Model Provisions

The nonprofit and academic communities have acknowledged that relationships between disease foundations and research institutions are evolving. Although in many ways this evolution presents new and exciting opportunities, these changes have also brought about new conflicts. In September 2014, *FasterCures* hosted a workshop that brought together more than 60 stakeholders representing academic research institutions, nonprofit disease foundations, industry, investors, and the legal community to explore some of the barriers to successful university-foundation partnerships and identify actionable solutions. One of the action items identified during that session was to develop template language that could serve as a model for grant agreements.

In response to this call for action, *FasterCures* developed template provisions directed at addressing the following areas:

- Early-Stage Research
- Commercialization of Inventions
- Royalty Sharing

These provisions reflect input from a wide variety of stakeholders, and we hope they can be used as a tool to spur further discussions and collaborations between patient foundations and universities.

This is not the end of this work, but represents one more step in our continued efforts to build stronger, more effective partnerships between universities and patient foundations.

Provisions to Enhance Sharing of Research Tools and Resources

We often hear that too much time and too many resources are devoted to negotiating provisions relating to research unlikely to yield intellectual property with commercial value. The provisions outlined below are designed to ensure that the research results will be used for the greatest public benefit, while also encouraging the grantee and grantor to communicate in good faith in the unlikely but not impossible event that important intellectual property is created.

NOTE TO READERS: This model language is designed to apply to early-stage research projects or programs where commercially relevant discoveries are unlikely. This model is especially useful in research projects, programs, or consortia designed to promote the sharing of data and research tools (including biological materials or biospecimens) amongst the foundation and one or more researchers.

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In return for your participation in the research program; participation in the consortium; use of funding; use of research tools; and/or use of one or more data sets:

[1. No IPRs in Provided Research Tools and Data Sets. You and your employer or sponsoring institution (individually and collectively, "**You**") shall not claim any proprietary intellectual property rights, including without limitation, any patent or copyright ("**IPRs**"), on the research tool, or any component or unmodified derivative thereof, and/or data set you receive through the [name of program or consortium] (the "**Program**"). [*NOTE: If counter-party is not receiving research tools or a data set then this section is unnecessary but note that definitions of "you," "IPRs," and "Program," which then must be defined below*.]

2. The Importance of Sharing Research Tools and Data. Progress in science depends upon prompt access to the unique research tools that arise from biomedical research laboratories throughout government, academia, and industry. Ideally, these new resources flow to others who advance science by conducting further research. To the extent You are not encumbered by supply problems or contractual obligations to a third party, You shall make research tools and/or data sets created or collected (in the case of biospecimens) broadly available to the research community under standard terms [as outlined in Appendix A, Access to Research Tools].

3. IPRs in Certain Inventions, Discoveries, Works and Results. Before You claim any IPRs on any invention, discovery, work, or result made in the course of your: a) participation in the research program; b) participation in the consortium; c) research funded by Disease Foundation pursuant to this grant; d) use of research tools provided by Disease Foundation pursuant to this agreement; and/or e) use of the data set provided by Disease Foundation pursuant to this agreement, you shall notify the Disease Foundation (at the contact identified in Section ___) and provide an analysis of the role of IPRs in advancing human health. If the Disease Foundation has concerns, You and Disease Foundation shall discuss the concerns and make good faith efforts to resolve them.

4. Research Only License: In the event that You obtain IPRs on any invention, discovery, work, or result made in the course of your: a) participation in the research program; b) participation in the consortium; c) research funded by Disease Foundation pursuant to this grant; d) use of research tools

Comment [MJ(1)]: Recognizing that these terms may need to be clearly defined with each specific grant agreement, a proposed definition is provided below:

Research tool: "the full range of resources that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools (such as PCR), methods, laboratory equipment and machines, databases, and computer software." *(modified from* 6/4/98 Report of NIH Working Group on Research Tools)

Comment [MJ(2)]: Recognizing that these terms may need to be clearly defined with each specific grant agreement, a proposed definition is provided below:

Unmodified derivative: "Substances created by the recipient [of funding, research tools, or data sets] which constitute an unmodified functional subunit or product expressed by the Original Material. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the original material, proteins expressed by DNA/RNA supplied by the [provider], or monoclonal antibodies secreted by a hybridoma cell line." (UBMTA)

provided by Disease Foundation pursuant to this grant; and/or e) use of the data set provided by Disease Foundation pursuant to this grant, You agree to offer a royalty-free license to Disease Foundation for Disease Foundation to distribute the invention, discovery, work, or result covered by the IPR solely for non-commercial purposes.

