

Institute of Medicine

FORUM ON DRUG DISCOVERY, DEVELOPMENT, AND TRANSLATION

Template for Material Transfer Agreements Developed by Jim Snipes, Covington & Burling LLP*

*This template and a companion clinical trial agreement template were developed by James Snipes of Covington & Burling LLP in the course of conducting a research paper commissioned by the IOM Forum on Drug Discovery, Development, and Translation (the Forum) on streamlining technology transfer agreements. The paper and accompanying templates were presented and discussed at a public workshop in San Francisco on April 27, 2009. The paper provides a full description of the process through which these templates were developed, and provides substantial explanatory information regarding the objectives and use of these templates. The Forum makes these available to the public in order that they may prove useful in improving the process of technology transfer. Please note that only the authors, and not the Institute of Medicine, the Forum, or members thereof, are responsible for the content of the paper or the templates. Questions about the development of these templates may be directed to the author, James Snipes (jsnipes@cov.com), or to the IOM Drug Forum (www.iom.edu/drug).

MATERIAL TRANSFER AGREEMENT

[Annotation: This form of material transfer agreement is intended for use in connection with transfers of materials other than biological materials, such as small molecule compounds, from a for-profit entity to an academic research institution for use in research that is not funded by the for-profit entity. An agreement for the transfer of biological materials should address, in addition to the issues addressed in this form, the rights (if any) of human subjects to the materials if the materials are subject-derived, and the creation and ownership of progeny and derivatives of the materials, among other issues.

If a research institution intends to use funding or materials received from multiple sources for the same research project, the parties will need to consider changes to a number of provisions of this form.]

This Material Transfer Agreement (this "Agreement"), dated as of _____, 200_ (the "Effective Date"), is entered into between _____ ("Transferor") and _____ ("Recipient"; with Transferor, the "Parties"; each, a "Party").

WHEREAS, Transferor desires to provide certain Materials (as defined below) to Recipient and Recipient desires to conduct research using the Materials;

NOW, THEREFORE, in consideration of the mutual promises set forth in this Agreement, the Parties hereby agree as follows:

1. TRANSFER OF MATERIALS.

1.1 Transfer. Transferor shall transfer the materials listed in Exhibit A (the "Materials") to Recipient. Transferor hereby grants to Recipient a non-exclusive, royalty-free license to use the Materials during the term of this Agreement for the sole purpose of performing the research specified in Exhibit B (the "Research"). Transferor represents that to the best of its knowledge it has the right to transfer the Materials to Recipient under this Agreement.

1.2 Restrictions on Transfer. Recipient shall restrict access to and use of the Materials to _____ (the "Principal Investigator"), who is an employee of Recipient, and to persons engaged in performing the Research in Recipient's laboratory under the Principal Investigator's direct control. Recipient may not store or use the Materials at any facility outside the control of Recipient. Recipient may not use the Materials in research funded by third-party commercial entities without the prior written consent of Transferor.

1.3 Purpose. Recipient agrees to use the Materials for research purposes only. Recipient may not use the Materials for research or testing in humans or in animals intended for human consumption, may not use the Materials for the commercial provision of services, and may not incorporate the Materials into products for commercial sale. Recipient may not use the Materials for any purpose other than the performance of the Research, and may not expand or

modify the scope of the Research as it relates to the Materials without the prior written consent of Transferor.

1.4 Supervision. Recipient shall supervise all persons engaged in performing the Research, and shall ensure that such persons are informed of and abide by the applicable terms of this Agreement.

1.5 Compliance. Recipient shall comply with all applicable laws and regulations, and all written instructions from Transferor, in the storage, handling, use, return, and disposal of the Materials.

1.6 No Encumbrances. Recipient shall not use the Materials in any manner that confers on any third party any proprietary rights in or to the Materials, or that creates obligations to disclose the results of Recipient's use of the Materials in the Research to any third party (excluding disclosures required by noncommercial funders and disclosures pursuant to the publication provisions set forth in Article 4). Notwithstanding the foregoing, Recipient may use the Materials in research activities funded by the United States Government. *[Annotation: Some Transferors may require disclosure in Exhibit B of federal government and other non-commercial sources of funding.]*

1.7 No Reverse-Engineering or Modification. Except as expressly set forth in Exhibit B, Recipient shall not attempt to modify or reverse-engineer (or otherwise determine the chemical structure or sequence of) any of the Materials without the prior written consent of Transferor.

