MATERIAL TRANSFER AGREEMENTS

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Scope

This Policy on Material Transfer Agreements applies to faculty, staff, predoctoral researchers, summer scholars and applicants ("Covered Individuals") of The Graduate School of the Stowers Institute for Medical Research ("The School").

Purpose

From time to time, scientific personnel at GSSIMR will seek research materials from academic institutions, other nonprofit research facilities, or private industry, or may receive requests for research materials from such sources. Typically, these transfers are made pursuant to a written material transfer agreement ("MTA") entered into between the provider and recipient of the research materials. The purpose of the MTA is to protect the intellectual and other property rights of the provider while permitting research with the material to proceed. In turn, the recipient is provided with tools and information necessary to continue with the research. The different missions and goals of the provider and recipient and obligations to third parties such as the National Institutes of Health ("NIH") often mean that the MTA terms must be negotiated to accommodate the needs of both parties. The usual areas of difference relate to rights to future discoveries, publication, indemnification and replication. These areas may cause delays or even prevent the issuance or approval of an MTA. Other factors such as foreign transfers and transfers of hazardous biological materials may also cause delays. This policy discusses the typical areas of differences, describes the types of transfers that may require additional time, and sets forth the procedure for requesting the approval or issuance of an MTA.

The School is included in the Stowers Group of Companies ("SGC") Organizations and has adopted the following policy as its own.

Policy

Typical Areas of Differences

Exchange of research materials between academic institutions and other nonprofit organizations is relatively straightforward and very little is negotiated. This is because the nonprofit research community considers the sharing of research materials to be an essential aspect of scientific citizenship. Most nonprofit organizations seek to minimize the accompanying paperwork and use standardized MTAs that follow NIH guidelines. In contrast, transfers of materials to or from private industry are usually negotiated on a case-by-case basis, with particular issues being more important to one company than to another. Set forth below are the typical areas of difference and the Institute's position in these areas.

Rights to Future Discoveries

While it is clear that ownership of the transferred research materials are and should remain the property of the provider, many MTAs include language that grants the provider the right to either own, or license exclusively, or obtain payments upon the sale of, discoveries that the recipient makes with the provider's materials. These are generally referred to as "reach-through" provisions, and are considered by many providers to be desirable because they allow the provider to obtain rights in such matter that the provider would not otherwise have through its ownership or patent coverage of the materials alone. The Institute, along with many other nonprofit recipients, considers these types of provisions inappropriate not only because they constitute an unreasonably high level of compensation to the provider for use of the research materials, but also because they burden all the discoveries made after the use of the research materials. This not only represents a direct economic loss to the Institute and its Covered Individuals by limiting future commercialization of such creations, but it can also cause indirect damage by limiting the freedom of Covered Individuals to continue a line of inquiry or by stifling publication. In addition, relinquishing ownership to NIH-funded research in this manner most likely violates the terms of such funding. Therefore, the Institute will generally not agree to reach-through rights with respect to transferred research materials, especially where such materials constitute research tools. Examples of research tools include cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools, methods, laboratory equipment and machines, databases, and computer software.

Confidentiality and Publication

Providers of research materials may require that recipients not disclose information transferred along with the material or may impose restrictions on the disclosure of the results of research using the materials, all of which information is considered to be confidential. While it is clear that agreeing to restrictions on the disclosure of research results will limit or even prevent Covered Individuals from publishing such results, agreeing not to disclose transferred information will also limit meaningful publication if the information is necessary for interpretation of such results. With respect to transferred confidential information, the Institute can avoid this result by (a) requesting that no confidential information be provided, (b) requesting that only confidential information that is not required for publication be provided (i.e., background confidential information), or (c) requesting an exception for provided confidential information which the Institute can demonstrate is necessary for meaningful publication. In addition, the standard exceptions to disclosure of confidential information must be present (e.g., information which becomes generally available to the public, information which was available to the Institute on a non-confidential basis prior to its disclosure by the provider, and information the Institute receives from a third party not bound by a confidentiality agreement).

