

Intellectual Property (IP) Rights and Responsibilities

General Overview

The EDRN is premised on the belief that an established integrated, multi-disciplinary environment will expedite clinical applications of biomarker research. NCI anticipates that EDRN members will 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 EDRN investigators have had active collaborations with industry. 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 its grants also become readily available to the broader research community in a timely manner for further research, development, and application, with the expectation that this will lead to products and knowledge of benefit to the public health.

Since it is the policy of the NIH to make available to the public the results and accomplishments of the activities which it funds, applicants who respond to an EDRN RFA are required to submit an intellectual property management plan (IPMP), which addresses the strategy to be followed for both solely or jointly owned inventions (including patenting and licensing issues) and how these resources will be made available to the broader scientific community, consistent with the EDRN initiative. This plan should be included in the program description of the RFA. Reviewers will comment, as appropriate, on the adequacy and feasibility of the sharing of research resources plan and the IPMP. 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. NCI 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.

The EDRN grantee shall provide written assurance that neither he/she, nor his/her home institution will compromise the intellectual property rights resulting from inventions of EDRN investigators and their collaborators by entering into agreements with pharmaceutical or biotechnology companies that would hinder the ability of EDRN investigators to have unrestricted access to institutional resources that have been developed through EDRN supported research or to participate fully in collaborations with other researchers. The grantee shall also include a written statement that any interactions with commercial entities during sponsored research agreements will be compliant with requirements of the *Bayh-Dole Act* (37 CFR 401; <http://grants.nih.gov/grants/bayh-dole.htm>), 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* and the *NIH Research Tools Policy* (http://grants.nih.gov/grants/intell-property_64FR72090.pdf). These documents define terms, parties, and responsibilities, prescribe the order of disposition of rights and provide 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 at <http://www.iedison.gov>. Applicants should also see 35 USC § 210 (c); Executive Order 12591, 52 FR 13414 (April 10, 1987) and Memorandum on Government Patent Policy (February 18, 1983).

If 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/filasurt.html>) and necessary IRB approval 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>.

If applicants plan to collaborate with third parties, the sharing plan must address how such collaborations will not restrict their ability to share biomedical research materials produced with NIH funding, to the scientific research community. Therefore, any relevant third parties (including external co-investigators, collaborators or consultants) should also provide written assurance that they are willing to follow these policies and detail the agreement between them and the grantee or his institution. An EDRN grantee (or the grantee's institution) should be familiar with the following document prior to entering into sponsored research agreements with commercial entities: *"Developing Sponsored Research Agreements: Consideration for Recipients of NIH Research Grants and Contracts"* (Federal Register, Vol. 59, No. 215; Tuesday, November 8, 1994; pp 5564-5567).

An applicant should become familiar with his institution's policies regarding technology transfer-related matters and or sponsored research in order to develop and submit a reasonable IPMP to the RFA. NCI provides resources (<https://ttc.nci.nih.gov/ip/sampleplans.php>) that give examples of approaches considered by other institutions in the development of IPMPs. In addition, NCI Program Directors are available to answer questions of the grantees regarding development of IPMPs.

IP Issues Related to Biomarker Discovery and Validation

During the biomarker discovery and validation phases of collaborative research, Intellectual Property (IP) issues can become complex given that diagnostic assay development on the basis of novel biomarkers can involve multiple institutions and industry collaborators. Further complicating matters, is the situation where these diagnostic assays are developed, to some extent, with proprietary biomarkers, reagents, and/or technologies supplied by collaborators.

For the situation where EDRN evaluates an individual biomarker from an individual source, then IP rights are maintained by the source as EDRN will not claim IP rights. If a pre-existing single individual biomarker with IP rights established for one use is later used for a different indication, for example the prostate specific antigen (PSA) used to screen for breast cancer, then IP rights could be sought for this marker on its completely new application.

A more complicated situation arises when various investigators contribute multiple biomarkers to a panel for EDRN evaluation. In this case, EDRN's policy is that *"No one partner or contributor will claim IP rights on the panel of markers they are contributing to. Each partner may claim and keep IP rights on their individual biomarker but the panel remains IP-free"*. In order to achieve this result and ensure fair and equitable outcomes for all parties involved, EDRN would publish positive or negative results on the

biomarker panel as quickly as possible through press releases and scientific publications. EDRN has considered the idea of “shared IP” with respect to biomarker panels where each party contributing a biomarker(s) to a panel would each share in the IP of the combined panel. This arrangement could be more problematic from the legal perspective given that each individual, company or institute would need to agree to the shared IP.