1.8 Disclosure. Recipient shall promptly disclose to Transferor any Invention (as defined below) owned by Recipient pursuant to Section 2.1. In addition, Recipient shall provide Transferor with written reports summarizing the results of any use of the Materials in the Research or any results obtained in any other use of the Materials at mutually agreed intervals during the term of this Agreement, including upon expiration or termination of this Agreement. Such reports shall include a summary of all data, and all information, inventions (other than Inventions previously disclosed to Transferor), discoveries, know-how, or any other intellectual property made or generated by or on behalf of Recipient relating to the Materials. At Transferor's request and reasonable expense, Recipient shall provide to Transferor a copy of all such data. *[Annotation: For longer research projects, the Parties may wish to attach a reporting schedule.]*

2. INTELLECTUAL PROPERTY RIGHTS. *[Annotation: The Parties may wish to alter the provisions of this Article 2 based upon the stage of development of the Materials. Some Transferors seek greater intellectual property rights in the case of transfers of materials perceived to have significant commercial potential.]*

2.1 Ownership of Intellectual Property. As between the Parties, Recipient shall own all right, title, and interest in and to (i) any patentable inventions that are made by or on behalf of Recipient in connection with the use of the Materials in the Research ("Inventions"), and (ii)

any data, results, know-how, and other intellectual property that are not Inventions and that are generated by or on behalf of Recipient in connection with the use of the Materials in the Research (“Know-How”). *[Annotation: In this and subsequent Sections, the Parties may wish to consider more precise formulations in lieu of “patentable inventions that are made”, such as “patentable inventions that are conceived or reduced to practice” or “patentable inventions that are conceived and reduced to practice.”]*

2.2 Right to Use Know-How. Transferor and its Affiliates (as defined below) shall have the unrestricted right to use for any purpose the Know-How owned by Recipient pursuant to Section 2.1, provided, however, that for a period of twelve (12) months following disclosure to Transferor of such Know-How, Transferor may not Publish (as defined below) such Know-How without Recipient’s consent, such consent not to be unreasonably withheld, before Recipient has published it in a peer-reviewed scientific journal, except to the extent that disclosure of such Know-How by Transferor would be permitted under Sections 3.2 or 3.3(c). Transferor shall indemnify, hold harmless, and defend Recipient, its officers, employees and agents from any liability resulting from Transferor’s use of the Know-How. Transferor may not enter into any settlement admitting fault on behalf of Recipient without Recipient’s prior written approval. For purposes of this Agreement, “Affiliate” means, with respect to any corporation or other entity, another corporation or other entity that, directly or indirectly, controls, is controlled by, or is under common control with such corporation or entity, where “control” means the direct or indirect ownership of more than fifty percent (50%) of the voting securities of an entity, or any other relationship that results in actual control over the management of an entity.

2.3 License to Inventions. Recipient hereby grants to Transferor a royalty-free, worldwide, non-exclusive license (with right to sublicense to Affiliates only) to make, have made, use, and otherwise practice the Inventions owned by Recipient pursuant to Section 2.1, under any rights of Recipient in and to such Inventions, for the purpose of exploiting the Materials. Transferor may make such Inventions available to its subcontractors in connection with its exploitation of the Materials solely for purposes of such exploitation. Except as otherwise mutually agreed by the Parties, the material terms of the license grant by Recipient to Transferor are as follows:

- Recipient disclaims any express or implied warranty of any kind with respect to the licensed Inventions and Know-How, including any warranty with respect to non-infringement of third party intellectual property rights;
- Recipient disclaims liability for any lost profits or any special, indirect, consequential, or punitive damages of any kind;
- Transferor agrees to indemnify, hold harmless, and defend Recipient, its officers, employees, and agents from any liability resulting from Transferor’s exercise of its rights under the license. Transferor agrees not to enter into any settlement admitting fault on behalf of Recipient without Recipient’s prior written approval; and
- Transferor agrees not to use the name or trademark of Recipient or its employees in any press release, publicity, or advertising without Recipient’s consent, except as required by law.

