Inventor's guide to technology transfer

unemed

tech transfer for nebraska

The *Inventor's Guide to Technology Transfer* outlines the essential elements of technology transfer at UNeMed—the publisher of this guide and the technology transfer and commercialization office for the University of Nebraska Medical Center and the University of Nebraska at Omaha.

This guide is organized to answer the most common questions that UNeMed typically fields from Nebraska researchers, clinicians, faculty, staff and students. This guide provides a broad overview of the technology transfer process and services.

Useful and new information can be found at www.unemed.com. Specific questions should be directed to UNeMed at 402-559-2468 or unemed@unmc.edu.

This guide is based, in part, on a similar guide produced by the University of Michigan, and combined with the expertise of UNeMed's experienced staff.

Some definitions were provided by various governmental sources and *Webster's New World College Dictionary*.

Credits: Graphic design by UNeMed. Photography by UNeMed, unless noted; icons courtesy FontAwesome.

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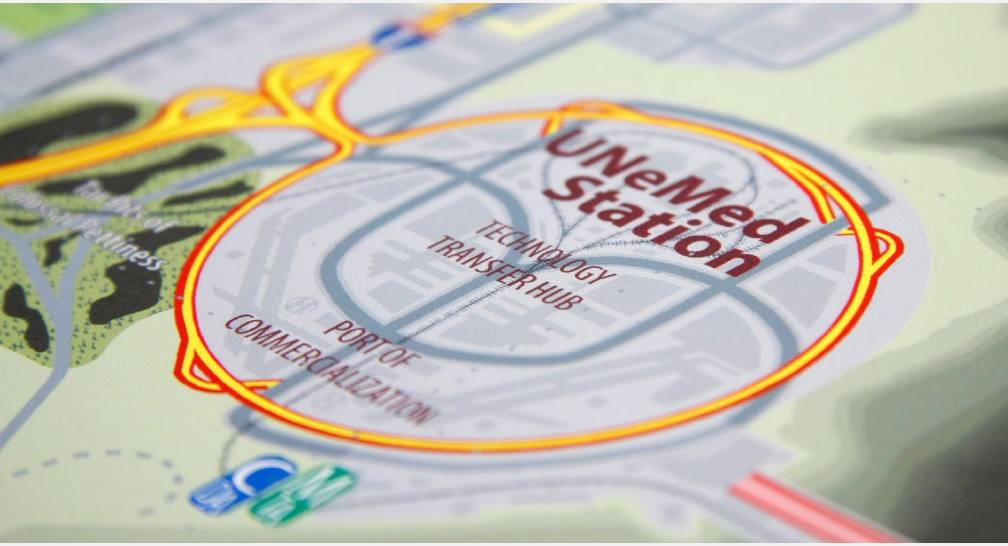


About UNeMed

The University of Nebraska Board of Regents created UNeMed in 1991. UNeMed is a not-for-profit entity responsible for all technology transfer activities at the University of Nebraska Medical Center and the University of Nebraska at Omaha.

UNeMed primarily builds and develops partnerships with industrial leaders who can help push innovations beyond the laboratory and into the marketplace.

Advancing and commercializing University technology can take many forms, whether it's creating a new startup company, licensing with a massive multinational corporation or helping secure sponsored research support. UNeMed uses every tool available and continues to seek—or even create new tools—to help innovations and discoveries reach their highest potential.

Mission

UNeMed fosters innovation, advances research and engages entrepreneurs and industry to commercialize novel technologies.

TECHNOLOGY TRANSFER OVERVIEW

In the most basic terms, technology transfer is the act of moving innovation and discoveries into the world for the benefit of all. At the University of Nebraska, technology transfer refers to the efforts of creating partnerships as a way to help finance and support further development of inventions, discoveries and innovations at the University of Nebraska.

Technology transfer for a reason:

- *Positive impact on society*
- *Personal fulfillment*
- *Recognition, financial rewards*
- *Attract additional funding*
- *Contractual obligation*
- *Create educational opportunities*
- *Link students to future job opportunities*

Protect first, then publish

Of course inventors and researchers may still publish, but publishing can affect an inventor's patent rights. It is therefore essential to submit a "**New Invention Notification**" form well before any public disclosure. There are significant differences between how early publication affects a potential U.S. or foreign patent. A public disclosure may significantly restrict or minimize the potential for patent protection outside of the United States. It's best to inform UNeMed of any previous or planned public presentations or disclosures of the invention. The disclosure could be a lecture, poster, abstract, website description, research proposal submission, thesis, grant submission, publication, or something similar. UNeMed has a few ways to quickly and easily protect an idea before a public disclosure can spoil an invention's chance at further development.

What is the Bayh-Dole Act?

The Bayh-Dole Act of 1980 provides ownership rights to universities and other non-profit institutions for discoveries resulting from federally funded research, as long as certain obligations are met. Obligations include:

- *efforts to protect and commercialize the discoveries*
- *submitting progress reports to the funding agency*
- *giving preference to small businesses that demonstrate sufficient capability*
- *sharing any resulting revenues with the inventors*

The Bayh-Dole Act is credited with stimulating technology transfer activities and generating increased research, commercialization, educational opportunities, and economic development in the United States.

TECHNOLOGY TRANSFER OVERVIEW

Tech transfer timeline

The process of protecting a technology—and finding the right commerical partner—may take months, even years. The amount of time will depend on the unique circumstances of the invention itself. Critical factors include the development stage of the technology; the market; competing technologies; the amount of work needed to bring a new concept to market-ready status; and the available resources and willingness of the licensees and inventors.

The actual timing of the process will vary because, by definition, no two inventions are alike. All that can be said with any degree of confidence is UNeMed will evaluate each invention and recommend the next steps within 30 days. Following that, there might be a need for further research, which may take months, or even years, to complete. Some inventions can be immediately marketed to commercial entities or private equity groups, but even then, that process could be as quick as a single email exchange or it could take years of back-and-forth with interested parties. Even when a license agreement is in place, the commercialization process could still take years to complete.

Often, additional development is

TECHNOLOGY TRANSFER OVERVIEW

required to refine an invention into a market-ready product.

Commercialization is most often a slow, methodical process that moves at seemingly glacial speeds. It will require patience and perseverance.

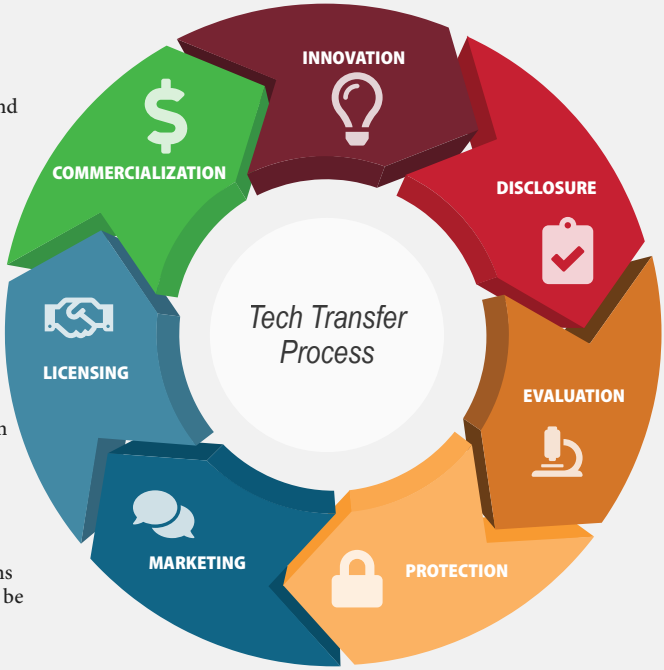
How UNeMed helps inventors

The best time to contact UNeMed is during the earliest stages of innovation. That applies to all potential inventors, whether it's a laboratory researcher planning experiments or a clinician sketching a concept or new device on the back of a napkin. Bringing UNeMed into the process early gives inventors the fullest range of options for the innovation, and the best possible steps for moving forward. UNeMed staff are trained experts, ready to help with questions about marketability, commercial partners, intellectual property, patents, new startups, institutional policies and procedures and much more. When an inventor works with UNeMed, they don't just get a licensing manager: They get all of UNeMed, and the wide range of profound expertise and experience that comes with it.

How inventors help UNeMed

- *When something new is created, discovered or conceptualized, call UNeMed at 402-559-2468.*
- *Submit a completed and signed "New Invention Notification" form before publicly disclosing your invention or submitting a manuscript for review and publication.*
- *To avoid losing patent rights, and possibly harming the opportunity to market an invention, contact UNeMed before any form of public disclosure such as presentations, publishing papers, grant submissions, writing abstracts, or presenting posters, to name a few. Fortunately, simple steps can quickly protect an invention before publishing or presenting.*
- *On the new invention notification form, include companies and contacts that might be interested in licensing. Such information will help UNeMed develop new leads, and perhaps create relationships that will prove fruitful for years to come.*
- *Respond to requests from UNeMed and outside patent counsel.*
- *Keep UNeMed informed of upcoming publications and interactions with companies.*

TECHNOLOGY TRANSFER PROCESS



INNOVATION:
An invention is any new and useful process, machine, composition of matter, or any improvement of those things. Contact UNeMed in the earliest stages of development for guidance on all phases of the process.

DISCLOSURE:
The process formally begins with the submission of a written New Invention Notification form, or NIN for short. The New Invention Notification paperwork is strictly confidential, and should fully document the invention so that all options for commercialization can be evaluated.

EVALUATION:
UNeMed reviews the technology as disclosed in the New Invention Notification, and searches publication and patent databases for similar innovations. UNeMed also analyzes potential markets and competitive technologies to determine commercialization possibilities.

PROTECTION:
When appropriate, UNeMed will protect inventions by filing applications for United States and foreign patents. Other protection methods include copyright, trademark, trade secrets and contractual use restrictions. Once basic protections are in place, UNeMed can begin marketing the technology to potential commercial partners.

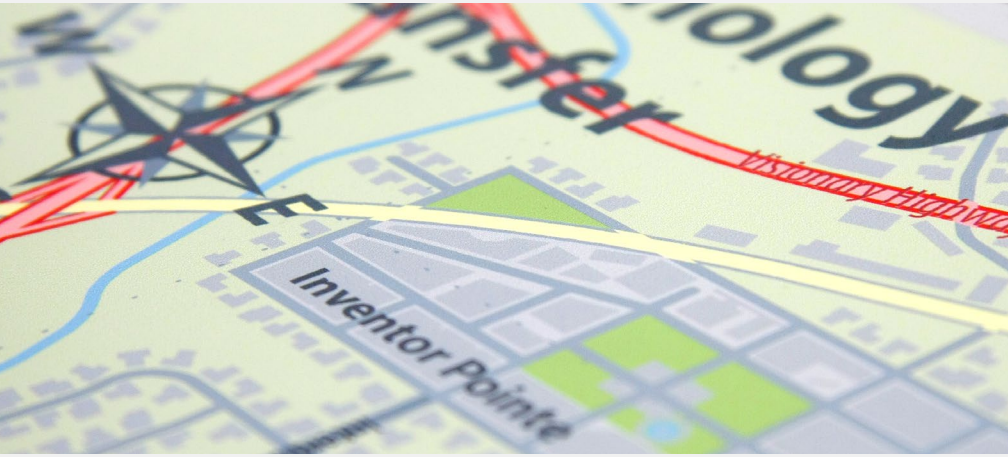
MARKETING:
UNeMed staff identify potential commercial partners who have the necessary expertise, resources and business networks to bring the technology to market. This may involve an existing company or forming a startup. UNeMed works with potential licensees to fully commercialize the technology.

LICENSING:
A license agreement is a contract in which UNeMed grants limited rights to a technology without giving up ownership. Most often those rights allow a licensee to use their resources to further develop a technology. An "option agreement" is sometimes used to enable a third party to evaluate a technology for a limited time before committing to a licensing contract.

COMMERCIALIZATION:
The licensee advances a technology, and makes it publicly available on the open market. This final step may require regulatory approval, sales and marketing support, training, product testing, and other activities appropriate to the technology and its market. A portion of any revenue is then distributed to inventors in accordance to institutional policy. The remainder of any revenue feeds additional research and more innovation.

TECHNOLOGY TRANSFER PROCESS

INNOVATION



What is an invention?

An invention is any new and useful process, machine, composition of matter, or any improvement of those things. Typical inventions include therapeutics, diagnostics, drug delivery platforms, medical devices, research tools, educational materials, apps and software. Inventions also include new uses of existing products and devices.

Inventions are important, but not everything important is an invention. What sets apart an invention from an idea is that an invention:

1. *Is different from what's already out there*
2. *Has product value*
3. *Has a good intellectual property position*
4. *Has good commercial potential*

When research becomes an invention

One good indicator that research qualifies as an invention is when a finding or development appears to solve a significant problem. Or, perhaps the research reveals something totally new and not yet published in any literature. When in doubt, contact UNeMed to discuss the invention and strategies for commercialization.

TECHNOLOGY TRANSFER PROCESS: **INNOVATION**

Research tools

Any new research tool that could benefit others is definitely worth pursuing as a new invention. Typically, research tools are materials such as antibodies, vectors, plasmids, cell lines, mice, and other biological materials used in the research process. Most research tools do not necessarily need patents to be licensed to commercial third parties and generate revenue. UNeMed commonly works with inventors to develop appropriate protection, licensing, and distribution strategies for research tools that have commercial or scientific value.

Student inventors

The University of Nebraska promotes student entrepreneurism, and students can be named as inventors under the Board of Regents' policies. The Board of Regents' policies indicate that student inventors are subject to the same rules and receive the same benefits as University employee inventors. The University does draw a distinction between graduate and undergraduate students, and under what function the students are performing the work. UNeMed would be happy to help student inventors navigate these gray areas.

TECHNOLOGY TRANSFER PROCESS

DISCLOSURE

New Invention Notifications

A New Invention Notification, or NIN, is a written description of an invention. NINs create a written, dated record of an invention, and provides information from which the patent and commercial potential can be evaluated. NINs also ensure compliance with U.S. federal laws, University policy and the policies of several research-funding agencies.

The New Invention Notification should list all collaborating sources of support, and include the information necessary to pursue protection, marketing and commercialization activities.

UNeMed uses the new invention disclosure to generate a non-confidential description to assist marketing efforts. More detailed exchanges of information are possible once potential partners have been identified, and basic protections are in place.

Submitting a new invention

Download the New Invention Notification form and simple instructions at https://www.unemed.com/services/inventions. Submit completed notification of new invention forms directly to UNeMed.

Contact UNeMed with any questions.

TECHNOLOGY TRANSFER PROCESS: **DISCLOSURE**

When to submit a NIN

Submit ideas to UNeMed well before publicly disclosing the discovery or idea through publications, poster sessions, conferences, press releases, grant applications, dissertation defenses, seminars or other communications. We cannot stress enough that inventions must be safely and confidentially disclosed to UNeMed before any public disclosure.

Be sure to inform UNeMed of any previous or planned presentations, lectures, posters, abstracts, website descriptions, research proposals, theses, publications, or other public disclosures that mention or in some way describe the invention.

A public disclosure results in the loss of foreign patent rights, and leaves one year (from the date of the public disclosure) to secure U.S. patent rights. Loss of foreign patent rights can decrease the value and overall appeal of a technology.

Working with UNeMed—early and often—is the easiest way to protect the rights of both the inventor AND the University.

If a researcher believes their work may contain patentable subject-matter, they should contact UNeMed. Inventors should submit a new invention notification as soon as they have something unique.

Why? Three good reasons

There are at least three good reasons to submit a new invention notification.

First, it is likely a condition of University employment to report inventions and new discoveries that are related to the work or that were developed with University or hospital resources.

Second, reporting new inventions is a requirement for federally funded research. Failure to report a new invention puts future federal funding at serious risk.

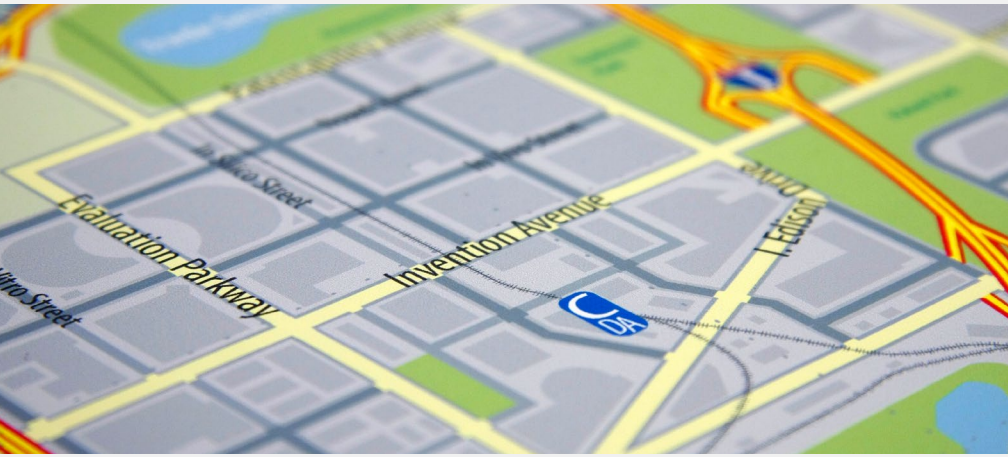
Finally, disclosure starts a process that brings to bear UNeMed's full toolkit of options and resources, giving the innovation its best chance to reach the market where it can actually help people.

Listing co-inventors from other institutions

All contributors to the ideas leading to an invention should be mentioned in the disclosure, even if they are not University of Nebraska employees. UNeMed, along with legal counsel, will determine the rights of such persons and institutions.
It is prudent to discuss with UNeMed all working relationships (preferably before they begin) to understand the implications for any subsequent inventions.

TECHNOLOGY TRANSFER PROCESS

EVALUATION



After submitting a NIN...

A member of UNeMed's licensing team examines each submission to review an invention for its novelty, protectability, marketability, market size and growth potential, resources required for further development, and potential competition from other products or technologies. This assessment may also examine whether the technology has potential as the foundation of a new startup company.

UNeMed does not evaluate the scientific merits or rigor of an invention. However, in the course of the evaluation process, UNeMed staff may learn things that could help inform researchers and inventors as they continue their work.

Once an invention's licensing manager completes their initial review of the invention, it is presented to UNeMed's Science and Technology Advisory Committee. The outcome depends on the marketability and patentability of the invention.

TECHNOLOGY TRANSFER PROCESS: **EVALUATION**

UNeMed may choose to immediately protect the invention, or request additional research to further strengthen an invention. Or, UNeMed may find that someone else has already patented the idea or discovery. In that case, UNeMed might be able to suggest a new line of approach for a different or related project where an inventor can break new ground.

More specifically, possible outcomes of the evaluation process usually include one of the following:

More research needed: When an invention needs further refining or development before it can be protected or marketed.

Protect and market: When an invention appears to have a solid market, a clear patent position and supporting data, it is ready for an active marketing campaign seeking commercial partners and investment,

Close: For any number of reasons, UNeMed may recommend closing or abandoning an invention. Common reasons for closing an invention include lack of patentability and little or no market potential. Recommendations like this can be disappointing, or even painful. In our experience this kind of negative feedback more often provides an inventor or researcher a new path of discovery that can lead to more successful routes of innovation with even more potential to help people.

The licensing manager assigned to the technology will meet with the inventor to discuss the evaluation and the committee's recommendation, and determine how to best most forward.

Unprotected inventions

If UNeMed decides not to pursue patent protection or chooses not to actively market an invention, the inventors may request a license from UNeMed to protect and commercialize the invention themselves. Such a license would be limited to the current invention and not future improvements.

TECHNOLOGY TRANSFER PROCESS

PROTECTION

Intellectual property

Once a decision is made to move forward with an invention, UNeMed may seek intellectual property protection, which might include patents, trademarks or copyrights, to name a few.

