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.fhcrc.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.)

![Home Page Image](Image)

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 site's 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

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**
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.
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.
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.
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
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
- ![Image](image.png) Click on the **Search for Content of Biological Specimen Survey** link
- Choose the type of survey to search and the PI’s name
- ![Image](image.png) Click on the **Search** button at the bottom of the page
- Choose the study name and ![Image](image.png) 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: BRPR/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:

<table>
<thead>
<tr>
<th>EDRN PI</th>
<th>Institute</th>
<th>Study Name</th>
<th>Specimen</th>
<th>Organ</th>
<th>Exist Cases</th>
<th>Controls Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>William Bigbee</td>
<td>University of Pittsburgh Cancer Institute (CDL)</td>
<td>BRPR/EGFR and Lung Cancer Risk</td>
<td>Buccal scrapings</td>
<td>Lung</td>
<td>25</td>
<td>0</td>
</tr>
<tr>
<td>William Bigbee</td>
<td>University of Pittsburgh Cancer Institute (CDL)</td>
<td>BRPR/EGFR and Lung Cancer Risk</td>
<td>Malignant primary</td>
<td>Lung</td>
<td>10</td>
<td>0</td>
</tr>
</tbody>
</table>

### 5.2 Search Specimen Surveys for Available Biological Specimens

To **SEARCH** for Biological Specimens:

On the homepage, ![Image](image.png) click on the blue **Resources** button on the left of the page.

![Image](image.png) 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 aero digestive
- 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.
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.

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


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


Related Link

[Bioconductor packages for the analysis of genomic data](http://www.bioconductor.org). 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
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**
7.3 Lead PI Updates

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

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

A note on bibliographic format: The DMCC format is modeled on “Uniform Requirements for Manuscripts Submitted to Biomedical Journals” (October 2001) produced by the International Committee of Medical Journal Editors (ICMJE).