Except as set forth in Section 1.1 and this Section 2.3, no license, express or implied, is granted by either Party under this Agreement. *[Annotation: Some institutions are unable to, or choose not to offer present grants of licenses in material transfer agreements. Of those institutions, some will require that any license grant by the Recipient be negotiated separately, while others will commit to issuing a license and will accept the language of this Section, provided that it is modified by substituting "Recipient shall grant to Transferor a royalty-free . . ." in the first sentence of this Section, and ". . . the material terms of the license will be as follows:" in the third sentence of this Section.]*

2.4 Option on Inventions. Recipient hereby grants to Transferor an option, valid for a period of ninety (90) days after disclosure to Transferor pursuant to Section 1.8 of any Invention owned by Recipient pursuant to Section 2.1, to commence exclusive negotiations for a worldwide, exclusive license to make, have made, use, and sell such Invention under any rights of Recipient in and to such Invention, for any purpose. The license may be royalty-bearing or royalty-free, and may or may not include a right to sublicense, as the Parties may agree. Upon the exercise of the option, the Parties shall proceed with such negotiations diligently and in good faith. The period of exclusive negotiations will terminate ninety (90) days after the exercise of the option, unless the Parties mutually agree to an extension. Prior to the expiration of the option period (or, if the option is exercised, prior to the termination of the negotiations), (i) neither Party shall disclose the Invention to any third party (other than (A) to its patent counsel or other agents for the purpose of filing a patent application, (B) to any governmental agency as required to satisfy Recipient's obligations under its funding agreement for the Research or under applicable law, or (C) by a Publication in accordance with Article 4), and (ii) Recipient shall not commence license negotiations relating to the Invention with any third party. If the negotiations are unsuccessful and are terminated by a Party pursuant to this Section 2.4, and if Transferor shall have made a written offer for such a license prior to the termination of such negotiations, then for a period of one year after such termination, Recipient may not grant such a license to a third party on terms which, taken as a whole, are more favorable to the third party than those Recipient offered to Transferor, without first offering Transferor such license on those more favorable terms (which offer Recipient shall hold open for Transferor for at least sixty (60) days). *[Annotation: Institutions that conduct research in facilities funded by tax-exempt bonds should consider the possible implications, under the IRS "private use" regulations, of grants of exclusive licenses.]*

2.5 Costs of Patent Application. At Transferor's request and expense, Recipient shall file a patent application claiming any Invention owned by Recipient pursuant to Section 2.1. Recipient may file a patent application on any Invention at its expense at any time, but has no obligation to do so, except pursuant to the preceding sentence.

2.6 Cooperation. Each Party shall execute and cause to be executed by its employees and agents all documents, and perform all acts, including providing reasonable assistance with the filing and prosecution of any patents, necessary to effect or evidence the ownership of any Invention as set forth in this Article 2, at the request and expense of the licensee of the Invention.

3. CONFIDENTIALITY.

3.1 Obligations. For purposes of this Agreement, the following is “Confidential Information” of Transferor: (i) any scientific, technical, business, or other data or information (collectively, “Data”) disclosed by Transferor to Recipient relating to the Materials, (ii) any Data disclosed in electronic or written form by Transferor to Recipient that is marked “Confidential” or that is generally regarded as confidential, and (iii) any Data disclosed orally by Transferor to Recipient that is reduced to writing and marked “Confidential” (which Data shall be deemed Confidential Information from the time it is reduced to writing and marked) or that is generally regarded as confidential. Furthermore, any Invention disclosure made by Recipient to Transferor pursuant to Section 1.8 is Confidential Information of Recipient. During the term of this Agreement and for a period of five (5) years after the expiration or termination of this Agreement, (w) a Party receiving Confidential Information of the other Party (the “Receiving Party”) shall maintain the confidentiality of such Confidential Information; (x) the Receiving Party shall not transfer or disclose any Confidential Information of the other Party to any third party; (y) Recipient shall not use the Confidential Information of Transferor for any purpose other than the Research; and (z) Transferor shall not use Confidential Information of Recipient for any purpose other than exploiting the Materials, in each case unless otherwise agreed in writing by the Parties.

