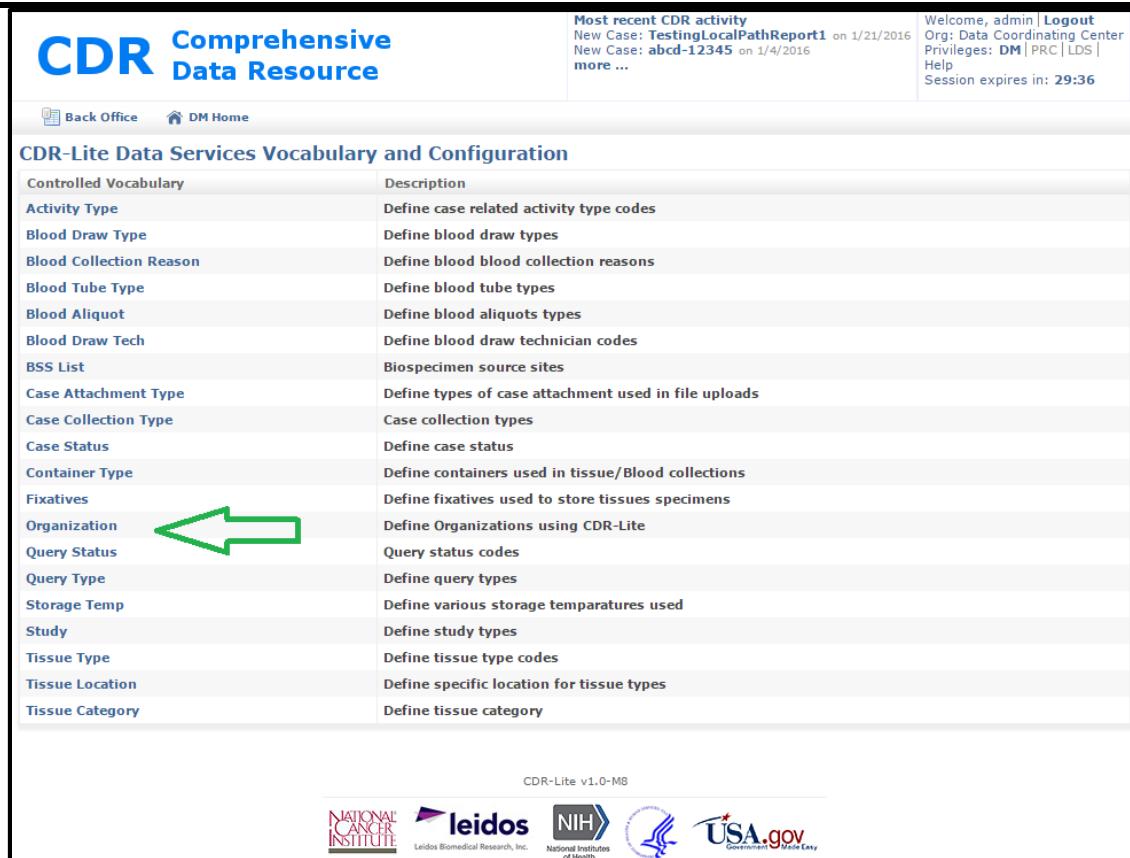
**Figure 76: Adding the DM Role in Adding an Organization**

2. Go to the DM Home screen, shown in Figure 77, by clicking on the **DM Home** image or text.



**Figure 77: Accessing Administrative Vocabulary Items**

3. Click on **Vocabulary** to go to the CDR-Lite Data Services Vocabulary and Configuration screen, shown in Figure 78.



Welcome, admin | [Logout](#)  
Org: Data Coordinating Center  
Privileges: **DM** | PRC | LDS |  
Help  
Session expires in: 29:36

**CDR-Lite Data Services Vocabulary and Configuration**

Controlled Vocabulary	Description
Activity Type	Define case related activity type codes
Blood Draw Type	Define blood draw types
Blood Collection Reason	Define blood collection reasons
Blood Tube Type	Define blood tube types
Blood Aliquot	Define blood aliquots types
Blood Draw Tech	Define blood draw technician codes
BSS List	Biospecimen source sites
Case Attachment Type	Define types of case attachment used in file uploads
Case Collection Type	Case collection types
Case Status	Define case status
Container Type	Define containers used in tissue/Blood collections
Fixatives	Define fixatives used to store tissues specimens
<b>Organization</b>	Define Organizations using CDR-Lite
Query Status	Query status codes
Query Type	Define query types
Storage Temp	Define various storage temperatures used
Study	Define study types
Tissue Type	Define tissue type codes
Tissue Location	Define specific location for tissue types
Tissue Category	Define tissue category