UNeMed most often protects University inventions with patents for things like devices, compounds or drug formulations. The life-span of a patent is about 20 years, and allows UNeMed to seek industrial partners who can fund the development of the invention into a product.

Expressions of creative works are protected by copyrights. Common examples of copyrights include books, music, movies, photos and artworks. Most copyrighted works at UNeMed are things like software applications or educational materials.

TECHNOLOGY TRANSFER PROCESS: **PROTECTION**

Ownership

Ownership depends upon the employment status of the inventors and their use of facilities. As a general rule, the Board of Regents owns inventions made by University of Nebraska employees who are acting within the scope of their employment or using University resources. In some cases, the terms of a sponsored research agreement or material transfer agreement may impact ownership. When in doubt, it is best to call UNeMed for guidance.

Inventions resulting from consulting work

The University encourages researchers to engage in external professional activities in order to broaden experience, increase exposure to new research, and develop strategic relationships. Policies establish the parameters and procedures for engaging in such consulting work, and for new inventions a researcher's obligations to the University must be the superior right in any consulting agreement. As an employee of the University, the researcher has a first obligation to the University to assign rights to any patentable inventions that result from the performance of duties within the scope of University employment or resulting from the use of University resources. Such inventions "shall be solely owned by the University" per Board of Regents Policy 4.4.2 (See page 59). Therefore, researchers must pay special attention when signing consulting agreements that they do not assign rights to any inventions that Policy 4.4.2 covers. If the innovation was performed outside the scope of employment duties and not using University resources, then the University does not own the invention and it could be assigned.

A researcher engaging a consulting opportunity is acting independent of the University. Therefore, UNeMed and University attorneys are unable to offer legal advice to the researcher. However, they could review a consulting agreement and warn if any provisions appear to potentially impinge the rights of the University. Plus, they have seen many agreements and can generally educate a researcher on common contract issues.

Authors vs. inventors

There is a profound difference between the legal definition of an inventor and who may be listed as an author on something like an academic paper. Under U.S. law, an inventor is a person who takes part in the conception of the ideas set forth in the claims section of a patent application.

To be listed as an inventor on a patent, the individual must have contributed something in the way of an idea, concept or feature

TECHNOLOGY TRANSFER PROCESS: **PROTECTION**

on the invention. Even if a friend, colleague or associate contributed large amounts of time and energy in support of the work, if they didn't conceive of the idea or contribute some small intellectual part of it, then they cannot be listed as an inventor.

No matter the size of the intellectual contribution, all contributions are viewed as equal in the eyes of the U.S. Patent and Trademark Office. There is no special importance attached to who is listed first or last.

In contrast, authorship carries a much lower standard, and a co-author credit might be afforded anyone who contributed in any capacity to a paper's creation. In a similar fashion, an employer or person who only furnishes money to build or practice an invention is not an inventor. Inventorship is a legal issue and may require an intricate legal determination by the patent attorney who prosecutes the application.

No detail is too small when determining who should—or should not—be listed among a patent's inventors. An error at this stage can later invalidate an issued patent.

UNeMed exerts a lot of time and energy to ensure this doesn't happen, but if it's determined that an inventor should be added to a non-provisional patent application, that person may be added at the time the provisional application is converted into a non-provisional application. If an inventor is identified after filing the non-provisional application, we can petition a change be made in inventorship but the process is costly.

TECHNOLOGY TRANSFER PROCESS: **PROTECTION**

Patents

A patent gives an invention its best chance to reach the most people. That might sound counterintuitive because a patent is, in essence, a legal monopoly to restrict others. A United States patent gives the holder the right to exclude others from making, using, selling, offering to sell, and importing the patented invention. A patent does not necessarily provide the holder any affirmative right to practice an invention.

The founders built the patent system into the U.S. Constitution for good reasons, not the least of which is allowing an inventor enough opportunity to recover costs, and perhaps even profit from the fruits of their labor and ingenuity. After about 20 years, a patent's legal protection goes away. The invention—requisitely described in mundane detail in the publicly accessible patent—becomes the property of anyone who has the means or inclination to build it.

Even if imperfect, it's a clever system that all at once protects, encourages and disseminates innovation.

The notion of ownership in academic biomedical research is a thorny one. Presumably, most researchers pursue future cures, treatments and medical devices for nothing less than noble purposes. They want to help those who need it most. They want to cure the incurable. They want to demystify the unknown.

A patent, it would seem, flies in the face of those noble aims. Biomedical discovery and innovations should be shared with the world, should they not? Yes, in a perfect world.

But in our less-than-perfect world, it can take more than a billion dollars to develop a new discovery into a new treatment. That development only happens if the technology is properly protected, giving the developer the opportunity to at least recover such significant expenses.

What that usually means for UNeMed and its inventors is finding an industrial partner who can pay for the needed development in exchange for certain rights to use the patented invention. Without a patent, it's exceedingly rare to see a novel technology go much further than the pages of an academic journal. The patent, however, encourages industrial partnerships that finance additional development and discovery.

Patentable subject matter

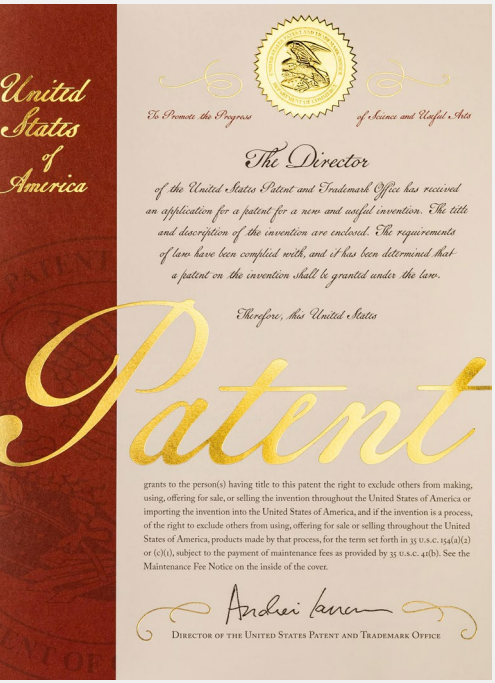
At the earliest stages, UNeMed must determine if a new technology meets the United States Patent and Trademark Office's criteria for a patent. It must also be noted that patentability has nothing to do with the scientific value of any invention. An invention

TECHNOLOGY TRANSFER PROCESS: **PROTECTION**

may still represent a significant contribution to science, even if the invention does not meet established patent criteria.

Patentable subject matter includes processes, machines, compositions of matter, articles, some computer programs, and methods. Methods can include methods for making compositions, methods for making articles, and even methods for performing business.

Naturally occurring substances—such as DNA sequences—are not patentable, unless some underlying utility has also been discovered. For example, an inventor may be unable to patent a piece of genetic code, but an inventor can patent a way to use that strip of DNA for some previously unknown purpose. A variation of a naturally occurring substance may be patentable, however, if an inventor can demonstrate substantial and "non-obvious" modifications that offer advantages over the original substance.



Determining the criteria for patentability can be accomplished by asking three questions:

1. *Is it new?*
2. *Is it useful?*
3. *Is it non-obvious?*

A new, or novel, invention must be different in some way from all other ideas that have already been publicly disclosed in any form. The invention must perform a useful function and somehow benefit society. And the invention can't be merely an obvious improvement to an existing technology in the eyes of those knowledgeable in the area.

Though these may seem like simple questions, they are serious and require extensive research. A lack of thoroughness at this point could amount to a costly mistake. If the USPTO rejects a patent application because it did not meet one or more of those three criteria, UNeMed will have squandered somewhere between $12,000 and $22,000.

TECHNOLOGY TRANSFER PROCESS: **PROTECTION**

Publications greatly impact the novelty and non-obviousness factors of patentability. It may be impossible to patent an invention if different publications so much as mention each of the separate elements of an invention. It doesn't matter if the mention appeared in the most widely read journals or the most obscure of niche publications.

Even an earlier public disclosure from the inventor can prohibit a patent. U.S. law allows for patenting an invention up to one year after disclosure, but nearly all foreign countries prohibit patenting once a public disclosure has occurred. Losing the ability to protect an invention overseas can make an invention less attractive to potential industrial partners.

Patent applications

UNeMed uses expert patent attorneys in diverse technology areas to help draft and prosecute patent applications. Inventors work with the patent attorneys to draft patent applications and respond to U.S. and international patent offices.

Patent process

The process for securing a United States patent is long and winding, and not without its fair share of nuance and complications. Start to finish, it can take anywhere from three to seven years. After a patent application has been filed, it might be 2-4 years before the USPTO reviews the application. It will take another 1-3 years of back-and-forth with the USPTO before a patent will be issued.

Once issued, a U.S. utility patent expires 20 years after its earliest, non-provisional priority date, but there are extensions available to offset any USPTO delays. However, the patent holder must pay maintenance fees, 3.5, 7.5 and 11.5 years after the patent issues to keep the patent alive for its full term.

Here is a more detailed, although dramatically simplified version of the process:

First, patent attorneys—usually with advanced degrees and expertise in at least one scientific field—are best suited to draft most patent applications. Inventors are asked to review patent applications before they are filed. At the time an application is filed, inventors sign documents that officially declare themselves inventors and assigns the application to the University.

Two or three years later, the USPTO will accept or reject the application in writing. The patent office usually rejects applications for two common reasons: Either certain formalities need to be cleared up, or "prior art" invalidates the listed claims. Prior art

TECHNOLOGY TRANSFER PROCESS: **PROTECTION**

could include previous patent applications, older patents, or any other published material that has been publicly disclosed.

The communication sent by the patent office is referred to as an "office action." If the application is rejected, the patent attorney must file a written response, usually within three to six months. The attorney may amend the claims or dispute the patent office's position. This procedure is referred to as "patent prosecution." Often, it will take at least two office actions before the application is resolved.

During this process, input from the inventor is crucial to confirm technical aspects of the invention. Patent prosecution ends when the patent office notifies UNeMed that the application is allowable or when it becomes clear that the patent office will not allow any subject matter.

When the claims are allowed, the patent can be issued. But, it is also possible to reject the patent office's allowed claims, and restart the entire process.

Patent timeline

Currently, the average U.S. utility patent application receives its first office action two or three years after filing, and then undergoes patent prosecution for another two to three years. Once a patent has issued, and all USPTO mandated maintenance fees are paid, a patent is enforceable for 20 years from its earliest filing date.

Provisional patent applications

In certain circumstances, U.S. provisional patent applications can preserve patent rights while temporarily reducing costs, and perhaps provide extra time to prepare a regular application. Provisional patent applications are less costly, but they only have a one-year lifespan and are never prosecuted or issued as full patents. Provisional applications do not need to include claims and are not examined during the year in which it is pending.

They essentially act as a protective placeholder while notifying the patent office of an invention. The provisional application also allows inventors more time to gather important data, if needed, and build a more robust patent application. The protection a provisional provides also allows UNeMed to open discussions with potential partners without risking an invention's patentability. These early discussions play a crucial role in gaining a better understanding on the marketability and patentability of a new invention.

A regular U.S. application—and related foreign applications—must be filed within one year of the provisional application to receive its early filing date. However, an applicant only

TECHNOLOGY TRANSFER PROCESS: **PROTECTION**

receives the benefit of the earlier filing date for material that is adequately described and enabled in the provisional application. As a result, the patent attorney will need the inventor's assistance when an application is filed as a provisional.

Foreign patents

Patents are territorial, meaning a U.S. patent only provides rights in the U.S. and a Chinese patent only provides rights in China. Foreign patent protection is subject to the laws of each individual country, although the process works much the same as it does in the United States. For world-wide patent coverage, one would have to secure a patent in every country in the world.

An international agreement known as the Patent Cooperation Treaty, or PCT, provides a streamlined filing procedure for most industrialized nations. For U.S. applicants, a PCT application is generally filed one year after the corresponding U.S. application has been submitted. The PCT application must be filed in the patent office of any country in which the applicant wishes to seek patent protection, and it must be filed within 30 months of the earliest claimed filing date.

The biggest difference in foreign countries is an inventor immediately loses patent rights

TECHNOLOGY TRANSFER PROCESS: **PROTECTION**

when they publicly disclose an invention anywhere in the world before filing a patent application. In stark contrast, the United States grants a one year grace period for inventors who publicly disclose their inventions before filing for a U.S. patent.

The cost of patents

Filing a regular U.S. patent application may cost between $8,000 and $18,000, plus an additional $12,000 to $20,000 in patent prosecution. Filing and obtaining issued patents in other countries could cost $25,000 or more per country. Also, periodic maintenance fees are often required to keep the patent alive.

Copyrights

Copyright is a form of protection provided to the creators of "original works of authorship." This includes literary, dramatic, musical, artistic, and certain other intellectual works, as well as computer software. This protection is available to both published and unpublished works. The Copyright Act generally gives the owner of a copyright the exclusive right to conduct and authorize various acts, including reproduction, public performance, and making derivative works. Copyright protection is automatically secured when a work is fixed into a tangible medium such as a book, software code, video, etc. In some instances, UNeMed registers copyrights, but generally not until a commercial product is ready for manufacture.

Derivative works

A derivative work is a work based upon one or more preexisting works, such as a translation, musical arrangement, dramatization, fictionalization, motion picture version, sound recording, art reproduction, abridgement, condensation, or any other form in which a work may be recast, transformed or adapted. A work consisting of editorial revisions,

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TECHNOLOGY TRANSFER PROCESS: **PROTECTION**

annotations, elaborations, or other modifications, which, as a whole, represent an original work of authorship, is a derivative work. The owner of a copyright generally has the exclusive right to create derivative works.

Trademarks and service marks

A trademark includes any work, name, symbol, device, or combination that is used in commerce to identify and distinguish the goods of one manufacturer or seller from those manufactured or sold by others. In short, a trademark is a brand name.

A service mark is any work, name, symbol, device, or combination that is used, or intended to be used, in commerce to identify and distinguish the services of one provider from those of others, and to indicate the source of the service.

It is not necessary to register a trademark or service mark with the United States Patent and Trademark Office. Trademarks generally become protected as soon as they are adopted by an organization and used in commerce, even before registration. With a federal trademark registration, the registrant is presumed to be entitled to use the trademark throughout the United States for the goods or services for which the trademark is registered. State trademark registration is also available in Nebraska.

Trade secrets

Trade secrets are confidential strategies or information that give their users a competitive advantage. The best examples of trade secrets are the recipes for Coca-Cola and Kentucky

An example of trade secret protection for a UNMC innovation is NeuroFreeze, a proprietary blend of four components that enable researchers to freeze brain cells with a remarkable 90 percent viability.

TECHNOLOGY TRANSFER PROCESS: **PROTECTION**

Fried Chicken. Trade secrets have limited legal protection. The best protection for a trade secret is limiting the number of people who can access the information while installing security measures and using confidentiality agreements.

What UNeMed protects, what it doesn't

Inventions at UNeMed are almost always early-stage innovations, the development of which require significant investments in time and money. The only way a commercial partner can recover that investment is with clear intellectual property protection in place. An invention that cannot be protected, often cannot be marketed or developed successfully. UNeMed prefers to include the high cost of patent fees into license agreements as a part of the investment contribution corporate partners make in developing a technology.

The decision on which inventions receive intellectual property protection is not taken lightly. Significant factors include the recommendation from UNeMed's Science and Technology Advisory Committee, and feedback from industrial and commercial contacts.

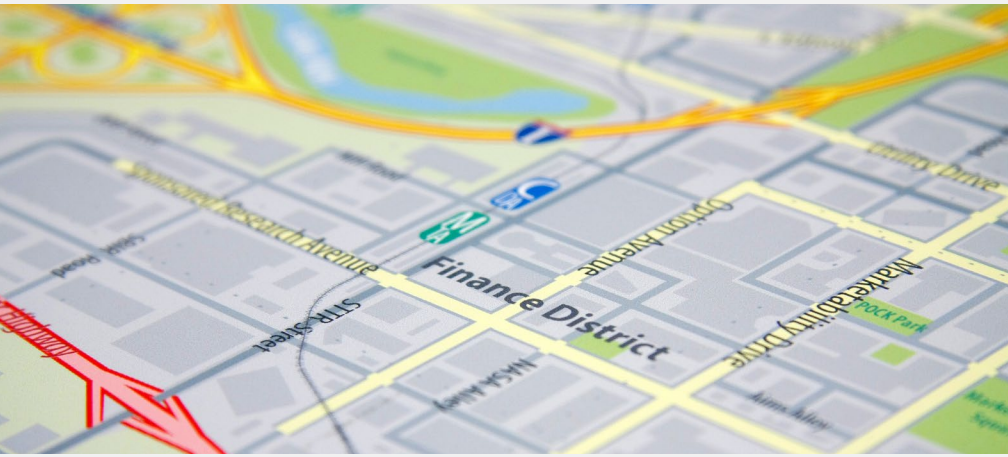
Often UNeMed accepts the risk of filing a patent application before a licensee has been identified. But eventually UNeMed must decline further patent prosecution if a commercial partner cannot be found after a reasonable amount of time.

University of Nebraska policy

The Board of Regents' Bylaw 3.10 and Policies 4.4.1 and 4.4.2 address the University of Nebraska's policies regarding intellectual property ownership and technology transfer. These regulations are available in the appendix on page 50 or online at http://nebraska.edu/regents/bylaws-policies-and-rules.

TECHNOLOGY TRANSFER PROCESS

MARKETING



Marketing an invention

UNeMed employs several strategies to identify potential commercial partners and licensees. Sometimes existing relationships of the inventors, UNeMed staff, and other researchers are useful in marketing an invention. UNeMed conducts extensive market research to identify prospective licensees. UNeMed also examines complementary technologies and agreements for more leads. UNeMed also uses its website to promote inventions, host conferences and industry events and makes direct contacts. Faculty publications and presentations, news reports, social media campaigns are often excellent marketing tools as well.

How inventors can help

Once patent protection has been sought, inventors can publish as many papers and give as many presentations describing the invention as possible. Inventors are also encouraged to talk with their licensing manager about the invention and any consulting relationships they might have.

These relationships are often helpful in identifying potential licensees and

TECHNOLOGY TRANSFER PROCESS: **MARKETING**

technology champions within companies. The most successful technology transfer results are obtained when the inventor and the licensing manager work together to market and sell a technology.

Finally, and perhaps most importantly, inventors give themselves the best chance just by being accessible and responsive.

Finding a licensee

It can take months and sometimes years of marketing to locate a potential licensee. Success depends on the attractiveness of the invention, its stage of development, competing technologies, and the size and intensity of the market. Most inventions tend to be in the early stages of the development cycle and thus require substantial investment, making it more difficult to attract a licensee.

Selecting a licensee

A licensee is selected on their ability to commercialize the technology for the benefit of the general public. Sometimes an established company with experience in similar technologies and markets is the best choice. In other cases, forming a startup company may be the better option.

Sharing data

It's common for inventors to express discomfort about sharing the technical details of a new invention with third parties. It is an understandable concern that a commercial enterprise might steal a proposed invention rather than enter a license agreement.

The truth: It is exceedingly rare for a potential licensee to simply steal an invention. But it's not unheard of, and that's why UNeMed takes every reasonable precaution to protect inventions before sharing details with anyone. The most common precautionary step UNeMed takes is some form of intellectual property protection, such as a patent applications and confidential disclosure agreements.

The technology manager will prepare non-confidential material that will be distributed to targeted industry personnel. Technical and confidential details of the invention will only be disclosed to a potential partner under a confidential disclosure agreement. Also known as a non-disclosure agreement (see page 31), such arrangements allow UNeMed to seek potential development partners while protecting an invention's ownership.

TECHNOLOGY TRANSFER PROCESS

LICENSING

License agreements

If a company remains interested in developing and commercializing an invention, the technology's licensing manager will negotiate terms. A licensing agreement is a contract obligating the licensee to help develop the technology and ultimately bring it to market.

