

Intellectual Property Policy for For-Profit Entities

Robert A. Goldstein, M.D., Ph.D.

Chief Scientific Officer

Juvenile Diabetes Research Foundation

JDRF Mission

To find a cure for type 1 diabetes and its complications through the support of research

- JDRF funds non-profit and for-profit organizations, including public and private institutions, based in the United States or abroad
- JDRF utilizes a variety of funding mechanisms to support research, including partnerships
- JDRF is committed to the dissemination of all information and materials developed using JDRF resources
- JDRF seeks to ensure that discoveries are utilized in the most productive way

IP policy for Non-profit Organizations

- IP resides with the grantee institution.
- Reporting an invention/patent filing is annually, as part of progress report
- JDRF does not provide support for patent filing
- Abandoning a patent or filing must be reported to JDRF
- JDRF reserves 'march-in' rights
- Net royalties will be shared with JDRF based on the relative contribution of JDRF support to the overall project

This policy is meant to encourage the dissemination of information, and the efficient utilization of discoveries

The policy 'works:' not seen as an impediment to scientific progress

JDRF Industry Discovery and Development Program

<http://www.jdrf.org/industry>

- Fosters collaborations between JDRF and industry partners to take promising research through discovery and development and towards commercialization
- Applicant companies must demonstrate a matching resource commitment to the proposed program that is equal to or greater than that requested from JDRF
- Contracts are negotiated on a case-by-case basis to establish research milestones and develop agreement on intellectual property and royalty issues
- In FY2005, JDRF funding in IDDP programs: \$3.1 Million (2.9% of total portfolio, 8 awards)

Intellectual Property and Revenue Sharing are negotiated before award activation, and case-by-case: prepare for delays

- JDRF requires that companies demonstrate a matching resource commitment that is equal to or greater than that requested from JDRF
- Companies seek 'freedom to operate' with regard to product development
- JDRF requires that companies report the filing and progress of patent applications, and the execution of any agreement with third parties governing the use or control of IP generated by JDRF-supported research
- Companies are more amenable to sharing income from future profits than sharing ownership rights

Reporting and Administration are more complicated: contracts are lengthy

- Contracts establishing research milestones and developing agreement on intellectual property and royalty issues are negotiated on a case-by-case basis
- Reporting: usually every 6 months, but may be more frequent; usually associated with achieving milestones
- Other issues:
 - ethical review and oversight
 - research management/participation
 - non-disclosure/confidentiality
 - dispute resolution
 - termination (due to failure to achieve milestones, bankruptcy, default)
 - liability and indemnification

Sample Terms and Conditions for Derivation of New hESC Lines:

- Agreement to make all reasonable efforts to make hESC lines available to others, especially to JDRF-funded investigators, without onerous conditions
- Agreement to disclose to JDRF, at time of award, any and all known encumbrances that may inhibit the free dissemination of new hESC lines worldwide
- Agreement to disclose to JDRF in a timely manner any new or potential encumbrances that may inhibit the free dissemination of new hESC lines
- Notice is given that JDRF will publicize the availability of new lines
- Agreement to JDRF's reporting requirements

Is it worth funding for-profit companies to do stem cell research?

- State of the science
- Commercial products have not lived up to market potential – the problem of individualized therapy
- Ethical controversy
- Freedom-to-operate and licensing issues
- Credible exit strategy required for investors

Should there be funding only for non-profits at this time?

Should companies be considered only for specific areas?

Should there be more academic-company collaborative projects?

And Not Least: an issue that needs to be addressed, patent rights claimed by WiCell

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The gatekeepers of hES cell products

Sander Rabin

Sander Rabin is at Whiteman Osterman & Hanna, LLP, One Commerce Plaza, Albany, New York 12260, USA. srabin@woh.com

Does every road to commercial products derived from human embryonic stem cells run through Wisconsin?

Access to human embryonic stem (hES) cells in the United States is controlled by a triumvirate comprising the Wisconsin Alumni Research Foundation (WARF; Madison, WI, USA), Geron (Menlo Park, CA, USA) and the US National Institutes of Health (NIH; Bethesda, MD, USA). The exclusive ownership of hES cells, endorsed in the contractual relationships among WARF, Geron and the NIH, has intensified the



The Wisconsin Alumni Research Foundation, based in Madison, to whom University of Wisconsin professor James A. Thomson (inset) assigned the rights to his human embryonic stem cell patents.

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