Comment [MJ(3]: This was suggested during the meeting as an alternative to forgoing patent/copyright protection.

5. Exceptions. Paragraph [3] shall not apply to:

a. Copyrights on articles publishing results of your work relating to the named investigator's participation in the research program; consortium; use of funding; use of research tools; and/or use of the data set, provided that Section 5 of this policy shall apply;

b. IPRs not arising directly from the named investigator's participation in the research program; consortium, use of funding; use of research tools; and/or use of the data set;

c. IPRs in any invention, discovery, work or result for which a contract, an applicable statute or government regulation requires You to assert such claim(s) in order to retain title or control;

d. IPRs for uses outside the Disease.

6. Results of Your Research. Within one hundred eighty (180) days after completion of your research with funding, research tools, and/or the data set received by You from or through Disease Foundation, You shall disclose the results of your research in writing to the Disease Foundation [**and the Program members**], provided that you may condition any such disclosure on one or more written non-disclosure agreements providing that the recipient shall not use or disclose your results prior to publication in accordance with Section 5. During the time that your results or work are your confidential information Disease Foundation shall not disclose your results outside Disease Foundation or Program.

7. Publication. In accordance with generally accepted standards applicable to scientific publication, You agree to submit for publication any results or other work arising directly from your participation in the research program; consortium; use of funding; use of research tools; and/or use of the data set that would be useful to scientists working on disease-related research or, if You do not publish such information within [**three years**] from the date that such results or work become(s) known to the Program or Disease Foundation and You cannot provide a reasonable explanation to the Disease Foundation for not publishing, You agree that Disease Foundation may publicly release and/or make available to scientific researchers such results or other work. Your results and other work shall be your confidential information until the earlier of (a) your publication thereof in accordance with this Paragraph 5; or (b) the public release under the above conditions. In any publication of your results or work, You and Disease Foundation shall give proper public attribution to the other in accordance with generally accepted standards applicable to scientific publication.

Comment [MJ(4]: Recognizing that there was no agreement about what the right timeframe was, we have proposed a 3-year timeframe which, along with the "reasonable explanation" language, would give foundations comfort that results will be publically accessible, while avoiding undue interference with academic freedom.

[**6. Agreement By All Program Members**. All other participants in the Program will be required to agree to the foregoing.] [*NOTE: If counter-party is not participating in a research program or consortium involving the exchange of scientific information among participants then this section is unnecessary*].

SAMPLE FUNDER ADDENDUM

Appendix A: Access to Research Tools

This Access to Research Tools Addendum supplements the Grant Agreement and sets forth the obligations of Principal Investigator and Sponsoring Institution (individually and collectively, "You") with respect to research tools created in the course of performing the funded research project. In the event of a conflict between the terms of the Grant Agreement and this Appendix, this Appendix shall take precedence. Failure to comply may result in withholding of additional research funds.

The Sponsoring Institution and the Principal Investigator agree that research tools will be made accessible as follows:

A. **Research Tools** shall be defined as: the full range of resources that scientists use in the laboratory, including cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry libraries, drugs and drug targets, clones and cloning tools (such as PCR), methods, laboratory equipment and machines, databases, and computer software.

Comment [MJ(5]: I have added a proposed definition taken from an NIH Working Group on Research Tools (available here: http://biotech.law.lsu.edu/research/fed/NIH/researchtools/Report98.htm).

B. **Scholarly Articles**

1. **Public Access:** A copy of any scholarly articles describing the funded research project shall be deposited in PubMed Central under terms identical to the NIH public access policy at http://publicaccess.nih.gov. You will report publications to the Disease Foundation within 30 days of acceptance.

