



BCRF Intellectual Property

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on behalf of
Breast Cancer Research Foundation

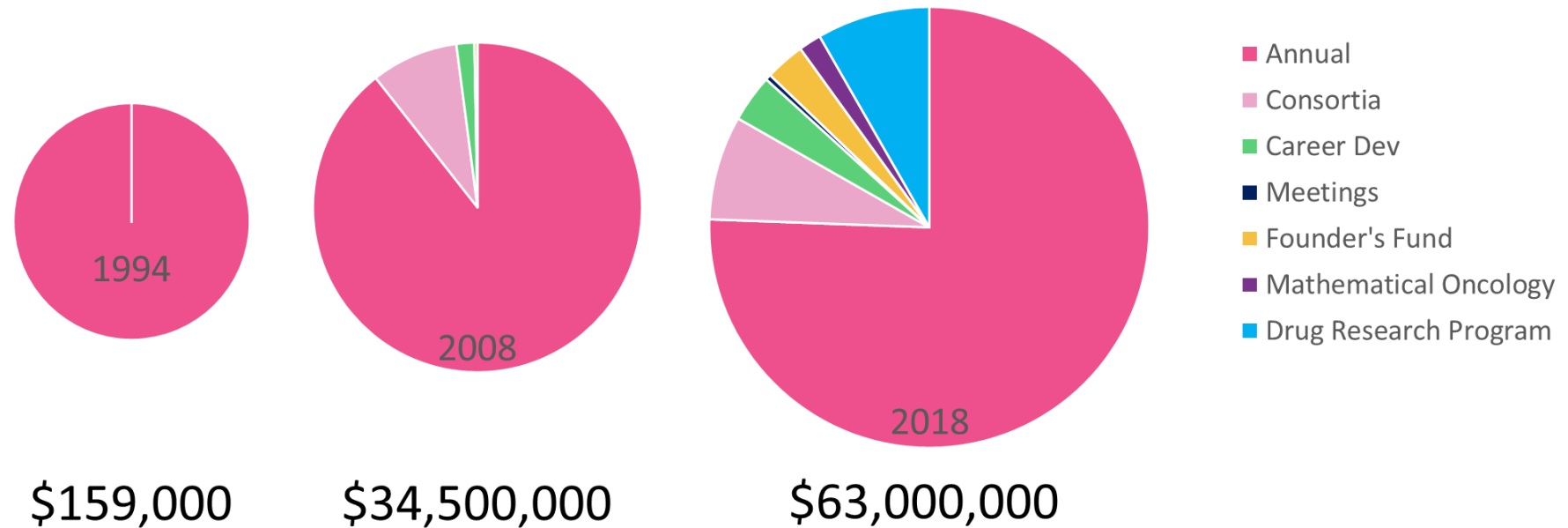
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Outline

- BCRF Background
- Why an Intellectual Property policy?
 - CFF, Kalydeco, \$3.3 billion, \$300,000 for patient
- The process of establishing a policy.
- The Policy
 - IP to be assigned to BCRF
 - Return to BCRF
 - Drug Research Collaborative
- Benefit from an Intellectual Property policy.
- Challenges, pitfalls, examples, case studies.
 - Is it worth it? Revenue? Benefits that can't be quantified?
 - Revenue that comes to universities is not that big (Shannon Greer)

Breast Cancer Research Foundation

- Founded in 1993 with a singular mission to fund research



- Has had some form of Intellectual Property policy since...early 2000s?
- Major overhaul in 2013
- Revenue from Intellectual Property to date: \$0

Why an IP Policy?



Why an IP Policy?

- Potential for financial returns
 - Fund more research, reinvest in the mission, help more people
 - CFF invested \$75M in Kalydeco, approved in 2012, returned \$3.3B in 2014
- Ensure potentially useful technologies make it to patients
- Encourage commercialization
- To align with other funders

- Understanding why you need/want an intellectual property policy will help you capitalize on the returns (qualitative and quantitative).