3.2 Exceptions. Notwithstanding Section 3.1, information shall be deemed not to be Confidential Information to the extent that it:

(a) is or later becomes publicly known other than through a breach of this Agreement by the Receiving Party, its employees (including the Principal Investigator), or its agents;

(b) is lawfully made available to the Receiving Party, its employees (including the Principal Investigator), or its agents by a third party that the Receiving Party reasonably believes owes no obligation of confidentiality to the other Party; or

(c) was already known to or is independently developed by the Receiving Party, its employees (including the Principal Investigator), or its agents as evidenced by written records.

3.3 Permitted Disclosures. Notwithstanding Section 3.1, Confidential Information may be disclosed:

(a) as permitted under Section 4.1, subject to the requirements of Article 4;

(b) to Recipient’s employees (including the Principal Investigator) or agents, but only to the extent required in connection with the performance of the Research, and only if such employees and agents are subject to obligations of confidentiality and non-use at least as restrictive as those in this Article 3; and

(c) to the extent and only in the manner that it is required to be disclosed by the Receiving Party by law or by order of any governmental authority; provided, however, that the

Receiving Party shall use reasonable efforts to disclose the minimum Confidential Information necessary to comply with such requirement, and the Receiving Party shall give the other Party advance notice of the disclosure when practicable, and prompt notice of the disclosure otherwise, to permit the other Party to seek a protective order to limit the disclosure.

3.4 Confidentiality of Terms. Each Party shall maintain the confidentiality of the terms of this Agreement, subject to the exceptions set forth in Sections 3.2 and 3.3. *[Annotation: Some academic research institutions are required by law or policy to make public the terms of their major commercial agreements. Many of these institutions, however, will maintain the confidentiality of certain information in attachments to the agreement.]*

4. PUBLICATION.

4.1 Right of Publication. Notwithstanding Section 3.1, and subject to this Article 4, Recipient may publish, otherwise publicly disclose (collectively, “Publish”; such a Publishing is a “Publication”), or submit for Publication an article, manuscript, abstract, report, poster, presentation, or other material that includes the results of the use of the Materials in the Research and identifying information regarding the Materials, as would be reasonably required for purposes of publication in a peer-reviewed scientific journal (such article, manuscript, abstract, report, poster, presentation, or other material, a “Manuscript”). *[Annotation: Certain Transferors may impose greater restrictions on the publication of Confidential Information.]*

4.2 Review Period. Not less than thirty (30) days prior to the earlier of Publication or submission for Publication of any Manuscript, Recipient shall, or shall cause the Principal Investigator to, provide Transferor with a copy of the Manuscript. If the Manuscript is an abstract, presentation, or poster, Transferor shall use reasonable efforts to complete its review as promptly as possible. Recipient shall consider in good faith any comments submitted by Transferor regarding the content thereof, and shall delete any Confidential Information of the Transferor (other than the identifying information regarding the Materials permitted to be Published pursuant to Section 4.1) that Transferor requests in writing be deleted.

4.3 Further Period. At Transferor’s request, Recipient shall delay Publication or submission for Publication of the Manuscript, as the case may be, for up to an additional sixty (60) days to allow patent applications to be filed, at Transferor’s expense, on one or more Inventions not previously Published that are disclosed in the Manuscript.

4.4 Use of Name. Except as expressly stated herein, nothing in this Agreement shall be construed to grant either Party the right to use the name, logo, or trademark of the other Party or its employees or Affiliates in any press release, publicity, or advertising without the prior written approval of the other Party, except as required by applicable law.

4.5 Acknowledgment. If required by the journal to which a Manuscript is submitted, or upon request by Transferor, Recipient shall publicly acknowledge in any Manuscript Transferor’s financial or editorial contribution to the Research, and Recipient may use Transferor’s name for that purpose.

5. INDEMNITIES AND INSURANCE.

5.1 Recipient Assumes Risk. Recipient assumes the risk of any damage, loss, or expense associated with or resulting from the conduct of the Research or Recipient's use, storage, handling, return, or disposal of the Materials.