IP Options and Licensing

Given these circumstances, a grantee and his institution may want to use an IP option to license inventions within narrow fields of use in order to allow additional individual collaborations with other companies to develop these inventions. Alternatively, a grantee’s institution could enter into a multi-party agreement that incentivizes the companies for moving the products forward. Possible approaches include:

- Granting an IP Option to each individual company for an exclusive commercialization license relating solely to such company’s products, or
- An IP Option for a co-exclusive license to intellectual property rights relating to a combination of products. If multiple patents are involved, but exclusive (or co-exclusive) access is not required, applicants and their collaborators may wish to explore the creation of patent pools, which would enable all necessary patents relating to a technology to be licensed non-exclusively at reasonable royalty rates. Further information on the use of patent pools for biotechnology patents can be found at the following website:

<http://www.uspto.gov/web/offices/pac/dapp/opla/patpoolcover.html>

The Cancer Therapy Evaluation Program’s website (<http://ctep.cancer.gov/industryCollaborations2/guidelines.htm>) provides a model of an intellectual property option (“IP Option”) given voluntarily by grantees of this NCI program. In this model, extramural grantees agree to give exclusive options to negotiate exclusive, world-wide, royalty bearing licenses for all commercial purposes, including the right to grant sub-licenses to all inventions resulting from the use of compounds supplied by collaborators. Cost related to the patenting and/or licensing of intellectual property may be allowable as F&A costs (see <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-045.html>).

The US Department of Justice and Federal Trade Commission (April, 1995) has published anti-trust guidelines for the licensing of Intellectual Property and can be found at the following website: <http://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/0558.pdf>. The Federal Trade Commission and the U.S. Department of Justice (April, 2000) has published anti-trust guidelines for collaborations among competitors and can be found at: <http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf>.

If an investigator decides to license methods or biomarker assays supported fully or in part by the NCI EDRN, a prior consultation with the NCI is required. NCI wants to ensure that the commercialization license should be broad enough to cover the research plan and relate to the proprietary product (device,

drug, test, etc.) of the collaborator. A research use license for resulting inventions in the final negotiated commercialization license should include the right to share such inventions with others for non-commercial purposes. In the event that institutions desire to use intellectual property resulting from such collaborations for the benefit of third parties for commercial purposes, they will want to obtain the consent of the relevant industry collaborators before doing so.

Protection of Confidentiality

The EDRN SC recognizes the necessity of protecting certain proprietary information relating to inventions and potential and/or present patent rights, research, development, business plans and other technology or confidential information. Therefore, the Committee has agreed that all discussions concerning unpublished data, research results, theories, drawings, figures or visual depictions of research data or results regardless of format that occur in the closed Committee sessions will be treated as proprietary and confidential.

The EDRN maintains the confidentiality of proprietary information by asking each individual to sign a Confidentiality and Non-Disclosure Agreement (CDA), which is a legally binding agreement to prevent disclosure of such information to non-EDRN associated individuals, unless the consent of the owning party has been secured. This enables investigators to share the results of their undisclosed or unpublished work in an atmosphere of openness and collegiality, which is essential in fostering the collaborative effort among investigators that the EDRN seeks to maintain. Grantees may view the EDRN CDA in Appendix 2 of this guidelines document.

Partnership with Public-Private Companies

Creating public-private partnerships is at the core of EDRN's achievements. Four federal agencies—The National Institute of Standards and Technology (NIST) (BDL), the Centers for Disease Control and Prevention (CDC) (CVC), the Pacific Northwest National Laboratory (PNNL) (BDL), and JPL (informatics support) – participate with EDRN through interagency agreements. Other intergovernmental collaborative partnerships are those between EDRN and FDA, and those among EDRN and NIH Institutes, including the National Heart, Lung, and Blood Institute (NHLBI) on the Women's Health Initiative for discovery and validation of biomarkers on sera/plasma from this 15-year clinical trial; the Collaboration of Consortium of Functional Glycomics (funded by NIH's National Institute of General Medical Sciences [NIGMS]); and Programs of Excellence in Glycosciences (supported by the National Heart, Lung and Blood Institute [NHLBI]). Two non-profit foundations, Canary Foundation, CA and Lustgarten Foundation, NY, are supporting discovery and validation studies on prostate and lung (canary) and pancreatic cancers (Lustgarten) in collaboration with EDRN.

