Responsible Conduct of Research

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Processes to Promote Responsible Conduct of Research

- Non-Disclosure Agreements
- Material Transfer Agreements
- Copyright Law
- Patent Law
Non-Disclosure Agreements

- Allows for the exchange of confidential and proprietary information.
- Confidential Information may be oral or in writing.
- Includes information which is of a non-public, proprietary or confidential nature
Material Transfer Agreements

- Establishes rights and obligations of parties when material is exchanged.
  - The provider retains ownership of the material.
  - The material is provided “AS-IS.”
  - The material will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the Provider.
  - If material to be used for commercial purposes then a commercial license may be required.
  - will not be transferred to anyone else within the Recipient organization without the prior written consent of the Provider.
Material Transfer Agreements

- Webform established at University to monitor and track MTAs.
- When the University of Delaware is the recipient of the materials, the MTA triggers appropriate health and safety alerts to the Environmental Health and Safety Office concerning the materials received.
- When the University of Delaware is sending materials off campus, the MTA permits review of applicable shipping regulations.
- An MTA permits review of intellectual property rights to protect the interests of the University of Delaware and individual University of Delaware researchers.
Copyright Law

- Copyright law in the U.S. is governed by federal statute - the Copyright Act of 1976.

- The Copyright Act prevents the unauthorized copying of a work of authorship.
Copyright Owner Rights

Copyright Act grants five rights to a copyright owner:

1. the right to reproduce the copyrighted work;
2. the right to prepare derivative works based upon the work;
3. the right to distribute copies of the work to the public;
4. the right to perform the copyrighted work publicly; and
5. the right to display the copyrighted work publicly.
Copyright Requirements

- Originality Requirement
  - For a work to be protected by copyright law, it must be "original."
    - The amount of originality required is extremely small.

- Works of Authorship
  - Congress included a list of eight works of authorship
    - literary works
    - musical works, including any accompanying words
    - dramatic works, including any accompanying music
    - pantomimes and choreographic works
    - pictorial, graphic, and sculptural works
    - motion pictures and other audiovisual works
    - sound recordings
    - architectural works
Not Protected by Copyright

• Works that have not been fixed in a tangible form of expression are not protected under the Copyright Act.
• Titles, names, short phrases, and slogans are not protected by copyright law.
• Copyright law does not protect simple product lettering or coloring, or the mere listing of product ingredients or contents.
• Ideas, procedures, principles, discoveries, and devices are all specifically excluded from copyright protection.
• Copyright protection is generally not available to articles which have a utilitarian function.
Copyright Protection

• Copyright protection exists the moment an original work of authorship becomes fixed.

• There is no need to file an application for copyright protection, or to place a copyright notice on a work.

• This automatic creation of copyright protection in the United States began in 1978.
Copyright Duration

- A work that is created on or after January 1, 1978 is typically given a term enduring for the author's life, plus an additional 70 years after the author's death.
Copyright Limitations

• Fair Use
  – Based on a fundamental belief that not all copying should be banned
    • For example - in socially important endeavors like such as criticism, news reporting, teaching, and research.
  – Four factors
    1) the purpose and character of the use, including whether such use is of commercial nature or is for nonprofit educational purposes;
    2) the nature of the copyrighted work;
    3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and
    4) the effect of the use upon the potential market for or value of the copyrighted work.
Copyright Notice

- Not required but suggested that a work protected by copyright contain a copyright notice and be registered with the U.S. Copyright Office.
  - it informs the public that the work is protected by copyright (and thereby helps to drive away potential infringers);
  - it prevents a party from claiming the status of "innocent infringer", which may allow a party to escape certain damages under the Copyright Act; and
  - it identifies the copyright owner and the year of first publication (so that third parties will know who to contact to request a license to the work).

Example: © 2010 Jane Doe
  - The symbol © (the letter C in a circle), or the word "Copyright" or the abbreviation "Copr.";
  - The year of first publication of the work; and
  - The name of the owner of copyright in the work.
Copyright Ownership

Joint Authorship
- a work prepared by two or more authors with the intention that their contributions be merged into inseparable or interdependent parts of a unitary whole.

Works Made for Hire
- the "author" of the work is no longer the individual who created the work. Instead, the "author" is considered to be the entity which hired the actual creators of the work.
Copyright Act

“In no case does copyright protection for an original work of authorship extend to any idea, procedure, process, system, method of operation, concept, principle, or discovery, regardless of the form in which it is described, explained, illustrated, or embodied in such work.”
Patent Law

- Congress shall have power . . . To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.
- Utility Patents
- Plant Patents
- Design Patents
Patent Requirements

  “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title”

- Patentable invention must be:
  - statutory,
  - new,
  - useful, and
  - nonobvious.
Patent Application

• Inventor applies

• Specification (Written Description)
  – Enabling
  – Best Mode

• Claims
Patent Rights

The right to exclude others from making, using or selling the invention throughout the United States.

• The rights granted under patent law are very different than rights granted under copyright law.
  – Patent law gives to the patent holder the right to exclude others from making, using, or selling the invention.
  – Copyright law prevents the copying of the expression of ideas (not the ideas themselves)