2. **Data**: All data supporting the publication shall be made available for download from a digital repository, no later than six (6) months after any publication describing the results of the funded research project, subject to any reasonably necessary delay related to patentability. You may comply with the above requirement by:
    a. Depositing a copy of the data in a third party digital repository from which it may be downloaded free of charge, or
    b. Offering such data for download on a Website without charge, or
    c. Distributing such data via disk, hard copy, or other widely accessible format, subject to a reasonable charge for the cost of reproduction and distribution

3. **Report to Disease Foundation:**
    a. Once papers are available in PubMed Central pursuant to B.1 above, You will submit working URLs to the Disease Foundation as part of its annual progress reports described in Section __.
    b. Once data supporting the publication has been uploaded or distributed pursuant to B.2 above, You will submit working URLs to the Disease Foundation as part of annual progress reports described in Section __.

C. **Materials**

1. To the extent You are not encumbered by supply problems or contractual obligations to a third party:
    a. You shall make tangible research materials created or collected (in the case of biospecimens) in the course of performing research funded by the Disease Foundation, broadly available to the research community pursuant to the Uniform Biological Material Transfer Agreement (UBMTA) (available at

http://www.autm.net/aboutTT/masterAgreement.doc) or the UBMTA simple letter agreement or appropriate equivalent.

b. You shall deposit tangible research tools created or collected in the course of performing research funded by the Disease Foundation, in an appropriate repository under the UBMTA or similar terms. For avoidance of doubt, the standard MTAs used by ATCC and Jackson Laboratories shall be deemed to be compliant with this requirement. Examples of "appropriate repositories" include:
    i. Jackson Laboratories
    ii. Coriell Cell Culture Repository
    iii. Addgene
c. Nothing in the foregoing should be interpreted to discourage You from offering such materials to for-profit entities under terms agreeable to both parties.

Provisions Regarding Commercialization of Inventions

Commercialization of Inventions

Perhaps one of the most contentious topics when negotiating grants between academic institutions and patient foundations concerns intellectual property. Some foundations are incorporating provisions into grant agreements which enable them to exercise rights to foundation-supported inventions in the event a grantee fails to meet certain development milestones. Research institutions find many of these provisions untenable and counterproductive to commercialization by making it difficult—if not impossible – to find third-party licensees.

Recognizing that many research institutions want to eliminate these clauses while many foundations see them as a critical component of ensuring grant-supported research continues to progress, the provisions below attempt to strike a middle ground by allowing grantors to participate in finding potential licensees without giving foundations unfettered march-in rights.

1. Inventions. Within sixty (60) days after written disclosure to the technology transfer or equivalent office of Sponsoring Institution, Principal Investigator and Sponsoring Institution (individually and collectively, "**You**") shall notify Disease Foundation in writing of any invention, discovery, work or other commercializable intellectual property made in the performance of research conducted by You that is funded in whole or part by Disease Foundation (**"Invention"**). Subject to the rights granted to Disease Foundation in this document, Title to any Invention shall reside with the Sponsoring Institution pursuant to applicable intellectual property law and the Sponsoring Institution's intellectual property ownership and licensing policies.

Comment [MJ(6]: Consistent with 37 CFR 401.14(c)(1)

2. Election to Pursue Intellectual Property Protection for Invention.

a. Sponsoring Institution may elect to pursue patent protection, copyright registrations, or other intellectual property registrations or protection authorized by law (each an "**IP Registration**") for any Invention.

b. Within [**180 days / 1 year / 2 years**] after disclosure of the Invention to Disease Foundation, Sponsoring Institution shall notify Disease Foundation of its election to pursue, or not to pursue, IP Registration for any such Invention. Disease Foundation shall extend the period within which such notification must be provided upon receipt of information from Sponsoring Institution reasonably explaining why and for how long an extension is required.

Comment [MJ(7]: Many foundation representatives expressed concern about keeping these timelines as tight as possible.

