



Tribal Health Research Office

Division of Program Coordination, Planning, & Strategic Initiatives
Office of the Director, National Institutes of Health

Intellectual Property Rights in Biomedical Research

What is intellectual property and why it is important in biomedical research?

- Intellectual property (IP) refers to 'creations of the mind' such as inventions, literary and artistic works, design and symbols, and names and images.
- In biomedical research, patents, trademarks, and copyrights are the most common forms of IP protections used to safeguard inventions, processes, materials, and ideas.
- The creation of IP is often considered a successful outcome of a research project when that outcome has potential commercial value. Protecting discoveries by IP usually requires a significant level of effort. Processes must be put in place to identify, protect, manage and license the IP.
- IP protection and management are essential to transfer technology to the private sector for further development and commercialization.

What is a patent?

- A patent is an exclusive right granted for an invention--defined as a creation, product or process--that can be used to prohibit others from making, using, or selling the invention for a limited time (usually 20 years).
- In order to be patentable, an invention must be:
 - New – substantially different from anything else that is publicly known;
 - Useful – must work and serve a useful purpose; and
 - Not obvious – to a person with ordinary skill in that field.

What ***cannot*** be patented in biomedical research?

- Natural, unaltered DNA sequences cannot be patented, whether from virus, bacteria, plant, animal or human
- Natural proteins and chemicals from nature without modification cannot be patented, e.g. newly discovered peyote chemical that reduces anxiety.
- Other Examples of what cannot be patented are abstract ideas, physical phenomena, and inventions that are not useful (e.g. a perpetual motion machine).

What *can* be patented in biomedical research?

- Examples of inventions in research that can be patented are genetically modified products; genes and DNA sequences spliced together; devices and products for practicing or using medical methods; new uses of natural products; and novel scientific or technical ideas, processes and findings that are not a product of nature.

What are NIH policies on Intellectual Property?

- It is NIH policy that the results and accomplishments of the activities it funds should be made available to the research community and the public at large.
- The Bayh-Dole Statute (35 U.S.C 200) has been a 'term and condition' of all federal funding agreements since 1980. It permits universities, non-profit organizations, or businesses receiving federal funds to pursue ownership of an invention rather than requiring inventors to assign the patent to the federal government.
- Any inventions and patent activities arising from NIH funded research projects must be reported to the agency and tracked through the electronic database iEdison.

What's important for Tribal Nations and communities to know?

- Discussions about possible IP rights should occur before research begins.
- Protect Rights - File enabled patent applications prior to any kind of public disclosure on invention e.g. disclosing through publications, presentations, speeches, posters, etc.
- Do not have substantive discussions/exchanges with any third-parties about unpublished research that could be an invention unless the exchanges are protected by confidentiality obligations.
- Tribal Nations and communities can develop their own policies that make clear how IP rights are handled. Such policies can specify joint ownership or Tribal ownership and ensure researchers understand what's required to enter into any research collaboration.

NIH Intellectual Property Resources

- Intellectual Property Policy: <http://grants.nih.gov/grants/intell-property.htm>
- Bayh-Dole Regulations: <http://grants.nih.gov/grants/bayh-dole.htm>
- Invention Reporting Timeline: https://era.nih.gov/iedison/invention_timeline.cfm
- Interagency Edison (iEdison) Reporting System, & Intellectual Property FAQs and Resources: https://era.nih.gov/iedison/iedison_faqs.cfm