



# Intellectual Property Guide

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## Introduction

The University of Kentucky Intellectual Property Development Guide is for all faculty, clinicians, staff and students who make a discovery or conceive or develop an innovation while at the University of Kentucky.

This guide provides information on how to disclose the discovery/innovation to the University, the role of the Intellectual Property Development Office in protecting and commercializing University discoveries/innovations, the Intellectual Property Committee, the patent process, and the clinician innovation process. This guide also contains a list of University contacts who will assist you with various intellectual property matters.

The University of Kentucky strives to provide an atmosphere where the spirit of inquiry flourishes and where this scholarly inquiry, in the form of research and other creative activity, ultimately leads to tangible benefits for society. In turn, new and innovative research enables the University to attract external funding as well as the best and brightest faculty and students to continue the tradition of a vital research university.

Innovative research also enables the University to assume a leadership role in addressing the issues and challenges facing Kentucky, the nation and the world. The commercialization of intellectual property stimulates economic development, results in new products and businesses, creates jobs, and strengthens the Kentucky economy.

The management and commercialization of intellectual property (IP) is a process and a partnership between the University and the faculty, staff and students who make the discoveries. The UK policies and procedures governing intellectual property are in AR 7:6 (formerly II-1.1-3).

## Acronyms

IP	Intellectual Property
IPC	Intellectual Property Committee
IPDO	Intellectual Property Development Office
VAC	Von Allmen Center for Entrepreneurship

## Contacts

Topic	Contact
Patents Licensing Inter-institutional Agreements	Don Keach Intellectual Property Development Office 148 ASTeCC 859.218.6556 <a href="mailto:dkeach@uky.edu">dkeach@uky.edu</a>
Material Transfer Agreements Confidential Disclosure Agreements	Natasha Jones Intellectual Property Development Office 140 ASTeCC 859.218.6554 <a href="mailto:tasha.jones@uky.edu">tasha.jones@uky.edu</a>
Online Disclosure Process Royalty Distributions	Sabrina Darnell Intellectual Property Development Office 144 ASTeCC 859.218.6555 <a href="mailto:sabrina.darnell@uky.edu">sabrina.darnell@uky.edu</a>
Copyrights Trademarks Trade Secrets Distance Learning	Katherine Adams Office of Legal Counsel 301 Main Building 859.257.2936 <a href="mailto:kadams@uky.edu">kadams@uky.edu</a>
Startup Companies Clinician Innovation & Commercialization Therix Medical Development	Dean Harvey Von Allmen Center for Entrepreneurship 107 ASTeCC 859.257.1930 <a href="mailto:harvey@uky.edu">harvey@uky.edu</a>
Sponsored Agreements, including Clinical Trial Agreements Conflict of Interest	Sponsored Projects Administration (OSPA) 109 Kinkead Hall 859.257.8311

## General FAQs

### What is intellectual property?

Intellectual property (IP) is the “tangible or intangible results of research, development, teaching, or other intellectual activity.” In other words, IP is any innovation or discovery conceived or developed by faculty, staff or students using University resources. “Use of University resources” is broad and includes all use of employee or student time, equipment, supplies or facilities and clinical practice. Even when no physical facilities have been used, an idea arising from your work is IP covered by this policy.

### Who owns the IP and what is the Bayh-Dole Act?

The University has the right to own all IP as defined above. The 1980 Bayh-Dole Act gives universities the right to retain ownership of IP resulting from federally funded research. This right of ownership allows UK to protect your rights to use the IP and to continue to build on your research. UK safeguards not only your rights as the originator but also safeguards the IP as the University works to bring the IP into public use.

The University does not claim any ownership rights in the area known as “traditional products of scholarly activity.” These work products, developed at the author’s initiative, include journal articles, textbooks, reviews, works of art including musical compositions and traditional course materials. The University considers these items the unrestricted property of the author or originator.

### What do you do if you have an idea?

It is the responsibility of each faculty member, staff member and student who develops IP to report it to UK’s Intellectual Property Committee by completing the online disclosure form at <https://uky.ttoportal.com>.

### What is the Intellectual Property Committee (IPC)?

The Intellectual Property Committee is a standing committee composed of faculty and staff with a wide range of technical expertise. The IPC decides if UK has a legal ownership interest in a property and makes an initial determination of who the inventors are and if all work was conducted at UK. The IPC also determines if the University of Kentucky Research Foundation (UKRF) should pursue appropriate protection and if there is potential for commercialization.