5.2 Indemnification. Recipient shall indemnify, defend, and hold harmless Transferor and its officers, directors, employees, and agents from any loss, liability, damage, or expense (including reasonable attorneys' fees and costs until such time as Recipient assumes the defense) from any claim that may arise from or in connection with Recipient's conduct of the Research or Recipient's use, handling, study, storage, return, or disposal of the Materials, provided, however, that to the extent that any such claim (a) is a direct result of any negligence or willful misconduct of Transferor or one of its officers, directors, employees, or agents, or (b) relates to the infringement or violation of any patent, copyright, or other proprietary right of a third party, Recipient shall have no such obligation. *[Annotation: Some academic research institutions are barred by statute, state constitution, or internal policy from offering any indemnification.]*

5.3 Indemnification Procedure. Transferor shall promptly notify Recipient of any claim, loss, or expense likely to lead to a claim for indemnification, along with all material, relevant information. If such notice is not prompt, Recipient's obligation under this Article 5 will be reduced to the extent such delay prejudices Recipient's defense of the claim. Recipient shall have the right to manage the defense and settlement of any claim, except that Recipient may not enter into any settlement admitting fault on behalf of Transferor without Transferor's prior written approval. Transferor may not enter into any settlement of any such claim without the written permission of Recipient. Transferor shall reasonably cooperate with Recipient in the defense of the claim. Transferor may hire its own counsel, at its own expense, to monitor the defense of the claim. In addition, Transferor may elect to assume control of the defense of such claim, in which case Recipient shall have no obligation to indemnify or further defend Transferor with respect to such claim.

5.4 No Warranty. Recipient acknowledges that the Materials are experimental in nature and may have unknown characteristics, may carry infectious agents, or may be otherwise hazardous. THE MATERIALS ARE PROVIDED "AS IS" AND TRANSFEROR DISCLAIMS ANY WARRANTY, EXPRESS OR IMPLIED, WITH RESPECT TO THE MATERIALS, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT, COPYRIGHT, OR OTHER PROPRIETARY RIGHT OF ANY THIRD PARTY. Without limitation of the foregoing, Transferor makes no representation or warranty as to the identity, purity, safety, or activity of the Materials.

6. TERM AND TERMINATION.

6.1 Term. This Agreement shall take effect on the Effective Date and shall expire on the earlier to occur of the completion of the Research and the _____ anniversary of the Effective Date, unless terminated earlier pursuant to Section 6.2.

6.2 Termination. Either Party may terminate this Agreement (a) in its sole discretion upon thirty (30) days' written notice to the other Party, or (b) for a material breach of this Agreement by the other Party, upon written notice to the other Party.

6.3 Obligations on Termination. Upon termination or expiration of this Agreement, Recipient shall, at Transferor's option and expense, return to Transferor within thirty (30) days any remaining Materials and any copies of Confidential Information of Transferor that are in the possession or under the control of Recipient; provided, however, that Recipient may retain an archival copy of such Confidential Information. At Transferor's request and expense, Recipient shall dispose of the remaining Materials in accordance with Transferor's instructions, subject to applicable law.

6.4 Survival. The rights and obligations of the Parties that have accrued prior to the expiration or termination of this Agreement, Articles 1, 2, 3, 4, 5, and 7, Section 6.3, and this Section 6.4 shall survive the expiration or termination of this Agreement.

7. MISCELLANEOUS.

7.1 Authority. Recipient represents that it has the requisite power and authority to cause those performing activities in connection with the Materials or the Research to comply with the applicable obligations of Recipient under this Agreement, including without limitation its obligations under Articles 1, 2, 3, and 4. *[Annotation: If the Research will be performed by persons not under Recipient's control (such as a subcontractor) or in a facility not under Recipient's control (such as a hospital that is not owned by Recipient), the Parties should modify Section 1.2 appropriately, and may wish to insert language here that requires Recipient to impose certain of its obligations under this Agreement on any third parties who will perform the Research or who control the relevant facility. In addition, some Transferors may seek a representation from Recipient that Recipient's obligations under this Agreement are consistent with its obligations under its other contracts.]*

7.2 Remedies and Waiver. The remedies provided in this Agreement are not exclusive and the Party suffering from a breach or default of this Agreement may pursue all other remedies, both legal and equitable, alternatively or cumulatively. Without limitation of the foregoing, Transferor may pursue any and all available remedies against Recipient for any use of the Materials for a purpose other than performing the Research. No express or implied waiver by a Party of any breach or default will be construed as a waiver of a future or subsequent breach or default. The failure or delay of any Party in exercising any of its rights under this Agreement will not constitute a waiver of any such right, and any single or partial exercise of any particular right by any Party will not exhaust the same or constitute a waiver of any other right provided in this Agreement.

