

## **CIRM's International Collaborations and Intellectual Agreements**

At the January 28, 2011 CFAOC meeting, Member Sadana asked how CIRM deals with intellectual property issues when it enters into collaborative funding agreements with national and international organizations. Currently, CIRM has entered into collaborative funding agreements with more than a dozen states, countries and foundations. Pursuant to these agreements, CIRM funds researchers in California who partner with researchers from another state or country on a joint research project. The work performed by the non-Californian scientists is funded by the collaborative funding partner. Below, we summarize how CIRM selects its collaborative funding partners and how it manages intellectual property issues that arise from those agreements.

Selection of Collaborative Partners: CIRM Grantees and Loan Recipients remain bound by all applicable CIRM intellectual Property Regulations even when they are involved in a multi-national research team. Therefore, one criteria for selecting collaborative funding partners is whether the prospective partner's intellectual property requirements are compatible with the CIRM intellectual property requirements. CIRM must ensure that a jointly funded research team can comply with the IP requirements of both funders. If it is not possible for them to do so, then teams will either not form or they will fall apart once they begin managing their intellectual property.

Before entering a Memoranda of Understanding with any partner, therefore, CIRM counsel engages in substantive discussions about IP with the prospective partner's counsel (or other representative). CIRM typically provides the prospective partner with access to all CIRM IP Regulations and explains how those regulations apply. We obtain parallel information from our prospective partners. Then, CIRM counsel analyzes whether the two sets of requirements are sufficiently compatible to allow the joint research team to function. If the IP requirements of the potential partner cannot be reconciled with the CIRM IP requirements, the partnership would not likely progress under the Collaborative Funding Partners model.

Memoranda of Understanding: CIRM enters Memoranda of Understanding (MOUS) with all its collaborative partners. The MOUs are non-binding document so, we do not include detailed IP requirements in the MOUs. They simply provide that CIRM Grantees must comply with all CIRM Regulations, including the IP Regulations. The MOUs also state that CIRM grantees will be required to explain how they will manage intellectual property in the context of a jointly funded team.

Funding Agreements: Intellectual Property is addressed in detail in the Funding Agreements that CIRM enters with funding partners after specific projects are recommended for funding by the Grants Working Group but before the ICOC considers the those funding recommendations. The Funding Agreements typically provide as follows concerning IP:

1. CIRM funded Grantees are subject to all applicable portions of the CIRM IP regulations;
2. The CFP Grantees are subject to all applicable portions of the CFP IP Regulations;
3. Joint teams must enter written agreements amongst themselves addressing IP issues such as ownership, revenue sharing, licensing and associated costs (“Grantee IP Agreements”). CIRM reviews those agreements only to ensure compliance with the CIRM IP Regulations and with the Funding Agreements. We do not impose requirements about the allocation of benefits and burdens in these Agreements. Funds do not flow to the CIRM Grantee or the Partner Grantee before the Grantee IP Agreement is approved by CIRM.
4. We also impose requirements on the Partner Grantees:
  - a. Partner Grantees are sometimes required to comply with the CIRM Access and Pricing components of the IP regulations (Sec. 100607) as if they were CIRM Grantees in the event that they commercialize a jointly invented Drug in the State of California.
  - b. Partner Grantees must comply with the CIRM Biomedical Materials Sharing requirements for purposes of sharing such materials with researchers in California;
  - c. Partner Grantees must satisfy various reporting obligations concerning scientific progress.