CDR-Lite v1.0-M8

**Figure 78: CDR-Lite Data Services Vocabulary and Configuration Showing Organization**

4. Click on **Organization** to bring up the Organization List screen, shown in Figure 79.



Welcome, admin | [Logout](#)  
Org: Data Coordinating Center  
Privileges: **DM** | PRC | LDS |  
Help  
Session expires in: 28:22

**CDR Comprehensive Data Resource**

Most recent CDR activity  
New Case: TestingLocalPathReport1 on 1/21/2016  
New Case: abcd-12345 on 1/4/2016  
more ...

**Organization List**

Name	Code	Description	Shipping Address	Is Bss
Data Coordinating Center	DCC			
PRC Example	PRCE	Example PRC	Here, Now	False
BSS 1	BSS 1	BSS #1	anywhere, USA	True
BSS2	BSS2	A second BSS	1313 Mockingbird Ct. Burbank, CA	True

CDR-Lite v1.0-M8

**Figure 79: Organization List with New Organization Indicated**

5. Click on **New Organization** to bring up the Create Organization screen, shown in Figure 80.

Most recent CDR activity  
New Case: TestingLocalPathReport1 on 1/21/2016  
New Case: abcd-12345 on 1/4/2016  
[more ...](#)

Welcome, admin | [Logout](#)  
Org: Data Coordinating Center  
Privileges: DM | PRC | LDS |  
Help  
Session expires in: 29:43

**Create Organization**

Name	<input type="text"/>
Code	<input type="text"/>
Description	<input type="text"/>
Shipping Address	<input type="text"/>
Is Bss	<input type="checkbox"/>

**Create**

CDR-Lite v1.0-M8

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**Figure 80: Create Organization Screen**

6. Fill in the fields of the form as follows:
  - i. Name: Enter the proper name of the organization, which is typically an institute name or acronym.
  - ii. Code: Enter the three or four characters used in labeling materials (e.g., tissues, reports) from this organization.
  - iii. Description: Describe the organization, including, for example, the types of resources this organization offers, contact points, or other reference materials.
  - iv. Shipping Address: Enter the organization's street address.
  - v. Is BSS: If the organization is a BSS, check this box; otherwise, leave it blank.

**Note:** Make sure that the new organization is identified as a BSS, or not, appropriately.

7. Click on the **Create** button.
8. If there are problems with the information entered about an organization, go to the Organization List screen (Figure 79). Click on the name of the organization with the information problem to go to the Show Organization screen, shown in Figure 81.

Most recent CDR activity  
New Case: TestingLocalPathReport1 on 1/21/2016  
New Case: abcd-12345 on 1/4/2016  
[more ...](#)

Welcome, admin | [Logout](#)  
Org: Data Coordinating Center  
Privileges: **DM** | PRC | LDS |  
Help  
Session expires in: 29:34

[Home](#) [Organization List](#) [New Organization](#)

**Show Organization**

<b>Id</b>	3
<b>Name</b>	BSS 1
<b>Code</b>	BSS 1
<b>Description</b>	BSS #1
<b>Shipping Address</b>	anywhere, USA
<b>Is Bss</b>	True

[Edit](#)

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**Figure 81: Show Organization Screen**

9. Confirm that this is the correct organization to modify. If not, use the Back button on the browser, or click on the Organization List icon. When you are satisfied, click on the **Edit** button to go to the Edit Organization screen, shown in Figure 80.
10. Make the appropriate changes and click on the **Update** button.

## 7.4 Associating a Study and Tissue Types with a BSS

Once you have added a study and an organization that is a BSS, the final step is associating the two. Take the following steps:

10. Log in to the CDR-Lite as an administrator.
11. Add the DM role.
12. Click on **DM Home**.
13. Click on **Vocabulary**.
14. Click on the **Study controlled vocabulary** hypertext. This will bring up the screen shown in Figure 74.
15. Click on the name of the study. The CDR-Lite will display the screen in Figure 82.

