Application Procedure, Receipt Dates, and Review

Procedures for application, dates for receipt of applications and review criteria.
To apply for Associate Membership, applicants must be sponsored by an EDRN Principal Investigator. Sponsors of Associate Members are responsible for submitting the initial membership application, representing their interests at Steering Committee meetings, and inviting them to EDRN meetings. Sponsors are also responsible for ensuring that the Associate Member is accountable, follows all EDRN policies and procedures, and, if requested, provide an update on their Associate Member's progress. For additional information and submission of applications please contact:

Dr. Christos Patriotis, Program Director
Executive Plaza North, Suite 3144
6130 Executive Blvd. MSC 7362
Bethesda, MD 20892-7362
(301) 496-3893
patriotisc@mail.nih.gov

Investigators who are not already funded by the EDRN, and who propose collaborative studies or affiliations within the scope and objectives of the EDRN are eligible to apply as follows:

- Contact an EDRN Principal Investigator directly, or one of the Chairs of the Collaborative Groups to sponsor the membership application.
- Develop a plan for collaboration with an EDRN Sponsor (Principal Investigator or Collaborative Group Chair), including funding options. The application for Associate Membership (based on PHS Form 398) is available for download in two parts: Part I, and Part II.
- Submit a collaborative proposal through EDRN Sponsor to the above contact Program Director at the NCI EDRN Program Office. The signed original and one eletronic copy of the proposal must be submitted for any of the receipt dates indicated below. The following NIH format and organization should be used:
- Single spaced, based on PHS Form 398. Preferably use 12 pt. or 11 pt., but no smaller than a 10 pt. font.
- EDRN sponsorship cover page (Part I) - completed and signed by EDRN sponsor.
- Title Page - page 1 of the PHS Form 398.
- Abstract (Summary of Proposal), Performance Sites, Key Personnel - use page 2 of PHS Form 398
- Bibliography of key personnel - use page 6 of PHS Form 398
- Scientific Proposal (limited to 5 pages) and References - Organized into Rationale/Hypothesis, Specific Aims/Deliverables, Introduction, Preliminary Data, Study Design (including Approaches and Technologic Design, Population Characteristics, Sample Size, and Statistics), Contribution to Translational Research and the EDRN. Address review criteria as established by the EDRN Steering Committee (see below).
- Budget - Use pages 4 and 5 of PHS Form 398. Adequate budget justification for direct costs is required.
- Checklist - (final page unless an Appendix section is included); use checklist form page of PHS Form 398. Facilities and Administrative (F&A) costs can be requested on this form according to NCI guidelines.
- Appendix - optional
- Receipt dates are March 1, July 1, and November 1, or on the first business day following a weekend receipt date. Applications not received by 5 p.m. EST of the receipt date will be held until the next scheduled review cycle.

All EDRN related projects must comply with regulations on research involving human subjects, children, minority groups, gender, animals, recombinant DNA, and hazardous materials. Approvals from relevant

committees, including Institutional Review Boards, must be submitted to the NCI EDRN Program Office before funds can be provided.

The application for Category C Members can disregard budgetary documents; however, their applications should explain how the applicant's participation at meetings contributes to the mission of the EDRN.

The EDRN Review Group evaluates applications for funding , while the Executive Committee performs accelerated review of applications that do not seek funds.

The number of amended (revised) versions of an application is limited to two, and these must be submitted within two years of the original submission. The Standing Review Group's comments should be included in the revised application packet. The application must include an Introduction of not more than 2 pages that summarizes substantial additions, deletions, and other changes. The Introduction must also include responses to the criticisms and issues raised by the reviewers.

Associate Members will agree to follow EDRN policies and procedures and submit an annual progress report to the NCI and a copy to their Sponsor.

Review Criteria (individually scored)

- Scientific merit
- Study design: e.g., prospective versus cross-sectional
- Technical parameters: reproducibility, sensitivity, specificity, throughput, automation, and cost
- Clinical or Translational impact: e.g., more common cancers or a significant impact for rare cancers; tests geared toward screening of the general or high risk populations for early detection of cancer versus risk assessment or prediction of disease progression, etc.
- Portfolio balance within EDRN and NCI's needs
- Practicality, Portability, and Feasibility: e.g., required sample size or amount of biospecimen; non-invasively obtained samples; bias in study population.
- Collaborative strength, including contribution of resources and technology. Collaboration is a central mission of EDRN.

Additional Criteria

1. Significance

The application must clearly state the scientific merit of the proposal.
Does the proposed research convey the urgency of scientific needs in the area of biomarker-based diagnostics possible only through a collaborative approach?
Will the approaches advance the field of biomarkers/reagents development in the context of cancer detection, risk assessment, or disease prediction?
Does the proposal uniquely discuss challenges and issues relevant to cancer detection and screening?
Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this field?
How would the proposed research complement or augment existing detection systems or methodologies?
Is the proposed approach or technology adaptable, or does it have the potential to analyze large samples in a population setting for screening purposes?
What is the immediacy of the research opportunity in light of the EDRN-established phases of biomarker development for early detection of cancer and potentials for moving biomarkers to Phase 2 or Phase 3?
Does the applicant have demonstrable evidence for bringing biomarkers to Phase 2 or Phase 3? This is particularly important for an analytical validation study.
To what extent are the specific aims integrated to address the proposed goals?

2. Collaborative Strengths:

The application must clearly state the need for such a collaboration and reason as to why this study requires collaborative platforms (expertise, infrastructure, resources) of the EDRN.

Are plans for collaborations provided for research objectives?

To what extent are these collaborations necessary for the successful completion of the research plan?

Only projects of collaborative nature are to be supported through the restricted funds.

Do the proposed experiments take advantage of unique features of the EDRN scientific environment and incorporate the best use of collaborative arrangements?

Will this team of investigators contribute unique skills to the proposed project?

Do the investigators state their willingness to collaborate and share information?

3. Portfolio Analysis:

NCI program staff will evaluate each application relative to other research projects being conducted within EDRN to ensure there is a fair representation of technologies and cancer types. Under- or over-representations will be included in determining the final recommendation. In addition, each proposal will be reviewed for:

Does the proposal compete against any already funded approach within the EDRN systems? If so, what is the added value?

Does the proposal fall under the NCI's Strategic Initiatives? To what extent is it supported by any other program, such as IMAT?