

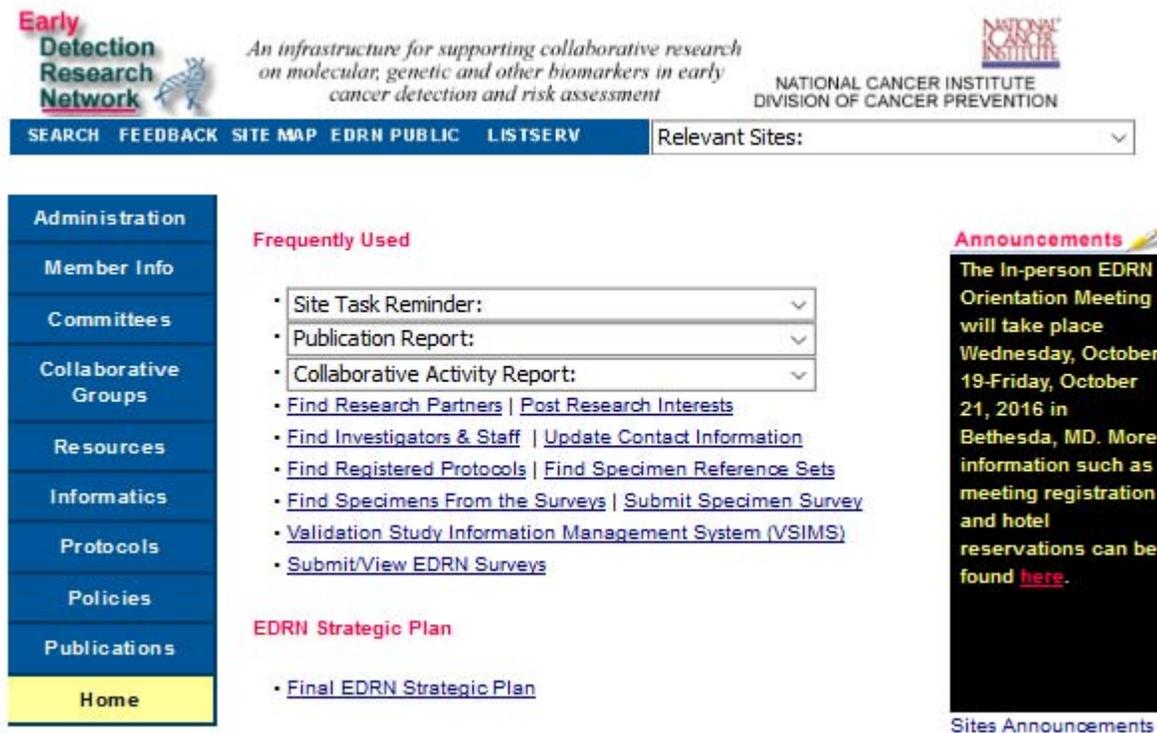
1.1 Appendix 9 – Secure Website Users Guide

SECTION 1 HOMEPAGE

1.1 Overview

This section describes the overall set up of the EDRN Secure Website that is used by all EDRN Sites (BDLs, BRLs, CVCs, Associate Members, NCI and DMCC). The URL used to access the website is <https://www.compass.fhcr.org/enteredrn/> and only those users with approval to access the site can get past the “Enter Page” (See Section 6.3 of the EDRN Manual of Operations for obtaining access to the EDRN Secure Website.)

Figure 1.1 – Home Page



A navigation bar is located at the top of every screen. The navigation bar consists of the following features: Search, Feedback, Site Map, EDRN Public and Listserv. There is also a pull-down list of other Relevant Sites that users may be interested in.

The Administration menu is only for the DMCC. The main menu consists of nine components: Member Info, Committees, Collaborative Groups, Resources, Informatics, Protocols, Policies and Publications.

The Home Page also consists of information pertaining to upcoming Meetings, regularly accessed Documents and Frequently Used tasks and links.

The following section contains instructions for completing the tasks and/or maintenance for which each **EDRN site is responsible**. It is up to each site to ensure that the Contact Information, Protocol Registration(s), Specimen information, Research interests, and publication list are up-to-date and accurate.

The easiest way to update all required items is to choose your name from the Site Task Reminder under Frequently Used and click the various hyperlinks to add/update your sites information.

SECTION 2 MEMBER INFO

The [Member Info](#) component allows a user to view the entire Members List or view by type of EDRN site ([BDL](#), [BRL](#), [CVC](#), [DMCC](#), [JPL](#), [NCI](#)). It also provides the following functions:

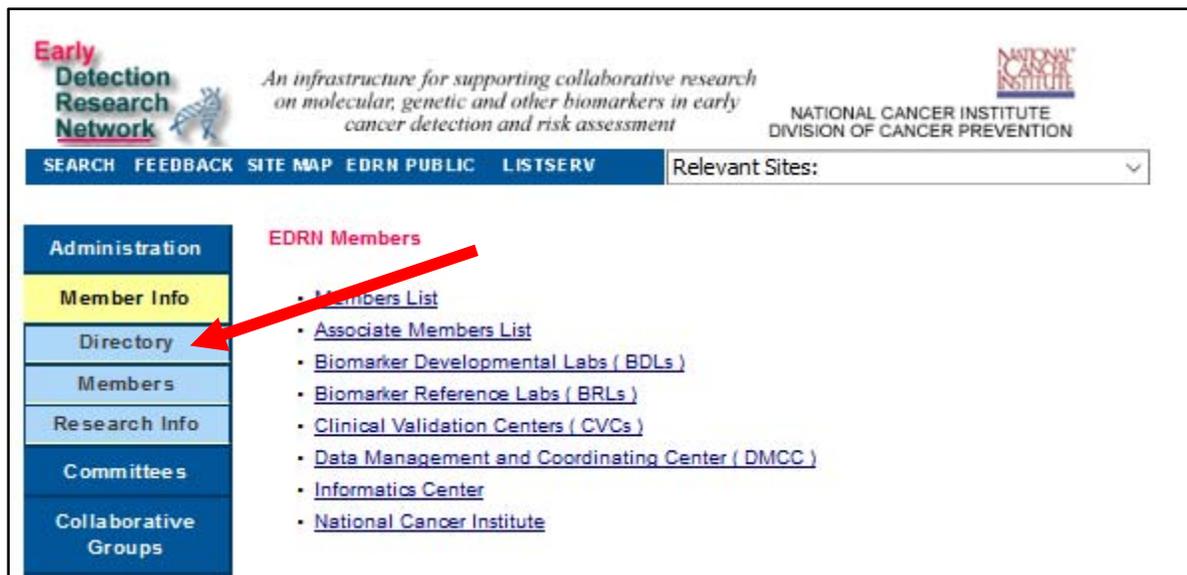
- Add, update or remove/reactivate contact information for anyone at your site.
- Search for contact information for any EDRN member.
- Add, update, remove or search for Investigator Research Information.

2.1 Contact Information

To **ADD**, **UPDATE** or **REMOVE/REACTIVATE** contact information from your EDRN site complete the following steps:

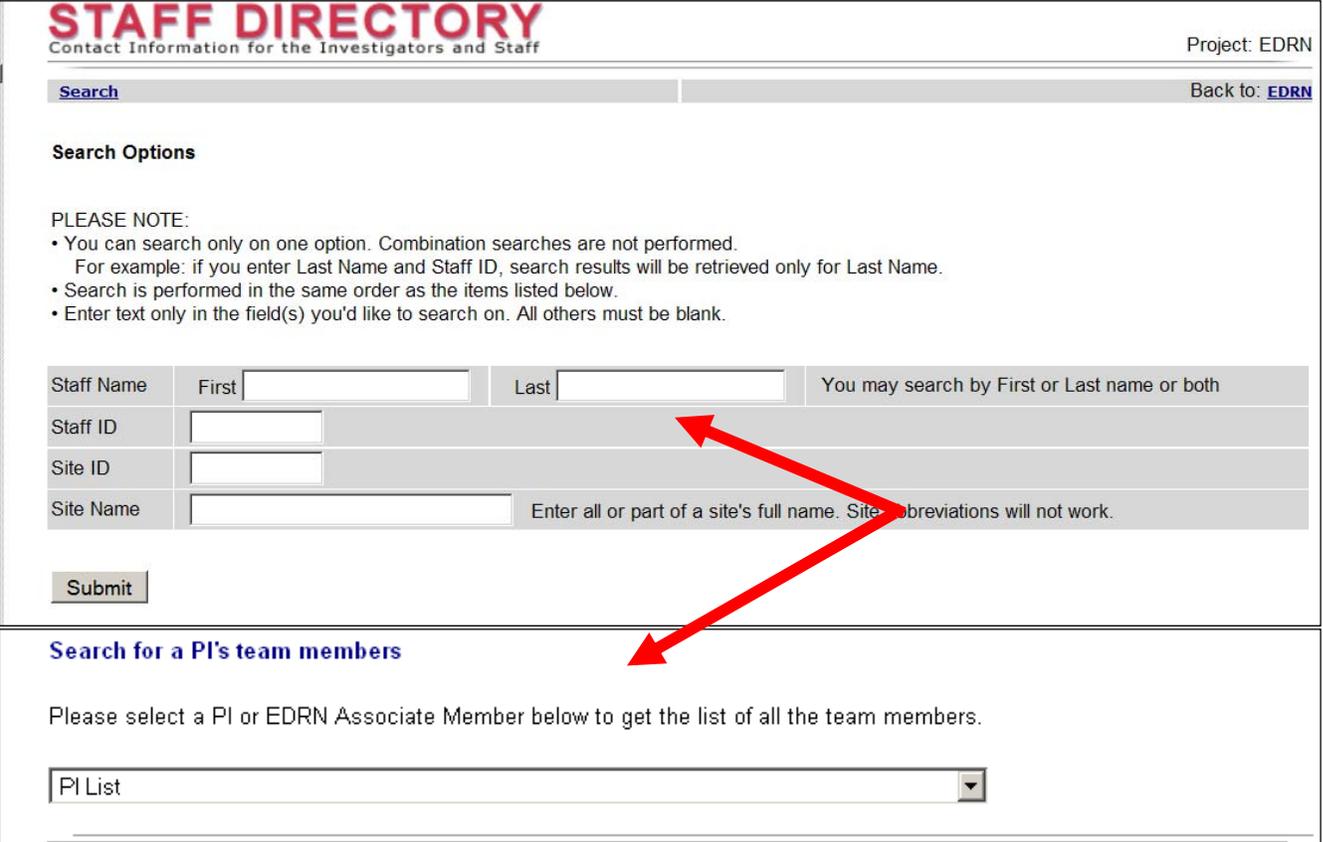
- On the homepage  click on the blue [Members](#) button on the left hand side of the page.
-  Click on the [Investigators and Staff Directory](#) link.
-  Click on the **[ADD](#)**, **[UPDATE](#)**, or **[REMOVE/REACTIVATE](#)** link on the left side
- Select your PI's name from the drop-down list
- To **ADD** contact information, enter all required information then  click on the [Submit](#) button at the bottom of the page.
- To **UPDATE** information, choose the person's name and click on the [Search](#) button at the bottom of the page. Update any information necessary then  click [Submit](#).
- To **REMOVE/REACTIVATE** contact information, select the person's name and choose either Active or Remove from the drop-down list and then  click [Submit](#).

