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Science Commons: Material Transfer Agreement Project

Access to unique research resources, such as biological materials and reagents, is vital to the success and advancement of science. Many research protocols require assembling a large and diverse set of materials from many sources. Yet, often the process of finding and negotiating the transfer of such materials can be difficult and time-consuming. The ability to locate materials based on their descriptions in journal articles is often limited by lack of sufficient information about origin and availability, and there is no standard citation for such materials. In addition, the process of legal negotiation that may follow can be lengthy and unpredictable. This can have important implications for science policy, especially when delays or inability to obtain research materials result in lost time, productivity, and research opportunities. These transactional barriers for material transfer may ultimately have more impact on the productivity of basic laboratory science than concerns related to patents or other intellectual property.[1]

Science Commons, a project of Creative Commons, is a non-profit initiative that promotes policy and technology that remove unnecessary legal and technical barriers to scientific collaboration and innovation. Science Commons's Material Transfer Agreement (MTA) Project seeks to reduce unnecessary barriers to the transfer and reuse of basic research materials and reagents, for both United States and international scientific collaboration, by proposing a scalable and flexible infrastructure for searching, negotiation, and tracking.

Creative Commons was founded in 2001 by cyberlaw and intellectual property pioneers, including James Boyle, Michael Carroll, Molly Shaffer Van Houweling, and Lawrence Lessig, MIT computer science professor Hal Abelson, lawyer-turned-documentary filmmaker-turned-cyberlaw expert Eric Saltzman, renowned documentary filmmaker Davis Guggenheim, noted Japanese entrepreneur Joi Ito, and public domain Web publisher Eric Eldred. Inspired by the open source movement, Creative Commons published a set of standardized copyright licenses free

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for public use in order to permit authors and artists flexibly to license their works for copyright, remixing, and sharing. These licenses have become very popular as a standard license for Web content, such as photographs on the Web site Flickr, blogs, Web sites, and multimedia presentations. In addition, they have been adopted by many open access publishers, such as Public Library of Science, Hindawi, and Biomed Central, all of which use the Creative Commons Attribution License to license their publications. Science Commons was founded as a project within Creative Commons to identify similar opportunities in science for facilitating exchange, re-use, and collaboration. The Materials Transfer Project arose from the recommendations of a conference of research funders, university technology transfer officers, and legal experts organized by Science Commons to explore ways to remove transactional barriers to research.

MATERIAL TRANSFER AGREEMENT

Material Transfer Agreements ("MTAs") are contracts that govern the transfer of tangible research materials from one research institution (the provider) to another (the recipient). They are most commonly employed in the transfer of "unique research resources" such as "cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines."[2] Non-biological and synthetic materials, such as certain nano-materials, chemical reagents, and chemical substrates may be shared under MTAs as well.

This system for transferring these research tools can give rise to a variety of transaction costs associated with finding and bargaining for such tools. These problems are particularly acute where the volume of transactions is high and the sources of unique research resources required for a given research protocol are diverse. The resulting delays and failures to agree can impose a significant cost in terms of lost productivity and research opportunities.[3]

First, it may be difficult to locate relevant materials, because most of them are not widely publicized and not searchable on the Web. The traditional method for a researcher to locate and assemble materials needed for research is to read relevant journal articles in the field of interest, design a suitable research protocol, and contact the providers referenced, unless the materials are widely known to be available from a commercial vendor. For materials that are not commercially available, locating available supplies of materials is potentially time-consuming, because the provider of the materials may not be identified, may not have sufficient supplies of the materials, may not be able to produce more at a reasonable cost, may not wish to share them, or may have moved to a different institution or job.

After a researcher has located the source of the materials, negotiation of the MTA may present the next hurdle. As the National Institutes of Health's Principles and Guidelines state, "each iteration in a negotiation over the terms of a license agreement or material transfer agreement delays the moment when a research tool may be put to use in the laboratory."[4] In many circumstances, the materials are

subject to non-standard agreements, whose terms are not widely publicized. This makes it hard to predict whether a request for the materials may be simple or difficult to negotiate. Sometimes, a particular material may be subject to multiple MTAs with potentially overlapping or inconsistent terms.

