Idaho State Board of Education
Institution Technology Licensing Guidelines

Adopted June 2013

The Idaho State Board of Education (Board) recognizes that institutions must share intellectual property with the public for the betterment of society. To provide a set of operating guidelines for such technology transfer, the Board has adopted these guidelines, derived from the "Nine Points" publication produced by the Association of institution Technology Managers (AUTM) and the "University Licensing Guidelines" adopted by the Regents of the University of California.

The College and Universities under the Board's governance (hereinafter collectively "institutions" or "institution") share certain core values that can and should be maintained to the fullest extent possible in all technology transfer agreements. The purpose of licensing institution intellectual property (IP) rights and materials is to: encourage the practical application of the results of institution research by industry for the broad public benefit; meet our obligations to sponsors of institution research; build research relationships with industry partners to enhance the research and educational experience of researchers and students; stimulate commercial uptake and investment; stimulate economic development; and ensure an appropriate return of taxpayer investments in institution research. Financial returns from technology licensing provide additional support for research and education, an incentive for faculty retention, and support of the institution technology transfer program. Institutions are charged to pursue these objectives in licensing institution IP. In carrying out these objectives, institutions are called upon to make complex licensing decisions based upon a multiplicity of facts and circumstances and by applying their professional experience, in consideration of the following guidelines. It is incumbent of the institutions to analyze each licensing opportunity individually in a manner that reflects the business needs and values of their institution, but at the same time, to the extent appropriate, also to bear in mind the concepts articulated herein when crafting agreements with industry. Multiple factors must be considered in each transaction, such as: the nature and stage of development of the technology; the breadth and complexity of the potential fields of use; the product development path and timeline; the extent of intellectual property protection; the relevant markets and market niches; specific campus practices; unique needs of prospective licensees; ethical considerations for the use of future products; and emerging issues, among other elements. All factors require careful consideration in developing a relationship with a prospective licensee, and the institution needs flexibility to address each of these issues. Further, the result of any one licensing decision may or may not be appropriate to another similar situation, as changes in knowledge and individual factors should be taken into consideration for each case-specific circumstance.

In all cases, the institution reserves the right, to the fullest extent permitted by Board policy and law, to exercise its discretion over decisions regarding its choice of licensee, the extent of rights licensed, and/or a refusal to license to any party.

GUIDELINES

1. The primary objective in developing a patenting and licensing strategy for an invention should be to support the education, research, and public benefit mission of the institution.

The institution recognizes the need for and desirability of broad utilization of the results of institution research, not only by scholars but also for the general public benefit, and acknowledges the importance of the patent system in providing incentives to create practical applications that achieve this latter goal.

In addition, with respect to federally-funded inventions (which comprise a large portion of the institution's invention portfolio), the Bayh-Dole Act (35 U.S.C. 200-212) requires the institution's use of the patent system to promote the utilization of inventions arising from federally supported research, to encourage maximum participation of small business firms, to promote collaboration between commercial concerns, nonprofits and universities and to promote free enterprise without unduly encumbering future research and discovery. As such, the institution is responsible for crafting a technology management strategy that supports the education, research, and public service mission of the institution. This requires establishing a balance of priorities between the timely transfer of technology to industry for commercialization while preserving open access to research results for use by the institution and the research community.

A primary licensing decision is whether to license exclusively or non-exclusively. The institution should consider licensing either non-exclusively, or exclusively within specific fields-of- use when an invention is broad in scope and can be used in multiple industries as well as for a platform technology that could form the basis of new industries. In general, institutions should consider granting exclusive licenses to inventions that require significant investment to reach the market or are so embryonic that exclusivity is necessary to induce the investment needed to develop and commercialize the invention or when the technology requires a company willing to dedicate financial resources and the additional research to realize the commercial potential. Finally, as noted below, exclusive licensing must have performance milestones connected to the continuation of such exclusivity.

Alternatively, an exclusive "field-of-use" license is a way to create market incentives for one company while enabling the institution to identify additional licensees to commercialize the invention in additional markets. In some cases, a limited-term exclusive license that converts to a non-exclusive license can be an effective strategy to meet the public benefit objective. Further, special consideration should be given to the impact of an exclusive license on uses of a technology that may not be appreciated at the time of initial licensing. A license grant that encompasses all fields of use for the life of the licensed patent(s) may have negative consequences if the subject technology is found to have unanticipated utility. This possibility is particularly troublesome if the licensee is not able or willing to develop the technology in fields outside of its core business. Institutions are encouraged to use approaches that balance a licensee’s legitimate commercial needs against the university’s goal (based on its educational mission and the public interest) of ensuring broad practical application of the fruits of its research programs.

Finally, the licensing strategy should ensure prompt broad access to unique research resources developed by the institution. To preserve the ability of the institutions to perform research, ensuring that researchers are able to publish the results of their research in dissertations and peer-reviewed journals and that other scholars are able to verify published results without concern for patents, the institution should consider reserving rights in all fields of use, even if the invention is licensed exclusively to a commercial entity, for themselves and other non-profit and governmental organizations. This is designed to practice inventions and to use associated information and data for research and educational purposes, including research sponsored by commercial entities and to transfer research materials and results to others in the non-profit and governmental sectors. Clear articulation of the scope of reserved rights is critical.