License agreements describe the rights and responsibilities related to the use and exploitation of an inventor's intellectual property. UNeMed's license agreements usually stipulate that the licensee should diligently seek to bring the intellectual property into commercial use for the public good and provide a reasonable return.

Typically, UNeMed also requires that the licensee make financial payments, and meet certain performance goals for developing an invention. The licensee is most often an established company, but it's not uncommon to license a technology to a new startup, which are sometimes founded by the inventors themselves. Any revenue from licensing agreements are shared with the inventors and other stakeholders, in accordance with institutional policy.

TECHNOLOGY TRANSFER PROCESS: **LICENSING**

Option license
A company might initially prefer a lower risk, option agreement. Option agreements allow commerical partners an extra amount of time to further evaluate the technology for a limited period of exclusivity. The terms of an option agreement are most commonly about six months long.

Multiple licensees
An invention can be licensed to multiple licensees, either non-exclusively to several companies; or exclusively to several companies, each for a unique field-of-use (application) or geography.

Inventors benefit from licenses
For UNMC inventors, one third of the net proceeds from a license are divided among inventors. For more information, review the Board of Regents policy 4.4.2 in the appendix on page 59 or online at http://nebraska.edu/regents/bylaws-policies-and-rules.

UNMC Policy 7001 for Royalty and Equity Distribution can also be found in the appendix on page 62 or online at https://wiki.unmc.edu/index.php/Royalty/Equity_Distribution.

Specific policies for the University of Nebraska at Omaha were not available at time of publication.

Potential financial rewards aside, most inventors enjoy the satisfaction of knowing their inventions are being developed for the benefit of the general public. New and enhanced relationships with businesses are another outcome that can augment one's professional life. In some cases, additional sponsored research may result.

One example of a licensed UNMC invention is the LeVeen Electrode Needle. Initially licensed in 1995 to RadioTherapeutics for further development, the device used radio frequencies to destroy tumors with greater precision. RadioTherapeutics was eventually acquired by Boston Scientific, and the LeVeen Electrode Needle went on to become the most widely used tumor ablation tool in the United States.

TECHNOLOGY TRANSFER PROCESS: **LICENSING**

Inventor-licensee relationships
In the early stages of development, many licensees require an inventor's active assistance to facilitate commercialization efforts. The type of arrangement can vary from infrequent, informal contacts to a more formal consulting relationship. Working with a new startup can require substantially more time, depending on the inventor's role.

UNeMed license agreements generally include:

Development plan—Milestones for commercialization, in accordance with a developmental and commercialization plan, are required at the time of license execution. Milestones may include regulatory filings, initiation and completion of clinical studies, or achievement of other research and development goals. The licensee must also submit annual development reports throughout the term of the license agreement. Development reports ensure that the licensee is actively developing the technology, which is also a requirement for licensing federally-funded research.

Financial obligations—May include up-front license fees, equity (in the case of a startup), milestone payments, royalty payments, minimum royalties, and maintenance fees. These fees will be determined based on the licensed technology. The licensee will be responsible for paying patent expenses, incurred and future.

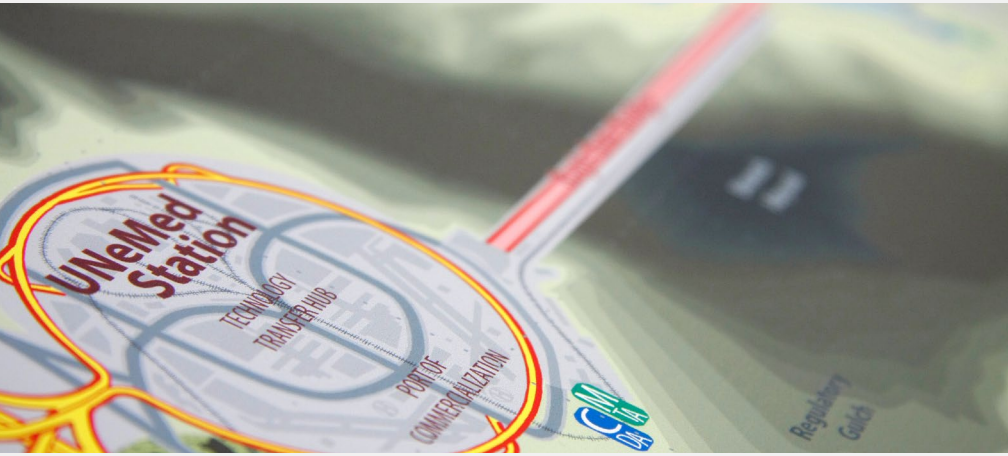
Earned royalties—Licensee pays a percentage of net sales to UNeMed.

Milestone fees—In addition to royalties, milestone payments may be required as the technology is successfully developed.

Minimum royalty—In royalty-bearing licenses, UNeMed might require payment of a certain minimum dollar amount, which generally reflects the minimum amount of expected sales.

TECHNOLOGY TRANSFER PROCESS

COMMERCIALIZATION



The commercialization process

Most licensees continue developing an invention after signing a license to enhance the technology, reduce risk, improve reliability, meet regulatory requirements, and satisfy the market. This can involve additional testing, prototyping, and further development to improve performance and other characteristics.

Inventor's role

The inventor's role varies, depending on their interest and involvement. The role also depends on the licensee's interest level in involving the inventor, and any contractual obligations related to the license or any personal agreements.

Commercialization revenues

Licensing fees can be modest or can reach millions of dollars. Royalties on the eventual sales of the licensed products can generate revenues, although this can take years. Equity, if included in a license, can yield returns when a successful equity liquidation event occurs, such as a public equity offering

TECHNOLOGY TRANSFER PROCESS: **COMMERCIALIZATION**

or selling the company. Most licenses do not yield substantial revenues. A recent study of licenses at U.S. universities demonstrated that only 1 percent of all licenses yield more than $1 million in total revenue.

Commercialization can fail at any time, for any reason.

Licenses typically include performance milestones that, if unmet, can result in the termination of the license. This termination allows for subsequent licensing to other businesses.

Failure does not necessarily negate the value of an invention, and might even help increase the odds of later success.

Distributing revenue

UNeMed is responsible for managing the expenses and revenues associated with technology agreements.

All revenue received from a licensed technology follows parameters set by Board of Regents policy 4.4.2.

First, the University is reimbursed for any funding provided to inventors and creators for research and development; or for facilitating commercialization of research, and for all costs associated with protecting, maintaining, defending and commercializing the technology.

UNeMed receives 15 percent to help cover expenses like payroll, equipment other overhead costs.

Also, a fund created with 10 percent of the first $2 million in revenue—20 percent thereafter—will then be divided proportionally among the colleges, institututes, departments and units, in accordance with their contribution to the invention.

Finally, all remaining revenue goes to the UNMC Chancellor's office to support services to faculty in the filing of disclosures, protection of intellectual property and the marketing, licensing and commercialization of technologies. A portion of these funds may be used for grants to develop prototypes and conduct additional research to facilitate commercialization of technologies.

Specific distribution arrangements for UNO were not available at time of publication.

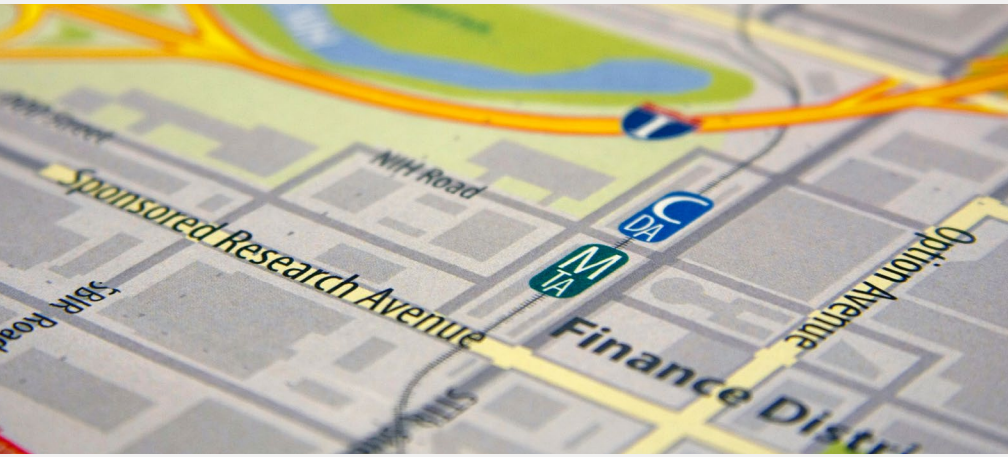
Distributions for multiple inventors

After a license agreement is signed, inventors enter into a royalty sharing agreement, and file the original agreement with UNeMed. Once UNeMed receives net proceeds, UNeMed follows the royalty sharing agreement to distribute the money. If UNeMed does not receive a royalty sharing agreement from the inventors before net proceeds are received, then UNeMed distributes them equally among inventors.

Tax implications

License revenues are typically taxed as income. Inventors should consult a tax adviser for specific guidance.

OTHER AGREEMENTS



Sponsored Research Agreements: *Partners help development*
Sponsored research agreements describe the terms under which sponsors—such as a pharmaceutical firm or a medical device manufacturer—provide support for additional research at the University. Often these type of agreements are in support of an early stage technology that needs additional testing, or to develop a working prototype of a medical device.

The University generally retains ownership of patent rights and other intellectual property resulting from sponsored research. However, the sponsor may have rights to license new intellectual property developed as a result of the sponsored research. Often, sponsored research contracts allow the sponsor a limited time to negotiate a license for any intellectual property that results from the research.

Even so, the sponsor generally will not have contractual rights to discoveries that are clearly outside of the scope of the research. Therefore, it is important to define the scope of work within a research agreement.

Material Transfer Agreements: *Sharing intellectual property & tools*
These agreements describe the terms under which faculty, students and staff at the University of Nebraska may share materials with outside entities, such as research collaborators. Intellectual property rights can be endangered if materials are used without a proper agreement.

OTHER AGREEMENTS

It is important to document carefully the date and conditions of use. These details are necessary to determine if the use influenced the ownership of any subsequent research or innovations. UNeMed can help draft a material transfer agreement to obtain materials from outside collaborators, or to send materials to an external collaborator.

Material transfer agreements attach certain terms to the use of tangible research materials allowing other researchers to use them while protecting rights associated with the materials and retaining the ability to commercialize.

A simple university-university MTA can generally be handled in a day or two. More complex MTAs—which might deal with foreign companies or proprietary materials from industry—can take longer to negotiate.

At UNMC, tangible materials can include molecular biology reagents, cell lines, recombinant mice, devices or even software.

Those interested in transferring materials should contact UNeMed's Contracts Manager at unemed@unmc.edu or (402) 559-2468.

To expedite the process you will need:

1. *Information related to the source of funding.*
2. *Original source of the materials, or any portion of the material.*
3. *A description of the intended research making use of the materials.*
4. *Information on the receiver or sender of the materials.*

Confidential Disclosure Agreements: *An added layer of protection*

Confidential disclosure agreements or nondisclosure agreements further enable discussion of business development opportunities or early-stage scientific collaboration. For protection of patent rights, CDAs are critical because premature public disclosure can limit or even preclude patent rights.

CDAs are used to protect the confidentiality of an invention during evaluation by a potential licensee. UNeMed uses these type of agreements to protect proprietary information shared with someone

OTHER AGREEMENTS

outside of the University of Nebraska system. These type of agreements also protect proprietary information of third parties when, for example, University researchers perform consulting work or sponsored research with a commercial partner or other collaborative entity.

Inter-Institutional Agreements: *Set ground rules for collaborations*
Inter-institutional agreements describe the terms under which two or more institutions will collaborate to assess, protect, market, license, and share in the revenues received from licensing jointly-owned intellectual property.

Option Agreements: *Industrial test drive*
Option agreements, or option clauses within research agreements, describe the conditions under which UNeMed preserves the opportunity for a third party to negotiate a license for intellectual property. Option clauses are often provided in a sponsored research agreement with corporate partners. Option agreements are also entered into with third parties who wish to evaluate a technology before entering a full license agreement.

Royalty Sharing Agreements: *Splitting proceeds*
A royalty sharing agreement is a formal document signed by each inventor of one or more technologies included in a license. The agreement spells out exactly how inventor proceeds from the license will be distributed between the inventors.

Consulting Agreements: *To each their own*
When personnel enter into consulting agreements, they are deemed to be acting outside of the scope of their employment. Therefore, UNeMed does not formally review or negotiate consulting arrangements. Personnel who enter into consulting agreements should familiarize themselves with the appropriate institutional policies related to consulting activities. The employee is expected to ensure that the terms of the consulting arrangement are consistent with policy, including those related to intellectual property ownership and use, and employment responsibilities. UNeMed can, and often does, provide informal advice on how consulting agreements relate to an inventor's intellectual property. Inventors are strongly advised to be careful not to enter into an overly broad agreement that surrenders their intellectual property rights.

OTHER CONSIDERATIONS

Conflict of Interest

A conflict of interest can occur when an employee, through a relationship with an outside organization, is in a position to:

1. *Influence the University's business, research or other areas that may lead to direct or indirect financial gain.*
2. *Adversely impact or influence one's research or teaching responsibilities.*
3. *Provide improper advantage to others, to the disadvantage of the University.*

The specific conflict of interest policy for the University of Nebraska Medical Center is listed on page 67 in the appendix or can be found online at https://wiki.unmc.edu/index.php/Conflict_of_Interest.

Policies specific to the University of Nebraska at Omaha were not available at time of publication.

Guidance

When in doubt, inventors should seek guidance from the Sponsored Programs Administration for research-related issues. For license-related issues contact UNeMed for guidance.

There are two times in particular when guidance is required: When research proposals are submitted to external sponsors; and when a faculty member, or any university employee, has an equity or management interest in a company that is considering entering into a license, option or material transfer agreement with the University.

Issues of concern

The main things reviewers look for when examining potential conflicts of interest are if the work is an appropriate use of research; the treatment and roles of students; the supervision of individuals working at both the University and at the licensee; and the conflict of commitment or the employee's ability to meet University obligations.

OTHER CONSIDERATIONS

Outside employment or Veterans Affairs appointment

Undisputable ownership of the intellectual property rights is an essential requirement for the University to be able to move forward in licensing a technology to a commercial partner.

In essence, before licensing, the intellectual property needs to have a clear title record, in the same way that it is necessary before transfering ownership for a car or home.

The common problem for intellectual property rights is when an inventor has multiple employers, each with a contract or policy dictating it has ownership to the rights of the invention. The result is that two entities own an invention and may have different plans for it. This can be problematic at times, especially if it is not immediately known and disclosed in the NIN. But UNeMed has a solid track record of being able to consolidate the rights for each co-owned invention through inter-institutional agreements. Those agreements clear any title disputes and enable UNeMed to move forward with licensing the invention to commercial partners.

For example, UNMC physicians with appointments with the U.S. Department of Veterans Affairs need to disclose their appointment in any NIN so that UNeMed can work with the VA to account for any rights the VA may have to the invention.

In other situations, an inventor that has entered into a consulting or other contract that may usurp the rights of UNMC, leaving the inventor in breach of the UNMC employment agreement and policies.

International Research

All UNMC research conducted at another site, including in another country, must comply with all applicable federal and state laws and University of Nebraska policies. A questionnaire will help prepare for performing research while abroad or for performing collaborative research with researchers who are in another country. Submit the questionnaire to the Sponsored Programs Administration as part of the planning process.

Important considerations include:

- *Human subjects research must still be performed to the same standards as required at UNMC, including approval by the UNMC IRB committee in addition to the collaborating institution or local review board.*
- *Animal research must be performed in an approved facility and the project approved by the UNMC IACUC as well as by the collaborating institution.*
- *Intellectual property or research that may result in new intellectual property may require a separate New Invention Notification for the country in question.*
- *The Department of Transportation has developed specific rules for the transportation of biological materials, including infectious disease specimens.*
- *The U.S. government has established controls on the export of strategic goods and technologies.*

Additional information for international projects can be found at: *unmc.edu/academicaffairs/compliance/areas/export*

OTHER CONSIDERATIONS

Getting started

An international project questionnaire is available to prepare researchers for international projects and travel. Anyone preparing an international project or grant must complete the questionnaire, which might also be requested for international travel.

The International Projects Questionnaire addresses these areas:

- *General Project Information*
- *Human Subjects*
- *Animal Use*
- *Materials and Equipment*
- *Personnel*
- *Logistics*
- *Travel*
- *Conflict of Interest*
- *Intellectual Property*

Submit completed questionnaires to:

- *SPAdmin with the application, if applying for external funding*
- *Export Control Office, exportcontrol@unmc.edu*

Export Controls

Export controls are U.S. government regulations that govern the export of strategic technologies, equipment, hardware, software, materials, and data, as well as the provision of technical assistance to foreign persons inside or outside the United States. See UNMC export control policy 8005 on page 64.

Export controls apply to, but are not limited to, the following activities:

- *Research activities conducted in the United States involving equipment, materials, or data subject to export controls, including nuclear, biological, or chemical materials, radionuclides, human and animal pathogens, and novel compounds*
- *Research activities conducted outside the United States*
- *Research where the sponsor prohibits or restricts participation by foreign nationals*
- *Research where the sponsor prohibits or restricts publishing the results*
- *Shipping or hand-carrying equipment, materials, software, or data to a foreign country*
- *Electronically transferring data or software to a recipient in a foreign country, or to a foreign national or entity, regardless of location*
- *Travel to an embargoed country for any purpose, including conducting research, attending a conference, or participating in clinical activities.*

OTHER CONSIDERATIONS

- *Plans to discuss unpublished research or other intellectual property with an external sponsor, vendor, collaborator, or other third party under a non-disclosure or other confidentiality agreement.*

Shipping or carrying items abroad for research

Exports of physical items, including by shipping, hand-carrying, or checked luggage, are subject to federal regulations and University of Nebraska policy. A Request for Export Controls Review Application form must be completed prior to shipping or traveling to another country with research items. The form must provide specific information about the items to be exported, the intended recipient and destination, and the intended end-use.

- *An export license may be required depending on the item and destination*
- *Shipping infectious substances that can affect humans or animals (Category A), biological substances (Category B), or exempt human or animal specimens and dry ice also requires a Training and Certification of International Shippers by the Environmental Health & Safety department.*
- *Any exports totaling $2,500 or more must be filed with Customs and Border Protection.*

Contact the Export Control Office prior to international shipping or traveling with research items, for more information or for assistance with export license applications and other required filings.

Required budget authorizations

All sponsored project budgets with international components are to apply the appropriate UNMC federally negotiated F&A rate. Authorizations for contracts unrelated to research

OTHER CONSIDERATIONS

should be submitted to the Associate Vice Chancellor for Business and Finance or the Director of Business Services at 402-559-5200.

International activities unrelated to research may still be subject to export controls. Please contact the Export Control Office with any questions about international activities.

International Travel

All travel outside of the United States for UNMC business, education, or research purposes must be submitted to the Vice Chancellor for Business and Finance for authorization.

International travel will be evaluated by the Compliance Office and/or the Export Control Office. International travelers may be asked to provide additional information regarding the scope of activities while traveling abroad.

Carrying a computer or other devices outside the U.S.

Departmental IT workstation specialists will help determine if any restrictions may prevent bringing an electronic device to a foreign country. They can also help determine how best to access email or other databases off site.