University representatives noted that reporting requirements that differ from NIH requirements can increase administrative burden in significant ways.

NIH regulations require this decision be made within two years of the date of disclosure. *See e.g.*, 37 CFR 401.14(c)(2).

Accordingly, we have bracketed this language and suggest that foundations and universities confer regarding this provision.

c. If Sponsoring Institution elects to pursue patent protection or other IP Registration that must be registered, Sponsoring Institution agrees to file at least one (1) application with the governmental or quasi-governmental agency authorized to receive such IP Registration to register the Invention as soon as practicable, and Sponsoring Institution agrees to provide confirmation of such filing to Disease Foundation in writing within thirty (30) days after such filing and offer the Disease Foundation an opportunity to confer with the Sponsoring Institution to identify and suggest potential licensees.

Comment [MJ(8]: This clause was suggested by participants during the June 2015 session at the BIO convention as a way to ensure that Foundation knowledge and insight is brought into the licensing process early on.

d. Thereafter, Sponsoring Institution agrees to notify Disease Foundation in writing within thirty (30) days after either the issuance of an IP Registration or a final confirmation or determination that such IP Registration will not issue.

3. Abandonment of, or Election not to Pursue, IP Registration for an Invention.

a. If Sponsoring Institution elects not to pursue IP registration for an Invention for which Disease Foundation contributed direct funding or intends to abandon patent protection for such an Invention, then Sponsoring Institution shall notify Disease Foundation at least thirty (30) days before any pending patent office deadline. Unless the Sponsoring Institution submits alternative plans for commercialization that do not require IP registration, to the extent legally able, upon such notification, Sponsoring Institution shall grant to Disease Foundation an exclusive, sublicensable license for the purpose of development and commercialization of such Invention.

Comment [MJ(9]: Consistent with 37 CFR 401.14(f)(3)

b. If Disease Foundation elects to pursue the license set forth in Section 3.a., then Disease Foundation shall assume the responsibilities for the management and commercialization of such Invention, including without limitation payment of IP Registration costs. Any revenue from a third party in return for the license or other transfer of the Invention shall be "**Payments**". Upon receipt by Disease Foundation of any Payments, Sponsoring Institution's and Disease Foundation's unreimbursed patent costs shall first be reimbursed pro rata. Thereafter, Disease Foundation shall retain all Payments.

c. This Section 3 shall be subject to, and shall not alter or amend, any rights or obligations created by federal or state statutes and regulations applicable to Sponsoring Institution.

4. Obligation to License Invention for Use in Practical Applications. If an Invention is not abandoned by Sponsoring Institution as set forth in Section 3, Sponsoring Institution agrees to take all reasonable steps necessary to award an income-bearing license in and to the Invention to a third party for the explicit purpose of bringing such Invention to practical application in the field(s) of interest for which scientific research was funded by the Disease Foundation.

a. Disease Foundation shall have opportunities to introduce to Sponsoring Institution bona fide third parties interested in obtaining a license in and to the Invention from You in return for Payments to Sponsoring Institution. To the extent legally able, Sponsoring Institution agrees to negotiate in good faith with any such potential licensee.

b. Notwithstanding subsection a., if You have not executed a license with a third party in and to an Invention for which Disease Foundation provided more than fifty percent (50%) of the direct funding within two (2) years after meaningful work on development of the Invention by You has ceased, then Disease Foundation shall have the right to identify a third party with a bona fide offer to license, option, or otherwise transfer such Invention, and Sponsoring Institution shall offer an income-bearing license in and to such Invention on customary terms and conditions to such third party.

Royalty-Sharing Provisions

Academic institutions invest in an academic environment that enables faculty, students, and other mentees to build their research careers and perform the research, which occasionally leads to inventions. Part of this investment covers administrative and infrastructure expenses that are necessary to keep research programs in operation. Additional investment is required to patent and license inventions, many of which do not generate any income.

At the same time, patient foundations are focused on ensuring that every dollar they give goes directly into research and are often unwilling to pay indirect costs. To begin to close this gap, we have proposed royalty language that gives institutions the ability to recoup some of the costs and expenses incurred.