This creates a number of possible factors contributing to delays or failure to obtain materials, particularly when a research protocol requires materials from many different sources. If the offered MTA is non-standard, then it must be carefully reviewed by a lawyer or specialist trained to understand legal issues and the institution's policies and objectives. These objectives can include ensuring rights to publish, disseminate, and use research results and to license for commercialization and avoiding conflicting obligations. The reviewer must identify any objectionable terms and reject them or offer counter-proposals. In some cases, the reviewer will consult with business managers and researchers to clarify essential business objectives. However, this process can cause significant delays or failure to reach agreement, frustrating research agendas and schedules.[5]

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While these negotiation practices may be useful in the context of high-value transactions with large payoffs to the parties, such as royalty-generating transactions, it is less justified in the context of low financial value transactions like material transfer for basic research. Due to constraints in available legal resources, many technology transfer offices or licensing counsel must prioritize revenue-generating transactions, and resources to negotiate MTAs are limited. This is one factor that may contribute to longer turn-around times for negotiating MTAs.

Some researchers avoid negotiation over MTAs through informal sharing. From an institutional perspective, such practices are unfavorable because they may subject an institution to legal risks, which might otherwise be mitigated by the use of MTAs. Such practices may also implicate the intellectual property management policies of the institution. Finally, informal sharing favors well-connected researchers and institutions, and therefore, may create or perpetuate disparities in opportunities for scientific research.

Science Commons proposes to reduce unnecessary transaction costs for sharing research materials by a creating voluntary and scalable infrastructure for rights representation and contracting represented by use standard agreements, Web-based metadata, and "human-readable deeds." These elements arise from design principles introduced by Creative Commons in creating the Creative Commons (CC) licenses for copyrighted works, which have created a large and scalable infrastructure for authors, scientists, artists, and educators to license their works in standard but flexible ways. This has created a large and thriving community of users and a commons of copyrighted materials available under CC licenses.

STANDARD CONTRACTS

An important element of the success of "open source" software is the use of standard licenses such as the Gnu Public License or others of the Open Source Initiative's approved licenses, which have provided a legal framework for collaborative software development. Such standard agreements reduce transaction costs by reducing negotiation costs within the communities that routinely use them and can facilitate regimes of frictionless exchange and re-use. Similarly, the CC licenses provide a framework for the copying, re-mix, and distribution of artistic works and other content.

One of the most prominent and successful efforts to standardize biological material transfers in the United States is the Uniform Biological Material Transfer Agreement (UBMTA), which was developed by the National Institutes of Health (NIH) in collaboration with research institutions and adopted by 320 signatories.[6] Institutions may sign and deposit a master UBMTA with The Association of University Technology Managers (AUTM) in order to be able to complete transactions by executing a short "implementing letter" or cover letter. A similar, shorter standard form called the Simple Letter Agreement (SLA) for non-profit use is published by NIH, which recommends its use in connection with NIH sponsored research.[7] However, use of such standards for intra-academic transfers is not universal, as signatories can opt to use them on a case-by-case basis, and some institutions may include in these MTAs additional modifications that would render them non-standard, and thus subject to individualized review and negotiation.

A further complication is that the UBMTA and SLA are not compatible with use by for-profit entities. This is because the UBMTA and SLA prohibit transfer to for-profit entities and restrict use to academic research. The lack of generally accepted standards for these transfers makes collaboration between academic and for-profit researchers complex and costly, even when only internal or evaluation use is contemplated.

The Science Commons MTA Project adopts a two-tiered strategy to reduce transactional barriers to exchanging materials for research. First, for intra-academic material transfer, we adhere to the NIH Principles and Guidelines for Recipients of NIH Research Grants and Contracts On Obtaining and Disseminating Biomedical Research Resources ("NIH Principles and Guidelines") in calling for

more widespread adoption and use of UBMTA or SLA in unmodified form. To provide incentives to adhere to these standards, we will provide tools and infrastructure to facilitate listing, searching, contracting, and tracking downstream impact for providers and recipients who are willing to take advantage of these existing standard MTAs. These capabilities rely on an extension of the same metadata framework that has made content under the Creative Commons licenses widely available for Web-based sharing, and we are adapting such metadata and software to work with the UBMTA and SLA.

The NIH Principles and Guidelines also encourage institutions to "simplify the transfer of materials developed with NIH funds to for-profit institutions for internal use by those institutions."[8] These guidelines recognize that while greater flexibility is required in this area, the same principles apply to considerations for internal use by for-profit entities. Science Commons, working with collaborators, has developed a set of new MTAs that use modular contract options to promote the development and evolution of standard MTAs for transfers between academia and industry. The new MTAs published by Science Commons will provide for a more flexible range of options, while at the same time adhering to the core guidelines articulated by the NIH Principles and Guidelines. For example, they distinguish between activities for internal use and commercialization, and they do not provide options that restrict publication or that contain reach-through royalties, grant backs, commercialization options, or other obligations with regard to downstream inventions made by the recipient. We are also developing a simple interface that can guide a user through key considerations and options associated with selecting a particular MTA.

