NATIONAL CANCER INSTITUTE
Technology Transfer Center

IP Sample Plan #1

Sample letter that shows how Universities including co-investigators, consultants, and collaborators can describe a data and research tool sharing plan and procedures for exercising intellectual property rights. The letter is to be used as part of the University's application.

RE: *[NIH OER Notice Number]* - Outline for data and research tool sharing plan and procedure for exercising intellectual property rights

The objective of this letter is to describe how the University of _____ [*insert name of applicant institution*] ("University") and [*insert list of institutions of all co-investigators, consultants and collaborators*] ("Collaborating Institutions") (collectively "Participating Institutions") will manage the intellectual property produced by their research within the [*insert name of NCI program*]. This letter is included as a part of University's application in response to [*NIH OER Notice Number*] , and will specifically address how the Participating Institutions will share data, share research materials, and patent and license intellectual property. University and Collaborating Institutions are experienced and knowledgeable in capturing and protecting biotechnology related intellectual property and have already shown the ability to stimulate the interest of commercial partners.

Sharing Data: University and Collaborating Institutions will follow NIH Grants Policies concerning the sharing of research data. As outlined by the NIH, University and Collaborating Institutions will make available to the public the results of this collaboration and any accompanying data that were supported by the NIH. In order to protect the disclosure of sensitive data and subjects' identities, University and Collaborating Institutions will restrict information in the dataset, restrict access to the data, and strip the dataset of items that could identify individual participants. This will ensure that data intended for broader use will be free of identifiers that could allow linkages to the research participants and free of content that would create unacceptably high risks of subject identification. If necessary, the investigators of the Participating Institutions will consult with statisticians to determine the best plan for data redaction and test the redaction process prior to the release of data. Where possible and appropriate, final research data will be stored as a Data Archive in secure computer databases. In accordance with NIH policy on Data Sharing, University's Cancer Center and the group of investigators of University and Collaborating Institutions working on this project within the [*NCI program*] have established the following policy and implementation plan for data sharing. Any research data obtained through the use of the Cancer Center Support Grant (CCSG) shared resources, Protocol-Specific Research, or the [*NCI program*] will be made

available to researchers and/or the general public as requested. The limitations on this policy are that data will not generally be available until such a time that it is submitted for publication. Also, all human subjects' rights to privacy will be protected and will not reveal the identity of human subjects.

All personnel involved in this research have completed or will be required to complete the OHRP-approved computer-based training course on the Protection of Human Research Subjects. All procedures included in this application will have approval by the respective institutional review boards of University and Collaborating Institutions. The actual timelines of availability of requested data will be specific to the data requested and any special sensitivity of the requested data set. For example, all data to be shared will adhere to all appropriate state and federal confidentiality requirements and privacy guidelines (e.g., the Health Information Portability and Accountability Act, HIPAA). In no case will data be disclosed that may pose a possibility of identifying human subjects of research. Data pending patent application may be withheld for a reasonable amount of time to evaluate the impact of disclosure on patentability as provided under the Bayh-Dole Act. Data will be provided in a timely fashion. Requests for data will be submitted to the Principal Investigator of this application (Dr. _____) who will consult with the Collaborating Institutions on the projects regarding the timeline and format for sharing final research data. Requests for data will be processed through the University Cancer Center's Data Archive Coordinator and Data Archive Coordinators at other institutions as needed. Requests will be evaluated for appropriateness and to ensure protection of confidentiality, as necessary.

Sharing Research Materials: University and Collaborating Institutions will also comply with the Federal requirements governing technology transfer, including 35 USC and associated Federal Regulations and adhere to the policies and guidelines of NIH addressing technology transfer and the distribution of NIH funded research materials. According to NIH guidelines, University and Collaborating Institutions in possession of materials generated during the course of the project (" [*NCI program*] Materials") will strive to make the unique research resources readily available for research purposes to members of the [*NCI program*], non-profit organizations, and commercial partners in accordance with NIH guidelines. Material transfer agreements will be used when appropriate and the Uniform Biological Material Transfer Agreement will be favored for the transfer of materials between non-profit institutions. This agreement will provide for the transfer of unpatented tools developed with NIH funds to other recipients for use in NIH-funded projects. When transferring materials to for-profit institutions the tools will be transferred with the fewest encumbrances possible.

Intellectual Property: Researchers at University and Collaborating Institutions will disclose "Subject Inventions" as defined in 35 USC 201(e) to their respective organizations. Subject Inventions will be reported to the NIH by the Participating Institution receiving disclosure of the Subject Invention and title will be elected as the Participating Institution believes is appropriate. All Subject Inventions to which title is elected shall be considered " [*NCI*

program] Inventions" and University and Collaborating Institutions will take steps to protect [*NCI program*] Inventions by filing patents.

Licensing of Intellectual Property: University and the Collaborating Institutions will openly communicate and cooperate with other [*NCI program*] institutions for the purpose of managing, protecting and licensing [*NCI program*] Inventions. Information on Subject Inventions will be made available as needed between Participating Institutions and other [*NCI program*] members and upon request the same will be made available to commercial collaborators involved with the project. Shared information will be treated as confidential by institutions and commercial collaborators as is necessary. Institutions having ownership of [*NCI program*] Inventions or possession of [*NCI program*] Materials will coordinate with each other to further the development of the technology. When ownership of [*NCI program*] Inventions involves multiple institutions, University and Collaborating Institutions will form agreements involving the consolidation and central management of intellectual property rights. Similarly, University and Collaborating Institutions will collaborate to package [*NCI program*] Inventions for licensing when necessary to commercially develop [*NCI program*] Inventions in a timely fashion.

University and Collaborating Institutions will make their own [*NCI program*] Inventions available for licensing to those commercial collaborators from which they received materials used to arrive at [*NCI program*] Inventions. Commercial collaborators interested in licensing [*NCI program*] Inventions shall notify the participating institution having ownership of the particular [*NCI program*] Invention in which they are interested. Licenses for commercial purposes will be made available to commercial collaborators having the resources and ability to adequately develop and/or commercialize [*NCI program*] Inventions. If multiple commercial collaborators exist, licensing will be restricted to the "field of use" or nonexclusive rights will be licensed. Options to license [*NCI program*] Inventions may be offered to commercial partners for reasonably limited times as long as the particular participating institution has appropriate ownership of rights being optioned. To the extent it is reasonable to believe that the objectives of the [*NCI program*] will be accomplished and when it is not in conflict with other preferences required by law, qualified commercial collaborators involved with the project will be given preference over other potential licensees with respect to commercial licenses. Once options have expired, University and Collaborating Institutions will be free to pursue other interested licensees as needed to facilitate the successful technology transfer of [*NCI program*] Inventions. Exclusive licenses will be executed when appropriate and milestones will be used to insure that the licensing leads to timely commercial development. In such licenses, University or the Collaborating Institution will strive to retain a "research use" license for any technology that is licensed.

The appropriate representative from each Collaborating Institution has read and concurred with the terms of _____ University's intellectual property management strategy.

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Source
URL:https://techtransfer.cancer.gov/intellectualproperty/ip-information-grantees-contractors/ip-sample-plan1