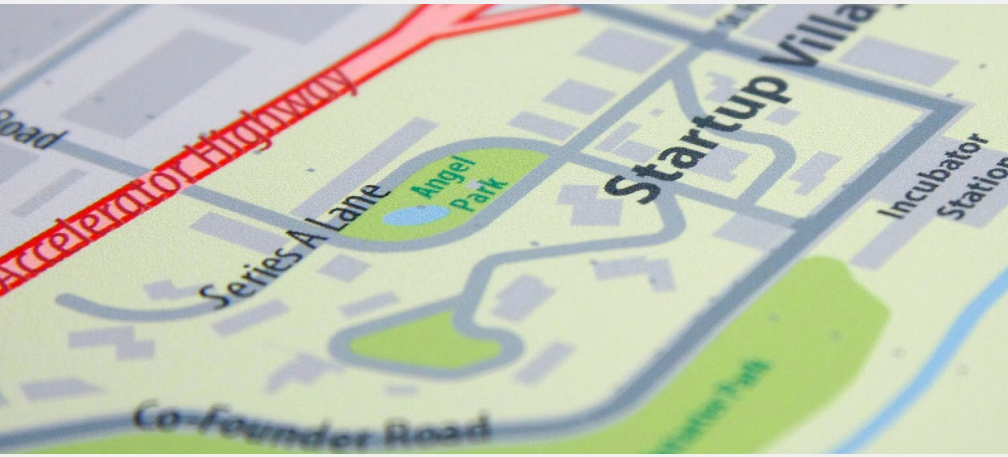
International research programs and resources at UNMC

- *Asia Pacific Rim Development Program, for questions regarding travel to and within China.*
- *Pediatric International Research, for pediatric investigators interested in international research collaborations, Program Coordinator 402-559-8845*
- *International Health and Medical Education, for general information regarding international travel, education, and resources.*
- *Center for Global Health and Development, a College of Public Health resource focused on international public health education, research, and practice.*

Contacts for international research requirements:

- *International Research Projects: SPAdmin, 402-559-7456*
- *Export Controls: Export Control Office, 402-559-4518*

CONSIDERATIONS FOR STARTUPS



It doesn't happen often, but there are certain technologies and inventions where it makes the most sense to start a new company. The reasons for starting a technology-based company are varied and depend on a number of factors that include the particular industrial sector, the stage of research or innovation, and the very nature of the related technology.

Most often, UNeMed helps an inventor build a startup when it appears unlikely that further development is possible with an established company. Potential industrial partners—those with the resources to finance such costly development—hesitate to invest in something surrounded by the level of uncertainty often found with early-stage innovations. But those same industrial partners might be willing to acquire a startup company that has worked out a lot of those questions and "de-risked" the technology.

There are also times when an inventor has the right kind of entrepreneurial spirit that can make a new company work.

In any case, UNeMed will always prefer the route that gives a technology and its inventor their best chance for ultimate success—whether that's negotiating a licensing deal with a large multinational corporation, working out a sponsored research agreement with a small niche-market biotech firm, or launching a new startup.

STARTUPS

A few key factors when considering a startup company:

- ***Development risk:*** *Early-stage technologies are risky and require a significant investment of time and money.*
- ***Development costs versus investment return:*** *Investors do not merely want to break even. Can the invention and its startup company meet those expectations?*
- ***Potential for multiple products or services from the same technology:*** *Few companies survive on one product alone.*
- ***Market position:*** *Would a startup possess a sufficiently large competitive advantage and target market?*
- ***Sustainability:*** *Are potential revenues sufficient to sustain and grow a company?*
- ***Business-sense:*** *It's critically important to have someone run the new company who has startup experience and investor contacts.*

UNeMed staff has significant experience with start-up companies, has deep ties within the local entrepreneurial ecosystem, and would be happy to help inventors evaluate these and other factors.

The inventor's role in a startup

Inventors typically serve as technology consultants, advisers or in some other technical developmental capacity. Rarely do inventors choose to join the startup full-time. In many cases, the inventor's role is suggested by the startup's investors and management team, who identify the inventor's best role based on expertise and interests.

As a company matures, and additional investment is required, an inventor's role may change. At UNMC, faculty involvement of any kind is also reviewed by a UNMC Conflict of Interest Committee (See page 71). Typically, startup companies with the most success are those that bring in or are led by a person with sound business training. Usually, the inventor is best left to focus on developing the technology or serving in a scientific advisory role.

Commitment

Starting a company requires a considerable amount of time, money and effort: More than most realize. It's often been compared to having a child. That level of commitment and resources makes it essential to have in place a management team experienced in business. The inventor will need to champion the formation effort

STARTUPS

until the management team is in place. After the team is in place, effort is required for investor discussions, formal responsibilities in or with the company, and institutional processes such as conflict of interest reviews.

Startup equity as terms
UNeMed can accept equity as part of the financial terms of a license. Equity may be substituted for other considerations that are often difficult for a startup. It is also a way for UNeMed to share some of the risk associated with the startup. UNeMed is always interested in helping a startup succeed, and will take any reasonable measures to help in that end.

Lonely startups
As a separate entity, a startup is expected to pay for its own legal matters, including all business incorporation matters and licensing expenses.

Legal issues
In addition to corporate counsel, the startup may need its own intellectual property counsel to assist with corporate patent strategy, especially if the company will be involved in a patent-rich area. The startup's counsel must be separate from UNeMed's counsel, though it is advisable and recommended that the startup counsel and the UNeMed patent counsel coordinate activities. Also, it is wise for investors' counsel to review agreements regarding roles within the startup to ensure that all personal ramifications—including taxation and liabilities—are clearly understood.

One example of a successful University startup is Virtual Incision, the result of a collaboration between a surgeon and a robotics engineer. Virtual Incision builds small robots (right) in an attempt to redefine minimally invasive surgery.

Photo: Virtual Incision

STARTUPS

So, you want to startup…

University faculty, staff and students thinking of starting a company with their own technology should evaluate whether it makes good business sense. Biotechnology companies typically require years of research and development before generating revenue. The need for capital investment and development financing is a constant pursuit.

To start a company with a University technology, a founder should first be able to answer these questions:

1. *What is the first product, and how much work is needed before it can be sold?*
2. *Who are the customers, and how does the product address their needs?*
3. *What is the product development plan, and how much money will be needed to complete it?*
4. *Will there be a sole founder of the company or will there be others?*
5. *What personnel will help the company overcome obstacles, and how can they be attracted to the company?*
6. *How will the company be funded in the beginning?*
7. *What incentives can be offered to potential investors?*
8. *What obstacles are anticipated, and how will they be overcome?*

Complete a business plan

Inventors who wish to build a startup company with UNeMed's support, will first need to write and submit a full business plan. Then, the inventor can license their technology from UNeMed. (Yes, an inventor will have to sign a licensing agreement, even for a technology they invented because, technically, the invention is actually owned by the Board of Regents of the University of Nebraska.)

There are many online guides on how to write a good business plan, but a founder must make a compelling case for their startup company, not just the research or the innovation. That is an important distinction.

The scientific merits of an invention might be intellectually interesting, but investors want one thing: a return on investment. Experiments must work, the data must be published, and the intellectual property must be protected. But that is still not enough.

Investors fund companies that can demonstrate how good science, published results and strong patents will eventually turn into a massive profit.

Make that case to UNeMed first. UNeMed will help refine

STARTUPS

the message before meeting potential investors. As an aspiring entrepreneur, founders will need to draft a business plan that communicates the financial plans, market opportunity and vision of the company.

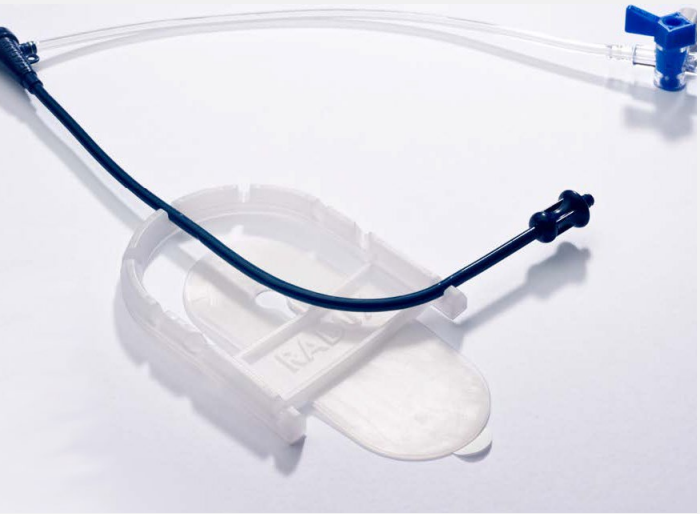
Decisions, decisions

The company needs to be registered and incorporated to become a legal entity. Then a CEO must be selected to run the company. The CEO and founder/inventor will negotiate a license for the technology with UNeMed.

First, hire a lawyer and consult with co-founders about whether it's a good idea to create a new company. Review with them the business plan, and discuss options and best ways to set up a new business. There are a variety of legal structures for businesses: partnerships, corporations and limited liability companies. UNeMed can help explain those options, and what might be best. But the final decision is between the inventor/founder, any co-founders, investors and the startup's lawyers.

Second, who makes the ultimate decisions about the company? It doesn't matter if it's a shareholder agreement, a management agreement or even a handshake with a co-founder. In any case, UNeMed will need to know how the company is going to make decisions and what rules will govern disputes.

A CEO will need to be selected to run the company. The CEO should be someone other than the inventor. Researchers are great at what they do and while some may be good with business, the job of a CEO includes things that



Radux is another example of a successful University of Nebraska startup. Radux is built on the "Stand Tall" device (left), which is a disposable mounting bracket that allows interventional radiologists to work more safely and comfortably in flouroscopic and radiological procedures.

Photo: Radux

STARTUPS

can't be delegated. The CEO is responsible for setting the company strategy and direction, modeling and creating the company's culture, building and leading the executive team, as well as raising and allocating company funds. A well-seasoned CEO is the best bet for commercial success.

Third, is there intellectual property? The University will treat an inventor like any other company that licenses its intellectual property, even its own inventors. The newly-formed company will need to pay royalties for future products, commit to a developmental plan, reimburse the University for intellectual property costs, and pay additional costs of renewing or continuing that protection.

Fourth, know there are options when licensing a technology from UNeMed. Perhaps the company would like to raise a small amount of capital to determine the technology's feasibility. Before signing a license agreement, the company may be able to negotiate a short-term option agreement that allows the company to further evaluate the technology and begin fundraising.

Mentoring

Once a license is executed, the company will have an ongoing relationship with UNeMed for support and assurance that contractual obligations and milestones are met.

UNeMed can provide guidance for registering for federal grant programs and several state-level grant programs that might help the company get started.

UNeMed's recent successes in startup formation can be partially attributed to a more concentrated effort in the area, but Nebraska has also become a more fertile entrepreneurial environment in recent years. Government incentives, local directives and several mentoring and funding programs all helped cultivate the burgeoning startup scene in Omaha and surrounding areas.

UNeMed plays an active role in this ecosystem, participating in local entrepreneurial organizations such as UNeTech, The Startup Collaborative, Pipeline, StraightShot and NMotion. We can serve as a concierge to make the introductions and help any entrepreneurial inventor make the most of that ecosystem.

Always remember: UNeMed has been a party to more than 60 startups over the years, and UNeMed wants each and every one of them to succeed. UNeMed has a vested interest—in time, treasure and a desire to bring biomedical innovation to market—in helping a new University-based startup achieve its goals. UNeMed will be an inventor-founder's greatest asset and ally.

STARTUPS—RESOURCES

UNIVERSITY RESOURCES—OMAHA

The Attic *(UNO College of Information Science & Technology: Center for Management of Information Technology)*

1110 S. 67th Street, PKI 172
Omaha, NE 68182
(402) 554-2029
khazanchi@unomaha.edu

Undergraduate and graduate students interested in web and mobile software development help create technology solutions for university and community partners. Students are mentored by IS&T full time staff members, transferring the skills they learn in the classroom to real world problems.

Projects often include mobile development, web development, game development, graphic design and animation.

Leon S. McGoogan Health Sciences Library (UNMC), Jim and Karen Linder Maker Studio

askus@unmc.edu
402-559-6221

For UNMC students, faculty, and staff to experiment, build, prototype, and be creative. The space is outfitted with technology and a layout that facilitates collaboration and hands-on learning. Maker studio users will have access to 3D printers, a 3D scanner, specialty cameras, a media preservation station, and other technology and materials.

Machining and Prototyping Core Facility (UNO College of Education, Health, and Human Sciences: Biomechanics)

Biomechanics Research Building
6160 University Drive South
Omaha, NE 68182
402.554.3228
bmchmpcore@unomaha.edu

Provides expert machining, electronic and additive manufacturing services for the University of Nebraska system and the local area. This core can design, prototype, manufacture and repair, maintain, or install a wide range of devices and instrumentation. Individuals interested in the use of the Machining and Prototyping Core Facility services can fill out a project initiation form.

UNeTech Institute

3929 Harney St.
Omaha, NE 68105
402-559-1181
hrunge@unmc.edu

Omaha's only university-supported startup incubator, UNeTech partners with business leaders to turn Nebraska discoveries into successful and impactful startups. Services are aimed at entrepreneurs, investors and experts interested in working with university innovators.

STARTUPS—RESOURCES

UNO College of Business Administration: Center for Innovation, Entrepreneurship & Franchising

Mammel Hall, Suite 303
6708 Pine Street
Omaha, Nebraska 68182
402.554.2706
entrepreneurship@unomaha.edu

A bridge between future entrepreneurs and Omaha's entrepreneurial community, providing advisory services to startups and small businesses. The Center also provides students with business fundamentals, opportunities through pitch and business plan competitions, and experience running a student-owned business.

UNO College of Business Administration: Nebraska Business Development Center

200 Mammel Hall
6708 Pine Street
Omaha, NE 68182
nbdc@unomaha.edu
(402) 554-6232

Supports small business growth with one-on-one business services, mostly at no charge. Services offer support for entrepreneurs in any stage, including assistance with business plans, financial projections, market research, securing government contracts or even the commercialization of new, innovative products.

UNIVERSITY RESOURCES—LINCOLN

The Combine Incubator

2125 Transformation Drive
Suite 1000
Lincoln, NE 68508

Statewide initiative supports high-growth entrepreneurs in food and agriculture. The program supports commercialization through mentorship and a capital readiness program, networking events, a network of partnering producers, and incubation space on Nebraska Innovation Campus.

Midwest I-Corps Node

midwesticorps@umich.edu

Part of a national network of NSF-funded researchers, the Midwest I-Corps Node hosts training programs to extend researchers' focus beyond the laboratory and accelerate the transfer of research into commercial success. Programs include one-on-one mentoring, de-risking, funding support.

Nebraska Innovation Campus

2021 Transformation Drive
Lincoln, NE 68508
innovate@unl.edu
(402) 472-5535

Nebraska Innovation Campus connects experts, companies and the University of Nebraska to create new, deeper partnerships.

STARTUPS—RESOURCES

Nebraska Innovation Studio

2021 Transformation DriveSuite 1500
Entrance B
Lincoln, NE 68508
(402) 472-5510

A collaborative workspace with areas for woodworking, fine arts, rapid prototyping and electronics. University faculty, students, staff and community members are welcome to join the studio for a monthly fee.

NIC Biotech Connector

Nebraska Innovation Campus
1901 N 21st Street
Lincoln, NE 68508
(402) 480-5837

Wet-lab space providing incubation space and services to bioscience startups and high-growth biotech and research-based businesses.

NMotion

151 N. 8th Street, Suite 517
Lincoln, NE 68508
info@nmotion.co
(402) 875 – 4166

Accelerator that helps move startups forward, faster. NMotion operates two main programs: Accelerator Studio and gBETA Lincoln. Accelerator Studio is a 16-week program that helps build from scratch a startup in Lincoln, Neb., culminating with a $100,000 investment. gBETA Lincoln is a free seven-week accelerator for early-stage companies.

UNL College of Business: Center for Entrepreneurship

HL H 315730 N. 14th Street
Lincoln, NE 68588
(402) 472-6273

The Center for Entrepreneurship offers mentorships, workshops, competitions and funding opportunities.

Weibling Entrepreneurship Clinic, University of Nebraska College of Law

Schmid Clinic Building
P.O. Box 830902
Lincoln, NE 68583-0902
eclinic@unl.edu
(402) 472-1680

Provides free advice and legal representation to startup business clients throughout the State of Nebraska. The E-Clinic handles a variety of early-stage legal matters, including entity formation, contract drafting and review, intellectual property protection, regulatory, compliance and other transactional legal matters. Law students provide these legal services under direct supervision of Professor Brett Stohs.

STARTUPS—RESOURCES

REGIONAL RESOURCES

City of Omaha Planning Department: Community Development Division

The City of Omaha offers several programs and resources aimed at encouraging small enterprises to locate or remain within important neighborhood business districts. Programs and services also support small businesses with the Small and Emerging Business Program.

Destination Startup

stephen.s.miller@colorado.edu

A collaboration among leading research universities and federal laboratories across the Intermountain West region. Destination Startup® helps innovative researchers and faculty ready themselves for the process of fundraising and the commercialization of their technology.

DoSpace

7205 Dodge Street, Omaha, NE 68114
hello@dospace.org
402-819-4022

On-going learning opportunities and resource access for potential entrepreneurs includes a Lunch & Learn seminar series and a makerspace for 3D design and printing.

Greater Omaha Chamber of Commerce

808 Conagra Dr. Ste. 400
Omaha, NE 68102
Phone: 402-346-5000

Serves the Omaha business community with an eye toward helping build and develop the local economy for the future. Several programs are offered specifically to startup companies and entrepreneurs, but there is a wide range of general support opportunities for any business in the Omaha metro area.

InvestMidwest

InvestMidwest highlights startups with the most promise for success in the Midwest region that are currently seeking Series A or B funding of $1M to $20M. The conference provides an ideal opportunity for entrepreneurs to raise capital and for all attendees to make new connections.

Metropolitan Community College Entrepreneur Program

Deb Gaspard, M.B.A., B.A.
MCC Entrepreneurship & Marketing Program Director
531-622-8255
dmgaspard@mccneb.edu

Entrepreneurial program at MCC prepares students with the core concepts of entrepreneurship, and helps them develop the skills and tools needs to starting a new business.

STARTUPS—RESOURCES

1 million cups

An inclusive group of communities of support to their local entrepreneurial ecosystems. The mission is to educate, engage and connect entrepreneurs with their communities in order to help them grow and succeed. There are several active communities in the Midwest including Omaha, Lincoln, Des Moines, Ames, and Kansas City. The core program is a weekly meeting each Wednesday morning, featuring startup presentations, with a Q&A that includes the question: "What can we, as a community, do to help you?" All events are free and open to the public…and the coffee is always free.

Pipeline

1919 W 45th Ave
Kansas City, KS 66103
913-307-0004
info@pipelineentrepreneurs.com

Fellowship program connects Midwest entrepreneurs to a national network of renowned experts that will guide and help entrepreneurs build their business. Pipeline takes zero equity in member companies, focusing on the entrepreneur first.

Small Business Adminstration

A massive entrepreneurial resource center from the federal government, housing guidance on virtually all things related to planning, launching, managing and growing a new business. Services also include consulting, counseling and funding opportunities.

StartOmaha

Perhaps the most complete directory of resources, and a good starting point for aspiring entrepreneurs of all stripes in Omaha.

Startup Collaborative

808 Conagra Dr. Ste. 400
Omaha, NE 68102
hello@startupcollaborative.co

A pre-seed venture capital fund aimed at entrepreneurs interested in building high-growth, software-centric companies. Helps founders get their company off the ground, find a product that fits the market and tackle early challenges. Entrepreneurs in the program earn incentives that include angel investment capital, staffing support, subsidized office space and access to a vast venture network.

STARTUPS—RESOURCES

FUNDING RESOURCES

Dundee Venture Capital

3717 Harney Street, Second Floor
Omaha, NE 68131

Seed-stage invest capital company, focused on high-growth, technology startups in the Midwest, with office locations in Omaha, Chicago, Minneapolis and St. Louis.

Innosphere Ventures

320 East Vine Drive, Suite 101
Fort Collins, Colorado 80524
970-221-1301

Science and technology incubator accelerates startups and emerging growth companies with a commercialization program, specialized office and laboratory facilities, and a seed-stage venture capital fund. The commercialization program focuses on ensuring companies are investor-ready, connecting founders with experienced advisers and early hires, making introductions to corporate partners, exit planning, and accelerating top line revenue growth.

