

The NIH Approach to IP Management of Public Health Research

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The National Institutes of Health (NIH) is an agency of the Department of Health and Human Services (HHS). It is composed of 27 Institutes and Centers whose collective mission is to conduct and sponsor medical research and training leading to improved public health. In addition to its intramural component operating predominantly at the Bethesda Maryland campus, the NIH supports basic biomedical research, training, pre-clinical and early stage clinical trials, contracts, grants, and co-operative agreements at extramural locations in universities, hospitals, and research institutions throughout the United States and abroad. Advancement of this early stage research into useful products available to the general public requires further resources and know-how from private industry. The private sector will not invest in such early stage work, however, without the security of exclusive market positions afforded by strong patent protection. Consequently, NIH seeks patents on those inventions requiring further research and development efforts and then exclusively licenses those intellectual property rights to private industry partners.

Most lab outcomes from this early-stage intramural and extramural research take the form of ideas, data, and research materials useful as resource tools to further investigate biological systems or to identify new products. Such research tools generally do not require further research and development investment or patent incentive to secure their use in the public or private sectors. Rather, the value of these research tools is best advanced through their rapid transfer and dissemination to the research community. The NIH has developed an intramural patent policy and extramural policy guidance advocating refrain from patenting research outcomes identifiable solely as research tools. Experience has taught us it is not always easy to distinguish inventions arising from early stage research that require patent protection from those that are solely research tools. Therefore, NIH recommends liberal patent strategies to protect the potential value of the invention to industry. As the significance of the invention to the marketplace becomes clear, however, NIH recommends a selective licensing policy to fine-tune these distinctions. Nonexclusive licensing of intellectual property rights can be used to protect research uses and research tools, whereas exclusive licensing provisions can be used to secure those aspects of an invention requiring further R&D for the licensee to bring a product to market.