CDR-Lite v1.0-MB

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**Show Study**

<b>Id</b>	1
<b>Name</b>	Brent1
<b>Code</b>	WBL
<b>Description</b>	Example Study

[Edit](#)

**Figure 82: Show an Individual Study Screen**

16. Click on the **Edit** button to show the screen in Figure 83.

The screenshot shows the 'Edit Study' interface. At the top, there are navigation links: Home, Study List, and New Study. Below that, the title 'Edit Study' is displayed. The form contains the following fields:

- Name:** Brent1
- Code:** WBL
- Description:** Example Study
- BSS List:** BSS 1 (checked), BSS2 (checked)
- Tissue Type List:** Kidney (checked), Colon (checked), Blood (checked), Ovary (unchecked), Lung (unchecked), Liver (unchecked)

A blue 'Update' button is located at the bottom left of the form.

**Figure 83: Edit Study Screen**

17. Update the study fields as appropriate. The BSS List and Tissue Type List reflect values previously added by the administrator. Discussion of editing those lists is above and following.
18. Click on the **Update** button. This will show the List Sites screen.
19. To avoid committing the changes, use the Back arrow on the browser, or click on either the Study List icon or the Home icon.

## 7.5 Administering Users

The following actions are available for administering user accounts:

- Add/create a user
- Modify an existing user
- Look up a user's current settings

**Note:** Each study needs at least three users, as shown in Table 8.

**Table 8: Types of Users Required for Each Study**

User Role	Roles (All Roles Specified)
BSS User	ROLE_BSS
Data Manager	ROLE_DCC, ROLE_DM
PRC Evaluator	ROLE_DCC, ROLE_PRC

**Note:** The user names should be all lowercase letters and numbers, with no spaces.

Use the following process to administer user accounts:

20. Log in to the CDR-Lite as an administrator.
21. From the CDR-Lite Project Home Destination page, click on the Back Office icon in the upper left (see Figure 84).



Figure 84: CDR-Lite Project Home Destination Page

22. Once in the back office, click on **User Administration**.

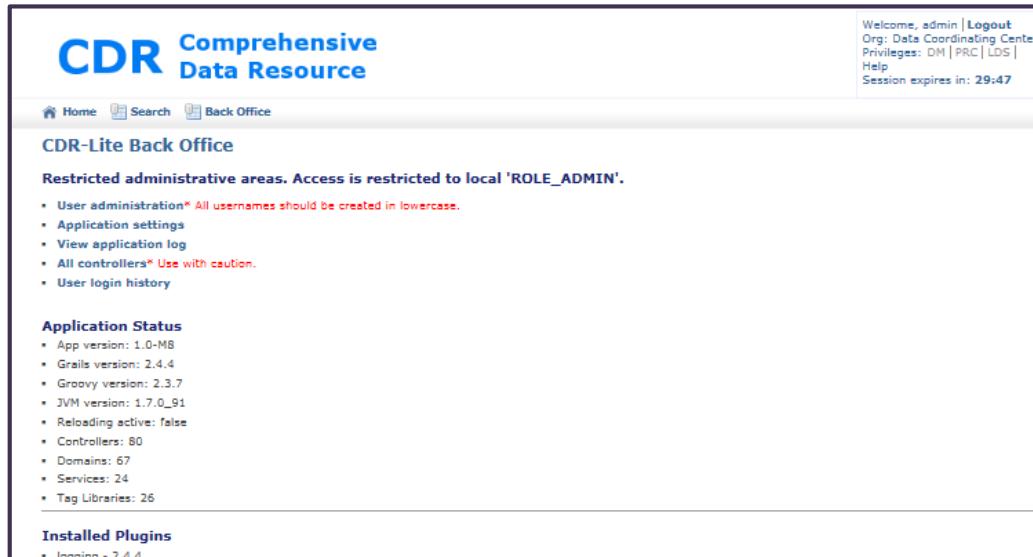


Figure 85: CDR Back Office

23. The screen will update to the Spring Security Management Console page, shown in Figure 86.



**Figure 86: Spring Security Management Console**

24. To modify restrictions on an existing account, use the following steps:

- i. Type in the user name of the account.
- ii. Click on the **Search** button.
- iii. Click on the check boxes to change restrictions.
  - a. Enabled: “True” or “Either” allows the user to log in. If “False” is checked, the user cannot log in.
  - b. Account Expired: “True” blocks the account from further activity until enabled by an administrator. If “False” or “Either” is checked, the account is available for login.
  - c. Account Locked: “True” blocks the account from further activity, typically for administrative reasons. If “False” or “Either” is checked, the account is available for login.
  - d. Password Expired: The password status is set either by the administrator or by a nightly process requiring passwords be changed periodically. When “True” is checked, the next time the account is used, the user must enter a new password.