Figure 2.1 – Investigators and Staff Directory



To **SEARCH** for contact information for any EDRN Site,  click the [Investigators and Staff Directory](#) then enter the name of the person you are searching for, or select PI's name from the drop-down list to search information for his/her entire site.

Figure 2.2 - Search



STAFF DIRECTORY
Contact Information for the Investigators and Staff

Project: EDRN

[Search](#) [Back to: EDRN](#)

Search Options

PLEASE NOTE:

- You can search only on one option. Combination searches are not performed.
For example: if you enter Last Name and Staff ID, search results will be retrieved only for Last Name.
- Search is performed in the same order as the items listed below.
- Enter text only in the field(s) you'd like to search on. All others must be blank.

Staff Name	First <input type="text"/>	Last <input type="text"/>	You may search by First or Last name or both
Staff ID	<input type="text"/>		
Site ID	<input type="text"/>		
Site Name	<input type="text"/> Enter all or part of a site's full name. Site abbreviations will not work.		

Search for a PI's team members

Please select a PI or EDRN Associate Member below to get the list of all the team members.

2.2 Investigators' Research Information

The Investigators' Research Information section of the website was created for EDRN investigators to enter information about their research interests so that they can be identified by other EDRN members looking for potential collaborators.

To **SEARCH** for Investigators' Research Information:

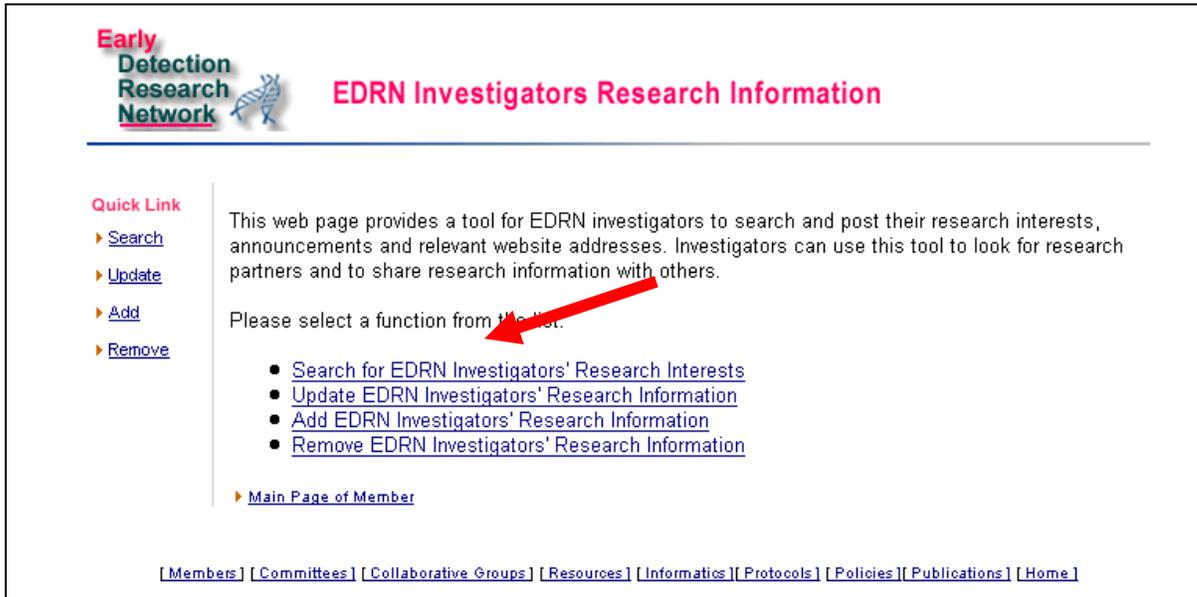
- On the homepage  click on the blue [Members](#) button on the left of the page
-  Click on the [Investigators Research Information](#) link
-  Click on the [Search for EDRN Investigators' Research Interests](#) link
- Search by EDRN site, Information Subject, or Keyword.

To **ADD**, **UPDATE**, or **REMOVE** research information for an investigator from your site:

- On the homepage,  click on the blue [Members](#) button on the left of the page
-  Click on the [Investigators Research Information](#) link
-  Click on [ADD](#), [UPDATE](#), or [REMOVE](#) Investigators' Research Information

- Select the PI's name from the drop-down list
 - Choose the person's name then  click on **Submit.**
- Use the **ADD** function to enter an Interest Topic that has not been entered before; for each Topic entered you must enter a corresponding Description.
- Use the **UPDATE** function to modify an Interest Topic that has already been entered into the system.

Figure 2.3 – Investigators Research Information



Early Detection Research Network  **EDRN Investigators Research Information**

Quick Link

- ▶ [Search](#)
- ▶ [Update](#)
- ▶ [Add](#)
- ▶ [Remove](#)

This web page provides a tool for EDRN investigators to search and post their research interests, announcements and relevant website addresses. Investigators can use this tool to look for research partners and to share research information with others.

Please select a function from the list.

