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| *Early Detection Research Network*  Part 1: Request For Specimen Reference Sets | | | | |
| Date of Submission: | | |  | |
| Investigator:  Name:  Institution:  Address: |  | | Phone:  Fax:  E-mail |  |
| Specimen Reference Set(s) Requested | | | | |
| Collaborative Group Oversight  Breast & Gynecological  Colorectal & Other GI  Lung & Upper Aerodigestive  Prostate & Other Urologic | | Organ Site    (e.g. lung, ovary, colon, etc) | | Specimen Type  Serum  Plasma  Other: Specify |
|  | | | | |
| Minimum volume of each sample required:        (microliters) | | 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: | | |

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| 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)   1. **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? 2. **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. 3. **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. 4. **Data Analysis Plan:** Specify whether you will need a training set in addition to a blinded test set. Provide adequate detail concerning how statistical analysis of your data coming from these samples will be performed and a justification that the requested references set(s) is/are large enough to demonstrate the utility of the biomarker. Describe the statistical resources at your disposal. If you require statistical support, EDRN can assist you with this. 5. **Future Plans**: If the biomarker is found to have promising performance characteristics, the EDRN might be interested in working with you to proceed to Phase II clinical validations. Address each specific scenario below according to your intentions:    1. Do you plan to approach EDRN for funding and collaboration in proceeding to a Phase II validation study? If not, do you have other resources where validation can be accomplished? Describe clearly other resources at your disposal and how they are sufficient to complete a larger Phase II validation study if you will not seek help from the EDRN.    2. Are you amenable to working within the collaborative framework of EDRN in proceeding to Phase II studies?    3. If deemed beneficial, will you be amenable to including your biomarker into a larger panel of biomarkers for Phase II validation?    4. If refinements will improve the performance of the biomarker test, will you concur with further development of the test? Will it be advantageous to include resources of EDRN for this purpose? |

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.

* I agree to complete the assays on the reference set specimens and return results to the

EDRN DMCC within 4 months of their receipt.

* I agree to release assay results for posting on eCAS, a secure domain on the EDRN    
  website, 3 months after I have received the unblinded results back from the DMCC  
  for my review.
* **The EDRN DMCC agrees not to release your data to anyone outside the immediate analytic team until after the 3 month interval has passed.**
* **The EDRN reserves the right to post the data to its public website at 12 months after the unblinded results have been provided to the investigator.**

     

Signature Date

Investigators applying for use of an EDRN 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 EDRN DMCC will claim any rights to your data including the statistical analysis conducted by the EDRN DMCC

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