1. Award. Disease Foundation approves the following amount in accordance with the terms and conditions set forth in this Agreement, including the project budget attached as Exhibit __:

Total: Up to $<Enter Value> (the "**Award**")

Payment of the Award is contingent upon the Principal Investigator and Sponsoring Institution (individually and collectively **"You"**) meeting the milestones specified in Exhibit __, and timely compliance with the reporting requirements specified in this Agreement, and is otherwise subject to the terms and conditions of this Agreement.

2. Inventions. Within sixty (60) days after written disclosure to the technology transfer or equivalent office of the Sponsoring Institution, Sponsoring Institution shall notify Disease Foundation in writing of any invention, discovery, work or other commercializable intellectual property made in the performance of research conducted by You that is funded in whole or in part by Disease Foundation (**"Invention"**).

3. Notification of IP Registration. If Sponsoring Institution elects to pursue patent protection or other IP Registration that must be registered, Sponsoring Institution agrees to file at least one (1) application with the governmental or quasi-governmental agency authorized to receive such IP Registration to register the Invention as soon as practicable, and Sponsoring Institution agrees to provide confirmation of such filing to Disease Foundation in writing within thirty (30) days after such filing and offer the Disease Foundation an opportunity to confer with Sponsoring Institution to identify and suggest potential licensees.

4. **Notification of License Or Other Transfer.** Within thirty (30) days after execution of any agreement with a third party, including without limitation an entity owned or controlled by Principal Investigator, to license or otherwise transfer any right, title, or interest in or to the Invention, including without limitation any option of the third party to license or otherwise transfer or to negotiate for such license or transfer of the Invention, for consideration ("**Outlicense**"), Sponsoring Institution agrees to notify and provide in writing such terms and conditions of the Outlicense that are relevant to calculation of Payments (defined below) to Disease Foundation and to promptly respond to any reasonable Disease Foundation questions regarding such terms and conditions. Disease Foundation will execute a non-disclosure or other agreement as reasonably necessary to permit disclosure of such information.

4. Payments. "Payments" shall mean any amount Sponsoring Institution receives from any third party for an Outlicense. Disease Foundation shall be paid a portion of such Payments, as outlined below.

Comment [MJ(10]: We note that some universities have raised concerns about having funding tied to deliverables or milestones whereas foundations see it as a useful mechanism to keep projects on track.

Comment [MJ(11]: Consistent with 37 CFR 401.14(c)(1)

Comment [MJ(12]: This clause was suggested by participants during the June 2015 session at the BIO convention as a way to ensure that Foundation knowledge and insight is brought into the licensing process early on.

a. First, Disease Foundation waives the receipt of income until the net Payments (net of any direct out-of-pocket patenting and licensing costs and indirect costs not paid under the award) from the Invention exceeds [$**100,000/$250,000/$500,000/$1,000,000**].

b. Second, once the net Payments exceed [$**100,000/$250,000/$500,000/$1,000,000**] Sponsoring Institution will pay to Disease Foundation a royalty in the amount of [X%].

c. Sponsoring Institution shall pay to Disease Foundation its share of the Payments on an annual basis, together with documentation reasonably supporting the share of Payments sent by Sponsoring Institution to Disease Foundation.

5. [***Consider inclusion of a cap*:**

Option A: Disease Foundation's share of Payments shall be limited to five (5) times the Disease Foundation award.

Option B: Disease Foundation's share of Payment(s) shall be limited to one-and-a-half (1.5) times the Disease Foundation award when Payments from the Outlicense amount to less than five (5) times the Disease Foundation Award. Disease Foundation's share of Payments shall be limited to five (5) times the Disease Foundation award when Payments from the Outlicense exceed five (5) times the Disease Foundation Award.]

Comment [MJ(13)]: The level of the threshold will vary depending on the size or impact of a grant award.

Comment [MJ(14)]: Although a flat rate provides predictability and avoids complicated discussions surrounding the Foundation's level of contribution, the appropriate percentage will vary depending on the size or impact of the grant.