



University/Foundation Relations – BIO Private Session

Date: Wednesday, June 17, 2015

Time: 2:00 – 4:00 p.m.

Location: BIO International Convention, Philadelphia

ATTENDEES (final list)

Gina Agiostratidou, Helmsley Charitable Trust
Mark Allegretta, National MS Society
Margaret Anderson, *FasterCures*
Usha Arunachalam, Leuk. & Lymph. Society
Sharon Hesterlee, Myotonic Dystrophy Ass'n.
Maureen Japha, *FasterCures*
Evelia Johnston, Michael J. Fox Foundation
Katharine Ku, Stanford University
Steven Kuemmerle, University of Chicago

Amy Laster, Foundation Fighting Blindness
Felice Lu, University of California
Kimberly McCleary, *FasterCures*
Teri Melese, UCSD
Fred Reinhart, UMass Amherst (AUTM)
Stephen Susalka, AUTM
Thelma Tennant, University of Chicago
David Winwood, PBRC (AUTM)
Roy Zwahlen, BIO

SUMMARY

In recent years, the nonprofit and academic communities have acknowledged that relationships between nonprofit 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. To advance the discussion around these relationships and brainstorm new paths forward, *FasterCures* convened over 15 stakeholders representing both universities and foundations, at a private session conducted in conjunction with the 2015 BIO International Convention held in Philadelphia, PA.

At the private session, Margaret Anderson, executive director of *FasterCures*, welcomed participants and introduced the topic. Maureen Japha, *FasterCures'* associate director of intellectual property, provided a brief summary of *FasterCures'* programmatic work that led to the afternoon's meeting. Specifically, *FasterCures* hosted a workshop in September 2014 to look at ways to improve University/Foundation partnerships. One of the action items suggested at that meeting was to develop model provisions that could help enhance the efficiency and effectiveness of grant agreement negotiations between foundations and universities. To that end, *FasterCures* developed proposed language directed at addressing the following areas: resource sharing in early-stage research, commercialization of inventions, and revenue sharing. *FasterCures* shared initial drafts of the proposed language with representatives from universities and foundations, and circulated draft versions reflecting this initial feedback in advance of the BIO meeting.

Maureen acknowledged, and many participants agreed, that while a model agreement is unlikely to satisfy all foundations or all universities, the proposed language has been a useful tool for promoting dialogue, hopefully leading to concrete improvements.

Efforts to Promote Sharing

With that in mind, the session opened with a review of the document entitled, “Provisions for Early-Stage Research.” Many voiced concerns about the concept of having different structures or provisions for “early-stage” vs. “later-stage research,” given the difficult reality of predicting what discoveries will be commercially viable. While agreeing to forego patent or copyright protection could lead to reduced time negotiating agreements, it’s not necessarily appropriate or advisable. This sentiment was expressed by participants from both foundations and universities.

This led to a critical discussion about what these provisions are intended to achieve. If the purpose is to promote sharing of research tools generated through foundation-funded research, participants suggested that this be more clearly identified. One university participant pointed out that rather than place limitations on an institution’s ability to obtain patent protection, it might be more appropriate to offer royalty-free grants back to the foundation to distribute research tools or datasets for non-commercial purposes. Participants from the university side noted that, while they can encourage faculty to share resources as appropriate, “there is only so much they can do” to enforce this behavior. Individuals from universities and foundations alike recognized that the real leverage may rest with foundations who can threaten to withhold future funding, or otherwise penalize the investigator’s refusal or reluctance to engage in collaborative behavior.

Participants also cited the need to have clear definitions for some terms, including, “unmodified derivatives” and “research tools.” Many participants pointed out that different resources or research tools may require different restrictions, and posited whether it would be more useful to create multiple versions of Appendix A that could be employed according to the particular type of “research product” being shared.

Finally, some university representatives expressed concern regarding requirements that create deadlines for publication. One participant noted that while investigators may have opportunities to publish in less prestigious journals they may want to wait for the best offer to help advance their career. A deadline imposed by funders could interfere with that decision. However, at *FasterCures*, we have heard from numerous foundations who want to retain the option to publically release the results of work they fund, in the event the investigator is not willing or able to do so in a timely manner. A proposed timeline coupled with a clause that gives investigators the opportunity to provide “reasonable explanations” for any delay was presented as the compromise position, although some university representatives were still uncomfortable including a deadline.