25. To create a new account, take the following steps:

- i. In the Spring Security Management Console (Figure 87), find the “User” menu and select the “Create” item from the menu list. The screen shifts to the Create User screen, shown in Figure 87.

The screenshot shows the 'Create User' interface in the Spring Security Management Console. The 'User Details' tab is active. The form includes fields for Username, First Name, Last Name, Email, Password, and several checkboxes for account status (Enabled, Account Expired, Account Locked, Password Expired). The Organization dropdown is set to 'Data Coordinating Center'. A 'Create' button is located at the bottom left.

**Figure 87: Create User: User Details**

- ii. Complete the following required fields:
  - a. Username: User names should be all lowercase letters with no spaces.
  - b. First Name: Enter the first name for the person associated with this account.
  - c. Last Name: Enter the family name for the person associated with this account.
  - d. Email: Enter the email address to which the CDR-Lite should send automatic alerts, warnings, and notifications.
  - e. Password: Enter the first password for the user logging in.
  - f. Enabled: This box is checked by default; uncheck it if the account should not be available when created (e.g., if you are creating the account proactively).
  - g. Account Expired: If this box is checked, the created account is blocked from use. Attempts to log in return the account expired error message.
  - h. Account Locked: If this box is checked, the created account blocks the user from making any changes.
  - i. Password Expired: If this box is checked, once the user logs in, they will have to change their password immediately.
  - j. Organization: By default, the organization is set to Data Coordinating Center.
- iii. Now click on the **Roles** tab.

**Note:** If the following step is not done, then no one can log in to this account!

- iv. Click on the check boxes specifying the roles that this user can assume:
  - a. ROLE\_ADMIN: Users with this role have administrative privileges, including creating new users, modifying the vocabulary, and creating new studies.
  - b. ROLE\_BSS: Specify this role for an account for a BSS, which is a place where biospecimens and data are collected.
  - c. ROLE\_DCC: This role is for Data Collection and Coordinating Center (DCC) activities.
  - d. ROLE\_DM: This role is for data managers.
  - e. ROLE\_LDS: This role allows the user to see PHI associated with a candidate/participant, such as procedure dates.

- f. ROLE\_PRC: This role allows the user to perform functions of the PRC.
- g. ROLE\_SERVICE: This role is for service accounts for accessing RESTful Web services.

**Note:** For ROLE\_ADMIN, ROLE\_DM, ROLE\_PRC, and ROLE\_QM, you should also specify ROLE\_DCC. Without this role, the user cannot go to the home screens.

The screenshot shows the 'Create User' interface in the Spring Security Management Console. At the top, there are tabs for 'Users', 'Roles', 'Registration Code', 'ACL', and 'Security Info'. The 'Roles' tab is currently selected. Below the tabs, the title 'Create User' is displayed. Underneath, there are two tabs: 'User Details' and 'Roles', with 'Roles' being the active tab. A list of available roles is shown, including: ROLE\_ADMIN, ROLE\_BSS, ROLE\_DCC, ROLE\_DM, ROLE\_LDS, ROLE\_PRC, and ROLE\_SERVICE. In the bottom left corner of the main area, there is a 'Create' button.

**Figure 88: Create User: Roles**

- v. After the information in *both* tabs is complete, click on the **Create** button in the lower left corner of the screen.
26. To search for users by role, use the following steps:
- i. In the Spring Security Management Console (Figure 88), click on the Users menu, and select the **Edit** item. This changes the screen to Edit Role, shown in Figure 89.
  - ii. Click on the **Role Details** tab.

The screenshot shows the 'Edit Role' interface in the Spring Security Management Console. At the top, there are tabs for 'Users', 'Roles', 'Registration Code', 'ACL', and 'Security Info'. The 'Roles' tab is currently selected. Below the tabs, the title 'Edit Role' is displayed. Underneath, there are two tabs: 'Role Details' and 'Users', with 'Role Details' being the active tab. A field labeled 'Authority' contains the value 'ROLE\_ADMIN'. In the bottom left corner of the main area, there are 'Update' and 'Delete' buttons.