2. Institution must meet existing third party obligations

Research projects increasingly involve a multiplicity of third party agreements and relationships. For some inventions, the institution will have existing licensing obligations to a company or other research partner based upon contractual commitments made under sponsored research, material transfer, database access, inter-institutional, or other third-party IP agreements. Institutions shall seek to identify all licensing obligations to third parties so that such obligations can be met. While the inventor(s) should be required to identify these obligations at the time of disclosure to the institution, the institution is encouraged to verify the completeness or accuracy of the inventor(s) obligations.

Direct discussions with the inventor(s) and/or review of system-wide and local contract and grant databases may help determine whether the appropriate agreements are identified. Careful review of these agreements is critical to understanding the nuances of any third party obligations. Copies of any relevant agreements should be retained in the licensing file for future reference and to document the basis for decisions affecting the status of such third party obligations.

In addition, the institution should evaluate any other factors that may affect the institution's right to license the invention. The institution should investigate whether an inventor's disclosed invention entails a possible claim to prior ownership rights by a third party based upon the inventor's previous or current outside activities, for example, consulting arrangements, visiting scientist agreements, inventor start-up companies, and other contract obligations, particularly in light of court decisions (e.g. Stanford v. Roche, Fed Cir., 2009).

3. The selected licensee should be capable of bringing the invention to the marketplace and the license should be structured in a manner that encourages technology development and use.

The institution should seek licensees capable of bringing the invention to the marketplace in a timely manner. While often only one potential licensee comes forward for any given institution invention, the institution should nevertheless assess the potential licensee's technical, managerial and financial capability to commercialize the technology. From a programmatic perspective, licensing preference should be given to small business concerns, when appropriate, pursuant to federal law and regulations, provided such small businesses appear capable of bringing the technology to the marketplace.

Institutions should use care when licensing multiple technologies, invention portfolios, or a single technology with multiple variant applications to a single commercial organization to ensure that the licensing strategy meets the institution's desire to maximize public benefit.

In selecting a licensee, the institution, should consider whether the potential licensee:

- has a general business plan that delineates a clear strategy to commercialize the invention
- has or can secure the technical, financial and personnel resources to develop and commercialize the invention in a timely manner
- has experience relevant to developing and commercializing the invention
- has appropriate marketing capabilities
- possesses a strong desire and commitment to make the product/technology a success
- is able to meet any regulatory requirements needed to commercialize the technology
- has, or can develop sufficient capacity to satisfy the market demand for the technology
- demonstrates commitment to the institution's invention in light of other technologies competing for resources in the company
- has goals that generally align with those of the institution with respect to public benefit

The institution should obtain and retain documents that address the licensee's ability to bring the technology to the market. In the case of a start-up company, not all factors necessary to commercialize the technology may be present at the outset. The institution should consider whether the start-up has an appropriate level of resources and technical capabilities, given the development stage of the company and the nature of the invention, as well as whether the start-up has the potential to acquire the necessary resources to successfully develop and market the technology in a timely manner.

Institutions also need to be mindful of the impact of granting overly broad exclusive rights and should strive to grant just those rights necessary to encourage development of the technology. Performance milestones are a necessary part of any license, and are even more import in exclusive licenses.

In situations where an exclusive license is warranted, it is important that licensees commit to diligently develop the technology to protect against a licensee that is unable or unwilling to move an innovation forward. In long-term exclusive licenses, diligent development should be well-defined and regularly monitored during the exclusive term of the agreement and should promote the development and broad dissemination of the licensed technology. Ideally, objective, time-limited performance milestones are set, with termination or non-exclusivity (subject to limited, but reasonable, cure provisions) as the penalty for breach of the diligence obligation.

Another means of ensuring diligent development, often used in conjunction with milestones, is to require exclusive licensees to grant sublicenses to third parties to address unmet market or public health needs ("mandatory sublicensing") and/or to diligently commercialize new applications of the licensed rights. Such a requirement could also be implemented through a reserved right of the licensor to grant direct licenses within the scope of the exclusive grant to third parties based on unmet need. In such situations, it is important to ensure that the parties have a common

understanding of what constitutes a new application or unmet need for the purpose of implementing such a provision.

3.A. Future Improvements

Although licensees often seek guaranteed access to future improvements on licensed inventions, the obligation of such future inventions may effectively enslave a faculty member's research program to the company, thereby exerting a chilling effect on their ability to receive corporate and other research funding and to engage in productive collaborations with scientists employed by companies other than the licensee – perhaps even to collaborate with other academic scientists. In particular, if such future rights reach to inventions made elsewhere in the university, researchers who did not benefit from the licensing of the original invention may have their opportunities restricted as well, and may be disadvantaged economically relative to the original inventors if the licensing office has pre-committed their inventions to a licensee.

For these reasons, exclusive licensees should not automatically receive rights to "improvement" or "follow-on" inventions. Instead, as a matter of course, licensed rights should be limited to existing patent applications and patents, and only to those claims in any continuing patent applications that are (i) fully supported by information in an identified, existing patent application or patent and (ii) entitled to the priority date of that application or patent.

In the rare case where a licensee is granted rights to improvement patents, it is critical to limit the scope of the grant so that it does not impact uninvolved researchers and does not extend indefinitely into the future. It is important to further restrict the grant of improvements to inventions that are owned and controlled by the licensor institution - i.e., (i) not made by the inventor at another institution, should they move on or (ii) co- owned with, or controlled by, another party. One refinement to this strategy would be to limit the license to inventions that are dominated by the original licensed patents, as these could not be meaningfully licensed to a third party, at least within the first licensee's exclusive field. As was discussed earlier, appropriate field restrictions enable the licensing not only of the background technology, but also of improvements, to third parties for use outside the initial licensee's core business. In all cases, a license to improvements should be subject to appropriate diligent development requirements.

