

METRC Policy & Procedure Manual

Title: METRC Intellectual & Material Property Policy

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General Description & Purpose: This document describes METRC's policy regarding intellectual and material property.

I. Intellectual & Material Property Plan

The Major Extremity Trauma & Rehabilitation Consortium (METRC) is committed to making the results and accomplishments of its research available to sponsors, the research community and to the public at large, and, where applicable, to accomplish the transfer to industry for commercialization. Below we describe how the METRC Coordinating Center (MCC) at Johns Hopkins University Bloomberg School of Public Health and METRC Collaborating Institutions manage the intellectual and material property produced by their research. We also address how the Collaborating Institutions share data within and outside the Consortium, share research materials, and patent and license intellectual property.

II. Sharing Data

Each Participating Institution owns the data it generates using METRC funding. The institutions share their data with the MCC for the purpose of conducting METRC approved research. These data are shared with the MCC using the REDCap web-based distributed data collection system. All sharing of data conforms to human subject protection practices and is compliant with all appropriate state and federal confidentiality requirements and privacy guidelines (e.g., the Health Information Portability and Accountability Act). All personnel involved in METRC research have documented training in the Protection of Human Research Subjects.

Each party has the right to publish and disseminate information derived from the performance of work as a member institution within METRC. In doing so, the institutions conform to the policies set forth by the Consortium's Publications & Presentations Committee, which are available to all partners and the public on the METRC website. The key principle of these policies is to defend the academic freedom of METRC investigators to publish results emanating from their own performance on METRC studies, while ensuring limitations on publication of results from any one center which could potentially threaten the integrity of collective data.

Research data obtained through METRC shared resources is made available to investigators and the general public as requested per the parameters described next. Generally, data become available after main study results are published. Availability, or timeliness of delivery of a dataset, may also be influenced by the nature of the data and/or the context or parent study from which the dataset is

derived. Data pending patent application may be withheld for a length of time necessary to evaluate the impact of disclosure on patentability as provided under the Bayh-Dole Act.

Shared data adhere to all appropriate state and federal confidentiality requirements and privacy guidelines (e.g., the Health Information Portability and Accountability Act). In no case is data shared which could possibly identify the human subjects of the research is shared. In order to protect the disclosure of sensitive data and subjects' identities, information in the dataset is restricted, access to the data is restricted, and the dataset is stripped of all items that could identify individual participants. These practices ensure that data intended for broader use are free of identifiers that could allow linkages to the research participants and free of content that would create unacceptably high risk of subject identification. METRC consults with statisticians to determine the best plan for data redaction as necessary. The redaction process is tested prior to the release of data. Where possible and appropriate, final research data are stored as a Data Archive in secure computer databases (and made available through the password-protected METRC website).

III. Sharing Research Materials

The MCC and all METRC Collaborating Institutions comply with the Federal requirements governing technology transfer, including 35 USC and associated federal regulations and adhere to the policies and guidelines of sponsors addressing technology transfer and the distribution government-funded research materials. Collaborating Institutions in possession of materials generated during the project are required to make the unique research resources readily available for research purposes to members of METRC, nonprofit organizations, and commercial partners in accordance with federal guidelines. Material transfer agreements are used when appropriate and the Uniform Biological Material Transfer Agreement is favored for the transfer of materials between nonprofit institutions. This agreement provides for the transfer of unpatented tools developed with government funds to other recipients for use in other government-funded projects. When transferring materials to for-profit institutions, the tools are transferred with the fewest encumbrances possible.

IV. Intellectual Property

Inventions developed under METRC funding are reported to the METRC Executive Committee and all participating institutions, as appropriate, for evaluation and pursuit of intellectual property protection strategies. METRC Collaborators evaluate inventions to decide and implement the most appropriate strategy for achieving the goals of the Consortium. In cases where METRC Collaborators determine that patent protection is the best strategy for introducing and distributing such inventions to the developing world it will pursue such strategies. Inventions, whether patentable or not, that are conceived and reduced to practice under METRC funding solely by one institution are owned by that institution. Inventions, whether patentable or not, conceived and reduced to practice jointly by two or more institutions are jointly owned by those institutions. In the case of jointly owned inventions, the joint owners negotiate in good faith suitable management agreements to permit the evaluation, protection and commercialization of the invention considering the goals of the project and the Consortium. With respect to pre-existing intellectual property, such pre-existing intellectual property remains the property of the party that created and/or controls it.

METRC is committed to move expeditiously in seeking to license an invention to a commercial entity that can develop the invention into a product or service that benefits the public at large. Inventorship is

determined by US patent law. Each collaborative partner (both inventors and non-inventors involved in METRC) is granted a non-exclusive, royalty-free, research license for the duration of the Consortium. If there is a single participating commercial partner, it is granted an option for a commercial license. If there are multiple commercial collaborators, they are granted an option for a non-exclusive commercial license. Licenses reserve a royalty-free, non-exclusive US government license for use of the technology for government purposes. Also reserved in collaborators research licenses is a sub-license right to other non-commercial enterprises, thus assuring distribution of research tools to the scientific community.

V. Resolving Disputes among Consortium Parties

Any dispute among METRC Partners relating to the management of Intellectual Property, as provided in the Plan, or to the interpretation of the Plan, is referred for resolution within a reasonable period of time and in a fair and equitable manner, to the respective officers of the Institutions involved, taking into consideration the objectives of the Consortium and any laws, statutes, rules, regulations or guidelines to which the involved Consortium Parties are subject. If a dispute relates to identification of Inventor(s) or Owner(s) of Project Intellectual Property, the Institutions may choose a competent patent attorney having no business or employment relationship with any METRC Partner to advise the Institution's designated officers regarding same. The costs of obtaining this advice are divided per capita among the Institutions having an interest in the invention being reviewed.

DOCUMENT HISTORY

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