INTELLECTUAL PROPERTY GUIDELINES FOR THE EARLY DETECTION RESEARCH NETWORK

Applicants are strongly encouraged to forge partnerships with industry, including biotechnology firms, to develop biomarkers, reagents, technologies, and assays. The Network continues to serve as an attractive source of collaborations for industry, since it will provide clinical opportunities for the evaluation of new technologies. The EDRN encourages collaborations with industry in order to leverage funds awarded under this RFA. NCI funds will be used to support the underlying infrastructure and the cost of studies not having direct implications for a company's product development or marketing strategy. NCI views partnerships with industry as an important component of the EDRN mission. However, with respect to new technologies and/or reagents provided by such participants that are part of development or product plans, the individual companies will be responsible for costs in such areas as technology standardization and quality assurance as well as scale-up of laboratory techniques, collection and formatting of specialized data required by regulatory agencies for device approvals, preparation of registration documents, and supporting a portion of the accrual to studies pivotal for registration.

The sharing of research resources and intellectual property plans must make unique research resources readily available for research purposes to qualified individuals within the scientific community in accordance with the NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps/) and the Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, December 1999 http://www.ott.nih.gov/pdfs/64FR72090.pdf) ("NIH Research Tools Guidelines"). These documents also define terms, parties, responsibilities, prescribe the order of disposition of rights, prescribe a chronology of reporting requirements, and delineate the basis for and extent of government actions to retain rights. Patent rights clauses may be found at 37 CFR Part 401.14 and are accessible from the Interagency Edison web page (http://www.iedison.gov); see also, 35 USC § 210(c); Executive Order 12591, 52 FR 13414 (Apr. 10, 1987); and Memorandum on Government Patent Policy (Feb. 18, 1983). If applicant investigators plan to collaborate with third parties, the research tools sharing plan must explain how such collaborations will not restrict their ability to share research materials produced with NIH funding. NCI believes that applicants can satisfy the requirement to submit the research resources plan and intellectual property plan in a number of ways.

GUIDANCE FOR PREPARATION OF RESEARCH RESOURCES PLAN AND INTELLECTUAL PROPERTY PLAN

The EDRN is premised on the belief that an established integrated; multi- disciplinary environment will expedite clinical applications of biomarker research. Comprised of 38 principal members, the EDRN is organized in four components: 23 BDLs, five BVLs, nine CEVCs, and one DMCC. From the outset, the NCI anticipated that EDRN members would collaborate with industry both to develop biomarkers and/or reagents and to provide a clinical environment for the evaluation of new technologies. Early interactions with industry are expected to permit research collaborations likely to benefit both EDRN grantees and industry partners. It is hoped that validated biomarkers may ultimately be commercialized into diagnostic products for early detection of cancer and cancer risk. Many of the EDRN investigators have had active collaborations with industry. While the one university/one company collaborations have worked well, there is general agreement that successful multi-institution/company collaborations have

been harder to implement. Restricted availability of unique research resources, upon which further studies are dependent, can impede the advancement of research.

The NIH is interested in ensuring that the research resources developed through this grant also become readily available to the broader research community in a timely manner for further research, development, and application, in the expectation that this will lead to products and knowledge of benefit to the public health. Investigators conducting biomedical research frequently develop unique research resources. The policy of the NIH is to make available to the public the results and accomplishments of the activities that it funds. To address this interest in assuring research resources are accessible, NIH requires applicants who respond to this RFA to submit a plan: (1) for sharing the research resources generated through the grant (e.g., human biospecimens and novel cancer biomarkers); and (2) addressing how they will exercise intellectual property rights, should any be generated through this grant, while making such research resources available to the broader scientific community consistent with this initiative. Therefore, the research resources tools sharing plan and intellectual property management plans must make unique research resources readily available for research purposes to qualified individuals within the scientific community in accordance with the NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps/) and the Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, December 1999 http://www.ott.nih.gov/pdfs/64FR72090.pdf) ("NIH Research Tools Guidelines"). These documents also: (1) define terms, parties, and responsibilities; (2) prescribe the order of disposition of rights and a chronology of reporting requirements: and (3) delineate the basis for and extent of government actions to retain rights. Patent rights clauses may be found at 37 CFR Part 401.14 and are accessible from the Interagency Edison web page, (http://www.iedison.gov); see also, 35 USC § 210(c); Executive Order 12591, 52 FR 13414 (Apr. 10, 1987); and Memorandum on Government Patent Policy (Feb. 18, 1983).

If applicant investigators plan to collaborate with third parties, the research tools sharing plan must address how such collaborations will not restrict their ability to share research materials produced with NIH funding. NCI believes that applicants can satisfy the requirement to submit the research resources plan and intellectual property plan in a number of ways. Reviewers will comment, as appropriate, on the adequacy and feasibility of the sharing of research resources plan and the intellectual property plan. Comments on the plans and any concerns will be presented in an administrative note in the Summary Statement. These comments will not affect the priority score of the proposal. NIH program staff will consider the adequacy of the plans in determining whether to recommend an application for award. The approved plans will become a condition of the grant award and Progress Reports must contain information on activities for the sharing of research resources and intellectual property.

Where it is anticipated that there will be an exchange of collections of human tissues, consideration should also be given to obtaining the appropriate assurances from the DHHS Office of Human Subject Protections (http://www.hhs.gov/ohrp/assurances/assurances_index.html) and necessary IRB approvals and/or exemptions. In addition, issues pertaining to the protection of patient identifiable information under the Privacy Rule of the Health Insurance Portability and Accountability Act of 1976 (HIPAA) should be addressed. For more information concerning the HIPAA Privacy Rule, see (http://www.hhs.gov/ocr/hipaa).

In the development of the research resource sharing and intellectual property management plans, applicants should confer with their institutions' office(s) responsible for handling technology transfer related matters and/or sponsored research. If applicants or their representatives require additional guidance in preparing these plans, they are encouraged to make further inquiries to the appropriate contacts listed above for such matters. Further, applicants may wish to independently research and review examples of approaches considered by other institutions such as those described on the NCI Technology Transfer Branch website (http://ttb.nci.nih.gov/IPPlans.html).