**Figure 89: Determining Which Users Have a Specific Role**

- iii. In the Authority field, type the desired role.

- iv. Click on the **Update** button, and then select the **Users** tab. This will display the accounts associated with that role.

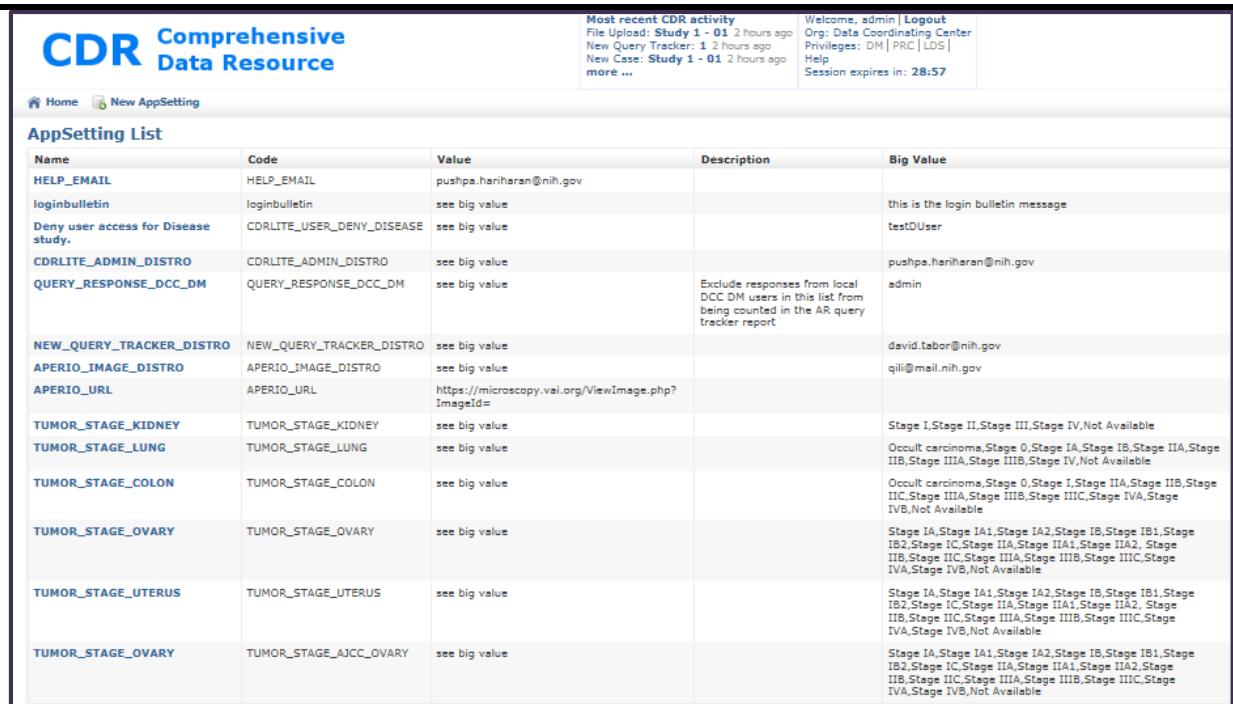
## 7.6 Administering Application Settings

This process configures the CDR-Lite with various installation-specific values. Some of these values will be set once and will not change. Others, such as the login bulletin, may need frequent updates to keep users alerted to changes or interruptions in website availability.

27. Log in to the CDR-Lite as an administrator.
28. Click on the Back Office icon in the upper left.
29. Once in the back office, click on **Application settings** (Table 9: CDR-Lite Basic Applications Settings).
30. The CDR-Lite will display the AppSetting List page, shown in Figure 90. As the CDR-Lite is tailored to specific studies, additional settings specific to a study may become available. Table 9 describes the meaning of each setting.