STANDARD RIGHTS DESCRIPTION FRAMEWORK

The use of semantic web metadata to identify rights associated with copyrighted works has contributed to powerful searching and filtering capabilities for Web-based works available under Creative Commons licenses. These metadata use the Resource Description Framework (RDF), a robust Web-based representation language for Universal Resource Identifiers (URIs) published by W3C.[9] This open framework allows physical resources in the world (such as unique research materials) to be represented in a machine-readable form that is designed to be compatible across a variety of software and operating system platforms. For example, more than 140 Million objects on the Web are tagged with Creative Commons licenses, and they can be found by using advanced search options available from search sites such as Yahoo! and Google. This has demonstrated considerable potential to create a scalable, low-cost infrastructure for describing resources and associated rights and permissions.

Science Commons will use a similar framework to describe unique research materials and the MTAs under which they are offered. Each material that is listed on the Web and available under a standard MTA can be associated or "tagged" with metadata, which allows for similarly powerful searching and filtering capabilities

by software and search engines. For example, an academic researcher might be able to search for all available animal models for neurobiological research that are available under the UBMTA or SLA, and her counterpart at a for-profit laboratory can search for similar materials that might be offered under a standard Science Commons MTA. This will permit researchers to plan research protocols with greater visibility into the likelihood that unique research resources will be available quickly or whether more extended negotiations will be required.

The association of this metadata with scientific articles may raise exciting new possibilities. For example, authors can supply a unique link from materials described in the "materials and methods" section of a scientific article to the hosting material depository where they can be found and ordered. Then, a researcher referencing such a link can use the supplied metadata to identify and filter acceptable MTA offers and then order online if possible. The widespread use of such a system may eliminate much of the detective work currently involved in tracking down materials and enable greater automation of ordering and fulfillment.

The association with materials with the literature using metadata can also permit the research impact of materials to be tracked and analyzed by software, giving researchers and funding institutions additional measures of scientific impact. Creative Commons has demonstrated this capability with its CCMixter software, which allows metadata to be used to track and analyze downstream impact of creative works, such as remixes and other derivative works originating from a given work.[10] In the materials context, this may permit the impact of research to be evaluated not only in terms of journal citations but also the frequency of re-use of unique research materials generated by that laboratory.

In addition to metadata, Science Commons is developing "human readable deeds" for each standard MTA. These deeds and asscociated metadata will be hosted at unique Web Uniform Resource Identifier (URIs) to which users and software applications can link. Each, in turn, provides links to the relevant legal text and associated metadata for that MTA. Each deed describes a unique standard agreement in summary terms, as intended to be understood by non-legal audiences, including basic iconography that will enable researchers to identify at a glance the most relevant rights and obligations associated with a material. These can also be printed out and attached to materials to describe relevant MTA limitations, similar to the way that Material Data Sheets summarize salient physical and chemical properties of materials.

Together, these elements create the basic outlines of an infrastructure for enabling Web-based transactions in materials. Web-based transactions have revolutionized e-Commerce, as evidenced by sites like Amazon.com and Ebay. Yet, so far, we have seen little evidence that these models are being adapted with nearly that level of success for solving material transfer problems. We believe that such success requires significant standardization of policies, contracts, and technology. The elements of our MTA project will offers nucleating agents around which such efforts can grow and evolve. We are also collaborating with the iBridge Network, a project of the Kauffman Innovation Network dedicated to creating a Web-based

clearinghouse of research tools and materials, [need to describe iBridge for non-specialists through footnote or briefly in text] to deploy the initial prototype of this MTA system. This will provide us with an opportunity to conduct a beta test of our software and tools and obtain feedback from key stakeholders.

Reducing the time it takes for scientists to obtain basic research materials is vital for accelerating scientific discovery. Standardization of policy, contracts, and technology is necessary in order to deliver the relatively frictionless transaction systems that have revolutionized Web commerce. The system that we propose, which includes greater use of standard contracts, a Web-based rights description framework, and other educational tools, is the first step in that direction. The possible benefits will accrue not only to immediate stakeholders, in the form of cost savings and increased productivity, but ultimately to society as a whole from greater innovation and scientific progress.

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