- [Search for EDRN Investigators' Research Interests](#)
- [Update EDRN Investigators' Research Information](#)
- [Add EDRN Investigators' Research Information](#)
- [Remove EDRN Investigators' Research Information](#)

▶ [Main Page of Member](#)

[[Members](#)] [[Committees](#)] [[Collaborative Groups](#)] [[Resources](#)] [[Informatics](#)] [[Protocols](#)] [[Policies](#)] [[Publications](#)] [[Home](#)]

SECTION 3 COMMITTEES

EDRN is comprised of three main committees (Steering Committee, Executive Committee and the Network Consulting Team). In addition, EDRN has several Subcommittees and Working Groups.

To obtain an overview of each committee and to view the members of each committee select **Committees** from the main menu bar then  click on the committee of interest.

Figure 3.1 – Committees



SECTION 4 COLLABORATIVE GROUPS

Collaborative Groups are informal, organ site-oriented groups designed to exchange information on organ related biomarkers. EDRN has four Collaborative Groups:

1. Breast and Gynecologic Cancers
2. GI and Other Associated Cancers
3. Lung and Upper Aerodigestive Cancers
4. Prostate and Urologic Cancers

To view the members of each Collaborative Group select **Collaborative Groups** from the main menu bar then  click on the group of interest.

Figure 4.1 – Collaborative Groups

Early Detection Research Network
An infrastructure for supporting collaborative research on molecular, genetic and other biomarkers in early cancer detection and risk assessment

NATIONAL CANCER INSTITUTE
DIVISION OF CANCER PREVENTION

SEARCH FEEDBACK SITE MAP EDRN PUBLIC LISTSERV Relevant Sites:

Members

Committees

Collaborative Groups

Resources

Informatics

Protocols

Policies

Publications

Home

EDRN Collaborative Groups

- Collaborative Groups are informal, organ site-oriented groups designed to exchange information on organ related biomarkers. An EDRN Principal Investigator serves as the Chair elected by Collaborative Group members. Collaborative Group membership is open to any investigator.

Collaborative Groups List

- [Breast and Gynecologic Cancers](#)
- [GI and Other Associated Cancers](#)
- [Lung and Upper Aerodigestive Cancers](#)
- [Prostate and Urologic Cancers](#)

[\[Members\]](#) [\[Committees\]](#) [\[Collaborative Groups\]](#) [\[Resources\]](#) [\[Informatics\]](#) [\[Protocols\]](#) [\[Policies\]](#) [\[Publications\]](#) [\[Home\]](#)

SECTION 5 RESOURCES

EDRN provides mechanisms for investigators to access information about Standard Specimen Reference Sets, SOPs for collection and processing of serum/plasma and search for Biological Specimens, Search for Content of Biological Specimen Survey, Submit Biological Specimen Survey, Update Biological Specimen Survey and provides a list of potential cohorts that have specimen banks. Every EDRN site is required to submit a Biological Specimen Survey and update the survey at least once per year.

Figure 5.1- Resources

Early Detection Research Network
An infrastructure for supporting collaborative research on molecular, genetic and other biomarkers in early cancer detection and risk assessment

NATIONAL CANCER INSTITUTE
DIVISION OF CANCER PREVENTION

SEARCH FEEDBACK SITE MAP EDNR PUBLIC LISTSERV Relevant Sites: ▾

Members

Committees

Collaborative Groups

Resources

Informatics

Protocols

Policies

Publications

Home

EDRN Resources

- The EDRN provides the expertise and resources of individual laboratories and centers for collaborative studies. These web pages provide tools for EDRN investigators to submit the Specimen Survey, search EDRN specimen resources, and search and update the facility information of EDRN labs.

Reference Sets & Specimen SOPs

- [Specimen Reference Sets](#)
- [Serum SOP](#)
- [Plasma SOP](#)

List of Resources

- [The Diagnostics and Biomarkers Statistical \(DABS\) Center](#). This website assembles resources for education about, application of, and new research on, statistical methods for evaluating diagnostics and biomarkers. The focus is on validation rather than on discovery.
- [David Chia Lab Tissue Microarrays](#)
- [MALDI DilutionData EDRN.zip](#) (147 MB). These data come from a dilution experiment aimed at elucidating which features in MALDI-TOF mass spectrometry data are informative for quantifying peptide content. The details of the experiment are described in Ref[1].pdf.
- [Program for Rapid Independent Diagnostic Evaluation \(PRIDE\)](#)
- [Search for Biological Specimens](#)

5.1 Biological Specimen Survey Information

To **SUBMIT** a Biological Specimen Survey online:

- On the homepage, click on the blue **Resources** button on the left of the page
- To **SUBMIT** a survey, click on the [Submit Biological Specimen Survey online](#) link
- Click on either [Tissue Repository Survey Form](#) or [Prospective Cohort Survey Form](#) at the top of the page
- Enter all information for your site's specimens and click **Submit** at the bottom of the form

Figure 5.2 – Biological Specimen Survey

Tissue Repository Survey Form
Prospective Cohort Survey Form

Tissue Repository

Please complete one tissue repository form for **each organ site** which specimens might potentially be available for EDRN projects.
Please note that you can only submit this form for your own EDRN site.

Name of Study: (required)

Study Principal Investigator 1: (other than EDRN PI)

To **UPDATE** a survey:

-  Click on the Update Biological Specimen Survey link
- Choose the type of survey to update and the PI's name
-  Click on the Search button at the bottom of the page
- Choose the study name and  click Search
- Update information as necessary then  click Submit

Figure 5.3 – Update Biological Specimen Survey

Update the Specimen Survey



Please note that you only can update specimen survey for a EDRN PI who signed your EDRN secure Web Site Access Application.