It should be recognized, however, that not all "improvements" have commercial potential (for example, they may not confer sufficient additional benefit over the existing technology to merit the expense of the development of new or modified products), in which case a licensee might not wish to develop them. In general, it may be best simply not to patent such improvements.

4. *The license agreement should include diligence terms that support the timely development, marketing, and deployment of the invention.*

The institution should include diligence provisions in a license agreement to ensure that the licensee develops and commercializes the invention in a timely manner, especially when an invention is exclusively licensed. The institution's commitment to public benefit is not met by allowing an invention to languish due to a licensee's lack of commitment, "shelving" the technology to protect its competing product lines, or inadequate technical or financial resources.

Appropriate diligence provisions are invention-specific and will vary depending on the circumstances. Common diligence obligations that an institution should consider include:

- the amount of capital to be raised (for a start-up) or the amount of funding committed (for an existing business) by the company to support the technology's development.
- specific dates by which the licensee must achieve defined milestones, such as: secure levels of regulatory approval; make a working prototype; initiate beta testing of a licensed product; receive formal market/customer feedback; achieve specific prototype performance thresholds (such as efficiency or size); establish a production facility; first sell the commercial product; or achieve a certain level of sales.

To ensure that the institution continues to manage its technologies as assets for the public's benefit, clearly defined diligence provisions allow verification of the licensee's compliance with its diligence obligations. Therefore, the licensing agreement language should be sufficiently specific so that both parties can determine whether the diligence obligations have been met. Further, the license should provide a remedy for failure to meet diligence obligations, such as termination of the license or, in the case of an exclusive license, a reduction to a non-exclusive license.

5. The license agreement should be approved as to legal integrity and consistency.

In order to ensure that the institution has the right to enter into licensing discussion, the institution should ensure that the inventors have signed an agreement that acknowledges the institutions patent policy, and institution claim of ownership of inventions under the Policy, and/or an actual Assignment Agreement that confirms the institution's ownership in the invention and that includes a present assignment of invention rights.

In determining the rights that can be granted in a license agreement, the institution should ask the inventors about past and present sponsors of their research, material providers, and independent consulting and other agreements (e.g., visitor, confidentiality, etc.) they have signed that could be related to the invention to determine if conflicting obligations exist between such agreements and the proposed license.

The institution shall ensure that the provisions of the license agreement are reviewed and approved by the institution Office of General Counsel, and comply with institution policies with regard to legal integrity and consistency, including the following concerns:

5.A. Use of Name:

The institution shall ensure that the license agreement prohibits the use of the institution's name, or the names of its employees, to promote the licensee or its products made under the license agreement, unless specifically approved by authorized institution personnel. The license may provide limited use of the institution's name where required by law, to give effective legal notice such as a copyright mark, or to make a statement of fact regarding the origin of plant material.

5.B. Indemnification:

The institution shall ensure that the license agreement contains an indemnification provision under which the licensee assumes all responsibility for any product or other liability arising from the exercise of the license covering the invention. The licensee should assume all responsibility as it has complete control over product development while the institution only provides rights under the patents it holds.

5.C. Limitation of Liability:

The institution shall ensure that the license agreement contains a provision that limits the institution's liability for any damages that may result from the licensee's acts under the license agreement (e.g., intellectual property infringement, lost profits, lost business, cost of securing substitute goods, etc.).

5.D. Insurance:

The institution shall ensure that the license agreement requires the licensee to carry sufficient insurance or have an appropriate program of self-insurance to meets its obligations to protect the institution, and provide evidence of such.

5.E. Limited Warranty:

The institution shall ensure that the license agreement contains a limited warranty provision stating that nothing in the license shall be construed as (i) a warranty or representation regarding validity, enforceability, or scope of the licensed patent rights; (ii) a warranty or representation that any exploitation of the licensed patent rights will be free from infringement of patents, copyrights, or other rights of third parties; (iii) an obligation for the institution to bring or prosecute actions or suits against third parties for patent infringement except as provided in the infringement provision of the license; (iv) conferring by implication, estoppel, or otherwise any license or rights under any patents or other rights of institution other than the licensed patent rights, regardless of whether such patents are dominant or subordinate to the licensed patent rights; and (v) an obligation to furnish any new developments, know-how, technology, or technological information not provided in the licensed patent rights.

5.F. Patent Prosecution:

The institution shall ensure that the license agreement contains a patent prosecution provision that stipulates the institution will diligently prosecute and maintain the patent rights using counsel of its choice who will take instructions solely from the institution. The institution will use reasonable efforts to amend any patent application to include claims requested by the Licensee. For an exclusive license, all such costs will be borne by the licensee. For non-exclusive licenses, a common practice is for each licensee to pay a pro-rata share of such costs.

5.G. Patent Infringement:

The institution shall ensure that an exclusive license agreement contains a patent infringement provision that stipulates that neither the institution nor the licensee will notify a third party (including the infringer) of infringement or put such third party on notice of the existence of any patent rights without first obtaining consent of the other party; with additional language that addresses infringement notification process, participation, control and prosecution of the suit, and payment of costs and sharing of awarded damages.