**Table 9: CDR-Lite Basic Applications Settings**

Name	Description
HELP_EMAIL	Email address for help desk queries, to which the browser sends email when users click on the <b>Help</b> button
Loginbulletin	Message displayed when a user logs in to the system
Deny user access for Disease study	Study-specific setting
CDRLITE_ADMIN_DISTRO	Email address or comma-separated list of addresses to which emails are sent when administrative events trigger inside the CDR-Lite
QUERY_RESPONSE_DCC_DM	Excludes responses from local DCC DM users in this list from being counted
NEW_QUERY_TRACKER_DISTRO	Email address or comma-separated list of addresses to which emails are sent when new query events trigger within the CDR-Lite
APERIO_IMAGE_DISTRO	Email address or comma-separated list of addresses to which emails are sent when a new Aperio image is received
APERIO_URL	URL used in connecting to the Aperio image server
TUMOR_STAGE_KIDNEY	Comma-separated list of applicable cancer stages
TUMOR_STAGE_LUNG	Comma-separated list of applicable cancer stages
TUMOR_STAGE_COLON	Comma-separated list of applicable cancer stages
TUMOR_STAGE_OVARY	Comma-separated list of applicable cancer stages
TUMOR_STAGE_UTERUS	Comma-separated list of applicable cancer stages



The screenshot shows the 'AppSetting List' section of the CDR-Lite application. At the top, there's a header bar with the CDR logo, navigation links like 'Home' and 'New AppSetting', and a user session summary. Below the header is a table with columns for Name, Code, Value, Description, and Big Value. The table contains various configuration items such as 'HELP\_EMAIL', 'loginbulletin', 'Deny user access for Disease study.', 'CDRLITE\_ADMIN\_DISTRO', 'QUERY\_RESPONSE\_DCC\_DM', 'NEW\_QUERY\_TRACKER\_DISTRO', 'APERIO\_IMAGE\_DISTRO', 'APERIO\_URL', 'TUMOR\_STAGE\_KIDNEY', 'TUMOR\_STAGE\_LUNG', 'TUMOR\_STAGE\_COLON', 'TUMOR\_STAGE\_OVARY', 'TUMOR\_STAGE\_UTERUS', and 'TUMOR\_STAGE\_OVARY'. Each row provides a detailed description of its purpose and value.

Name	Code	Value	Description	Big Value
HELP_EMAIL	HELP_EMAIL	pushpa.hariharan@nih.gov		
loginbulletin	loginbulletin	see big value		this is the login bulletin message
Deny user access for Disease study.	CORLITE_USER_DENY_DISEASE	see big value		testUser
CDRLITE_ADMIN_DISTRO	CDRLITE_ADMIN_DISTRO	see big value		pushpa.hariharan@nih.gov
QUERY_RESPONSE_DCC_DM	QUERY_RESPONSE_DCC_DM	see big value	Exclude responses from local DCC DM users in this list from being counted in the AR query tracker report	admin
NEW_QUERY_TRACKER_DISTRO	NEW_QUERY_TRACKER_DISTRO	see big value		david.tabor@nih.gov
APERIO_IMAGE_DISTRO	APERIO_IMAGE_DISTRO	see big value		qili@mail.nih.gov
APERIO_URL	APERIO_URL	https://microscopy.vai.org/ViewImage.php?ImageId=		
TUMOR_STAGE_KIDNEY	TUMOR_STAGE_KIDNEY	see big value		Stage I,Stage II,Stage III,Stage IV,Not Available
TUMOR_STAGE_LUNG	TUMOR_STAGE_LUNG	see big value		Occult carcinoma,Stage 0,Stage IA,Stage IB,Stage IIA,Stage IIB,Stage IIIA,Stage IIIB,Stage IV,Not Available
TUMOR_STAGE_COLON	TUMOR_STAGE_COLON	see big value		Occult carcinoma,Stage 0,Stage I,Stage IA,Stage IB,Stage IIC,Stage IIIA,Stage IIIB,Stage IIIC,Stage IVA,Stage IVB,Not Available
TUMOR_STAGE_OVARY	TUMOR_STAGE_OVARY	see big value		Stage IA,Stage IA1,Stage IA2,Stage IB,Stage IB1,Stage IB2,Stage IC,Stage IIA,Stage IIA1,Stage IIA2,Stage IIB,Stage IIC,Stage IIIA,Stage IIIB,Stage IIIC,Stage IVA,Stage IVB,Not Available
TUMOR_STAGE_UTERUS	TUMOR_STAGE_UTERUS	see big value		Stage IA,Stage IA1,Stage IA2,Stage IB,Stage IB1,Stage IB2,Stage IC,Stage IIA,Stage IIA1,Stage IIA2,Stage IIB,Stage IIC,Stage IIIA,Stage IIIB,Stage IIIC,Stage IVA,Stage IVB,Not Available
TUMOR_STAGE_OVARY	TUMOR_STAGE_AJCC_OVARY	see big value		Stage IA,Stage IA1,Stage IA2,Stage IB,Stage IB1,Stage IB2,Stage IC,Stage IIA,Stage IIA1,Stage IIA2,Stage IIB,Stage IIC,Stage IIIA,Stage IIIB,Stage IIIC,Stage IVA,Stage IVB,Not Available