Invest Nebraska

801 R Street, Suite 1
Lincoln, NE 68508
402-742-7860

Invest Nebraska administrates the state's Seed Investment Program, which matches up to $500,000 of seed-stage investments.

Nebraska Angels

PO Box 81431
Lincoln, NE 68501
info@nebraskaangels.org

A network of investors who invest in about eight deals annually, deploying close to $5,000,000 in capital. Because Nebraska Angels is a network rather than a fund, decisions to invest are made individually. However, terms are the same for all angels.

Nebraska Department of Economic Development

301 Centennial Mall South, 4th Floor
Lincoln, NE 68508
(800) 426-6505

The state provides several services. For entrepreneurs and innovators, resources include prototyping grants, academic research and development grants, and a matching fund program for the federal SBIR/STTR grant programs.

Proven Ventures

1004 Farnam Street, Suite 400
Omaha, NE 68102

Venture capital fund for Nebraska entrepreneurs uses a debt-equity model for its investments.

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University of Nebraska

Board of Regents Bylaws *(revised: 4/25/16)*

3.10 Ownership and Commercialization of Inventions and Discoveries.

The Board encourages the commercialization of inventions and discoveries arising from research activities of the University, and when appropriate, the pursuit of patents or other intellectual property protection, as a method of bringing recognition and remuneration to the University's inventors and to the University itself. Every invention or discovery by members of the faculty and staff that results from the performance of duties within the scope of their University employment, or from the use of University personnel, property, facilities, or other resources, except where such use is minimal, shall be solely owned by the University provided that the inventor or inventors shall have a share of no less than one-third (1/3) of the net proceeds received by the University resulting from licensing or sale of University owned intellectual property rights associated with such invention or discovery. Further, and unless otherwise explicitly and specifically agreed to in writing, should by operation of law or otherwise it is determined that the inventor or inventors own any rights in the University's inventions and discoveries beyond that described in this section of these Bylaws, then it shall be a condition of employment at the University of Nebraska that any such rights shall be assigned to the University. The Board shall adopt a formal Patent and Technology Transfer Policy which shall govern the disclosure of inventions and discoveries resulting from performance of duties by faculty or staff within the scope of their employment, or from the use of University personnel, property, facilities, or resources. The President, or any administrative officers designated by the President, shall have authority to act for the University with respect to inventions or discoveries owned by the University as required by this section and the Board's Patent and Technology Transfer Policy.

Board of Regents Policies *(revised: 6/25/21)*

4.4 Intellectual Property

4.4.1 Ownership of Intellectual Property

Central to the University of Nebraska's mission is the creation, preservation, and dissemination of knowledge.

The University of Nebraska is committed to providing an environment that supports the research, teaching, and service activities of its faculty, students, and staff. As a matter of principle and practice, the University encourages all members of the University community to publish their articles, books, and other forms of scholarly communication in order to share openly and fully their findings and knowledge with colleagues and the public. This Policy is intended to promote and encourage excellence and innovation in scholarly research and teaching by identifying and protecting the rights of the University, its faculty, staff, and students.

Patent and copyright ownership and their associated rights are concepts that are defined by federal law. This Policy and the University's patent policies are structured within the context of those federal laws. The University's patent policies have been in operation within the University for many years and are hereby incorporated into this Policy.

The long standing academic tradition that faculty own the copyright to academic, scholarly and educational works resulting from their research, teaching, and writing is the foundation of the copyright policy described in this document. Exceptions to this rule may result from contractual obligations, from employment obligations, from certain uses of University facilities, or by agreement governing access to certain University resources. This Policy is intended to clarify many of these situations.

As used in this Policy, "University" shall refer to the University of Nebraska or one of its campuses and shall include any organization of the University whose primary purpose is to facilitate technology transfer and commercialization of the University's Intellectual Property. "Intellectual Property" shall include, but

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is not limited to patentable inventions, mask works, tangible research property, trademarks, and copyrightable works, including software.

This Policy is included in the terms of employment of all University employees. Admission as a student at the University constitutes an agreement to abide by the terms of this Policy.

1. General Policy Statement

The prompt and open dissemination of the results of research undertaken at the University of Nebraska and the free exchange of information among scholars are essential to the fulfillment of the University's obligations as an institution committed to excellence in research, education, and service. Matters of ownership, distribution, and commercial development nonetheless arise in the context of technology transfer, which is also an important aspect of the University's commitment to public service. The University of Nebraska as a public institution has a responsibility to recognize the State's contribution of tax support for research and creative activity by devoting an appropriate share of the products of that research to the further benefit of the University as a whole. The University must also recognize the intellectual contribution of Authors and Inventors, the need to provide incentives for enhanced intellectual activity, and the role such incentives play in recruiting and retaining creative individuals at the University.

"Author(s)" and/or "Inventor(s)" are defined herein as faculty, staff, and other persons employed by the University of Nebraska, whether full or part-time; visiting faculty and researchers; and any other persons, including students, who create or discover Intellectual Property using University resources, as those terms are subsequently defined.

2. Early Disclosure and Incentives for Creative Effort; Use of the University's Name

a. Early disclosure and incentives to create

This Policy is a framework to provide guidance in understanding the relationship between the University and those persons engaged in creative efforts at the University. In some instances, the result of the creative effort will be the property of the University, while in others some or all of these rights of ownership shall belong to the Author or Inventor. Where ownership rests with the University, the University will seek to recognize and provide incentives for those persons who make significant contributions to the University's mission.

In some instances it may be difficult to foresee with certainty whether Intellectual Property created in a particular context is the property of the University or the employee. In such instances, the employee is encouraged to disclose in writing the nature of any creative endeavor that has potential commercial applications as soon as possible to the employee's immediate administrative supervisor. This disclosure will provide an opportunity to discuss incentives, seek any necessary interpretation of this Policy, and secure the University's support for the creative endeavor.

b. Use of University's name

The University has an interest in how its name is used and an interest in protecting the value of that name. Individual Authors or Inventors cannot alone decide whether a project should be associated with the University's name. An employee of the University may identify his or her affiliation with the University, but without prior written approval, may not otherwise suggest the University's participation or endorsement of the conclusions of any study or research. Similarly, the University's name may not be used, without prior written permission, in association with the sale or commercialization of the products of research by University employees. Again, early written disclosure will facilitate agreement between interested parties.

3. Ownership of Intellectual Property; General Provisions

a. Applicable to all technologies and

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media

The issue of ownership of Intellectual Property resulting from activities of University employees arises in a number of different contexts involving a variety of creative works. Increasingly, University employees utilize new technologies and media to create new inventions, to improve the educational process, and to enhance the delivery and exchange of information. This Policy is intended to apply to all creative works, except patentable subject matter, regardless of the media in which they are distributed or the nature of their technological manifestation, now known or later developed.

b. Patent policies not affected

Notwithstanding anything otherwise stated in this Policy, ownership of patents shall be determined in accordance with University patent policies in Section 3.10 of the Bylaws of the Board of Regents of the University of Nebraska and Regents Policy 4.4.2, or as those patent policies may from time to time be amended.

It is essential, however, that Authors and/or Inventors understand that early publication of their patentable research results without notification to the University can compromise the University's patent rights in the research, and by implication, the Authors ' and/or Inventors' royalty interest therein. Therefore, if an Author or Inventor wishes to publish research results which involve patentable subject matter, the Author or Inventor should first submit a patent disclosure to the University patent administrator and also disclose the existence of the pending publication so as to allow for the appropriate filings to preserve the University's patent rights.

c. Residual Authors' or Inventors' Rights

Notwithstanding the University's ownership of any particular Intellectual Property, the University shall not engage in any activity which unreasonably interferes with an Author's or Inventor's ability to continue the creative process. Therefore, except in such instances where the University can show that its interests will be significantly compromised, an Author or Inventor, while still in the employ of the University, shall be permitted to make revisions to and develop new works based upon the original creation. Except to the extent that an Author or Inventor may have a right to receive income based upon royalties or other fees generated from a work, this Policy provides no portability of other rights to University-owned Intellectual Property should the employment relationship between the University and the Author or Inventor terminate. However, in many cases it may prove possible for the University to grant a royalty-free license or an appropriate royalty-bearing license to the Author or Inventor to continue to use the techniques or other aspects of a creative work, even when the Author or Inventor is no longer employed by the University.

Comment
When a faculty member leaves the employment of the University, the University will continue to honor the terms of any agreement it has with the faculty member regarding University-owned Intellectual Property. For example, the University may agree to pay a faculty member a royalty for the development of a University-owned distance learning program. If the faculty member leaves, the University will continue to pay in accordance with the agreement with the faculty member. The faculty member may not, however, take other rights of ownership in the Intellectual Property, unless it is agreed to by separate written license agreement between the faculty member and the University.

d. Classification of creative works

The ownership of Intellectual Property created by a University employee is determined by the nature of the activity resulting in the Intellectual Property. Under this Policy, Intellectual

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Property not governed by Section 3.b (Patent Policy) is classified as either:

1) an Independent Work governed by Section 4;

2) a University Supported Work governed by Section 5;

3) an Institutional Work governed by Section 6; or

4) a Contractual Work governed by Section 7.

The ownership of Intellectual Property produced by non-employees, including students, arising out of activities associated with the University is governed by Sections 8 and 9 of this Policy.

Comment
The intent of this section is to categorize all works which may contain Intellectual Property rights into one of the listed categories and to allocate the Intellectual Property rights accordingly. Thus any work must be in only one category. It should be understood that the determination of whether a work is an Independent Work, a University Supported Work, or an Institutional Work depends on the context in which the work is created. Any of these works may be transformed into a Contractual Work by an agreement between the University and the Author or Inventor.

4. Independent Works

a. Independent Works Defined; Ownership

An Independent Work is a work that is not:

1) a University Supported Work, pursuant to Section 5;

2) an Institutional Work, pursuant to Section 6; or

3) a Contractual Work, pursuant to Section 7.

A University employee as the Author or Inventor of an Independent Work owns the Intellectual Property rights in that work.

Comment
It is the policy of the University of Nebraska that faculty shall own all rights to materials prepared and developed at their own initiative, without the use of any University resources, and not pursuant to an approved agreement. The University does not claim ownership of books, articles and other scholarly publications, or to popular novels, poems, musical compositions, or other works of artistic imagination that are created by the personal effort of faculty, staff and students and which do not make use of University resources.

5. University Supported Works

a. University Supported Work defined

A University Supported Work is a creative work developed in whole or in part with the customary use of University resources. "University resources" means all tangible resources provided by the University of Nebraska to Authors or Inventors, including salary, office, lab, studio space and equipment; computer hardware, software, and support; secretarial service; research, teaching, and lab assistants; supplies; utilities; funding for research and teaching activities; travel; and other funding or reimbursement.

b. Ownership of University Supported Works that do not involve use of substantial University resources

By long-standing tradition and the contemporary need to remain competitive in recruiting and retaining a creative faculty, the faculty own the copyright and other rights associated with Traditional Works of Scholarship. "Traditional Works of Scholarship" are defined as works reflecting research or creativity which, within the University, are considered as evidence of professional advancement or accomplishment. Such works result from scholarly endeavors, and include instructional materials, journal articles, research bulletins, monographs, books, plays, poems, and artistic works, and do not involve substantial use of University resources as described in Section 5.c of this Policy. Accordingly, except for (1) University Supported Works involving use of substantial University resources, and (2) patents, patentable subject

APPENDIX I: **POLICIES**

matter, trade secrets and commercially viable discoveries and inventions governed by the patent policies described in Section 3.b of this Policy, the faculty member shall own the copyright and have the right to register the same and to receive royalties or other income from a University Supported Work, including books, films, cassettes, CDs, software, works of art, or other material. However, such ownership and rights are subject to the requirements of Section 3.11 of the Bylaws of the Board of Regents of the University of Nebraska prohibiting a faculty member from having a financial interest in or receiving compensation from the sale of educational materials used by students of the University, except royalties on books or other educational material from publishing houses of standing. In addition, the following specific rules apply to University Supported Works for which the faculty member owns the copyright:

1) Research Materials. Materials such as lab notebooks and research files shall remain the property of the individual responsible for directing the project, except when agreements governing Contractual Works described in Section 7 require otherwise. However, should such an individual depart the employ of the University or otherwise terminate responsibility for directing the project, he or she shall provide the University with such copies of the research material as may be reasonable in order that the University may protect its rights in any Intellectual Property as well as that of the departing Author's or Inventor's colleagues.

2) Instructional Materials. "Instructional Materials" are other than Institutional Works, the primary use of which is for the instruction of students. Such works include textbooks, syllabi, lectures, lecture notes, and study guides. Instructional Materials developed by a faculty member in the process of delivering a course of instruction to students shall be the property of the faculty member. However, in the absence of a specific written agreement, and with the exception of books or other educational materials covered by Section 3.11 of the Bylaws of the Board of Regents, no royalty, rent or other consideration shall be paid to a faculty member when Instructional Materials are used at the University. Should the Author of Instructional Materials depart the employ of the University, he or she will provide the University with copies of the Instructional Materials (not including lecture notes) and shall grant the University a non-exclusive, royalty free license thereto, when it is determined by the University that such Instructional Materials are necessary to carry out the educational programs of the University. Recordings of lectures shall be the property of the faculty lecturer, unless the recording is an Institutional Work or a University Supported Work Involving use of substantial University resources.

c. Ownership of University Supported Works involving use of substantial University resources

1) Notwithstanding Section 5.b, in circumstances in which use of substantial University resources is involved in the creation of a work, the University shall own the work, including the right to obtain a copyright and the right to royalties or other income. Circumstances involving use of substantial University resources include:

a) substantial University financial, staff, or other assistance;

b) extensive use of special or rare University holdings, such as museum collections;

c) significant use of voice or image of students or staff in a product (other than the author or inventor), or substantial creative contribution by staff or students

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to the preparation of a work or product; or

d) use of the name or insignia of the University or any of its units (other than for purposes of identification of individual faculty members) to identify or to promote the distribution of a work or product, or other identification or promotion that implies the approval or endorsement by the University or one of its units.

Comment
The references in subparagraph a) to "substantial University financial staff or other assistance" and in subparagraph b) to "special or rare University holdings, such as museum collections" mean the use of University funds, facilities, equipment, or other resources significantly in excess of the norm for educational and research purposes in the department or unit in which the creator holds his or her primary appointment. The University does not regard the provision of an employee's salary, office, usual library resources, usual facilities and equipment, and office staff, or personal computers as constituting "substantial use of University resources" unless such resources were made available specifically to support the development of a work to be owned or acquired by the University or was previously designated by the University as a substantial University resource. The reference in subparagraph to c) to "substantial creative contribution by staff and students" means providing original ideas or new techniques that are essential to the creation of the product or significantly improve its value. For example, devising a new way to test one of the major hypotheses in a study would normally count as such a contribution, but providing ordinary research assistance or conducting standard data analysis would not.

2) When the responsible Dean or Director determines that any of the circumstances involving use of substantial University resources described above in subparagraph 1) of this Section 5.c obtain, the University will accord to the Author a non-exclusive, royalty free license to use the work for non-commercial purposes. Further, and in keeping with the University's strong desire to promote creative efforts, the University will negotiate in good faith with the Author to determine the extent to which the Author should share in the rights to royalties or other "ownership" rights to such work.

Comment
The allocation of rights for University Supported Works in Section 5 is modeled after the policy of Harvard University. It attempts to distinguish between traditional works of scholarship for which faculty members hold the copyright and those works created with substantial University involvement. Where the University is involved to a greater extent than ordinarily prevails, the University should be entitled to share in the economic returns of resulting works and to receive reimbursement for its additional costs. It is recognized that the determination of whether a particular project involved substantial university involvement may not always be clear. In such circumstances it is important that the faculty member make early disclosure to the Dean or Director and that, if an interpretation of this policy is required, the procedures adopted in Section 13 be initiated.

6. Institutional Works

a. Institutional Works defined

An Institutional Work is a work created at the specific instigation of the University and under the specific direction of the University, by a person acting within the scope of his or her University employment. Institutional Works are often referred to in copyright law as works-made-for-hire. A creative work

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produced on the initiative of a faculty member pursuant only to the general obligation of faculty members to engage in research or creative activity is not an Institutional Work, but may be a University Supported Work involving use of substantial University resources as described in Section 5.c of this Policy or a Contractual Work as defined and described in Section 7 of this Policy. However, Institutional Works may include creative works generated within a specific project initiated by the University. Institutional Works also include committee minutes, internal memoranda, business files, personnel files and other business records created in the ordinary course of the general administration of the University.

Comment
Institutional Works are works that are created at the initiative of the University. In addition to works related to the general administration of the University, such as committee reports, minutes, and business files, an Institutional Work may include more traditional creative works. For example, the products of a University initiated program in distance learning where an employee or numerous employees are assigned the specific task of creating instructional content would be Institutional Works.

b. Ownership of Institutional Works

The University owns all rights to Institutional Works. However, in keeping with the University's strong desire to promote creative efforts, the University may determine that the Author or Inventor should share in the rights to royalties and other rights in Institutional Works discussed in this Policy. The Author or Inventor should engage in early written disclosure to the University of the potential for any valuable Intellectual Property rights associated with Institutional Works in order to facilitate agreement regarding such shared rights. Failure to do so will be an important factor in assessing whether the Author or Inventor is entitled to share in any financial returns from the work.

7. Contractual Works (Sponsored Research)

Ownership of the Intellectual Property rights in creative works developed in the course of or pursuant to a sponsored research program or other contractual arrangement will be determined according to the terms of such program or contract, provided that the program or contract was approved by the University. If the program or contract does not provide for the allocation of Intellectual Property rights, such rights will be determined by the other provisions of this Policy. Notwithstanding other provisions of this policy, the University may elect to enter into a contract with an individual employee regarding the creation of specific intellectual property.

Comment
University personnel and visitors should contact the office on their campus responsible for sponsored programs for information or assistance regarding drafting or interpretation of research contract terms. The terms of such sponsored research agreements apply not only to inventions made by faculty and staff, but also to those made by students and visitors, whether or not paid by the University, who participate in performing research supported by such agreements. Care should be taken to assure that any contract for sponsored research is approved and signed by a University administrative officer having proper Authority to approve and sign such a contract on behalf of the University.

Patents: Research contracts sponsored by the Federal Government are subject to statutes and regulations under which the University acquires title to inventions conceived or first reduced to practice in the performance of the research. The University's ownership is often subject to a non-exclusive license or grant of other rights to the government and the requirement that the University retains title and take effective steps to develop the practical applications of the invention by

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licensing and other means.

Contracts with outside research sponsors are negotiated on a case-by-case basis with ownership and other rights to the discovery of any patentable invention determined in the course of the negotiations.

Copyright: Normally, research contracts sponsored by the Federal Government provide the government with specified rights in copyrightable material developed in the performance of the research. These rights may sometimes place title to such material exclusively in the government, but more often consist of a royalty-free license to the government with title vesting in the University.

When a work is created under the terms of a sponsored research agreement, Authors of copyrightable works should be aware that there may be contractual terms relating to the form of the research report, advance notice to the sponsor before publication, and other limitations or obligations.

8. Ownership of Works Produced by Non-employees

According to federal law, copyright of commissioned works of non-employees is owned by the Author and not by the commissioning party, unless there is a written agreement to the contrary. All University personnel are cautioned to ensure that independent contractors agree in writing that ownership of commissioned work is assigned to the University, except where special circumstances apply and it is mutually agreed that the Author will retain ownership.