Choose what type of specimen survey you would like to update.

Tissue Repositories and Prospective Cohort

Tissue Repositories

Prospective Cohort

Choose Which EDRN member's specimen surveys you would like to update.

To **SEARCH** for information contained in the Biological Specimen Surveys:

- On the homepage,  click on the blue **Resources** button on the left of the page
-  Click on the [Search for Content of Biological Specimen Survey](#) link
- Choose the type of survey to search and the PI's name
-  Click on the **Search** button at the bottom of the page
- Choose the study name and  click **Search**

The information contained in the survey selected will be displayed.

Figure 5.4 –Biological Specimen Content Results



Content of Specimen Survey

Biological Specimen Survey - Prospective Cohort

Name of Study: GRPR/EGFR and Lung Cancer Risk
 Study Principal Investigator: Jill M. Siegfried, Ph.D.
 EDRN PI: William Bigbee

Do you obtain participant consent for research use of biological specimens? Yes
 Does your consent allow for the use of specimens by a third party? No

What Information is available about the subjects with specimens in the collection?

- ◆ Demographic (e.g., age, sex, race, ethnicity)
- ◆ Vital status
- ◆ Diagnosis

EDRN Specimen Storage



Click on EDRN PI's name for the contact information:

EDRN PI	Institute	Study Name	Specimen	Organ	Exist Cases	Controls Availability	
William Bigbee	University of Pittsburgh Cancer Institute (BDI)	GRPR/EGFR and Lung Cancer Risk	Buccal scrapings	Lung	25	0	Possible
William Bigbee	University of	GRPR/EGFR and	Malignant primary	Lung	10	0	Possible

5.2 Search Specimen Surveys for Available Biological Specimens

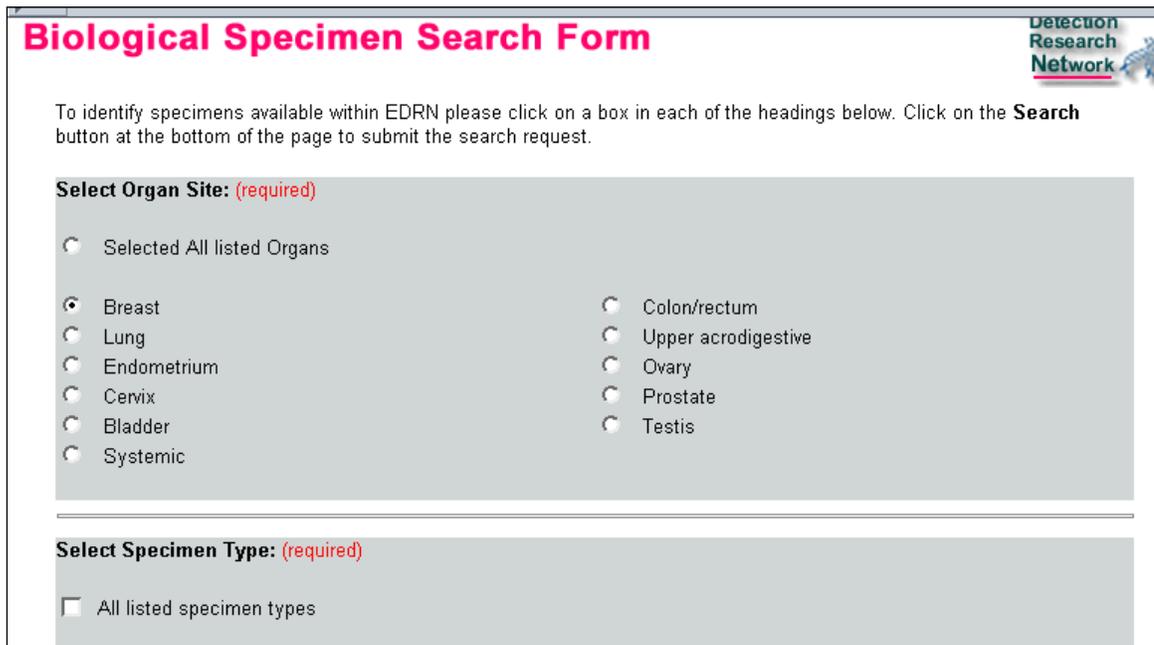
To **SEARCH** for Biological Specimens:

On the homepage,  click on the blue **Resources** button on the left of the page.

 click on the [Search for Biological Specimens](#) link.

Select the organ site, specimen type, and EDRN PI you want to search on, or broaden your search by selecting “All” for a specified category, then  click on **Search**.

Figure 5.5 –Biological Specimen Search



Biological Specimen Search Form

To identify specimens available within EDRN please click on a box in each of the headings below. Click on the **Search** button at the bottom of the page to submit the search request.

Select Organ Site: (required)

Selected All listed Organs

Breast

Lung

Endometrium

Cervix

Bladder

Systemic

Colon/rectum

Upper acrodigestive

Ovary

Prostate

Testis

Select Specimen Type: (required)

All listed specimen types

SECTION 6 INFORMATICS

EDRN provides mechanisms for investigators to Search the EDRN Research Network Exchange for Biological Specimens, view Common Data Elements, access Study Design Guidance Tools and determine Check Digit Algorithms.