Typically, the originator meets with the IPC to describe the innovation and answer questions. The IPC will notify the originator of UK’s plans to pursue its legal interests in the IP. If the committee determines that UK has a legal interest in the IP, the Intellectual Property Development Office will work with outside patent counsel to determine the appropriate protection – trade secret, copyright or patent.

A list of IPC members for 2012-13 is on page 13, and the 2012-13 IPC meeting dates are on page 14.

**What happens after you submit your disclosure online at <https://uky.ttoportal.com>?**

First, the IPDO Director determines if a commercialization assessment needs to be conducted. If so, the inventor will meet with an IPC member and a representative from the Von Allmen Center for Entrepreneurship (VAC) for a structured interview, and the VAC representative will prepare the commercialization assessment.

After the commercialization assessment is complete, or if no commercialization assessment was needed, the IPC chair will schedule a date and time for the IPC to review the disclosure and render a decision. The inventor may attend the IPC meeting but is not required to do so. If the disclosure addresses a clinician innovation, the IPC Chair refers the disclosure to Therix Medical Development rather than scheduling an IPC meeting for that disclosure. More information about clinician innovations and Therix Medical Development is provided in the FAQs below.

At the IPC meeting, the IPC will determine (1) if the university has a legal interest in the technology, (2) who the inventors are, and (3) whether UK will pursue the appropriate protection for the technology at this time. Due to the time and substantial expense associated with patent prosecution, UK will take into account the coverage possible along with the commercial market in deciding whether or not to pursue patent prosecution. As a result of the review, not all IP will be patented.

If UK does not pursue appropriate protection and the research was federally funded, IPDO will work with the inventor to have the rights transferred to the inventor by the federal agency that funded the research. If UK does not pursue appropriate protection and the research was sponsored by any other entity, the sponsor typically has the right of first refusal, but the terms of the contract will control its rights. If UK does not pursue appropriate protection and the research leading to the IP was not federally funded and not sponsored, the IP will be released to the faculty, staff or student inventor.

**Who is the inventor?**

An inventor is one who conceives either in whole or in part the invention. An invention may have one or more inventors, and each inventor must be listed in the patent application. It is a question of law whether or not an individual is an inventor. Inventorship is strictly based on identifiable contributions to the patentable elements of an invention. Even someone who actively participated in a research project that resulted in an invention might not be a co-inventor for patent purposes.

**What is a publication?**

When asked if any “publication” has effectively described the invention, most researchers tend to think first of traditional forms of publications such as journal articles. To be on the safe side, however, you should consider most forms of communication – written, verbal or electronic – with any person outside the University to be a publication. Articles, abstracts (which may appear months before the article), electronic postings, student theses and dissertations, student public defenses, poster presentations, PowerPoint presentations, grant proposals and any other uncontrolled dissemination of the information should be considered a publication.

### **What is a laboratory notebook?**

A laboratory notebook is an important tool that provides a detailed record of a research project. The notebook is used for research management and can have important implications for issues ranging from intellectual property management to fraud prevention. A laboratory notebook should be a hardbound book with numbered pages in which no pages have been deleted or added. The cover should have the project name and the start and finish dates for the project. Entries in the notebook should be in ink and deletions should be done with a single line through the deleted material. It is good practice to sign and date the notebook on a daily basis and have someone familiar with the research, but not involved with the research, sign and date the notebook weekly. Electronic lab notebooks may be possible but must meet all requirements for the traditional notebook, and must ensure that it cannot be altered.

### **How can you publish and protect your ability to get a patent?**

In a university setting, the desire to publish new results (in forums including posters, grants, presentations, abstracts, and electronic media) can limit or negate patent protection. Although U.S. patent law has recently changed to become more like foreign countries, the changes take effect over time. At present, under U.S. law, a patent application may still be filed within one year of the date of any “publication” that effectively describes the invention. Most foreign countries require that a patent application be filed before the date of any publication (unless a U.S. patent application has already been filed). Beginning March 16, 2013 U.S. patent law will change to provide that any publication by anyone other than you or those working with you will bar a patent. If you have any questions regarding your publication, please contact the Intellectual Property Development Office, 859.218.6555.

### **How do you benefit from a patent?**

The University licenses its intellectual property to business & industry and University startup companies. Licensing can happen at the same time as patenting—UK does not need an issued patent to license its IP. Often a UK inventor will form his or her own startup company and that company will license the IP the inventor generated.