9. Ownership of Copyrights in Theses, Dissertations and Other Student Works

The ownership of copyrights in student works is governed as follows:

a. Theses, Dissertations and Other Student Works

Students will own the copyrights to their theses, dissertations, and other student works; however, a student must, as a condition to a degree award, grant royalty-free non-exclusive permission to the University to store copies of such works for archival purposes and to reproduce and publicly distribute copies of his or her thesis or dissertation within the University education and research missions; provided however, that should the student identify any legitimate proprietary interest the student may have in the work, or should the University determine that it has an ownership interest in any patentable or otherwise protectable Intellectual Property interest in the work, the University shall then delay any public access to the work for up to one year following the presentation of the work, in order for the student to consult with the University regarding the protection of the proprietary interest. Copyright ownership of theses or dissertations generated by research that is performed in whole or in part by a student with the support of a sponsor or grant shall be determined in accordance with the terms of the sponsored research or grant agreement, or in the absence of such terms, the copyright shall be owned by the University.

b. Software, Patentable Subject Matter and Non-Copyright Intellectual Property

Software, patentable subject matter, and other Intellectual Property (other than copyright as described in Section 9.a and Section 9.c of the Policy) contained or disclosed in theses, dissertations and other student works shall be subject to and governed by the policies that apply to University employees.

c. Student Writings Other Than Theses or Dissertations

Students shall own the copyrights to all student writings not commonly referred to as theses or dissertations and to other creative expressions required in the course of class assignments. The University shall retain the right to keep original examination scripts and to possess a copy or record of other student

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works for purposes of assigning grades, maintaining archival materials, and record keeping.

Comment
In cases where a dissertation or thesis contains patentable or otherwise protectable subject matter belonging to the University, the students and faculty involved with the project have a duty to disclose the existence of the thesis or dissertation to the University office responsible for patent matters. The students and/or faculty members should also contact the campus Dean for Graduate Studies regarding the shelving of the thesis or dissertation with the University's Library. The campus Dean can provide for the secured storage of the thesis or dissertation for up to one year so as to preserve the patent or other rights of the University in the subject matter of the thesis or dissertation.

10. Intellectual Property Rights for Multiple Creating Parties

Due to the nature of current research practices and multi-media creations, it is common for more than one individual to claim part of the recognition as Author or Inventor for a particular creation. In such instances, participating Authors or Inventors are strongly encouraged to define their respective rights to the creation in a written agreement, signed by all of the contributing parties. Misunderstandings between the contributing parties can be avoided if such agreements are entered into as early as is practicably possible. Should the co-Authors or co-Inventors fail to so agree in writing, it is presumed that any benefits to be shared by them shall be shared equally.

11. Ownership of Trade and Service Marks

Ownership of trademarks shall be governed by the provisions of this Policy. Thus, trademarks that are Independent Works will be owned by the Author; trademarks that are Institutional Works will be owned by the University; ownership of trademarks that are University Supported Works will be determined by the provisions of Section 5 of this Policy; and ownership of trademarks that are Contractual Works will be determined by the provisions of Section 7 of this Policy. Note however, that the University owns many valuable trade and service marks, most of which are registered with the appropriate state or federal agencies. Any trade or service marks derived from or based upon University-owned marks shall belong to the University.

12. Assignment of Property Rights by the University

The University may assign to the Author or Inventor any rights of ownership it may acquire pursuant to this Policy.

13. Resolution of Ambiguities and Policy Interpretation

Should any issue arise regarding interpretation of this Policy, for example, whether Use of Substantial University resources has occurred or will occur, the issue shall be referred to the Author's or Inventor's Dean, Director, or similarly situated administrator. After reviewing the relevant facts, such administrator shall recommend a resolution to the Vice Chancellor responsible for research, sponsored programs and technology transfer (e.g. Vice Chancellor for Research or Vice Chancellor for Academic Affairs). Any campus may establish a committee of peers to review the facts and circumstances surrounding any particular interpretation of this Policy and make recommendations to the Vice Chancellor. The Chancellor will make the final decision on all interpretations under this Policy, based on the recommendation of the Vice Chancellor. The Chancellor's decision will be final with respect to the University.

14. Supplemental Income from Commercial Applications

This Policy on ownership rights in no way alters the ability of an Author or Inventor to receive supplementary income from the University under any separate policy, as a result of the commercial application of Intellectual Property created by the

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Author or Inventor.

15. Review of Policy

This policy will be reviewed periodically and revised as deemed necessary to accommodate new technologies and to incorporate changes warranted by experience with its administration.

4.4.2 Patent and Technology Transfer Policy

Section 3.10 of the Bylaws of the Board of Regents provides that it is the policy of the Regents to encourage the commercialization of inventions and discoveries arising from research activities of the University, and when appropriate, the pursuit of patents or other intellectual property protection, as a method of bringing recognition and remuneration to the University's inventors and to the University itself. This Patent and Technology Transfer Policy is adopted for the purpose of providing general policy regulations to implement Section 3.10 of the Bylaws of the Board of Regents:

1. Ownership of Inventions Resulting From Performance of Duties of Employment; Prompt Disclosure to University

Each invention[1] by a member or members of the faculty or staff of the University resulting from performance of duties within the scope of University employment, or resulting from the use of University personnel, property, facilities, or other University resources, except where such use is minimal,[2] shall be solely owned by the University. Questions concerning whether a use of University resources is minimal shall be resolved in accordance with the process set forth in Section 9 of this Policy. Each such invention and any improvement(s) made thereto while under the employment of the University shall be promptly disclosed in writing to the designated campus patent and technology transfer administrator (the "Administrator").[3]

A disclosure of an invention shall be properly made when it is submitted to the campus Administrator in such manner and form as may be determined by the Administrator. Any disclosure of an invention shall contain information in such detail as is deemed necessary by the Administrator to allow for a review of its patentability and commercial potential, and shall detail the specific utility or application of the invention.

2. The Campus Administrator

The Chancellor of each campus and/or the Chancellor's designee shall designate a campus patent and technology transfer administrator who shall be responsible for the administration of all campus patent and technology transfer activities, and who will provide a central source of information and help in handling the different aspects of patents and technology transfer.

3. Patent and Technology Transfer Advisory Committee

The Administrator in consultation with the Chancellor and/or the Chancellor's designee shall establish an advisory committee on technology transfer (the "Committee"). The Committee will be

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1. For purposes of this policy, the term "invention" shall mean patent able inventions or discoveries, computer software, trade secrets and all other intellectual property not addressed under Regents Policy 4.4.1.

2. The determination as to whether any use of University personnel, property or facilities is or was "minimal" under this policy shall be made based on the following considerations:

a) Whether the invention was conceived of or reduced to practice pursuant to an employee or faculty member's job duties;

b) Whether any funding for the work leading to the conception or reduction to practice of the invention was provided by or facilitated through the University;

c) Whether any University facilities were utilized in the conception or reduction to practice of the invention, and if so, the extent of such use; and

d) Whether any University students or staff were utilized in or contributed to the conception or reduction to practice of the invention.

3. The Bayh-Dole Act of 1980, 35 U.S.C. §§ 200-212, allows Universities and other non-profit organizations to retain title to federally-funded inventions and requires that strict reporting requirements be met. It is therefore critical that inventors provide a prompt and thorough disclosure to the University so that the University can properly evaluate the disclosure and elect to either retain or decline title to such inventions in a timely manner.

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available to assist the Administrator in the review of disclosures of inventions, and provide advice and peer group scientific review on issues relating to (i) intellectual property development and licensing or other technology transfer issues, and (ii) other related assistance as requested.

4. Review of Invention Disclosures; Acceptance for Technology Transfer by University or Transfer to Inventor

The Administrator, the Committee, and/or the Administrator's designees (one or more of which are referred to herein as the "Reviewers") shall aim to evaluate all disclosures of inventions on behalf of the University within six (6) months from the date the disclosure is formally submitted to the Administrator. The disclosure shall be evaluated by the Reviewers for the ability to obtain effective intellectual property protection on the invention, and the potential of the invention to stimulate business interest and contribute to economic development. Upon the conclusion of the Reviewers' evaluation of an invention, the Administrator shall communicate to the inventor(s) any intent on behalf of the University to pursue protection of the invention. The University shall proceed, in its sole discretion, to seek appropriate intellectual property protection on the invention, and/or market the invention to interested parties. The terms of any license or agreements related to an invention, and the manner in which they may be enforced, litigated or settled shall be at the sole discretion of the University.

The inventor or inventors of a disclosed invention shall assist the University and any counsel retained by the University in the preparation, filing and prosecution of any patent applications based on inventions disclosed to the University, and shall sign any and all necessary documents, including assignments, declarations, oaths and affidavits related thereto.

At any time during the technology transfer process, the University may, for any reason which in its sole discretion it determines is in the best interests of the University, assign title to the invention to the inventor(s). In such cases, however, the University may retain a non-exclusive, paid-up, royalty-free license to the invention, if it so desires.

Although the University may assign title to an invention to the inventor(s), any improvement or modification to or separate invention derived from or based on such invention that results from the use of University personnel, property or facilities, except where such use is minimal, shall be owned by the University subject to this Policy. The inventor(s) shall promptly disclose such improvement, modification or separate invention to the Administrator in the same manner as is described in Section 1 of this Policy.

Should an inventor leave the University and wish to continue research on an invention which the inventor has disclosed to the University, the University shall provide an appropriate royalty-free, non-commercial, research only license to allow the inventor to continue his or her research.

5. Division of Net Royalties and Proceeds

With respect to any invention subject to this Policy, the University shall first be reimbursed for any and all expenses incurred by it that are associated with evaluation of the technology, obtaining of patent or other intellectual property protection, and licensing or other technology transfer activity, including legal expenses related thereto.[4] In the event of any infringement action or other legal action involving technology disclosed under this Policy, the University shall also be reimbursed for any and all expenses borne by the University associated with such action. After such expenses are reimbursed, royalties and other proceeds from licenses or other technology transfer activities related to an invention, or patent or other intellectual property protection based thereon, shall be distributed as follows:

(a) One-third to the inventor or inventors; and

4. The University shall make every effort to recover all or part of these expenses from any licensee of University-owned intellectual property upon the execution of the license agreement.

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(b) Two-thirds in accordance with a separate distribution policy to be established and implemented by each University campus, such policy to take effect following approval by the Board of Regents upon recommendation of the relevant campus' Chancellor.

6. Distribution of Equity to Inventors

In the event that the University receives equity or an option to acquire equity in exchange for any license or other intellectual property, the share of such equity due to the inventor(s) shall be based upon the distribution of royalties and proceeds provided in Section 5 of this Policy. Such equity will be distributed directly to the inventor(s) once such equity is transferable. The University shall make every effort to distribute such equity in a timely manner, but the University shall not be responsible for changes in value which might occur before receipt of equity by an inventor.

In the event the University or an affiliated entity of the University receives equity or an option to acquire equity in exchange for something other than a license or other intellectual property right (e.g. performance of a service or clinical trial), the equity interest shall not be subject to distribution under Sections 5 or 6 of this Policy.

7. Division of Inventor's Share Among Co-Inventors

Should there be more than one inventor per license or other source of royalties and other proceeds under Sections 5(a) and 6 of this Policy, the inventors' shares shall be divided and distributed among themselves in accordance with an agreement to be signed by the inventors and filed with the Administrator. Should the inventors fail to sign such an agreement governing distribution among them, then the proceeds shall be distributed equally among the sum of inventors per license or other source of royalties.

8. Conflicts of Interest

Conflicts of interest are more likely to present themselves to inventors, University personnel and the University as an entity in the context of intellectual property licenses or other contracts related to technology transfer activities. As such it is of utmost importance that in addition to any compliance required under this Policy, that all involved in technology transfer also comply with any conflict of interest policies as required by law, Section 3.8 of the Bylaws of the Board of Regents or Regents Policy 3.2.8, as those requirements may exist or as they may be amended in the future.

9. Resolution of Issues Concerning Administration or Interpretation of this Policy

Should any issue arise regarding administration or interpretation of this Policy or Section 3.10 of the Bylaws of the Board of Regents, the issue shall be referred to the campus vice chancellor responsible for research, sponsored programs and/or technology transfer activities (e.g. Vice Chancellor for Research or Vice Chancellor for Academic Affairs). The campus patent and technology transfer advisory committee may review the facts and circumstances surrounding any such issue and make recommendations to the Vice Chancellor. The Vice Chancellor shall then make a report and recommendation for resolution of the issue to the Chancellor, who will make the final decision on all issues concerning administration or interpretation of this Policy or Section 3.10 of the Bylaws of the Board of Regents. The Chancellor's decision will be final with respect to the University.

10. Survival of Policy

The provisions of this Policy and Section 3.10 of the Bylaws of the Board of Regents shall survive the death or termination of employment of any inventor of intellectual property owned by the University. The provisions of this Policy shall inure to the benefit of and be binding upon the heirs and assigns of (1) any inventor of intellectual property owned by the University, and (2) all others who agree to be bound by it.

11. Campus Patent and Technology Transfer Policies and Procedures

The Chancellor of each campus, or the

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Chancellor's designee, is authorized to adopt and implement more detailed campus patent and technology transfer policies and procedures that are consistent with and supplemental to Section 3.10 of the Bylaws of the Board of Regents and this Policy.

UNMC Policy 7000 *(revised: 3/15/10)*
Science and Technology Advisory Committee Policy

Purpose

According to the University of Nebraska Board of Regents Patent and Technology Transfer Policy RP-4.4.2 approved in November 2003, UNMC is required to establish a Science and Technology Advisory Committee (STAC) for the review of new inventions. Each new invention is evaluated for the potential to obtain effective intellectual property protection, stimulate business interest, and contribute to economic development. STAC makes recommendations based upon these criteria to the UNMC Patent Administrator and the Vice Chancellor for Research, who have authority for decisions regarding intellectual property development, licensing and other technology transfer issues. STAC also may be called upon to make recommendations to the Vice Chancellor for Research concerning the administration of RP-4.4.2 "Patent and Technology Transfer Policy" or Section 3.10 of the Bylaws of the Board of Regents.

Membership

- Members of STAC are selected by the UNMC Patent Administrator in consultation with the Vice Chancellor for Research.
- Qualifications to be considered for appointing members include knowledge, experience, enthusiasm and ability.
- STAC will be composed of UNeMed personnel. Additionally, STAC has within its purview the ability to utilize the expertise of UNMC faculty and outside consultants as ad hoc members of STAC to review specific technologies. All individuals will be under confidentiality agreements.
- The Patent Administrator in consultation with the Vice Chancellor for Research may invite other participants with applicable expertise to specific meetings as needed.

Responsibilities

- Inventions will be evaluated by STAC for their potential to obtain effective intellectual property protection; to stimulate business interest; and to contribute to economic development.
- STAC members are expected to put aside individual agendas and seek to work for the common good, as they evaluate inventions using these criteria.
- STAC members should attend every meeting. The date, time and location of meetings will be determined by the Patent Administrator. An agenda and minutes will be prepared for each meeting. Written descriptions of the inventions to be discussed will be provided to members at least three (3) days in advance of meetings so that members of STAC may be prepared for the discussions.
- Information about inventions and about discussions at the meeting are confidential and not to be shared with persons outside of STAC. All members and attendees shall execute confidentiality agreements with the Board of Regents before receiving confidential information.
- Any written descriptions of inventions distributed outside UNeMed are to be returned to UNeMed without having been copied. Outcomes of the meeting will be relayed to inventors by a representative of UNeMed.

UNMC Policy 7001 *(revised: 5/3/21)*
Policy for Royalty and Equity Distribution

Basis for Policy

Section 5 of the RP-4.4.2 Regents' Patent and Technology Transfer Policy includes information on the division of net royalties and proceeds:

"With respect to any invention subject to this Policy, the University shall first be reimbursed for any and all expenses incurred by it that are associated with evaluation of the technology, obtaining

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of patent or other intellectual property protection, and licensing or other technology transfer activity, including legal expenses related thereto. In the event of any infringement action or other legal action involving technology disclosed under this Policy, the University shall also be reimbursed for any and all expenses borne by the University associated with such action. After such expenses are reimbursed, royalties and other proceeds from licenses or other technology transfer activities related to an invention, or patent or other intellectual property protection based thereon, shall be distributed as follows:

a. One-third to the inventor or inventors; and

b. Two-thirds in accordance with a separate distribution policy to be established and implemented by each University campus, such policy to take effect following approval by the Board of Regents upon recommendation of the relevant campus' Chancellor."

Policy

The University of Nebraska Medical Center implements this policy, consistent with RP-4.4.2, which outlines the distribution of royalties and other proceeds from the commercialization of technology.

1. To assure that the University is reimbursed for all costs associated with protecting and commercialization of the particular technology, the following expenses shall be recouped prior to any further distribution of proceeds from the technology:

a. Any funding provided to inventors or creators by UNMC, the University of Nebraska, UNeTech or UNeMed for research and development or for facilitating commercialization of research.

b. All out-of-pocket direct expenses incurred by UNMC or UNeMed in protecting, maintaining, defending and commercialization of the technology. On technologies with guaranteed annual minimum royalties, out-of-pocket expenses may be allocated over several years to facilitate immediate payment of royalties to inventors.

2. After the deductions authorized by paragraph 1, the remaining net proceeds from the commercialization of the technology shall be distributed as follows:

a. One-third will be distributed to the inventors pursuant to RP 4.4.2. Royalties will be distributed among all inventors based on their relative contributions to the development of the invention and should be agreed upon by inventors prior to the distribution. If no agreement exists, royalties and proceeds will be distributed equally among all inventors.

b. A technology management fee of 15% of the proceeds will be charged as overhead associated with the technology. Such overhead shall be used to support the administrative costs associated with UNeMed.

c. Ten percent of the net royalties up to the first $2 million of cumulative annual UNMC royalties will be transferred to a fund that will be distributed to the College(s) or Institute(s) to support and enhance research. The royalties will be distributed to the Colleges based on their proportional contribution to the fund. College(s) or Institute(s) share will increase to 20% of net cumulative annual UNMC royalties over $2 million.

d. The remaining proceeds will be distributed to the UNMC Chancellor's office to enhance the services of the technology development office to support services to faculty in the filing of dis*closure, protection of intellectual property and the marketing, licensing and commercialization of technologies. A portion of these funds may be used for grants to develop prototypes and conduct additional research to facilitate commercialization of technologies.*

3. The UNMC Chancellor's office may

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enter into agreements with third parties which modify the distribution of non-inventor net proceeds described in paragraph 2 subparts b, c and d. Any such modification shall be presented to the UNMC Research Resources Board or its functional equivalent.

4. For inventions with inventors from multiple colleges/institutes, the individual college/institute portion will be proportional to the contribution of faculty agreed upon in section 2.a. above.

5. For intercampus collaborative projects, intellectual property protection/prosecution efforts will be led by the campus with the majority interest in the invention. Net royalties will be divided between campuses based on their equity share in the intellectual property and distribution of net royalties within each campus will be dictated by the relevant campus policy.

6. If equity is taken in lieu of royalties that otherwise would be distributed under this policy, the equity will be held by UNeMed. Any dividends or proceeds from liquidation of the equity interest shall be distributed in accordance with this policy as though they were royalties.

Additional Information

- Contact UNeMed or the Director, UNeMed
- University of Nebraska Board of Regents Bylaws
- University of Nebraska Board of Regents Policies

UNMC Policy 8005 *(revised: 11/09/20)*

Export Control Policy

Authority

Statutes, regulations, and policies related to export controls include, but are not limited to:

- The Arms Export Control Act, 22 U.S.C. § 2751 et seq.
- The Export Controls Act, 50 U.S.C. § 4801 et seq.
- Assistance to Foreign Atomic Energy Activities, 10 C.F.R. § 810
- The Export Administration Regulations (EAR), 15 C.F.R. §§ 730-774
- The International Traffic in Arms Regulations (ITAR), 22 C.F.R. §§ 120-130
- The Foreign Assets Control Regulations, 31 C.F.R. §§ 500-599
- University of Nebraska Travel Policy TO-01
- UNMC Policy No. 8000, Compliance Program
- UNMC Policy No. 8006, Code of Conduct

Definitions

EXPORT: Any item that is taken, transferred, or sent from the United States to a foreign destination is an export, including, but not limited to, commodities, software, technology, instrumentation, chemicals, biological materials, circuit boards, blueprints, design plans, retail software packages and technical information.