Figure 6.1 –Informatics

Early Detection Research Network
An infrastructure for supporting collaborative research on molecular, genetic and other biomarkers in early cancer detection and risk assessment

NATIONAL CANCER INSTITUTE
DIVISION OF CANCER PREVENTION

SEARCH FEEDBACK SITE MAP EDRN PUBLIC LISTSERV Relevant Sites:

Administration

Member Info

Committees

Collaborative Groups

Resources

Informatics

Protocols

Policies

Publications

Home

EDRN Informatics

- EDRN informatics provides information technology tools for investigators. These tools include Common Data Element documents and dictionary, an EDRN-wide specimen search network, protein and DNA searching tools, research information surveys, and some useful algorithms.

List of Informatics Tools

- [Common Data Elements \(CDEs\)](#)
- [Study Design Guidance](#)
- [EDRN Informatics Survey](#)

6.1 Common Data Elements

Common data elements (CDEs) have been, and are being developed for studies conducted by EDRN sites. The Core EDRN CDEs represent the minimum information that should be collected in all EDRN studies. The CDEs will standardize data that is collected and stored at all EDRN sites to ensure consistency in data and specimen sharing. The CDE tools enable sites to view all existing groupings of CDEs on forms, create and modify their own forms, and view all information associated with the EDRN CDEs.

Figure 6.3 –CDE Tool

Data Elements & Forms

This website allows EDRN sites and users to view common data elements and forms. The DMCC will maintain this information online for all interested sites.

Forms

[View Forms](#) View created forms and their modification history

Common Data Elements

[DE Search](#) Search data elements

[Core CDE's](#) Core Baseline and Follow-up CDE's

6.2 Study Design Guidance Tools

EDRN provides sites with various Study Design Guidance Tools to assist investigators in designing studies. The Tool lists various publications that have been written on Study Design mechanisms, a Sample Size Formula and Look-up Table and Relevant Links.

Figure 6.4 –Study Design Guidance Tools

Study Design Guidance Tools

Publications

- Pepe MS, Etzioni R, Feng Z, Potter JD, Thompson ML, Thornquist M, Winget M, Yasui Y. Phases of biomarker development for early detection of cancer. [Journal of the National Cancer Institute](#) 2001; 93(14):1054-61 (July 18).
- Baker SG, Kramer BS, Srivastava S. Markers for early detection of cancer: Statistical guidelines for nested case-control studies. [BMC Medical Research Methodology](#) 2002;2(1):4 (February 28).

Comment from DMCC statisticians: The sample size in Baker et al. is based on controlling the precision of sensitivity and specificity measures, not based on statistical power. The DMCC statisticians suggest sample sizes based on both precision and adequate statistical power. See [Thompson et al.](#) for further explanations and comparisons.

Sample Size Formula and Look-up Tables

- [Sample Size Calculations for Phase 2 Studies](#), 326 KB (26 pages) in pdf format. From the book: Pepe MS. The Statistical Evaluation of Medical Tests for Classification and Prediction. New York: Oxford University Press - USA (in press). (Citation last updated March 11, 2003)

Related Link

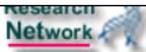
[Bioconductor packages for the analysis of genomic data.](#) Bioconductor is an open source bioinformatics software project based on R.

6.3 EDRN Informatics Survey

EDRN recommends that all sites provide the DMCC with information pertaining to their hardware platforms and operating systems used locally, as well as contact information for their IT support staff.

Figure 6.5 –Web Survey

EDRN WEB SURVEY
A Web Survey Tool for EDRN Investigators and Staff



Menu ▾ **Submit Survey** ▾ Back to: **Web Site List** ▾

[Survey List](#)

EDRN Informatics Survey (DRAFT)
The fields with * sign are required.

EDRN Members *	<input type="text"/>	
Informatics Contact Person	<input type="text"/>	
Contact Email	<input type="text"/>	
Contact Phone Number	<input type="text"/>	
Title	<input type="text"/>	
Hardware Platforms	<input type="text"/>	
Operating Systems	<input type="text"/>	

SECTION 7 PROTOCOLS

7.1 General Questions

1. Why obtain an EDRN Protocol ID?

- Registration of your EDRN protocols provides NCI (and EDRN members) with an easy way of finding out about activities that are going on within EDRN. NCI will use this system to make a report of both individual site studies as well as collaborative studies that are being conducted within EDRN. These reports will be used to evaluate sites for renewal as well as to evaluate EDRN overall. To register a protocol please contact the DMCC at edrndmcc@fhcrc.org or at 206-667-6972.
- You can print or download the reports to include in your annual renewal to inform NCI of your collaborative activities.
- Protocol registration results in a unique ID being assigned to each protocol. The protocol ID is one of three CDEs that are essential for uniquely linking study participant data with their specimens.
- All protocols that you are conducting either as a single EDRN site or jointly with other EDRN sites should be registered. If you want NCI and other EDRN investigators to know about the activity, register it.

2. What information is needed to obtain an EDRN Protocol ID?

- You will need your IRB approval number, date of approval, and information about the specimens you will collect (if applicable).
- Other information such as study design and study abstract is optional for single-site studies, but required for collaboration and validation studies. The abstract can be copied from a Word document and pasted into this field.

3. What information about the specimens is needed?

- You will need to know whether the specimens are newly collected or previously collected.