Working Together to Move Inventions Forward

As the discussion transitioned to a review of the draft provisions labeled “Commercialization of Inventions” and “Revenue Sharing,” participants began to move away from discussing the draft language to identifying policies or procedures that could improve the overall relationships.

Throughout the afternoon, the need to build trust, improve information sharing, and maintain open dialogue were emphasized. Participants widely acknowledged that foundations can contribute many

assets beyond grant dollars, such as connections with potential licensees or access to patients or patient registries. Indeed, participants were in strong agreement that it is important to notify patient groups as research moves forward. There was consensus that both sides could benefit from adopting a regular practice of notifying patient groups upon the filing of a patent application, thereby giving patient groups the opportunity to be involved in licensing discussions before decisions are made. However, while university representatives welcomed the advice and input of foundations, they strongly objected to giving a foundation the right to pre-approve a licensee. Such requirements can severely limit the university's ability to secure a licensee.

One university representative suggested that it would be more efficient and less administratively burdensome if the reporting schedules in grant agreements were consistent with federal guidelines. Relatedly, one representative from a patient foundation noted that reporting requirements can also be a burden on organizations that have to monitor and enforce those requirements. In a recent survey jointly administered by *FasterCures* and the Health Research Alliance, responding foundations indicated that while they spend a great deal of time negotiating provisions, they devote relatively few resources to enforcing agreements once they have been executed. Given these sentiments, uniform reporting requirements for all funders may be a more effective way of improving and enhancing information sharing.

Identifying a "Fair Share"

In the context of assessing royalty sharing, participants from universities represented at the meeting largely seemed open to sharing revenue with foundation funders, but suggested that predictability in identifying that percentage share would make these provisions more palatable and administratively feasible. Indeed, many participants acknowledged the challenge of isolating the relative contribution to an invention of one funder when multiple funders are involved. Accordingly, a general consensus emerged that a flat royalty rate, along with a cap, was the preferred way to structure these provisions. One foundation representative pointed out that in setting that royalty rate, it is important to account for the different contributions a foundation may have made. In particular, she noted that many foundations are doing the critical work needed to "create the market" for certain diseases, and the royalty share should reflect this added value.

Other participants highlighted the benefits of provisions that require payments reach a certain threshold before royalty sharing is triggered. A university representative noted that many universities seek patent protection on all patentable inventions, regardless of market potential. As a result, her institution incurs a great deal of expense in filing and maintaining patent applications, with only a small percentage generating revenue back to the institution. Threshold provisions serve the dual purpose of helping institutions recoup some of those costs, while also eliminating the administrative burden associated with sharing royalties on relatively small payouts.

Throughout the session, participants emphasized the importance of building trust in these relationships to improve the negotiation process. The potential for mutually beneficial relationships was widely

recognized, and participants were optimistic that through open and honest dialogue, a “common sense of intent” could be established that will allow for development of more effective partnerships.

The following suggestions were generally endorsed by participants:

- Develop more systematic mechanisms to employ all the assets foundations bring to the table, beyond grant dollars, to introduce more efficiencies to the technology transfer process while also enhancing its impact.
- Engage with the University-Industry Demonstration Partnership to learn from and perhaps model best practices.
- Explore funding opportunities outside traditional research grants, such as covering patent costs or funding full time employees
- Adopt a standard practice of notifying all funders, including patient foundations, upon the filing of a patent application. In addition, invite the patient foundation to contact the technology transfer office so information and ideas around appropriate licensees can be exchanged.
- Continue to identify and share real-world examples that demonstrate the need for effective partnerships and look for opportunities to continue the discussion at Partnering for Cures and other forums.
- Establish a “common sense of intent,” whether that is reflected in model language, proposed principles, or some hybrid of the two.

FasterCures will continue to work to promote stronger collaborations and better working relationships between universities and foundations. We will count on your continued dialogue and contributions to advance this initiative.