The following activities constitute exports:

- International shipments;
- Checking items into luggage for international travel;
- Hand-carrying items for international travel;
- Transfers by any means of information, data, or software to recipients outside the United States (including transfers to U.S. Persons); and
- Providing services to Non-U.S. Persons.

DEEMED EXPORT: A transfer by any means of information, data, software, or services to a Non-U.S. Person in the United States is deemed an export to all countries of nationality of the Non-U.S. Person.

U.S. PERSON: A U.S. Person is a natural or legal person in any of the following categories:

- Citizens of the United States;
- Lawful permanent residents of the United States;
- Refugees, asylees, and other

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individuals protected under 8 U.S.C. 1324b(a)(3);

- The government of the United States or of any state or territory; or
- Corporations, business associations, and other organizations incorporated or otherwise authorized to do business in the United States.

NON-U.S. PERSON: A Non-U.S. Person is any natural or legal person who is not a U.S. Person. This includes UNMC Personnel, international organizations, foreign corporations, foreign governments (including diplomatic missions), and foreign universities.

RESTRICTED PARTIES: Restricted Parties are entities and individuals subject to export sanctions under federal law. U.S. Persons are prohibited from exporting some or all items to Restricted Parties without an export license or other federal approval.

TECHNOLOGY CONTROL PLAN: A Technology Control Plan is a security protocol required for UNMC activities that involve export-controlled components. Technology Control Plans are used to manage physical and information security requirements, individual access controls to equipment and data, and project closeout procedures.

UNMC PERSONNEL: UNMC Personnel include, for the purposes of this policy:

- Faculty;
- Staff;
- Students;
- Volunteers;
- Visitors; and
- Any other individuals who participate in any activity on behalf of UNMC, irrespective of appointment, compensation, or the location of the activity.

Scope

This policy applies to all UNMC personnel, irrespective of appointment, compensation, or the location of the activity.

Background

The University of Nebraska Medical Center is committed to leading the world in transforming lives to create a healthy future for all individuals and communities through premier educational programs, innovative research and extraordinary patient care. To fulfill this mission, UNMC encourages partnerships and collaborations with the best and brightest individuals and institutions throughout the world. While the majority of research and global engagement may proceed without restrictions, the United States government imposes controls on certain exports to protect the spread of strategically important technology, services, and information to foreign countries and Non-U.S. Persons. The University recognizes the importance of these regulations and requires compliance with these export controls from every member of the UNMC community.

Statement of Policy

All UNMC Personnel must comply with all applicable United States laws and regulations while teaching, conducting research, providing care, traveling internationally, or participating in other activities at or on behalf of UNMC. As such, UNMC Personnel are required to comply with the laws, regulations, and University of Nebraska policies governing the transfer of items, information, technology, software, and funds to destinations and persons outside of the United States, as well as to Non-U.S. Persons in the United States, including UNMC and/or Nebraska Medicine personnel.

UNMC Personnel will not engage in any export transaction unless all required licenses or other approvals are in place.

There are no exceptions to this policy.

Responsible Parties

Empowered Official for ITAR

Pursuant to 22 C.F.R. 120.25, the University of Nebraska's Senior Empowered Official may appoint one or more individuals to serve as Empowered Official for ITAR for UNMC. The Empowered Official for ITAR has independent authority to oversee UNMC's compliance with the International Traffic in Arms regulations, including the

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following authorities and responsibilities:

1. Serving as UNMC's sole signatory authority on applications for export licenses and other requests for approval under the International Traffic in Arms Regulations;

2. Inquiring into any aspect of a proposed export or temporary import;

3. Verifying the legality of all export and temporary import transactions and the accuracy of the information to be submitted to the relevant government agencies;

4. Refusing to sign any license application or other request for approval without prejudice or other adverse recourse;

5. Taking appropriate measures to enforce this policy, including without limitation halting or suspending activities and exports; and

6. Any other authorities and responsibilities enumerated at 22 C.F.R. 120.25.

Export Control Office

The director, officers, managers, and coordinators of the Export Control Office are responsible for developing, maintaining, and enforcing UNMC's export policies and procedures. Specifically, the responsibilities of the Export Control Office include:

1. Serving as the primary point of contact for UNMC Personnel regarding this policy and export controls generally;

2. Advising UNMC and UNMC Personnel on transactions and other relationships with Restricted Parties;

3. Providing guidance to UNMC Personnel regarding international travel and export transactions;

4. Assisting UNMC Personnel in developing and maintaining compliance protocols for export-controlled activities;

5. Providing training and other educational resources related to export compliance to UNMC Personnel;

6. Working with other UNMC offices as appropriate to support compliance with federal law and University of Nebraska policy, including assisting in reviewing agreements governing international transactions and/or export-controlled activities, reviewing international shipments, and reviewing disclosures of foreign support;

7. Serving as UNMC's sole signatory authority for export license applications related to any activities subject to the Export Administration Regulations, the Foreign Assets Control Regulations, and other regulations governing exports;

8. Supporting the Empowered Official for ITAR;

9. Performing periodic and ad hoc audits of UNMC activities subject to export controls to verify compliance with this policy and federal export laws and regulations; and

10. Investigating reported or suspected violations of this policy or federal export laws or regulations.

UNMC Personnel

All UNMC Personnel are responsible for:

1. Disclosing international research, service, clinical activity, and travel to the Export Control Office;

2. Complying with the terms of awards or service agreements subject to export controls, including, as necessary, developing Technology Control Plans in coordination with the Export Control Office;

3. Monitoring compliance with any Technology Control Plan(s) for themselves and any other UNMC Personnel under their supervision;

4. Reporting any violations, or suspected violations, of this policy or export control laws or regulations to the Export Control Office or anonymously through the UNMC Compliance Hotline;

5. Completing export compliance training as assigned by the Export Control Office; and

6. Taking any other steps or compliance actions as directed by the Export Control Office.

Violations

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Failure to comply with this policy will result in corrective or disciplinary action as provided under UNMC Policy No. 1098, Corrective and Disciplinary Action, including termination, dismissal, or exclusion from participation in federally funded activities. Failure to comply with US export law may result in significant criminal and civil penalties for both the individual in violation and UNMC.

Additional Information and Resources

- For more information about the applicability of export controls to specific activities (including research, shipping, and international travel), please contact the UNMC Export Control Office (402-559-9328).
- UNMC Compliance Hotline: 1-844-348-9584 or www.nebraska.ethicspoint.com
- UNMC Export Control Website
- UNMC Transporting and Shipping Internationally website
- UNMC Policy No. 1098, Corrective and Disciplinary Action
- UNMC Policy No. 8014, Disclosing Foreign Support and International Activities
- Directorate of Defense Trade Controls website
- Bureau of Industry and Security website
- Office of Foreign Assets Controls website
- National Nuclear Security Administration website

UNMC Policy 8010 *(revised: 9/20/21)*

Conflict of Interest Policy

Basis for Policy

Statutes, regulations, University policies and accreditation standards related to conflict of interest identification and management are:

1. "Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors" regulations at 42 CFR Part 50 and 45 CFR Part 94
2. "Financial Disclosure by Clinical Investigators" Food & Drug Administration regulations at 21 CFR Part 54
3. Nebraska Conflict of Interest Statute at Neb. Rev. Stat. §49-1493 et. seq.
4. Bylaws of the Board of Regents of the University of Nebraska Sections 3.10, 3.4.5 and 3.8
5. Board of Regents Conflict of Interest Policy, RP-3.2.8
6. Board of Regents Patent & Technology Policy, RP-4.4.2
7. UNMC Human Research Protections Policy #1.25, "Financial Conflicts of Interest"
8. UNMC Policy No. 1049, Outside Employment
9. UNMC Policy No. 8015, Health Care Vendor Interactions
10. Executive Memorandum No. 36, Disclosure of Conflicts of Interest and Conflicts of Commitment

Policy

Potential conflicts of interest arise in a variety of circumstances in the academic health sciences center environment when an individual's private financial interests either conflict with or create the appearance of conflicting with UNMC's public interests. This policy applies to potential conflict of interest arising in any UNMC activity, including but not limited to research, teaching, patient care, outreach to underserved populations and the associated business activities in support of them. Covered Persons shall disclose all financial interests related to their University of Nebraska responsibilities so that an analysis of potential conflict of interest may be conducted. When a conflict of interest is identified, the conflict will either be managed or eliminated to reduce the appearance of bias and maintain responsible stewardship of public resources. This policy shall be publicly posted in the UNMC Policies and Procedures manual on the UNMC internet site.

Definitions

Covered Person under Regents Policy 3.2.8 shall mean:

1. University administrative officers and employees, specifically including any

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University employees with delegated signature, purchasing or contracting authority on behalf of the university;

2. University employees and faculty engaged in outside employment or other activities specified in this policy (tech transfer/use of University facilities or equipment) that may create a Conflict of Interest; and

3. Sponsored research investigators who participate in sponsored research; and non-sponsored research investigators participating in human subjects or animal subjects research.

Investigator under PHS regulations shall mean the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct or reporting of research which may include graduate students, post-docs, residents, collaborators or consultants. Conflict of Interest (COI) under Regents Policy 3.2.8 shall mean situations when a Covered Person's direct or indirect personal financial interest, (whether or not the value is readily ascertainable) may compromise, or have the appearance of compromising, the Covered Person's professional judgment or behavior in carrying out their obligations to the University of Nebraska. This includes indirect personal financial interests of a Covered Person that may be obtained through third parties such as a Covered Person's immediate family, business relationships, fiduciary relationships, or investments.

De minimus means any remuneration received as payment for services and/or equity interests of $499 or less is not required to be disclosed. Any remuneration received for services and/or equity interests of $500 or greater is required to be disclosed.

Equity includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value.

Financial Conflict of Interest (FCOI) under PHS regulations means a Significant Financial Interest that the COI Officer or COI committee reasonably determines could directly and significantly affect the design, conduct or reporting of research.

Immediate Family under Regents Policy 3.2.8 shall mean an individual who is a spouse, child, brother, sister, grandchild, or grandparent, by blood, marriage, or adoption of the Covered Person.

Institutional Conflict of Interest (ICOI) may occur when the University or a Covered Person in a senior administrative position has a financial interest in a commercial entity that itself has an interest in a University research project, including potential conflicts with equity/ownership interests or royalty arrangements.

Institutional Responsibilities means professional responsibilities on behalf of the University of Nebraska which may include activities such as professional service including patient care, teaching, research & research consultation, outreach, administrative, institutional committee membership including service on panels such as the Institutional Review Board or Data and Safety Monitoring Boards, and other duties as specified in the Covered Person's job description and/or employment agreement.

Remuneration includes salary and any payment for services not otherwise identified as salary including but not limited to consulting fees, honoraria, and paid authorship.

Senior/Key Personnel means the Project Director (PD)/Principal Investigator (PI) and any other person identified as senior/key personnel in the UNMC grant application, progress report, or any other report submitted to the PHS by UNMC.

Significant Financial Interest means a financial interest of the Investigator or their Immediate Family Member that reasonably appears to be related to the Investigator's Institutional Responsibilities, and:

1. If with a publicly traded entity, the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of the disclosure, when aggregated, exceeds $5,000;

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2. If with a non-publicly traded entity, the value of any remuneration received exceeds $5,000 or when a research Investigator or Immediate Family holds any equity interest;

3. Intellectual property rights and interests upon receipt of income related to such rights and interests, excluding income paid by the University of Nebraska.;

4. For PHS-funded research investigators, includes reimbursed or sponsored travel, excluding travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an Institution of higher education.

Conflict of Interest Management Roles and Responsibilities

COI Officer

The UNMC Conflict of Interest Officer shall be responsible for implementing the UNMC COI management program. The COI management program shall also include review and approval of the "Application for Authorization to Engage in Outside Professional Activity" forms as delegated by the Chancellor with associated management of conflict of commitment under Regents Policy 3.8. and UNMC Policy 1049, Outside Employment. The COI Officer shall:

1. Ensure UNMC policy meets Board of Regents policy and state and federal regulatory requirements;

2. Implement annual disclosure requirements for Covered Persons and monitor to ensure compliance. The UNMC electronic Annual Disclosure of Financial Interest form is incorporated into this policy by reference. The Annual Disclosure of Interest and Application for Authorization to Engage in Outside Professional Activity forms are located at: https://unmc.coi-smart.com.

3. Coordinate identified conflict of interest matters with Sponsored Programs Administration, UNeMED, the Institutional Review Board (IRB), the Institutional Animal Care and Use (IACUC) committee, the Assistant Vice Chancellor, Business and Finance (for business COI), and the Continuing Medical and Nursing Education offices as relevant. Whenever a potential COI involving activities with another University of Nebraska campus or university affiliated entity is disclosed or identified, notify the other campus or university affiliated entity COI contact and collaboratively review and manage the potential COI.

4. COI Education. Provide COI education to Covered Persons at time of hire, and every four (4) years thereafter, and immediate re-education when there are policy changes or when investigators fail to comply with the COI policy. For investigators conducting Public Health Service (PHS) sponsored research, education shall be completed prior to the expenditure of any PHS funds.

5. When Covered Persons have significant financial interests related to their institutional responsibilities, present information to the COI committee for potential COI management plan creation.

6. Report FCOI to PHS. When the COI committee has implemented a COI management plan for PHS-funded research, update the PHS e-Commons with the FCOI report provided by the COI committee. Provide initial, annual and revised FCOI reports, if applicable for both UNMC and its subrecipients. Revised FCOI reports shall be submitted within 60 days of identification for new Investigators added to a grant, or newly identified FCOIs for existing investigators. The FCOI report shall contain the following elements:

1. The role and principal duties of the conflicted Investigator in the research project;

2. Conditions of the management

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plan;

3. How the management plan is designed to safeguard objectivity in the research project;

4. Confirmation of the Investigator's agreement to the management plan;

5. How the management plan will be monitored to ensure Investigator compliance; and

6. Other information as needed.

7. Conduct retrospective review. If UNMC identifies a significant financial interest that was not disclosed by a research Investigator in a timely manner, or was not reviewed by UNMC, the COI officer shall, within sixty (60) days: review the significant financial interest and determine whether it is related to PHS-funded research. The COI committee shall determine whether a financial conflict of interest exists, and, if so, implement an interim COI management plan. Within 120 days, the COI committee shall complete a documented retrospective review of the research Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research conducted during the period of non-compliance was biased in the design, conduct or reporting of such research. The documented review shall contain all of the elements required by the PHS regulations.

8. Reporting Bias & Mitigation Report. If bias is found with the design, conduct or reporting of PHS-funded research, the COI Officer shall notify the PHS awarding component promptly and submit a Mitigation Report containing the retrospective review information and a description of the impact of the bias on the research project and UNMC's plan of action taken to eliminate or mitigate the effect of the bias.

9. If the research is clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, the COI committee shall require the Investigator to disclose the FCOI in each public presentation of the results of the research, and request an addendum to previously published presentations, in addition to any applicable disclosure listed below in Disclosure of Financial Interest.

10. Public Disclosure. Disclose Financial Conflicts of Interest (FCOI) of senior/key personnel involved in Public Health Service funded research only as determined by the COI Committee in response to public requests within five (5) business days of the request as required by PHS regulations. These requests shall be coordinated with the University of Nebraska Records Management Officer.

11. Board of Regents Annual Report. Submit the annual Conflict of Interest and Outside Activities report to the University of Nebraska Director of Internal Audit and Advisory Services for review by the Board of Regents Audit Committee.

Covered Persons

1. Annual Disclosure of Financial Interest. Individuals covered under this COI policy shall complete a UNMC Annual Disclosure of Financial Interest Questionnaire through the UNMC electronic e-Disclosure system annually. Covered Persons shall receive an e-mail notification from the Compliance Department to complete the form. The UNMC Disclosure of Financial Interest form contains all elements required under Board of Regents policy and federal regulations (including PHS regulations) and is incorporated into this policy by reference. The electronic system may be accessed at: https://unmc.coi-smart.com. Individuals shall disclose all financial interests related to their University of Nebraska (institutional) responsibilities.

2. Research Investigators shall review and update their Annual Disclosure of Financial Interest when sponsored grants and contracts are submitted, including PHS-funded research. Investigators

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shall update their Annual Disclosure of Financial Interest form within thirty (30) days of discovering or acquiring a Significant Financial Interest and on an annual basis thereafter during the period of the award.

3. Education. Covered Persons shall complete education on Board of Regents COI policy, UNMC COI policy, and PHS COI regulations, and their disclosure responsibilities prior to initially completing the Annual UNMC Disclosure of Financial Interest, and every four (4) years thereafter. Covered Persons shall not spend any PHS research funds until education has been completed.

4. Disclosure of Financial Interest. Covered Persons who are research Investigators shall disclose the nature of all financial interests related to their research (e.g. consulting advisory board, intellectual property) in all publications and presentations and to all UNMC personnel involved in the research project, including students. In human subjects research, Investigators shall disclose their financial interests related to the research in the informed consent, as required by UNMC HRPP Policy 1.22.

5. Appeal Rights. Covered Persons may appeal adverse decisions made under this policy to the Senior Vice Chancellor for Academic Affairs. The appeal shall be in writing and contain a description of the adverse decision, justification for why the decision should be changed, and the change desired. The appeal request shall be submitted to the COI Officer. The VCAA shall respond in writing to the Covered Person with their decision within thirty (30) days of receipt. The VCAA's decision is final.

COI Committee

The UNMC COI Committee composition and operating procedures are contained in Appendix A. The COI Officer shall be a member of the COI committee and shall provide administrative support for the committee. The COI committee shall:

1. Provide oversight over the UNMC COI program, advise the COI officer, and provide guidance on UNMC COI policy matters.

2. Review Significant Financial Interests. Review Disclosures of Financial Interest in the amount of $5,000 and above for research Investigators and determine if these Significant Financial Interests are related to the research, and, if so related, whether the Significant Financial Interest constitutes a Financial Conflict of Interest. A Significant Financial Interest is a Financial Conflict of Interest if it could directly and significantly affect the design, conduct , or reporting of research, including PHS-funded research.

3. Create COI Management Plans for Financial Conflicts of Interest.

4. Conduct retrospective reviews of newly identified Significant Financial Interests as described in Conduct Retrospective Review above.

5. Review COI Policy violations and recommend sanctions, if appropriate, to the Senior Vice Chancellor for Academic Affairs and to the appropriate UNMC administrator responsible for supervision of the individual(s) violating the policy.

Sponsored Programs Administration

Sponsored Programs Administration shall:

1. Notify all research Investigators submitting sponsored grant/contract proposals to review their Annual Disclosure of Financial Interest form and update the information as needed.

2. Coordinate with the COI Officer when Investigators disclose significant financial interests related to the sponsored project to determine if a COI management plan is required.

Subrecipients. Include provisions in PHS-funded subrecipient agreements that:

1. the subrecipient certifies that its FCOI policy complies with PHS regulations or that the subrecipient will follow the UNMC COI policy; and

2. the subrecipient shall report identified FCOIs for its Investigators in a timely manner so UNMC can report

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identified FCOIs to the PHS in the time frames in Report FCOI to PHS and Conduct retrospective review above.

Vice Chancellor for Business, Finance and Business Development

The Vice Chancellor for Business, Finance and Business Development shall manage business conflict of interest by reviewing all Annual Disclosure of Financial Interest questionnaires completed by Covered Persons with contract signature authority under Executive Memorandum 13 and 14; Covered Persons with purchasing authority; Covered Persons who identify family member(s) with a financial interest with the University of Nebraska; and any other potential business-related financial interest identified by the COI Officer through the annual COI disclosure process or by any other person at UNMC. Business COI management plans shall be created to minimize the appearance of bias in decision-making and ensure state and federal regulations and University of Nebraska business-related policies are followed. Business COI management plans shall be reported through the UNMC COI committee and reported on the Annual COI report to the Board of Regents Audit committee.