If UK receives royalties from licensing, those royalties are shared (after patent costs are recovered) with the inventor (40%), the department (20%) and the college (20%). The remaining 20% is reinvested in the commercial development of university-based technologies and businesses through UKRF. See UK Administrative Regulation 7:6 Section VII.

A patent may also attract interest from industry or other collaborations leading to additional research funding.

### **When do you use a confidential disclosure agreement and a material transfer agreement?**

Both MTAs and CDAs provide additional protection for you and UK.

If you will be collaborating with industry and others outside the University on a project, you should first contact the Intellectual Property Development Office to determine if a confidential disclosure agreement (CDA) or Collaboration Agreement should be instituted.

The IPDO also negotiates material transfer agreements (MTA). You are required to contact the IPDO before any tangible research material (chemical or biological) leaves the University. In addition, the IPDO reviews MTAs for incoming materials.

**What office handles sponsored agreements and clinical trial agreements (CTAs)?**

The Office of Sponsored Projects Administration (OSPA) is authorized by the University to negotiate and legally accept sponsored agreements. This includes clinical trial agreements and financial interest disclosures. OSPA also administers the conflict of interest policy.

# Clinician Innovation, Disclosure and Commercialization FAQs

## What is a clinician innovation?

Clinician innovations are ideas for a medical device or diagnostic that arises from clinical practice and that is not part of a funded research project. As employees of the University, clinicians are required to disclose these ideas to the University. Clinician innovations do not have to be reduced to working prototypes before they are disclosed.

## How does a clinician disclose an idea?

It is the responsibility of each clinician—faculty member, staff member and student—who develops IP to report it to UK's Intellectual Property Committee by completing the online disclosure form at <https://uky.ttoportal.com>.

## What happens after the disclosure is submitted?

After the disclosure has been submitted via <https://uky.ttoportal.com>, the IPDO Director determines if a commercialization assessment needs to be conducted. If so, the inventor will meet with an IPC member and a representative from the Von Allmen Center for Entrepreneurship (VAC) for a structured interview. The purpose of the interview is to gather more detail on the idea and the clinical problem it solves. The clinician is requested to bring any drawings or data to the interview if available, but the primary purpose is to start documenting the idea without placing an undue burden on the clinician's time. If at any time it is determined that extramural funding is involved, the disclosure will be immediately forwarded to the UK IP Committee following the normal research disclosure process.

Following the interview, the VAC representative will prepare the commercialization assessment. After the commercialization assessment is complete, or if no commercialization assessment was needed, the IPC chair will refer the disclosure to Therix Medical Development.

## What is Therix Medical Development Inc. (Therix)?

Therix Medical Development is a for-profit company founded by Kentucky Technology Inc., UK's for-profit corporation, for the purpose of commercializing medical device and diagnostic concepts originating in the six colleges that support UK HealthCare. Therix has a highly experienced business team with access to rapid prototyping, patent strategy, FDA assessment, reimbursement planning, investor relations and industry partners. All discussions with Therix personnel are covered under an umbrella confidentiality agreement between UK and Therix.

## If the clinician and Therix decide to partner to develop the technology, what happens next?

First, the clinician and Therix must reach mutual agreement before Therix licenses the concept from University of Kentucky Research Foundation (UKRF), a not-for-profit Kentucky corporation, under its master agreement.

Next, a Therix project team will be assigned to work closely with the clinician to move the project forward. Additionally, the clinician and Therix may mutually agree for Therix to retain the clinician under a consulting arrangement. Please see UK Administrative Regulation II-1.1-1 regarding faculty consulting agreements (available at <http://www.uky.edu/econdev/sites/www4.uky.edu/econdev/files/ar032.pdf>).

The clinician, the UK department and college, automatically share in any royalties received by UK from Therix as prescribed in the UK Administrative Regulation 7:6.

**Is a clinician required to partner with Therix?**

No, the clinician retains the option to choose a partner other than Therix Medical Development. If Therix declines to license the technology or if the clinician decides not to work with Therix, then the disclosure is referred to the IPC for final resolution—whether to release the IP to the clinician or whether to pursue the appropriate protection for the innovation and/or partner with a different company to commercialize. Note that intellectual property associated with a clinician innovation remains University property unless formally released to the clinician by the IPC.

# Patents

A patent is a property right granted by the federal government that allows the owner to exclude others from making, using or selling the patented invention for the life of the patent. Patents are authorized by the U.S. Constitution and have a life of 20 years from patent filing.

An invention must meet three criteria in order to be patentable.