4. What is meant by “newly collected” vs. “previously collected?”

- Newly collected specimens are those that are actively being collected under the protocol. Previously collected specimens are those that were collected under a previous protocol and are being used for the current protocol.
- If the protocol involves collecting new specimens, then the EDRN specimen processing questions must be answered:
 - ✓ Type of specimen collected (e.g. Blood, Bone marrow, Urine, Tissue, etc.)
 - ✓ Type of specimen stored (e.g. Whole blood, DNA, RNA, Plasma, etc.)
 - ✓ Temperature of original sample prior to processing:
 - ✓ Approximately how long was the original sample maintained at the above temperature:
 - ✓ Temperature of specimen during processing:
 - ✓ Elapsed time from collection to final storage:

5. What if I don't know how the specimens are/were processed?

- The answers to these questions must be written in the study protocol. If the protocol involves the use of previously collected specimens, the answers to the specimen processing questions are optional, but if the information is known, please provide it.
- 6. What is a Single Site Study?**
- A Single Site Study is a study that is conducted with EDRN funds and involves only one EDRN site. Non-EDRN sites may or may not be involved in the study.
- 7. What is a Collaborative Study?**
- A Collaborative Study is a study conducted with EDRN funds in which more than one EDRN site is involved. Non-EDRN sites may or may not be involved. Collaborative studies include studies conducted for the purpose of assay validation. There are two types of Protocol Registration for Collaborative Studies. Pre-Registration and Registration.
- 8. What is a Network Approved Collaborative Study (eg., Validation Study, Standard Specimen Reference Set)**
- A Network Approved Collaborative Study is a study conducted with EDRN funds for the purpose of clinical validation of a biomarker. By definition, the study will include more than one EDRN site. At a minimum a Validation Study must include the DMCC and at least one BDL.

7.2 Search Protocols

To **SEARCH** for information on a registered protocol:

☞ Click on the [Search EDRN Protocols](#) link, then select the EDRN Site, Study Type, Specimen Collection or Study Cancer Type from the appropriate drop-down list and the search results will display.

Figure 7.1 – Search EDRN Protocols

EDRN PROTOCOL
Search, Register, Update and Report EDRN Protocol

[Quick Search](#) [Detail Search](#) [Protocol Manager](#) Back to: Web Site List

Please select a search option from the lists below to get a list of protocol names.

Search by:

EDRN Site	<input type="text"/>	<input type="text"/>
Protocol Name	<input type="text"/>	<input type="text"/>
Study Type	<input type="text"/>	<input type="text"/>
Specimen Collection	<input type="text"/>	<input type="text"/>
Study Cancer Type	<input type="text"/>	<input type="text"/>
Study Relationship Type	<input type="text"/>	<input type="text"/>

Please enter a single search term to get a list of protocols that match any part of the name.

Enter search terms for:

Protocol Name	<input type="text"/>	<input type="text"/>
Protocol ID	<input type="text"/>	<input type="text"/>

Search

7.3 Lead PI Updates

Figure 7.2 – Lead PI Updates

The screenshot shows the EDRN PROTOCOL website interface. At the top, the logo for 'Early Detection Research Network' is visible. Below the logo, the text 'EDRN PROTOCOL' is displayed in large red letters, followed by the subtitle 'Search, Register, Update and Report EDRN Protocol'. A navigation bar contains a dropdown menu for 'Collaborative Activity Report' (currently set to 'EDRN PI List') and a 'Back to:' dropdown menu (currently set to 'Web Site List'). Below the navigation bar, there are four main menu items: 'Quick Search EDRN Protocols', 'Detail Search EDRN Protocols', 'Leading PI Updates', and 'Lead & Involved Investigator Updates'. A red arrow points to the 'Leading PI Updates' link. Below the menu items, there is a section titled 'Please select a function from the menu.' which contains five rows of links and descriptions:

Quick Search EDRN Protocols	Select from four fields to quickly find basic Protocol & Project information.
Detail Search EDRN Protocols	Create custom searches to find exactly the Protocols and Projects of interest.
Leading PI Updates	Update the Protocol or Project information abstracted from documentation supplied to the DMCC.
Lead & Involved Investigator Updates	Update the Protocol or Project information for each involved investigator's site & supply milestones, comments, dates and other specifics of your research.
Request initialization of new protocol	The DMCC initializes all EDRN Protocols and Projects by entering some "shell" information obtained from approved proposals. The lead PI is able to view the information and request changes if needed.

At the bottom of the page, there is a footer with the text: 'Secure site maintained by COMPASS, Fred Hutchinson Cancer Research Center ©. Last updated on 3/2/2011' and 'Contact: edrndmcc@fhcrc.org'.

To UPDATE a protocol that you are the Lead PI for, Click “Leading PI Updates” then select your protocol from the drop down list and supply answers to the following questions:

- Protocol/Project Design Type
- Protocol/Project Study Design Description
- Protocol/Project Timing
- Objective
- Specific Aims
- Eligibility Criteria
- Abstract
- Is there a Data Sharing Plan? Explain
- Blinding Policy? Explain
- Field of Research
- Analytic Method
- Biomarkers Evaluated (list)
- Finish Date
- Final Sample Size
- Results Outcome

7.4 Involved/Lead PI Updates

Figure 7.3 – Involved/Lead PI Updates

EDRN PROTOCOL
Search, Register, Update and Report EDRN Protocol

Collaborative Activity Report: Back to:

[Quick Search EDRN Protocols](#) [Detail Search EDRN Protocols](#) • [Leading PI Updates](#) [Lead & Involved Investigator Updates](#)

Please select a function from the menu.

Quick Search EDRN Protocols	Select from four fields to quickly find basic Protocol & Project information.
Detail Search EDRN Protocols	Create custom searches to find exactly the Protocols and Projects of interest.
Leading PI Updates	Update the Protocol or Project information abstracted from documentation supplied to the DMCC.
Lead & Involved Investigator Updates	Update the Protocol or Project information for each involved investigator's site & supply milestones, comments, dates and other specifics of your research.
Request initialization of new protocol	The DMCC initializes all EDRN Protocols and Projects by entering some "shell" information obtained from approved proposals. The lead PI is able to view the information and request changes if needed.