Royalty Sharing

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 which gives institutions the ability to recoup some of the costs and expenses incurred.

Royalty Sharing Provisions

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 ~~ninety (90)~~ 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

Commented [MJ(1): Unfortunately, we did not have time to address concerns related to milestone-driven grant agreements. 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.

I have left this language in but welcome feedback.

Commented [MJ(2): Mirrors 37 CFR 401.14(c)(1)

Commented [MJ(3): This is intended to capture the mechanism described in the session.

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.

a. First, Disease Foundation waives the receipt of income until the net Payments (net of any direct out-of-pocket patenting and licensing costs) 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%] ~~shall receive an amount that shall be calculated by multiplying the Payments received by Sponsoring Institution by a fraction, the numerator of which is the amounts actually paid to Sponsoring Institution by Disease Foundation for the research under the Award, and the denominator of which shall be the total direct and indirect costs incurred by You in creating the Invention. Notwithstanding the foregoing, if the application of the foregoing fraction results in a share of payment Payments to You of less than 50%, your share shall be 50%.~~

~~e. — Where the royalty-bearing license was the result of Disease Foundation identifying a potential licensee pursuant to Section 4.b in the Commercialization Section above, Disease Foundation's right to receive a share of Payments shall be increased by twenty percent (20%) after application of the calculation set forth in the paragraph above, provided that You shall retain at least fifty percent (50%) of the Payments.~~

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-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.]

~~4.7. **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; 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) 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 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.~~

Formatted: Highlight

A common complaint provisions the TRAIN workshop and other forums is that too much time and too many resources are devoted to negotiating provisions relating to research unlikely to yield intellectual property with commercial value. One proposal to address this is to develop provisions which ensure that the research results will be used for the greatest public benefit and that encourage the grantee and grantor to communicate in good faith in the unlikely but not impossible event that important intellectual property is created.

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; 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) 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 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.

45. 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.

46. 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.

75. 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 [~~one year/ two years~~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.

Commented [MJ(6): Recognizing that there was no agreement about what the right timeframe was, I am suggesting including a 3-year window, 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 ____

Access to Research ~~Products~~Tools

This Access to Research ~~Products~~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 ~~products~~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 ~~products~~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.

A.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 A.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 A.B.2 above, You will submit working URLs to the Disease Foundation as part of annual progress reports described in Section ____.

B.C. Materials

- 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

Commented [MJ(7): There was recognition that this would need to be modified depending on the type of Research tool at issue (e.g. research tools derived from human tissue samples would be subject to further restrictions not necessarily contemplated here).

For purposes of this model agreement, general consensus appeared to be that we would keep this at a high level. That said – if you have suggestions or examples about how it can be tailored to address different types of data/research tools/etc, please send them to me and we can incorporate or at least link to alternative resources on this subject.

Commented [MJ(8): I have added a proposed definition taken from an NIH Working Group on Research Tools. I welcome input for suggestions or modifications. (online copy available here: <http://biotech.law.lsu.edu/research/fed/NIH/researchtools/Report98.htm>).

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.

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.

Provisions Regarding Commercialization of Inventions

1. **Inventions.** Within ~~thirty-sixty (3060)~~ 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.

Commented [MJ(1)]: Mirrors 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 one hundred eighty (180) days 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.

Commented [MJ(2)]: NIH requires this decision be made within two years of the date of disclosure. See e.g., 37 CFR 401.14(c)(2)

This may need to be a point of ongoing discussion – some foundations may be fine with extending to two years, but others may want to push for more timely disclosures, with reasonable extension as needed.

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.

Perhaps the model provisions can leave a placeholder with suggested options and link to the NIH reporting requirements, showing that streamlining these reporting requirements will ease the burden on TTOs?

Commented [MJ(3)]: This language is intended to capture the mechanism described in the session. Again, I welcome your feedback.

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 ~~more than fifty percent (50%) of the~~ 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, ~~which Disease Foundation must elect to pursue within sixty (60) days of receiving notification from Sponsoring Institution of election not to commercialize.~~

Commented [MJ(4): 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.