EDRN has fostered collaborations with industry as the needs of the Network have evolved. During its inception, EDRN worked with NCI's Technology Transfer Center to develop innovative methods for sharing confidential information with industry, and EDRN's Technology Resources Sharing Committee developed guidelines for working with industry. EDRN has also conducted a workshop on Public-Private

Partnerships. Several collaborations with industrial partners and foundations have been established and are yielding benefits (see the EDRN 5th Report <http://edrn.nci.nih.gov/docs>).

Roles and Responsibilities of the EDRN

The EDRN recognizes that it can play a major role in advancing the collaboration and partnering of industry with academia and perhaps even industry with industry. EDRN has considerable experience in facilitating and forming collaborative efforts. Its infrastructure is set up and designed to encourage and reward its own members for their collaborative work through their cooperative agreement funding policies. However, EDRN may be able to further collaborative research by: 1) allowing companies to realize the full value of their new products or platforms and their research investments (i.e. by validating their products in large scale assays with “gold standard” specimens); 2) connecting the research community to new products, reagents, technologies and services that industry can provide; and 3) most importantly, EDRN can act as an honest broker. The role of the honest broker is important in keeping with the idea of encouraging all parties to set appropriate terms and conditions at the very outset of any partnering agreement. Being the conduit of transparency and ensuring that all parties understand their role and responsibilities as well as their rights may be one of the most important contributions that EDRN can make in advancing and streamlining collaborative efforts. Since cooperative agreements and contracts are the mainstay of its funding opportunities, EDRN has the experience necessary to outline, streamline and clarify the documentation required to undertake collaborative efforts.

Responsibilities of Collaborating Parties

When setting up collaborations (one-to-one, one-to-many, many-to-many) specific documentation is to be outlined and agreed upon by all parties that will include the areas described below. Clarity and understanding of these issues will lead to greater supportive trust among the stakeholders. A template agreement could be formulated by EDRN in conjunction with industry to streamline these arrangements.

(1) Resources and contributions to the project: Clear documentation describing the contribution of specimens, reagents, labor, supplies, and resources to be outlined and agreed upon at the outset of the partnership. These can be set up similarly to the Statement of Work (SOW) of a contract. In turn, the recipients (investigators, companies, etc.) of the resources who are utilizing the “gold standard” repository specimens will be obligated to share the resulting data with EDRN.

(2) Success/non-success of the project: Clear definitions, milestones, goals and metrics of the project’s successes are to be outlined and made available for all parties. These are to be negotiated and agreed upon by all partners prior to any collaborative research or transfer of materials. Clear definitions of action(s) to be taken when the goals and milestones are not met in a timely fashion are to be written and agreed upon at the outset of the collaborative project.

(3) Data sharing and statistical support: There must be agreement and written documentation on how the data will be shared among the collaborators; on the “language of the data” and the analysis of combined datasets; which partners will be responsible for the statistical support; which partners will

have access to the data and when and how the data will be used for regulatory filings or further development.

SAMPLE

NON-DISCLOSURE AGREEMENT

The EDRN Steering Committee Meeting participant ("Participant") named below agrees not to disclose any portion of the Confidential Information presented or discussed during the 27th EDRN Steering Committee Meetings held on March 4-6, 2014 to any third party without prior written permission from the entity disclosing the Confidential Information ("Disclosing Party"). Participant shall use reasonable care to maintain the confidentiality of the Confidential Information. Confidential Information shall include, but not be limited to, unpublished data, research results, theories, drawings and figures or visual depictions of research data or results regardless of format. The proceedings of the EDRN Steering Committee Meeting will be recorded.

The obligation of confidentiality shall extend for a period of three (3) years from the date of the disclosure, unless permission to disclose at an earlier date is granted by the Disclosing Party. The obligations above shall not extend to any part of the Confidential Information (a) that can be demonstrated to have been in the public domain or publicly known at the time of disclosure; (b) that can be demonstrated to have been in the possession of or that can be demonstrated to have been readily available to Participant from another source prior to the disclosure; (c) that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by Participant; (d) that can be demonstrated as independently developed or acquired by Participant without reference to or reliance upon such Confidential Information; or (e) that is required to be disclosed by law. Participant further agrees not to use the Confidential Information or attempt to commercialize it, its derivatives, or products using or embodying either, unless and until further agreement is made.

Participant Name(s): _____

Institution/Organization Name: _____

Authorized Official's Signature

Date

Printed Name

Title of Authorized Official