

Whenever possible, non-exclusive licensing should be pursued as a best practice. A non-exclusive licensing approach favors and facilitates making broad enabling technologies and research uses of inventions widely available and accessible to the scientific community. When a genomic invention represents a component part or background to a commercial development, non-exclusive freedom-to-operate licensing may provide an appropriate and sufficient complement to existing exclusive intellectual property rights.

In those cases where exclusive licensing is necessary to encourage research and development by private partners, best practices dictate that exclusive licenses should be appropriately tailored to ensure expeditious development of as many aspects of the technology as possible. Specific indications, fields of use, and territories should be limited to be commensurate with the abilities and commitment of licensees to bring the technology to market expeditiously.

For example, patent claims to gene sequences could be licensed exclusively in a limited field of use drawn to development of antisense molecules in therapeutic protocols. Independent of such exclusive consideration, the same intellectual property rights could be licensed non-exclusively for diagnostic testing or as a research probe to study gene expression under varying physiological conditions.

License agreements should be written with developmental milestones and benchmarks to ensure that the technology is fully developed by the licensee. The timely completion of milestones and benchmarks should be monitored and enforced. Best practices provide for modification or termination of licenses when progress toward commercialization is inadequate. Negotiated sublicensing terms and provisions optimally permit fair and appropriate participation of additional parties in the technology development process.

Funding recipients and the intramural technology transfer community may find these recommendations helpful in achieving the universal goal of ensuring that public health consequences are considered when negotiating licenses for genomic technologies.

PHS encourages licensing policies and strategies that maximize access, as well as commercial and research utilization of the technology to benefit the public health. For this reason, PHS believes that it is important for funding recipients and the intramural technology transfer community to

reserve in their license agreements the right to use the licensed technologies for their own research and educational uses, and to allow other non-profit institutions to do the same.

Conclusion

PHS recognizes that these recommendations generally reflect practices that may already be followed by most funding recipients and the intramural technology transfer community with regard to licensing of genomic and other technologies. PHS also acknowledges the need for flexibility in the licensing negotiation process as the requirements of individual license negotiations may vary and may not always be adaptable to these best practices.

Dated: November 14, 2004.

Mark L. Rohrbach,

*Director, Office of Technology Transfer,
National Institutes of Health.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Apoptosis in Liver Cells.

Date: December 14, 2004.

Time: 3 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Lakshmanan Sankaran, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National

Institutes of Health, Room 777, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-7799, Is38oz@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 15, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel, Mortality and Fecundity in Two-sided Search for Male.

Date: December 1, 2004.

Time: 2 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Marita R. Hopmann, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, 6100 Building, Room 5B01, Bethesda, MD 20892 (301) 435-6911, hopmannm@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and