5.G.1. Infringement Action Considerations

In considering enforcement of their intellectual property, it is important that universities be mindful of their primary mission to use patents to promote technology development for the benefit of society. All efforts should be made to reach a resolution that benefits both sides and promotes the continuing expansion and adoption of new technologies. Litigation is seldom the preferred option for resolving disputes.

However, after serious consideration, if a university still decides to initiate an infringement lawsuit, it should be with a clear, mission-oriented rationale for doing so- one that can be clearly articulated both to its internal constituencies and to the public. Ideally, the university's decision to litigate is based on factors that closely track the reasons for which universities obtain and license patents in the first place, as set out elsewhere in this paper. Examples might include:

- Contractual or ethical obligation to protect the rights of existing licensees to enjoy the benefits conferred by their licenses; and
- Blatant disregard on the part of the infringer for the university's legitimate rights in availing itself of patent protection, as evidenced by refusal on the part of the infringer to negotiate with or otherwise entertain a reasonable offer of license terms.

5.G.2. Patent Aggregators and "Flippers"

As is true of patents generally, the majority of university-owned patents are unlicensed. With increasing frequency, university technology transfer offices are approached by parties who wish to acquire rights in such 'overstock' in order to commercialize it through further licenses. These patent aggregators typically work under one of two models: the 'added value' model and the so-called 'patent troll' model.

Under the added value model, the primary licensee assembles a portfolio of patents related to a particular technology. In doing so, they are able to offer secondary licensees a complete package that affords them freedom to operate under patents perhaps obtained from multiple sources. As universities do not normally have the resources to identify and in-license relevant patents of importance, they cannot offer others all of the rights that may control practice (and, consequently, commercialization) of university inventions. By consolidating rights in patents that cover foundational technologies and later improvements, patent aggregators serve an important translational function in the successful development of new technologies and so exert a

positive force toward commercialization. For example, aggregation of patents by venture capital groups regularly results in the establishment of corporate entities that focus on the development of new technologies, including those that arise from university research programs. To ensure that the potential benefits of patent aggregation actually are realized, however, license agreements, both primary and secondary, should contain terms (for example, time-limited diligence requirements) that are consistent with the university's overarching goal of delivering useful products to the public.

In contrast to patent aggregators who add value through technology-appropriate bundling of intellectual property rights, there are also aggregators (the 'patent trolls') who acquire rights that cut broadly across one or more technological fields with no real intention of commercializing the technologies. In the extreme case, this kind of aggregator approaches companies with a large bundle of patent rights with the expectation that they license the entire package on the theory that any company that operates in the relevant field(s) must be infringing at least one of the hundreds, or even thousands, of included patents. Daunted by the prospect of committing the human and financial resources needed to perform due diligence sufficient to establish their freedom to operate under each of the bundled patents, many companies in this situation will conclude that they must pay for a license that they may not need. Unlike the original patent owner, who has created the technology and so is reasonably entitled to some economic benefit in recognition for its innovative contribution, the commercial licensee who advances the technology prior to sublicensing, or the added value aggregator who helps overcome legal barriers to product development, the kind of aggregator described in this paragraph typically extracts payments in the absence of any enhancement to the licensed technology. Without delving more deeply into the very real issues of patent misuse and bad-faith dealing by such aggregators, suffice it to say that universities would better serve the public interest by ensuring appropriate use of their technology by requiring their licenses to operate under a business model that encourages commercialization and does not rely primarily on threats of infringement litigation to generate revenue.

A somewhat related issue is that of technology 'flipping', wherein a non-aggregator licensee of a university patent engages in sublicensing without having first advanced the technology, thereby increasing product development costs, potentially jeopardizing eventual product release and availability. This problem can be addressed most effectively by building positive incentives into the license agreement for the licensee to advance the licensed technology itself – e.g., design instrumentation, perform hit-to-lead optimization, file an IND. Such an incentive might be to decrease the percentage of sublicense revenues due to the university as the licensee meets specific milestones.

5.H. Third Party Obligations and Conflicts of Interest:

Technology transfer offices should be particularly conscious and sensitive about their roles in the identification, review and management of conflicts of interest, both at the investigator and institutional levels. Licensing to a start-up founded by faculty, student or other university inventors raises the potential for conflicts of interest; these conflicts should be properly reviewed and managed by academic and administrative officers and committees outside of the technology transfer office. A technology licensing professional ideally works in an open and collegial

manner with those directly responsible for oversight of conflicts of interest so as to ensure that potential conflicts arising from licensing arrangements are reviewed and managed in a way that reflects well on their university and its community. Ideally, the university has an administrative channel and reporting point whereby potential conflicts can be non-punitively reported and discussed, and through which consistent decisions are made in a timely manner.

5.I. Export Controls

Institution technology transfer offices should have a heightened sensitivity about export laws and regulations and how these bodies of law could affect university licensing practices. Licensing "proprietary information" or "confidential information" can affect the "fundamental research exclusion" (enunciated by the various export regulations) enjoyed by most university research, so the use of appropriate language is particularly important. Diligence in ensuring that technology license transactions comply with federal export control laws helps to safeguard the continued ability of technology transfer offices to serve the public interest.