7.3 Assignment. Neither Party may assign this Agreement without the prior written consent of the other Party, except that either Party may assign this Agreement to an Affiliate or in connection with a merger or sale of all or substantially all of its assets. Any Party making an assignment pursuant to this Section 7.3 (other than to an Affiliate) shall provide prompt written

notification to the other Party. An assignee shall assume all of the obligations of the assignor under this Agreement.

7.4 Independent Contractor. In performing activities under this Agreement, Recipient, including the Principal Investigator and its other employees, is operating as and has the status of an independent contractor to Transferor, and shall not act as and is not an agent or employee of Transferor. The relationship between the Parties does not constitute a partnership, joint venture, or agency. Neither Party shall have the authority to bind the other Party without that other Party's express, written permission.

7.5 Force Majeure. Noncompliance by a Party with this Agreement due to any cause beyond the reasonable control of the Party, such as war, civil commotion, destruction of production facilities and materials, fire, flood, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers (each, an event of "Force Majeure"), shall not constitute a breach of this Agreement. That Party shall be excused from performance under this Agreement to the extent and for the duration of such event of Force Majeure, provided, however, that it first notifies the other Party in writing thereof and that it uses reasonable efforts to cause such event of Force Majeure to abate.

7.6 Further Assurances. Each Party shall execute such other instruments, give such further assurances, and perform acts reasonably necessary or appropriate to effectuate the provisions of this Agreement.

7.7 Choice of Law. This Agreement is governed by the laws of the State of _____, without regard to its rules of conflicts of laws. *[Annotation: In many material transfer agreements, Transferors and Recipients agree to remain silent on the choice of law.]*

7.8 Notices. The Parties shall send notices in writing, referencing this Agreement. Notice shall be deemed given when: (i) delivered personally; (ii) one (1) day after having been sent by facsimile, with a copy sent promptly by registered or certified mail, return receipt requested, postage prepaid; (iii) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (iv) two (2) days after deposit with a nationally recognized overnight carrier, with written verification of receipt. Notice shall be given to the addressee below (or to such other addressee as a Party subsequently designates pursuant to this Section 7.8):

To Recipient: _____

Attention: _____

with a copy to the Principal Investigator

To Transferor: _____

Attention: _____

7.9 No Third-Party Beneficiary. This Agreement is for the sole benefit of the Parties and does not confer any rights on any third party.

7.10 Entire Agreement; Amendments. This Agreement, together with the Exhibits hereto, constitutes the entire agreement of the Parties with respect to its subject matter, and supersedes all previous written or oral representations, agreements, and understandings between the Parties with respect to that subject matter. This Agreement may only be amended by a written document signed by both Parties.

7.11 Severability. If any provision of this Agreement is held to be unenforceable for any reason, that unenforceability shall not affect the enforceability of any other provision of this Agreement, and the Parties shall negotiate in good faith to substitute an enforceable provision with similar terms.

7.12 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which is deemed an original, but all of which together constitutes one instrument.

7.13 Headings. The Section and Article headings in this Agreement are for convenience only, and shall not affect the interpretation or meaning of any provision of this Agreement.

7.14 Interpretation. Unless the context of this Agreement requires otherwise, words of one gender include the other gender; words using the singular or plural number also include the plural or singular number, respectively; the terms "Article" and "Section" refer to the specified Article and Section of this Agreement; and the term "including" means "including, without limitation."

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

[_____]

[_____]

By: _____
Name: _____
Title: _____

By: _____
Name: _____
Title: _____

READ AND ACKNOWLEDGED:

By: _____

Name: _____

Title: Principal Investigator

Exhibit A

Materials

Exhibit B

Research