With respect to limitations on the disclosure of research results, providers often require the recipient to provide an advance copy of any manuscript or proposed public disclosure of results obtained with the material. The purpose for such requirement is not unreasonable. It is to allow the provider to determine whether its own confidential information has been improperly disclosed in the manuscript or presentation, and whether there are new intellectual property rights that may be need to be protected. However, the publication provision may be stated in

unacceptable language. For example, the MTA may give the provider control of publication, and may assert that nothing is to be published or otherwise disclosed without provider approval. Other agreements may demand excessive delays. The Institute will not permit delays of more than 30 days for review of manuscripts prior to submission, with the possibility of an additional 30-day delay (i.e., 60 days in total) for filing of patents. In the case of abstracts for oral disclosure, the Institute will permit no more than 7 days for review.

Indemnification

The provider of research materials often requests that the recipient indemnify (i.e., compensate) the provider against any losses it may sustain as a result of use of the research materials by the recipient. It is a shifting of economic responsibility from the provider to the recipient. If such losses result from an act or failure to act by the recipient, such provision can be justified. However, if such losses result from an act or failure to act by the provider, including negligent actions or inactions such as failure to provide proper warnings with respect to associated hazards or needed precautions, indemnification in such event would be akin to releasing the provider from responsibility. The Institute will generally not agree to indemnify the provider against losses resulting from the provider's own actions or inactions, and will in no event indemnify the provider against losses resulting from the provider's own negligence.

Replication

Many scientific journals require that materials be made available to other investigators for independent verification of research results. The Institute therefore requests that providers of research materials to Covered Individuals agree to provide those same materials to other investigators at universities and other nonprofit research facilities who wish to repeat the published experiments. Although some providers argue that such a provision would jeopardize the provider's control over its own material, a middle ground can usually be found that accommodates each party's needs.

Transfers Requiring Additional Time

Certain types of transfers, such as international transfers and transfers of hazardous biological materials, will most likely require additional time due to additional legal requirements. In such cases, which are discussed below, the Covered Individual should request the approval or issuance of an MTA as soon as possible in order to avoid unnecessary delays.

Receipt of Research Materials from Other Countries

Foreign providers of research materials may employ agreements similar to the MTAs used in the United States. This policy applies to MTAs entered into with foreign providers in the same manner as it applies to MTAs entered into with U.S. providers. In addition, the Institute may need to comply with USDA import regulations covering the transferred materials. For example, importation of many biological materials to the U.S. requires USDA permits. If the proper documentation does not accompany packages, they may be quarantined or otherwise delayed, and they may suffer damage in the process. Therefore, additional time will most likely be required for these types of material transfers.

Export of Research Materials to Other Countries

Likewise, exports from the U.S. to other countries may require analogous permits (sometimes called export licenses, not to be confused with intellectual property licenses) and import permits from the receiving country. Under U.S. export control laws, automatic licenses can apply to most biological materials. In some cases, however, a license may be required from the Bureau of Export Administration of the Department of Commerce. There are, for instance, controls on the export of materials that could possibly be used in chemical or biological weapons. Examples given of such materials include human pathogens, toxins, animal pathogens, genetically modified microorganisms, and plant pathogens. As with transfers from other countries, these types of material transfers will most likely require additional time.

Transfer of Hazardous Biological Materials

There are regulations covering the methods used to package and transport hazardous biological materials. In addition, these regulations require that providers and recipients of such materials be pre-registered with the Centers for Disease Control and Prevention (CDC), and that the individual transfer be registered with that agency. The Institute will most likely require additional time to perform the necessary registration and ship the material correctly.

Approval Process

Incoming MTA with a Non-Profit Organization

Every MTA has a signature line on which an authorized representative of the Stowers Institute indicates that we agree to comply with the terms of the MTA as an institution. Only the President and CEO of the Institute, or his or her designee, may sign an incoming MTA on behalf of the Stowers Institute as an institution. This signature line typically is labeled "Authorized Representative," "Institutional Official," or "Authorized Signatory." Covered Individuals must not sign an incoming MTA on behalf of the Stowers Institute except with written permission from the President and CEO of Stowers.