6. The institution should receive fair consideration in exchange for the grant of commercial licensing rights.

The institution should ensure that institution receives fair consideration for commercial licenses of its inventions (as public assets created using public funds, supplies, equipment, facilities, and/or staff time) to private entities. Generally, the value of the consideration received by the institution should be based on the licensee's sale or distribution of licensed products or licensed services by the licensee. Other factors that impact the negotiation of the institution's consideration may include:

- the type of technology and industry
- the stage of development and market consideration
- the perceived value to the licensee's business and competitive position ("must-have" vs. "nice-to-have")
- the market potential, contribution of the technology to market penetration, and market sector dynamics (i.e. growing, static, declining?)
- the projected cost and risk of product development and marketing
- the competitive advantage over alternative products; is the invention a seminal "game-change" one or an incremental improvement?
- the likelihood of competing technologies
- the net profit margin of the anticipated product
- comparable prices for similar technologies or products
- the scope and enforceability of the institution's patent claims, extent of freedom-to- operate required, and years remaining on patent term
- the projected decrease in the cost of production or R&D expenditures
- the scope of license (exclusive/nonexclusive, narrow/broad fields of use, U.S./non- U.S.)
- the opportunity for accelerated time to market based upon the necessity for meeting a critical public need.

In general, the fair consideration to the institution should be in cash, but other forms of consideration may be accepted in partial lieu of cash fee(s) such as equity in the company (discussed below). The form of such consideration negotiated by the institution may vary widely based on case-specific factors.

The institution should consider including some or all of the following elements as part of the consideration:

6.A. Reimbursement of institution's patent costs:

The licensee pays for domestic and/or foreign patent applications either through an up-front fee that covers past and future costs and/or through a requirement to reimburse past, present and future costs upon invoicing by the institution. Where the technology is licensed to multiple parties, reimbursement may be done on a pro-rata basis. Full reimbursement by an exclusive licensee is standard institution practice.

6.B. License Issue fee:

The licensee pays a fee to the institution upon final execution of the license agreement either in a lump sum or on an agreed upon schedule. The amount of this fee should reflect the value of the invention at the time it is made available to the licensee. Such fees range widely, depending on the circumstance. Under some circumstances, the issue fee for small companies or start-ups may be partially postponed until sufficient investment capital is secured, or may be replaced in part by the institution's acceptance of equity in the company (see *Equity* below).

6.C. Running royalties:

The licensee pays ongoing consideration to the institution in the form of a running (or earned) royalty, typically calculated as a percentage of net sales or use of licensed products or services that incorporate the technology. Such royalties should not be "capped" at a pre-determined dollar level, as the institution should share fully in the success of any commercial use of technology made available to the licensee. In some rare cases, a running royalty value may be difficult to assess due to the particular market and the type of products being developed. In such cases a fixed amount for each unit of licensed product sold or a one-time or annual fee may be contemplated, where the fee should reflect the value of the invention over the projected length of patent protection (both U.S. and foreign).

6.D. Annual maintenance fee/minimum annual royalty:

The licensee pays an annual license maintenance fee which serves as a form of diligence and represents the licensee's continuing interest in and a financial commitment to commercialize the invention. A minimum annual royalty begins in the first year of commercial sales and serves not only as a diligence obligation but also incentivizes the licensee to achieve sales generating royalties that meet or exceed the minimum annual royalty. Typically, annual maintenance fees cease after commercial sales begin when they are replaced by the minimum annual royalty. Minimum annual royalties, if paid in advance, are generally creditable against the running

royalty due that year. The institution may use these fees singly, in combination, or not at all as judgment dictates, however, including such fees not only creates diligence obligations but also provides annual income to support the institution's research and education mission.

6.E. Sublicensing fees:

Under an exclusive license where the licensee is permitted to transfer rights to third parties (a sublicense), the licensee pays the institution consideration for sales or use of licensed products or services by its sublicensees. The institution should receive a fair share of all consideration, including royalty and non-royalty income, received by the licensee from the sublicensee. It is institution practice not to include sublicensing rights under its non-exclusive licenses as the granting of such rights could place the licensee in direct licensing competition with the institution, except in those cases where the sublicensee's activities are necessary for the sublicensor to commercialize the licensed technology (e.g. sublicensee is a contract research organization or contract manufacturer providing a vital component to the sublicensor necessary for the licensed technology, etc.).

6.F. Equity:

To encourage commercialization of institution technology, the institution may accept equity in a company as partial consideration for invention licensing in a manner consistent with Board and institution policies. This option may be particularly useful in working with small or startup companies where financial considerations limit the company's and its investors' willingness to pay cash to the university for licensing costs, such as license issue fees and annual maintenance fees. When accepting equity, institutions should consider the risk- adjusted value of equity and the potential loss of value associated with dilution of equity.

6.G. Other:

The institution may negotiate forms of consideration other than those described above, such as milestone payments upon the completion of certain licensed product development events or upon financing or investment triggers (e.g., investment rounds, merger or acquisition, or a public stock offering). Other unique exchanges of value occasionally may be appropriate forms of fair consideration. The institution should note, however, that such non-monetary forms of consideration (other than equity) fall outside the royalty-sharing provisions of the institution Patent Policy. The institution should take care to not designate research funding as a form of consideration in a license as license income is subject to the royalty-sharing provisions of the institution Patent Policy whereas research funding is not consideration for a license but is fixed at a level to pay for the cost of conducting the research (Singer v. The Regents, 1996).

Finally, the institution should be aware that "overly-aggressive" negotiation of financial consideration may impede commercialization of an invention and may not be consistent with certain research sponsor guidelines (e.g., Federal, State, or non-profit extramural sponsorship policies). However, undervaluing a commercial license reduces the additional monetary support for research and education and compromises the principle of seeking a fair return on the public asset that is the institution's technology. The institution should weigh all appropriate

factors discussed above in crafting a commercial license to create an optimal structure and fair consideration.