Secure site maintained by COMPASS, Fred Hutchinson Cancer Research Center ©. Last updated on 3/2/2011 Contact: edrndmcc@fhcrc.org

To UPDATE a protocol that you are involved with, regardless of whether or not you are the Lead PI, Click “Lead & Involved Investigator Updates” then select your protocol from the drop down list, then select your site and supply answers to the following questions:

- IRB Approval Information
- Contact Information
- Select the “Roles” your site will have in the protocol
 - Funding Source
 - Discovery
 - Reference
 - Coordinating Center
 - Specimen Contributing Site
 - Specimen Storage
 - Analysis Lab
 - Statistical Services
 - Consultant
- Specimen the stages your site will be involved in throughout the protocol
 - Development Stage
 - Funding Stage
 - Protocol Development Stage
 - Procedure Development Stage
 - Retrospective Sample Identification Stage
 - Recruitment Stage
 - Lab Processing Stage

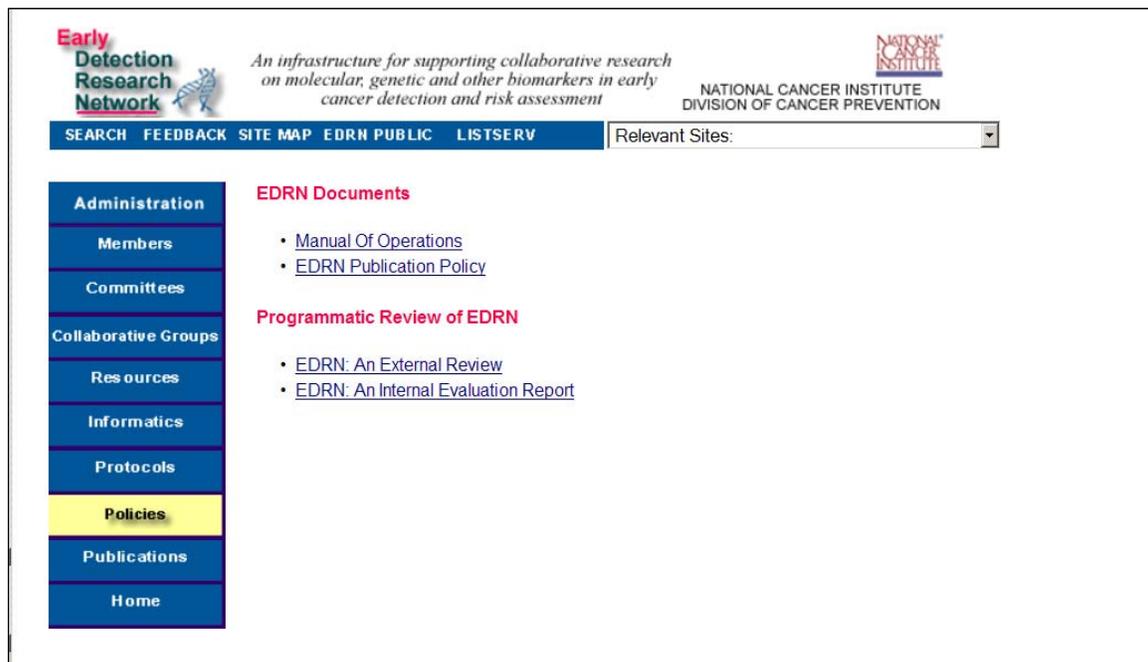
- Blinding Stage
- Lab Analysis Stage
- Statistical Analysis Stage
- Publication Stage
- Completed

Subsequently, for each role/stage supply milestones for estimated start/finish dates and actual start/finish dates.

SECTION 8 POLICIES

The EDRN Policies section of the website displays the EDRN Manual of Operations and the EDRN Publication Policy.

Figure 8.1 – Policies



SECTION 9 PUBLICATIONS

The EDRN Publications section of the website allows EDRN members and NCI to easily find out about published activities in EDRN. Sites can also print or download their information into a Word document to include in their annual Progress Report to NCI.

Each site is responsible for entering and maintaining their EDRN publication information.

To **ENTER, UPDATE or VIEW** publications  click on the blue **Publications** button on the left of the page. You may enter your publications by PubMed ID or manually.

Figure 9.1 – Publications

The screenshot shows the EDRN Publications page. At the top, there is a navigation bar with links: SEARCH, FEEDBACK, SITE MAP, EDRN PUBLIC, and LISTSERV. A dropdown menu for 'Relevant Sites:' is visible. On the left, a vertical navigation menu includes: Administration, Members, Committees, Collaborative Groups, Resources, Informatics, Protocols, Policies, Publications (highlighted in yellow), and Home. The main content area is titled 'Publications' and contains several sections: 'Enter Publications' with options for 'Manually' and 'Using PubMed ID', each with a 'for' dropdown; 'Update Publications' with a 'for' dropdown; 'View' options set to 'All Publications' with a 'Search' button; a 'Search by Keywords' section with a text input, a 'Match Any Word' dropdown, and a 'Search' button; a 'Search by Date' section with a text input, a 'Before This Year' dropdown, and a 'Search' button; and a 'Print Annual Publication Report' section with a 'for' dropdown. A note at the bottom explains the bibliographic format used, citing the 'International Committee of Medical Journal Editors (ICMJE)'.