1. The invention must be novel (not already invented).
2. The invention must be useful (referred to as utility).
3. The invention must not be obvious.

There are three types of patents that protect many types of inventions.

- Utility (most university inventions are subject to protection by utility patents)
- Design
- Plant

The University only pursues domestic patents, which have a lifespan of 20 years from filing. An international patent will be pursued if a licensee agrees to cover the patent expenses (see the Patent Cooperation Treaty in the International Protection section of the U.S. Patent & Trademark Office Web site).

## **Understanding the patent process**

The patentability opinion is prepared by outside patent counsel knowledgeable about your research area. The opinion is based on a prior art search. The patentability opinion is the patent attorney's expert opinion of whether or not the innovation is patentable and the scope of coverage likely to be available in light of the prior art search.

The provisional patent holds an invention's "place in line" for one year while a regular patent is pursued. Provisional patents are typically filed when a publication is pending or a potential licensee needs time to do a commercial market assessment.

The patent application contains a detailed description of the background information and "prior art" as well as a complete description of the new invention and how the invention overcomes any problems and disadvantages considered to exist in the prior art. The application contains a number of "claims" that define the scope of the invention.

As the inventor, you will work closely with the outside patent attorney through the Intellectual Property Development Office to describe the invention fully. Failure to describe the invention fully may cause the application to be rejected or may result in issuance of a patent whose claims fail to provide necessary protection for the invention.

It is important to understand that the patent prosecution process is adversarial in nature and the majority of patent applications are initially rejected. A patent examiner from the U.S. Patent & Trademark Office (USPTO) will examine all claims in the patent application. Written responses are generally necessary to respond fully to positions taken by the examiner. As the inventor, your time and assistance is critical in the preparation of each response.

# Copyright, Trademark, and Trade Secret

## **Copyright**

Copyright is a form of protection provided by U.S. law and is automatically established when a work is first fixed in a tangible medium. Registration with the Copyright Office is not required to secure copyright protection. Generally, the copyright owner has exclusive rights to use the copyrighted material, including any derivative uses.

The current copyright law does provide for limited use of copyrighted material under the principle of “fair use” (for purposes such as criticism, comment, news reporting, teaching, scholarship, and research).

Although use of a copyright notice is not required to claim copyright protection, it is desirable to use a notice to put others on notice that the owner does assert copyright protection. The notice should read:

Copyright [YEAR WRITTEN] University of Kentucky [or name of author(s) if a traditional scholarly work].

Additional information identifying the unit or how to contact the author may also be included if desired immediately below the copyright notice.