7. The license agreement should support the academic principles of the institution.

The institution should ensure that the provisions of the license agreement support the institution's academic teaching and research mission, including the following concerns:

7.A. Open Dissemination of Research Results and Information:

License agreements with external parties shall not limit the ability of institution researchers to disseminate their research methods and results in a timely manner. The most fundamental tenet of the institution is the freedom to interpret and publish, or otherwise disseminate, research results to support knowledge transfer and maintain an open academic environment that fosters intellectual creativity.

7.B. Accessibility for Research Purposes:

The institution should ensure that the license agreement protects the ability of institution researchers, including their student and research collaborators, to use their inventions in future research, thus protecting the viability of the institution's research programs. The institution has a commitment to make the results of its research widely available through publication and open distribution of research products for verification and ongoing research. The institution also seeks to foster open inquiry beyond the interests of any one research partner, particularly where the invention is a unique research tool. One way in which the institution addresses this is through the retention in the license agreement of the institution's right to use and distribute inventions to other non- profit research institutions for research and educational purposes.

7.C. Broad Access to Research Tools:

Consistent with the NIH Guidelines on Research Tools, principles set forth by various charitable foundations that sponsor academic research programs and by the mission of the typical university to advance scientific research, universities are expected to make research tools as broadly available as possible. Such an approach is in keeping with the policies of numerous peer-reviewed scientific journals, on which the scientific enterprise depends as much as it does on the receipt of funding: in order to publish research results, scientists must agree to make unique resources (e.g., novel antibodies, cell lines, animal models, chemical compounds) available to others for verification of their published data and conclusions.

Through a blend of field-exclusive and non-exclusive licenses, research tools may be licensed appropriately, depending on the resources needed to develop each particular invention, the licensee’s needs and the public good. The drafting of such an exclusive grant should make clear that the license is exclusive for the sale, but not use, of such products and services; in doing so, the university ensures that it is free to license non-exclusively to others the right to use the patented technology, which they may do either using products purchased from the exclusive licensee or those that they make in- house for their own use.

8. *All decisions made about licensing institution inventions should be based upon legitimate institutional academic and business considerations and not upon matters related to personal financial gain.*

It is important that the institution conduct the technology transfer process, including patenting, marketing, and licensing in a manner that supports the education, research, and public service missions of the institution over individual financial gain.

Because institutions and inventors may have the opportunity to influence institution business decisions in ways that could lead to personal gain or give advantage to associates or companies in which they have a financial interest, the institution and the inventor must comply with existing Board policy, institution policy and State law concerning such potential conflicts of interest. Under Board policy and State conflict of interest law, any institution employee or representative is prohibited from making, participating in making, or influencing an institution decision (including selection of licensees and other decisions made in the course of commercializing institution technology) in which they have a personal financial interest. Certain specific actions may be taken, however, consistent with Board policy, institution policy and State law, to allow participation in the licensing process by such inventors. An inventor's expectancy of receiving money or equity as inventor share under the institution Patent Policy is not a disqualifying financial interest.

For institutions who have a personal financial interest in potential licensees, this situation can be readily managed by having the invention case assigned for management to another institution without a financial interest. For inventors who have a personal financial interest in potential licensees, another individual with appropriate scientific and technical background may be able to carry out the duties and responsibilities typically handled by the inventor. In both cases, personal disqualification requirements would need to be satisfied under Board policy, institution policy and State law.

Institution inventors, however, may not be able to reasonably remove themselves from involvement in the process under disqualification requirements as their expertise and input may be essential to successful technology transfer. It may be necessary for the inventor to work closely with the institution and with potential licensees, or involve themselves in companies that are potential licensees, with the objective of commercializing institution inventions, even when they have a personal financial interest. It is in this context, when the inventor is involved in the process, that the selection of a licensee and other commercialization decisions may have the potential to raise concerns about conflicts of interest. Some inventor contributions to the licensing process are primarily technical advice and do not constitute "participation in" or "attempting to influence" a licensing decision under State conflict of interest law. They are called "ministerial." An action is ministerial, even if it requires considerable expertise and professional skill, if there is no discretion with respect to the outcome. Thus an inventor can provide technical or scientific information about an invention where necessary without being considered to be participating in a licensing decision. This exception, however, does not apply

to technical tasks such as most data gathering or analysis in which the inventor makes professional judgments which can affect the ultimate decision in question.

Therefore, the institution and inventor(s) should discuss: i) the disqualification option; ii) an approach to and level of inventor involvement in the technology transfer process; iii) compliance with Board policy, institution policy and State law concerning potential conflicts of interest; and (iv) where helpful, these institution Licensing Guidelines.

In general, the role in the technology transfer process of any inventor who has a personal financial interest in a potential licensee should be kept to the minimum necessary to successfully achieve the institution's objectives in patenting, marketing, and licensing. When an inventor has a personal financial interest in a potential licensee and does not fully disqualify him or herself from involvement in the process, an independent substantive review (Licensing Decision Review - LDR) and recommendation concerning the licensee selection and other licensing decisions is required. Thus, both the institution and the inventor should understand that the extent to which the inventor is involved in the technology transfer process may be a factor in the considerations and ultimate recommendations of the LDR body. The LDR body, composed of one or more qualified individuals with appropriate expertise, knowledge and professional judgment, must independently check the original data and analysis upon which recommendations for the selection of licensees and for other licensing determinations were made by the institution and make its own independent recommendations concerning those decisions. The LDR may be performed by the a institution committee responsible for review and management of conflicts of interest; such committee, when undertaking an LDR, should have the expertise, knowledge and professional judgment required of the LDR body under these Guidelines.

