

*Early Detection Research Network*

**Part 1: Request For Preliminary Benign Disease Tissues**

Date of Submission:

Investigator:

Name:  
Institution:  
Address:

Phone:  
Fax:  
E-mail

**Specimen Reference Set(s) Requested**

Collaborative Group Oversight

Benign Breast Reference Set

Specimen Type

Tissue Slides

Expected Length of Study:  
months

**Institutional Approval**

Do you have IRB approval to work with the requested samples?

- Yes: Institution:  
Approval Number:  
 No  
 Pending: Expected Date:

**Funding**

How will testing of the reference set(s) be funded?

- Current NIH-funded grant:  
Grant No.  
Annual Direct Costs:  
Funding Period:  
 Other Sponsorship: Please provide a letter of commitment from the sponsoring agency, company, or foundation.  
 Other: Specify:

## Part II: Scientific Proposal

Using the standard PHS 398 Continuation Page (<http://grants.nih.gov/grants/funding/phs398/continuation.doc>) address the following items as outlined. (3-5 pages recommended)

- I. **Clinical Relationship:** Clearly state the clinical question that you are trying to address: risk assessment, early detection, diagnosis or prognosis. How would the reference samples expedite addressing the intended clinical question?
- II. **Background and Significance:** Clearly state the scientific rationale of the proposal for using the requested specimen reference set(s). Describe your biomarker/platform and how you came upon its discovery/development for potential application in cancer detection.
- III. **Preliminary Data & Methods:** Provide sufficient information describing how experiments were performed, details on convenience samples used, and presentation of data in terms of specificity, sensitivity, and variance of your measurements. Explicit description of your studies will facilitate review considerations. Figures and other supporting documentation can be appended after your proposal.
  - a. **Data Analysis Plan:** Specimens will be provided blinded in regards to case-control status. Provide adequate detail concerning how statistical analysis of your data coming from these samples shall be performed. The DMCC will conduct the data analysis and findings will be provided to the investigators so that they can pursue publication results.
  - b. **Future Plans:** Describe future research plans if results from the proposed study are found to be promising.

## Part III: Conditions for the Release of Reference Sets

- |  | Yes                      | No                       |
|--|--------------------------|--------------------------|
| • I agree not to resell or release the reference set or sub-aliquots from this set to an investigator not directly connected with this application.                        | <input type="checkbox"/> | <input type="checkbox"/> |
| • I agree to complete the assays on the reference set specimens and return results to the EDNRN DMCC within 4 months of their receipt.                                     | <input type="checkbox"/> | <input type="checkbox"/> |
| • I agree to release assay results for posting on eCAS, a secure domain on the EDNRN website, 3 months after I have received the results back from the DMCC for my review. | <input type="checkbox"/> | <input type="checkbox"/> |
| ➤ <b>The EDNRN DMCC agrees not to release your data to anyone outside the immediate analytic team until after the 3 month interval has passed.</b>                         |                          |                          |
| ➤ <b>The EDNRN reserves the right to post the data to its public website at 12 months after the unblinded results have been provided to the investigator.</b>              |                          |                          |

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

**Investigators applying for use of an EDNRN reference set will be notified within 3 months about approval for use of a set. Investigators who successfully apply must also complete a separate MTA with the National Cancer Institute. Neither NCI nor the EDNRN DMCC will claim any rights to your data including the statistical analysis conducted by the EDNRN DMCC**

**Please save a copy of this application for your records.**