## **Trademark**

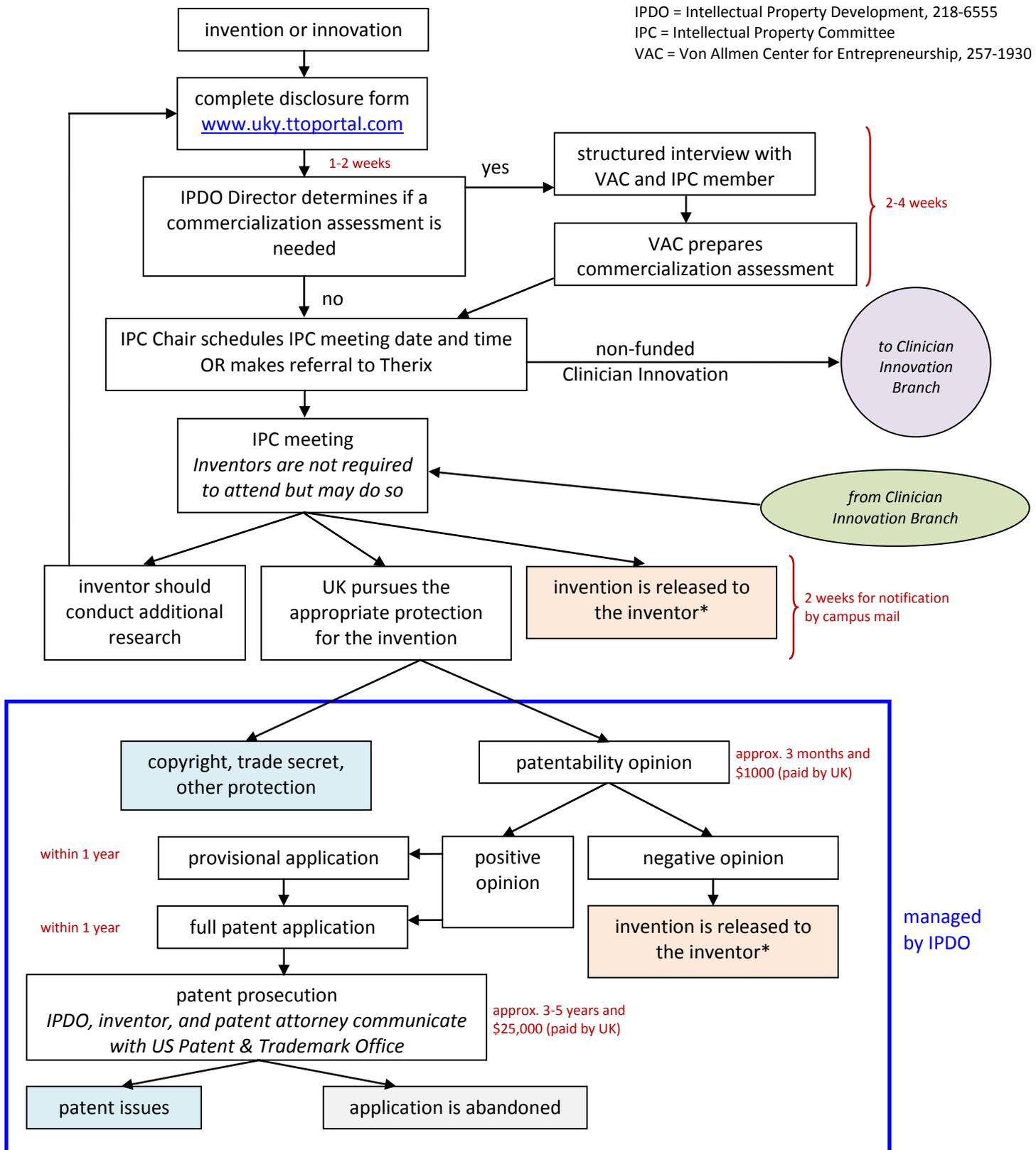
Trademark is a word, name symbol or device or combination of these, used by a manufacturer or seller of goods to distinguish his products from those of other manufacturers or sellers.

## **Trade Secret**

Trade Secret is a plan, process, mechanism, compound or “proprietary information” known only to its owner and to his or her employees to whom it is necessary to confide it.

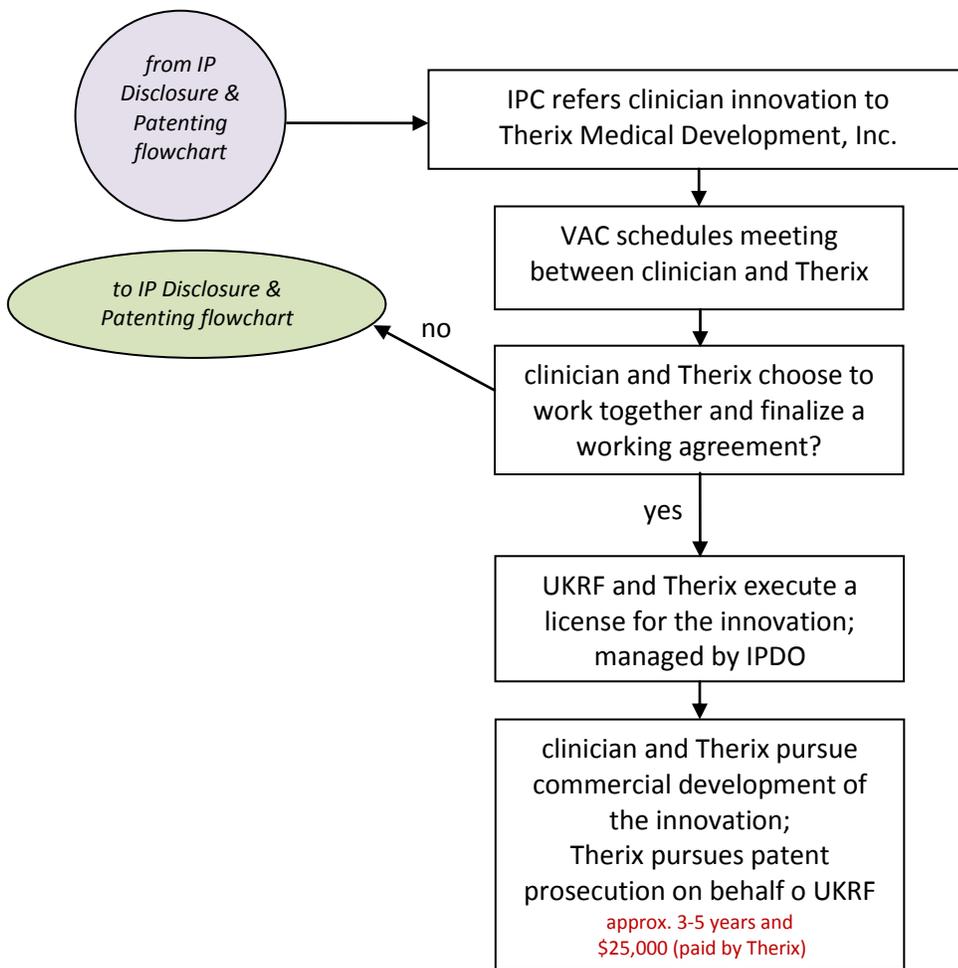
# UK's Intellectual Property Disclosure and Protection Process