The institution must ensure that disclosure and management of potential inventor conflicts of interest are handled in accordance with institution policy. By doing so, the institution can help ensure that the inventor may continue to participate in the technology development process while remaining in compliance with institution policies and State law in this area. Future issues may arise, such as an inventor's desire to bring technology back to the institution for further testing, development, and purchase for use in the lab as the licensee further develops the technology. If the institution becomes aware of such issues, the institution should ensure that other institution officials impacted by such activities on the part of the inventor (e.g., procurement, C&G office, Conflict of Interest review board, etc.) are educated about the rationale and processes needed for a successful technology transfer program.

9. Technology-specific Considerations

The following guidance supports a general understanding of the objectives, practices and issues involved in the institution licensing program with respect to specific technologies. The licensing strategies described herein are not intended to be applied in an absolute or mechanical manner. Each licensing decision is unique and a matter of professional judgment. The institution's ALOs retain complete discretion in choosing the appropriate licensee and technology management strategy for its technologies.

9.A. Research Tools

In determining an appropriate licensing strategy for an invention that is used primarily as a research tool, the institution should analyze if further research, development and private investment are needed to realize this primary usefulness. If it is not, publication, deposition in an appropriate databank or repository, widespread non-exclusive licensing, or electing not to file a patent application may be the appropriate strategy. Where private sector involvement is necessary to assist in maintaining (including reproducing), and/or distributing the research tool, where further research and development are needed to realize the invention's usefulness as a research tool, or where a licensee has the ability to enhance the usefulness, usability, or distribution of the research tool, licenses should be crafted with the goal of ensuring widespread distribution of the final research tool to the research community. Any such license should also contain a provision preserving the institution's ability to continue to practice the licensed invention and allow other educational and non-profit institutions to do so for educational and research purposes. If carefully crafted, exclusive licensing of such an invention, such as to a distributor that will sell the tool or to a company that will invest in the development of a tool from the nascent invention, could support the institution's objectives.

One particular concern is royalties assessed on sales of products that are developed using (directly or indirectly) an institution invention that is a research tool ("reach-through" royalties), rather than assessed on products actually incorporating the institution invention. The institution should note that reach-through royalties may impede the scientific process or create unreasonable restrictions on research and therefore generally should be avoided. Licensing of research tools should encourage prompt and broad access through a streamlined process. For NIH-funded inventions, see the NIH "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources."

9.B. Global Health

While many of the licensing strategies discussed below are presented in the context of global health issues, such strategies are equally applicable to other current and future emerging technologies that can be used to support humanitarian efforts in underprivileged populations (e.g., clean water, sustainable sources of energy, food sources, etc.).

As innovative healthcare technologies are discovered and, after meeting extensive development and regulatory hurdles, introduced as publicly available therapeutic or diagnostic products, the ability of underprivileged populations to access and afford these technologies may be constrained by price or distribution. In particular, healthcare and agricultural products may not be readily accessible and affordable to the world's poorest people in developing countries and as a public institution striving to uphold its public benefit mission, the institution should consider such public benefit and broad societal needs when developing licensing strategies for such technologies.

Developing "successful practices" is an evolving process, particularly for an issue as complex as balancing access by developing countries to biomedical products with ensuring timely and appropriate development and commercialization of the product. Such practices demand creative and

flexible rather than rigid approaches. Entirely new business models coupled with nuanced intellectual property management strategies may be needed to produce the desired outcomes. Each situation is unique and must be addressed based on its own fact pattern to encourage licensees to make the substantial and risky investment necessary to develop biomedical products. Without appropriate and timely investments, the healthcare technology may never be developed into a product, thus eliminating access by all patients. A prescriptive approach may discourage licensees because of a perceived need to overcome too many obstacles in product development. Institutions frequently need to balance conflicting objectives and must be able to make compromises in the interest of moving a technology forward.

As part of the institution's public benefit mission, the institution should carefully consider patenting and licensing strategies that promote access to essential medical and agricultural innovations in developing countries. Although a multitude of downstream factors may affect the accessibility and affordability of essential technologies in developing countries, e.g. healthcare infrastructure, poverty, food security, international treaties and laws, sanitation, energy, and political stability, it remains possible for the institution to impart a profound life- changing impact in the developing countries through humanitarian patenting and licensing strategies.

One patenting strategy that the institution and its licensee might pursue is to limit patent protection to those developed countries with a healthcare infrastructure that can afford the healthcare products and not seek patent protection in developing countries thereby allowing other manufacturers to freely practice the technology. Some examples of alternate licensing strategies to consider could be: (i) inclusion in a license agreement of mechanisms to allow third parties to create competition that affects or lowers prices in developing countries, create incentive mechanisms for widespread distribution of the licensed product, or reserve a right for the institution to license third parties under specific humanitarian circumstances, (ii) inclusion of license terms requiring mandatory sublicensing to generic or alternative manufacturers in a developing country or a program that requires the distribution of the healthcare product at low or no cost to underprivileged populations with assurance that the licensee will continue to develop, manufacture and distribute the product to all such populations; and (iii) inclusion of uniquely crafted diligence provisions or other creative pricing tied to the patient's ability to afford the technology that are consistent with sponsor's march-in rights provision (if applicable).