Some MTAs have a signature line on which the user of the transferred material indicates that the user acknowledges the Agreement's terms as an individual. The user's signature line typically has the label "Scientist," "Recipient Scientist," "Investigator," or Recipient Investigator." The Principal Investigator may specify whether the Principal Investigator and/or another lab member will sign the MTA as an individual. Covered Individuals requesting the approval or issuance of an MTA should complete a New Incoming MTA Request in the Laboratory Information Management System (LIMS) which will be routed to Operations and Services. If an incoming MTA contains terms and conditions incompatible with this policy, the Institute will make a reasonable effort to negotiate compatible terms with the other party. If it is not possible to negotiate compatible terms with a provider, alternative sources for the requested research material must be sought, including purchasing such materials from a commercial source.

Outgoing MTA with a Non-Profit Organization

A laboratory receiving a request for material will complete a New Outgoing MTA Request in the LIMS which will be routed to Operations and Services. The President and CEO of the Institute or

his/her designee will determine if an MTA is required. An MTA may not be required if the material is non-hazardous or non-human biological material for in vitro research. If an MTA is required, the President and CEO of the Institute or his/her designee will determine the form of MTA to be used and execute it. Standard material transfers will be covered under the Uniform Biological Material Transfer Agreement and Letter (Form F606a). Other forms of MTAs will be used where special considerations apply.

If the recipient of an outgoing MTA requests modifications which are incompatible with this policy, the Institute will make a reasonable effort to negotiate compatible terms with the other party. If compatible terms cannot be negotiated, the Institute will not transfer the research materials sought by the recipient.

Incoming or Outgoing MTA with a For-Profit Organization

An incoming or outgoing MTA with a for-profit company will be reviewed and executed by the President and CEO of the Institute or his/her designee in consultation, as necessary, with General Counsel.

MTA Archive

Executed MTAs can be viewed at K:\Research Administration\MTA archive.

Obligations of Covered Individuals with Respect to Research Materials

Research Materials Received by the Institute

Covered Individuals using research materials received from a third party should become familiar with the terms of the MTA. These terms may include limits on the use of the materials for specifically approved research purposes, restriction of access to the materials and distribution to third parties, the requirement to make available to the provider materials or discoveries made using the materials, pre-publication review rights, procedures to ensure the proper handling of material-related confidential information, and proper acknowledgment of the contribution of the provider in all written or oral disclosures. It is the obligation of Covered Individuals to comply and assist the Institute in complying with such terms. If a Covered Individual does not understand a term of the MTA or his or her obligations with respect to such term, the Office of the President and CEO should be consulted. All uses of the research materials and the individual's compliance with the terms of the MTA should be documented in a thorough manner.

If the Institute receives research materials pursuant to an MTA that grants the provider rights to materials or discoveries made using the materials, the Covered Individual should use alternative materials to the extent possible. This will minimize the impact of such grant of rights on Institute research, publication, and commercialization of discoveries.

Research Materials Transferred by the Institute

The Institute's outgoing MTA form may grant the Institute certain rights or impose certain obligations on the recipient. These rights and obligations must be enforced and policed. Covered Individuals, especially those who have requested that such materials be transferred, should be familiar with the terms of the outbound MTA and assist the Institute in enforcing and policing

such MTA, including notifying the Institute of any known breach of such MTA. The individual should also assist the Institute in determining whether such transfer would violate other MTAs, which may occur if the material to be transferred includes material that is owned by a third-party provider.

The Checklist for Shipping Materials must be completed before materials can be transferred. This form can be found on Helix under Resources, Environmental Health and Safety.

This policy was approved by the GSSIMR Board of Directors on September 5, 2018.
This policy was last updated by the GSSIMR Board of Directors on November 09, 2020.
This policy will be reviewed by the GSSIMR Board of Directors in 2022.