Figure 90: CDR-Lite AppSetting List

## 7.7 Modifying Tissue List to Include New Types of Specimens

This process configures the CDR-Lite to include the various types of tissues collected in a study:

31. Log in to the CDR-Lite as an administrator.
32. Add the DM privileges by clicking on **DM** in the “Privileges” list in the upper right corner of the screen. You will receive an on-screen notification that the DM flag was enabled and that you now have DM access.
33. Click on **DM Home** under “Choose your Destination” to open the DM home page.
34. On the DM home page, click on **Vocabulary** in the “DM Areas” list. The CDR-Lite Vocabulary and Configuration page will open.
35. On the vocabulary page, click on **Tissue Type**. The Tissue Type List page will open.
36. On the Tissue Type List page, see if all tissue types used in this study are available under the “Name” column. If they are not, click on **New Tissue Type** at the top of the list to open the Create Tissue Type page.
37. Complete the following fields and click the **Create** button.
  - i. Name: Enter the common name of the tissue for collecting; this field is required.
  - ii. Code: Enter the code used for code lookups by the system; this field is required.
  - iii. Description: Describe details of this tissue type; this field is optional.
 If any errors are displayed, you must correct them before clicking **Create** again. If there are no errors, the tissue type value is added, and the Show Tissue Type page will open. From there, you can edit or delete the tissue type.
38. To add more tissue types, click on the **Tissue Type List** link to return to the Tissue Type List page and follow the instructions starting at #6 above.

## 7.8 Modifying the List of Organizations

This process adds organizations to the CDR-Lite. Some organizations can be designated as BSSs.

39. Log in to the CDR-Lite as an administrator.
40. Add the DM privileges by clicking on **DM** in the “Privileges:” line in the upper right corner of the screen.
41. Click on **DM Home**, then click on **Vocabulary**.
42. On the vocabulary page, click on **Organization**.
43. Click on **New Organization** at the top of the list to go to the Create Organization page. Complete the following fields:
  - i. Name: Enter the name of the organization; this field is required.
  - ii. Code: Enter a unique set of letters (preferably all uppercase) to serve as a code; this field is required.
  - iii. Description: Describe the organization.
  - iv. Shipping Address: Enter the organization’s shipping address; this field is required.
  - v. Is Bss: Click on this box if the organization is a BSS; this field is optional.
44. When you are finished, click **Create**.

**NOTE:** All studies in the CDR-Lite need at least three organizations:

- Data Coordinating Center: Where the information in the CDR-Lite is checked and queries are started.
- PRC: Where the collected specimen’s histology is confirmed.
- BSS: Where the biospecimen is originally collected and initial information is gathered.

**NOTE:** Associating a BSS with a study requires an additional step. See Section 7.3.

## Key Terms

The following table defines and explains terms and acronyms relevant to this document.

Term	Definition
BSS	Biospecimen source site: An institute from which human tissue is initially collected
CDR	Comprehensive Data Resource
CDR-Lite	Comprehensive Data Resource – Non-study specific version
DM	Data management: The people and activities preserving data integrity
GORM	Grails Object Relational Mapping
Grails	A powerful computer software framework based on the Groovy programming language and emphasizing rapid software development of Web-based applications
LDS	Limited data set: A reflection of the central data where PHI and PII have been protected
PHI	Protected health information: Health information, including demographic information, that relates to an individual's physical or mental health or the provision of or payment for health care
PII	Personally identifiable information: Individually identifiable health information
RESTful	A type of Internet service interface, typically between programs, that exchanges information
SOP	Standard operating procedure: A detailed document precisely describing the performance of a protocol