Financial terms for products that address diseases that disproportionately affect developing countries should, where possible, facilitate product availability in the country of need. At a minimum, the financial terms should recognize the low profitability of such products. The institution could also consider foregoing royalties on products distributed in such countries or requiring the licensee to sublicense other companies if the licensee is unwilling to invest in the development of a product distribution network within that country.

To be most effective in promoting global health, the institution needs to pursue creativity and consider a wide variety of patenting and licensing strategies, since the most impactful approach in one situation may fail in others. Prescriptive guidelines dictating limited strategies could be particularly detrimental to achieving the institution's goals of public benefit. Creative patenting and licensing strategies addressing global health should focus on effectiveness and should aim to achieve the greatest impact worldwide.

9.C. Software

Because of the cross-over of software and other digital media between the patent and copyright policies, licensing of these technologies are less straight-forward than simple patent or copyright licenses. In addition, under institution Copyright Policy, an institution may have implemented procedures and supplementary local policies regarding licensure, disposition of royalty income, and other rights related to copyrights. As such, copyright licensing practices will vary from institution to institution.

9.D. Diagnostics

Licensing clinical diagnostics technologies, regardless of type (genetic or otherwise), should balance the need of the licensee to achieve a fair return on investment with the public's need to have the test as broadly available as possible, including enabling patients to obtain a second opinion by accessing the test from an alternative provider. Licenses should also reserve the right for the academic community to use the diagnostic for research purposes, including studying and independently validating the test and employing it to advance medical research. The institution will need to take into account that licensees can elect to commercialize the technology (i) as an FDA-approved kit sold to end-users, (ii) as a testing service business using an in-house Laboratory Developed Test (LDT) subject to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 administered by the Centers for Medicare and Medicaid Services, or (iii) a sequential combination of (i) and (ii) whereby the licensee initially enters the market to generate near-term revenue with an LDT-based testing service and subsequently obtains market approval via the costlier and lengthier FDA review process to market a kit for sale. Licensors that have academic medical centers need to structure their licenses to take into account the needs of their own clinical laboratories to insure affordable access to the licensee's FDA-approved kit or to have the right to provide an LDT in their CLIA labs (either as a carve-out or an affordable sublicense from the licensee).

For markets that can reasonably support two diagnostics developers (e.g. melanoma), the institution should consider co-exclusive licensing. However, for more limited markets, in order to assure maximum availability and multiple sources, the institution might consider such approaches as (i) a time-limited exclusive license that automatically converts to a nonexclusive license after several years, or (ii) a license grant for the exclusive right to sell and a non-exclusive right to make and use the patented technology. In this way the licensor can be the sole provider of an FDA-approved kit while clinical labs that cannot afford the kit can still serve patient needs with their own LDTs.

Lastly it is important to appreciate that whereas a single-source provider of an FDA-approved kit provides patients with a uniform, consistent product, LDTs developed by different clinical labs (commercial and academic) may vary in performance quality and have different degrees of false-positive and false-negative results. Thus a given patient's diagnostic outcome could vary depending on which CLIA lab performs the test.

However, insuring test availability from more than one source can mitigate the variability from center-to-center.

9.E. Genetic Resources/Traditional Knowledge

Country laws or international treaties may influence licensing decisions where inventions are derived from genetic resources or traditional knowledge. The institution should investigate all project sponsored or collaborative research agreements, including material transfer agreements, to identify if any genetic resource or traditional knowledge was used in making the invention and if any specific requirements apply to the use of such resources. In some situations, the requirement may be attached to a collection permit or a visa document.

Even in the absence of such laws, treaties or contractual requirements, the institution should carefully consider biodiversity issues and negotiate individual agreements that recognize the origin or source of the material. Where possible, such agreements should consider benefit sharing arrangements with indigenous and custodial communities or governments in consideration for access to such biological material or traditional knowledge.

9.F Emerging Technologies

Over time, whole new fields of technology and innovation will emerge that will raise new issues for consideration. As with any emerging technology area, the evolution of "successful practices" will require careful and conscientious decisions that may vary from previously released guidance. The institution should thoughtfully consider how best to address these emerging issues so as to optimally manage institution-developed technologies for public benefit.

10. Assignment of Ownership of Institution Intellectual Property

Under certain circumstances, the institution may be required by federal law to assign rights in institution intellectual property to the federal government. In those instances when the institution determines that it is not interested in pursuing protection and commercialization, the institution may also find it necessary, under federal law and institutional policy, or desirable, in the absence of legal or contractual requirements, to assign rights in institution intellectual property to the original institution inventor(s) or author(s). In such cases, the assignment of institution intellectual property is considered appropriate. These Guidelines presume, however, that licensing is the most appropriate mechanism for commercialization of the public asset that is the institution’s intellectual property. Except with respect to assignments to those board-approved research foundations affiliated with the institution, assignment of institution intellectual property to a third party, for commercialization or use by the third party, should be a rare occurrence. Any such assignment should be negotiated on a case-by-case basis, dependent on unique circumstances that demonstrate that a license is not appropriate, and should be made only with the approval of the institution president, or his or her designee. In no case should the institution make a present assignment of future rights in institution intellectual property.