IPDO = Intellectual Property Development, 218-6555  
 IPC = Intellectual Property Committee  
 VAC = Von Allmen Center for Entrepreneurship, 257-1930



\* release must be in accordance with the terms of the applicable grant or funding agreement

## UK's Intellectual Property Disclosure and Protection Process— Clinician Innovation Branch



### Questions?

How to make a disclosure .....Sabrina Darnell, [sabrina.darnell@uky.edu](mailto:sabrina.darnell@uky.edu), 218-6555

Patents & Copyrights .....Don Keach, [dkeach@uky.edu](mailto:dkeach@uky.edu), 218-6555

Clinician Innovations .....Dean Harvey, [harvey@uky.edu](mailto:harvey@uky.edu), 257-1930

All other questions .....Don Keach, [dkeach@uky.edu](mailto:dkeach@uky.edu), 218-6555

## 2012-13 Intellectual Property Committee Members

### Committee Members

Bruce Webb, Chair, Entomology  
Czarena Crofcheck, Biosystems and Agricultural Engineering  
Todd Hastings, Electrical & Computer Engineering  
Bert C. Lynn, Chemistry  
Eric Munson, Pharmaceutical Sciences  
Brian Rymond, Biology  
Peter Spielmann, Biochemistry  
Daret St. Clair, Toxicology  
Gary Van Zant, Internal Medicine  
Bruce Walcott, Electrical and Computer Engineering

### Ex Officio Members

James W. Tracy, Vice President, Research  
Don Keach, Director, Intellectual Property Development  
Taunya Phillips

### Counsel

Katherine Adams, Associate General Counsel

UK Administrative Regulation III-4.0-4 addresses the Intellectual Property Committee (available at <http://www.uky.edu/econdev/sites/www4.uky.edu/econdev/files/ar118.pdf>).

## 2013 Intellectual Property Committee Meeting Dates

After you have submitted your IP disclosure online at <https://uky.ttoportal.com> and a structured interview has been conducted, the IPC Chair will designate a date and time for the IPC to review your disclosure and render its decision regarding UK's having a legal interest in the technology and pursuing protection for the technology.

All inventors listed on a disclosure are welcome to attend the IPC meeting where the invention is discussed, but attendance is not required.

Where: ASTeCC Building, Room 157

When: The IPC meets on the third Thursday of each month during the academic year, assuming UK is open on that day.

- January 17
- February 21
- March 21
- April 18
- May 16

The IPC is in session between 1:30 - 5:00 p.m., and each technology on the docket is assigned a specific time. If you choose to attend the meeting, please arrive 15 minutes prior to your scheduled time and wait in the chairs in the hallway outside ASTeCC 157.

Please note that the IPC meeting dates and times are subject to change.

## Royalties

Under UK Administrative Regulation 7:6 Section VII (Royalty Income Sharing Policy), net calendar year royalty or license income derived from commercialization of UK intellectual property shall be shared as follows:

- 40% to the originator,
- 20% to the originator's department or immediate administrative unit,
- 20% to the dean of the originator's college, and
- 20% to UKRF.

Where more than one individual is considered the originator, such persons will determine among themselves the individual share each will receive. In the event that they cannot reach such agreement, the determination shall be made by the IPC after giving each individual an opportunity to present a personal position. Such determination by the IPC shall be final.

Administrative Regulation 7:6 ("Intellectual Property Disposition and Administrative Regulation") is available at <http://www.uky.edu/econdev/sites/www4.uky.edu/econdev/files/ar7-6.pdf>.