No employee, officer, or agent may participate in the selection, award, or administration of a contract supported by a Federal award or non-federal entity if they have a real or apparent conflict of interest. Such a conflict of interest would arise when the employee, officer, or agent, any member of their immediate family, their partner, or an organization which employs or is about to employ any of the parties indicated herein, has a financial or other interest in or a tangible personal benefit from a firm considered for a contract.

Institutional Review Board (IRB)

The IRB shall require all Covered Persons listed on the IRB application who have a financial interest to update their Annual Disclosure of Financial Interest form pursuant to UNMC HRPP Policy 1.22. The IRB shall review and approve proposed COI management plans as described in HRPP Policy 1.22.

UNeMED

The President of UNeMED or designee shall coordinate with the COI officer on UNeMED activities where it appears that a Covered Person's or UNMC's financial interest may be a potential individual or institutional conflict of interest, including intellectual property interests and equity interests involving technology transfer companies.

Continuing Education Offices

UNMC is accredited by the Accreditation Council for Continuing Medical Education (ACCME). The Continuing Medical Education (CME) office shall review disclosures of financial interest for UNMC employees who are serving as course directors, faculty or peer reviewers for UNMC CME courses, as required by the ACCME Standards for Commercial Support.

Institutional Conflict of Interest Management

In order to avoid real or perceived favoritism in relationships with research sponsors, each/every potential Institutional COI shall be reported. Any Covered Person who has knowledge of potential Institutional COI shall report the information to the COI Officer. Potential Institutional COI may be identified through the Annual Disclosure of Financial Interest questionnaire for senior administrative personnel. The COI Officer shall convene a group of senior UNMC officials appointed by the Chancellor to review the disclosure and propose a management plan for Chancellor approval if appropriate. It is important to note that PHS COI regulations do not cover institutional conflict of interest.

Records Retention

All Disclosure of Financial Interest information, COI management plans and all Public Health Service-funded Financial Conflict of Interest-related records shall be retained for the fiscal year in which the grant or contract is closed plus seven (7) years as required by Board of Regents Records Retention Schedule 170-8, "Sponsored Projects (Grants)". No

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destruction of records shall take place if there is a Preservation Hold in effect, or if any litigation, claim, negotiation, audit or other actions involving the records have been started before the expiration of the retention period. The records must be retained until completion of the action and resolution of all issues which arise from it, or the seven year retention period, whichever is later, as required under 45 CFR 74.53 and 92.42.

Public Accessibility of PHS-funded Senior/ Key Personnel FCOI

Upon request, the COI Officer shall make available to the public information concerning identified FCOIs held by Senior/Key personnel receiving PHS research funding as required by PHS regulations. Information shall be provided in writing within five (5) business days of the request. The COI officer shall coordinate these public requests with the University of Nebraska Records Management Officer. All other financial interest disclosure information and conflict of interest determinations shall remain confidential and may be withheld from the public as permitted under Neb. Rev. Stat. 84-712.05, "Records which may be withheld from the public; enumerated."

Sanctions

Covered Persons who violate this policy may receive corrective action under UNMC Policy No. 1098, Corrective and Disciplinary Action Policy. The COI Committee may also recommend other corrective action such as additional training, or for serious violations, recommend that research funding be withheld or recommend other appropriate sanctions to maintain the integrity of the research. The Senior Vice Chancellor for Academic Affairs shall review and approve all proposed sanctions. The sanctions shall be coordinated with the respective Dean, Director or Vice Chancellor for enforcement.

Policy 8010 Appendix A
Conflict of Interest Committee (COIC)

Governance

COI Committee Composition. The COI Committee shall have at least 16 members representing the following areas:

- Associate VC, Academic Affairs
- College of Allied Health Professionals
- College of Medicine
- College of Dentistry
- College of Pharmacy
- College of Nursing
- College of Public Health
- Eppley Cancer Institute
- Compliance Officer
- Sponsored Programs Administration
- Associate General Counsel
- Business and Finance
- Vice Chancellor for Research
- Research Compliance (Institutional Review Board)
- Continuing Education
- Community Member

Membership Term. COI Committee members shall serve for a term of three years, which may be automatically renewed upon mutual agreement of the member and the Chancellor or their designee. New members shall be nominated by the department/unit and approved by the Senior Vice Chancellor for Academic Affairs or their designee. The Chancellor or their designee shall appoint a faculty chair of the COI Committee. The Vice Chancellor of Academic Affairs or their designee shall select the community member. The Chancellor or his designee can appoint additional voting and non-voting members.

Quorum. A quorum is required for meetings to be conducted. More than half of the membership present will constitute a quorum.

Voting. All committee members are eligible to vote. No regular motion shall pass unless a majority of the COI Committee members present vote in favor of the motion.

COIC Member Conflicts. If a COIC

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member has a conflict of interest with a specific matter being discussed, the member shall declare that they have a potential conflict and shall not vote on the matter. Such conflicts may arise when:

1. the member is participating in the research under review;
2. the member has a financial relationship with a research sponsor under review; or
3. the member has a personal relationship or conflict with the individual under review that could potentially cause the member to be perceived as less than objective in their review.

Committee Review by Telephone/ Electronically. While face-to-face and/ or Zoom meetings will normally be held, committee review of potential conflicts may be conducted by telephone or electronically at the discretion of the COI Committee chair.

Meeting Minutes. The Compliance Manager or their designee shall prepare meeting minutes and present them for approval at the next scheduled COI Committee meeting.

Additional Information

- Contact the Chief Compliance Officer
- Contact the Assistant Vice Chancellor for Business and Finance
- Business Conflict of Interest Procedures
- Research Conflict of Interest Procedures
- UNMC Policy No. 1049, Outside Employment
- UNMC Policy No. 8015, Health Care Vendor Interactions
- Application for Authorization to Engage in Outside Professional Activity
- Annual Disclosure of Financial Interest Questionnaire
- UNMC Statement of Understanding Training Information document
- Executive Memorandum No. 36, Disclosure of Conflicts of Interest and Conflicts of Commitment

UNMC Policy 8014 *(Revised: 1/7/20)*
Disclosing Foreign Support and International Activities

Authority

Statutes, regulations, and policies related to disclosures of foreign support and relationships with foreign entities or individuals include, but are not limited to:

- Nebraska Conflict of Interest Statute, Neb. Rev. Stat. §49-1493
- Board of Regents Bylaws sections 3.4.5, 3.8 and 3.10
- Board of Regents Policy RP-3.2.8, Conflict of Interest and conflict of Commitment
- Board of Regents Policy RP-4.4, Intellectual Property
- University of Nebraska Travel Policy
- UNMC Policy No. 1098, Corrective/ Disciplinary Action
- UNMC Policy No. 6014, Travel and Reimbursement
- UNMC Policy No. 8005 Export Control
- UNMC Policy No. 8010, Conflict of Interest

Definitions

Foreign Entities include, by way of example: foreign governments and agents thereof; foreign colleges, universities, and research institutions; business associations organized under or otherwise subject to the laws of foreign jurisdictions; foreign journals and professional organizations.

Foreign Individuals include individuals, regardless of citizenship, employed by or otherwise acting on behalf of a Foreign Entity.

Support(ed) includes any financial or non-financial support for any aspect of any activity. Non-financial support may include exchanges of data or materials; donations of equipment, software, or other materials; or payment of travel and related expenses, including meals and lodging.

Activities Supported by Foreign Entities or Individuals are any activity for which a Foreign Entity or Foreign Individual provides financial or non-

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financial Support, including without limitation:

a. Serving as an employee or agent of a Foreign Entity or Foreign Individual;

b. Collaborating in research with a Foreign Entity or Foreign Individual, including designing experiments, collecting and analyzing data, preparing manuscripts for presentation or other publication, and presenting or otherwise publishing the results of research;

c. Providing consulting services to a Foreign Entity or Foreign Individual, whether or not such services are compensated;

d. Developing partnerships or other business relationships with a Foreign Entity or Foreign Individual;

e. Accepting gifts, including donations of funding, accommodations, travel-related expenses, equipment, software, or any materials to be used in support of research or clinical activities, from a Foreign Entity or Foreign Individual; and

f. Any other activity or relationship subject to a disclosure requirement under University of Nebraska policy or state or federal law that involves a Foreign Entity or Foreign Individual.

UNMC Personnel include, for the purposes of this policy:

a. Faculty;

b. Staff;

c. Students;

d. Volunteers;

e. Visitors; and

f. Any other individuals who participate in any activity on behalf of UNMC, irrespective of appointment, compensation, or the location of the activity.

Scope

This policy applies to all UNMC Personnel, irrespective of appointment, compensation, or the location of the activity.

Purpose

Establish requirements for disclosing Support

UNMC is committed to building partnerships on a global scale. At the same time, federal and state law and University of Nebraska policy require transparency with respect to certain activities and relationships involving Foreign Entities or Foreign Individuals. The purpose of this policy is to establish requirements for disclosing Support received from Foreign Entities or Foreign Individuals by UNMC personnel.

Supplement and clarify existing policy

This policy is designed to supplement and clarify existing University of Nebraska and UNMC policies on reporting conflicts of interest and commitment involving Foreign Entities or Foreign Individuals, and does not replace or supersede disclosure requirements imposed by federal or state law or other University of Nebraska or UNMC policies, including those listed above.

Statement of Policy

Disclose nature of Support

All UNMC personnel who receive Support from a Foreign Entity or Foreign Individual must disclose the nature of the Support in accordance with RP 3.2.8 and UNMC Policy No. 8010. Additionally, UNMC personnel engaging in research must make such disclosures prior to or while applying for federal research funding or participating in federally funded research. In no event will any federal funds be spent or committed until all disclosure requirements related to Support from a Foreign Entity or Foreign Individual have been fulfilled.

Obtain permission from Vice Chancellor for Business and Finance

All UNMC Personnel who wish to

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establish a clinical practice or for-profit or non-profit business outside the United States must obtain permission from UNMC's Vice Chancellor for Business and Finance prior to establishing the practice or business.

Obtain permission from Vice Chancellor for Research

All UNMC Personnel who wish to establish a research laboratory outside the United States, or to engage in research physically located at a foreign institution, must obtain permission from UNMC's Vice Chancellor for Research prior to commencing the conduct of such research.

Disclosure Requirements

Comply with UNMC Policy No. 8010

Activities Supported by Foreign Entities or Individuals must be disclosed using the mechanisms for conflict of interest assessment prescribed in UNMC Policy No. 8010. Disclosures of Activities Supported by Foreign Entities or Individuals are subject to review by the relevant academic program leader, the Chief Compliance Officer, the Export Control Director, and other UNMC officials as appropriate.

Comply with any funding organization disclosure requirements

When applying for external research funding, UNMC personnel must also comply with any disclosure requirements imposed by the funding organization. In many cases, this may require making separate disclosures to UNMC in addition to any disclosures required by the external funding organization.

Violations

Failure to comply with this policy will result in corrective or disciplinary action as provided under UNMC Policy No. 1098, Corrective/ Disciplinary Action, including termination, dismissal, or exclusion from participation in federally funded activities.

Additional Information

- Contact the Chief Compliance Officer
- Contact the Export Control Director
- Department of Energy Order 486.1, Department of Energy Foreign Government Talent Recruitment Programs
- NIH Notice No. NOT-OD-19-114
- NSF Letter 19-200

APPENDIX II

GLOSSARY OF TERMS

article of manufacture One of four principal categories of things that may be patented in United States patent law. The other three are a process (or method), a machine, and a composition of matter. The Supreme Court has defined "manufacture" as "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery." Examples of articles of manufacture are ceramics, cast metal articles, hammers, crowbars, chairs, shovels, gloves, shoes, envelopes and mouse-pads. Articles of manufacture may have parts, but any interaction among the parts is usually static. A natural article, even if subjected to a process, is not an article of manufacture. *(Source: Wikipedia)*

assignment Legal transfer of a claim, right or property.

AUTM Association of University Technology Managers was founded in 1974 as the Society of University Patent Administrators to address a concern that inventions funded by the U.S. government were not being commercialized effectively. AUTM now provides professional development and networking opportunities for technology transfer professionals and from similar organizations worldwide.

Bayh-Dole Act Passed in1980, provides ownership rights to universities and other non-profit institutions for discoveries resulting from federally funded research, provided certain obligations are met. Obligations include efforts to protect and commercialize the discoveries; submitting progress reports to the funding agency; giving preference to small businesses that demonstrate sufficient capability; and sharing any resulting revenues with the inventors.

commercialization The application of business methods as a way to advance a new technology to market.

composition of matter One of four principal categories of things that may be patented in United States patent law. The other three are a process (or method), a machine, and an article of manufacture. The Supreme Court has defined "composition of matter" to mean "all compositions of two or more substances and all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids." *(Source: Wikipedia)*

confidential disclosure agreement (CDA) A legal contract between at least two parties that outlines confidential material, knowledge, or information that the parties wish to share with one another for certain purposes, but wish to restrict access to or by third parties. Also known as a nondisclosure agreement (NDA), it is a contract through which the parties agree not to disclose information covered by the agreement. The contract creates a confidential relationship between the parties, typically to protect any type of confidential and proprietary information or trade secrets.

continuation A patent application that allows an inventor to expand the claims or scope of a previous or "parent" patent application while using the same description and priority date of the orginal. Continuations are sometimes used to expand the coverage of patent claims, reduce overall costs or buy more time for additional research.

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copyright A form of intellectual property protection for expressions of creative works. Common examples of copyrights include books, music, movies, photos and artworks.

declarations The part of a U.S. patent application where the inventor asserts that they are the original inventor, that they've read and understand the application and promise to disclose any relevant information to the Patent Office.

disclosure Any description of an invention that that would sufficiently enable the audience to recreate the invention. An enabling disclosure could be conversation at a dinner party, publishling a paper or poster, a grant application or delivering an open seminar or even an email.

discovery The act of being the first to find, know about or see something. Discoveries of laws of nature are not patentable and do not have intellectual property rights.

innovation The creation of something new that improves an existing process, product or service.

intellectual property Inventions or material that may be protected under patent, trademark, trade secret or copyright laws.

inter-institutional agreement Terms under which two or more institutions will collaborate to assess, protect, market, license, and share in the revenues received from licensing jointly owned intellectual property.

invention Any new and useful process, machine, composition of matter, article of manufacture, or any improvement of those things.

invention evaluation An examination of an invention's novelty, protectability, marketability, market size and growth potential, related intellectual property already on the market, resources required for further development, and potential competition from other products or technologies.

inventor A person who contributed something in the way of an idea, concept or feature on an invention that is included in a patent application.

license agreement A contract describing the rights and responsibilities related to the use and exploitation of intellectual property. Usually, a UNeMed licensee is obligated to develop a technology and ultimately bring it to market in return for a royalty on net sales.

machine One of four principal categories of things that may be patented in United States patent law. The other three are a process (or method), an article of manufacture, and a composition of matter. The Supreme Court has defined the term "machine" as "a concrete thing, consisting of parts, or of certain devices and combination of devices." This "includes every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result." The parts must interact (usually dynamically) with one another, otherwise they might be parts of an article of manufacture. Examples of machines are steam engines, sewing machines, and TV sets. Electronic circuits have usually been considered machines, although they may lack moving parts. *(Source: Wikipedia)*

material transfer agreement (MTA) Terms under which faculty, students and staff at the University of Nebraska may share materials with outside entities, such as research collaborators.

method *See "process"*

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milestone A target of achievment set forth in a license agreement that creates incentives to meet timelines and performace goals while also setting conditions for penalties upon failure to meet those goals.

new invention notification (NIN) A written description of an invention that creates a dated record and provides information from which the patent and commercial potential can be evaluated.

nondisclosure agreement *See "confidential disclosure agreement"*

non-obvious One of five requirements for patentability of an invention under U.S. patent law. Non-obviousness is the subjective determination that an invention was an unpredictable and unique combination of existing inventions, if any such combining elements exist. The other four patent requirements are that an invention be comprised of eligble subject matter, be useful, be novel, and be adequately described.

office action A patent examiner's summary of findings regarding the allowability of the inventor's claims in a patent application.

option agreement A description of the conditions under which UNeMed preserves the opportunity for a company to negotiate a license for intellectual property. Options are often used with companies who wish to evaluate a technology before entering a full license agreement.

patent agent A person who has passed the rigorous U.S. Patent and Trademark Office patent bar exam, and can legally work on, file and initiate patent applications. Unlike a patent attorney, however, a patent agent may not draft contracts or advise clients about potential courtroom proceedings.

patent attorney A lawyer who has passed the U.S. Patent and Trademark Office patent bar exam, and is legally qualified to represent clients in court regarding intellectual property. Patent attorneys can also draft contracts as well as perform the same functions as patent agents.

patent claims Describe specifically the "metes and bounds" of a patented invention. The full scope of the invention is limited to what is covered in the claims.

Patent Cooperation Treaty (PCT) An international treaty that makes it possible to file for patent protection in more than 150 foreign patent offices with a single application.

patent examiner A federal employee at the USPTO who determines whether or not a patent can be granted.

patent prosecution The patent application process of drafting, filing and negotiating with the U.S. Patent and Trademark Office. This does not include litigation, which is only possible after a patent has been issued.

prior art Any evidence that an invention is already known.

process One of four principal categories of things that may be patented in United States patent law. The other three are an article of manufacture, a machine, and a composition of matter. A process is a series of steps for performing a function or accomplishing a result. While the terms "method" and "process" are largely interchangeable, "method" usually refers to a way to use a product to accomplish a given result, and "process" usually refers to a series of steps in manufacture. Thus, one might speak about a method for curing headaches that comprises the

APPENDIX II: **GLOSSARY**

administration of a therapeutically effective dose of aspirin or speak about a process for making soap or candles. *(Source: Wikipedia)*

protection Tools used to guard an invention or intellectual property from theft or appropriation. Tools include patents, copyright, trademark, trade secrets and contractual use restrictions.

provisional patent application A simplified patent application that preserves patent rights, without the need of listing claims. Provisional applications are not examined during the one-year they are pending, which allows inventors to do things like collect more data, refine a prototype or produce a more complete patent application.

rights, exclusive Grants only the licensee, and no one else, the right to use, make or sell a protected intellectual property.

rights, non-exclusive Grants the licensee the right to use, make or sell a protected intellectual property, but UNeMed may still grant similar rights for the same intellectual property to any number of other entities.

royalty sharing agreement A formal document signed by each inventor of one or more technologies included in a license. The agreement spells out exactly how inventor proceeds from the license will be distributed between the inventors.

royalty Payment made for the right to use an intellectual property.

Sponsored Program Administration (SPA) Assists UNMC faculty and administration with negotiating terms for governemnt and non-profit grants and contracts. SPA also reviews and approves budgets and applications to external sponsors, and tracks pending and future funded projects.

sponsored research agreement The terms under which sponsors—such as a pharmaceutical firm or a medical device manufacturer—provide support for additional research at the University.

startup A newly established business.

technology transfer The process of protecting and moving an invention as a concept or early-stage technology in academia to a tangible product or process that is available on the open market.

trade secret Confidential strategies or information that give their users a competitive advantage. Examples of trade secrets are the recipes for Coca-Cola and Kentucky Fried Chicken.

trademark Any work, name, symbol, device, or combination that is used in commerce to identify and distinguish the goods of one manufacturer or seller from those manufactured or sold by others.

USPTO United States Patent & Trademark Office.

utility patent One of three patent types available through the U.S. Patent and Trademark Office. Utility patents are the most common type, conferred to inventions that are machines, articles of manufacture, compositions of matter or processes that are novel, non-obvious, and useful. The other patent types are design patents, which protect the way things look, and plant patents, which protect new varieties of asexually produced plants.

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