How to develop your policy

- Keep your focus on the why
- Use the HRA resources that Shannon and Michael already presented
- Don't be afraid of "simple policies."
- Organize your policy in to sections or chunks.
- Use a pro-bono law firm if you have one!

	BCRF	Komen	Avon Breast Cancer Crusade	American Cancer Society	Cancer Research Institute	Damon Runyon Cancer Research Foundation	Leukemia and Lymphoma Society	Lymphoma Research Foundation	National Multiple Sclerosis Society
				notice to avoid lapse or abandonment of IP rights.					
Addressing infringement	N/A	N/A	N/A	Society and Beneficiary must inform one another of suspected infringement of patent or proprietary rights in the Invention.	N/A	N/A	N/A	N/A	N/A
Joint funding by non-gov't third party	N/A	If other organization has IP policy which conflicts, will negotiate rights in good faith.	N/A	N/A	N/A	N/A	N/A	Will confer, in good faith, to arrive at mutually satisfactory disposition of rights.	If any other arrangement with contributor would prevent Beneficiary from entering revenue-sharing agreement with NMSS, Beneficiary must disclose it when accepting NMSS grant or prior to entering into other economic agreements.
Joint funding with US Government	N/A	Deference to Government policy upon written notice by agency or	N/A	N/A	N/A	N/A	N/A	Deference to Government policy upon written notice by agency or	N/A

10 Points of Evaluation

- ownership of IP generated under the grant award
- notification requirements
- patenting requirements
- handling of infringement actions
- joint funding with non-government third parties
- joint funding with the U.S. Government
- income, payment and royalty terms
- requirements to commercialize inventions
- audits and reporting requirements
- permitted non-commercial use of inventions.

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Ownership, Notification, and Patenting

- Generally agree the beneficiary/beneficiary's institution owns to the invention.
 - Only exceptions when the institution does not have a policy
- “As early as possible” vs “within 3 months of conception”
 - Avoid lapse or abandonment of patent or patent application
- Option reverts to BCRF if beneficiary chooses not to pursue protection
- There has never been an institution without some kind of policy.
- Can you really enforce this? Can you enforce something you don't know about?
- Can BCRF actually pursue the patent protections?
 - Need time – review by SAB, gathering information from institution, submitting applications
 - Institutions have asked for royalties.

Income and Royalty

- Licensing Costs
 - No payments until licensing costs are recouped.
 - Threshold
 - Start payment after first \$250,000
 - Royalty structure
 - 10% of net royalties
 - Cap
 - No cap
- This seems fairly standard?
 - This seems relatively arbitrary. But BCRF grants are \$250,000/year so maybe that's where it comes from?
 - Royalty structure: percent of investment vs. flat percent.
 - 5x cap in some agreements, which is reasonable. But homerun clause?

Royalty Structure

➤ Percentage of investment

- Example 1: Total cost for invention was \$1M. BCRF gave \$250,000 so BCRF gets 25% of the profits.
- Example 2: BCRF gives a \$250,000 grant for a risky project very early in development. Nobody else thinks it's going to work. That \$250,000 allowed the investigator to demonstrate proof of concept which got him/her another \$250,000 from somewhere else. They were able to leverage that in to another \$500,000 that eventually got the product to market. Does BCRF still only get 25%? Without BCRF this product would not exist. BCRF invested at a critical time that was necessary for success. Shouldn't the early investor receive a larger piece of the returns?

➤ <https://politics.com.ph/alexandra-ocasio-cortez-takes-on-greedy-drug-companies-taxpayers-fund-drug-research-big-pharma-takes-all-the-profits/>

You've developed an IP policy, what next?

- Remember why you developed an IP policy in the first place
 - (hopefully it wasn't for revenue...)
- Develop a plan to capture relevant invention information.
- Do you want to actively request invention information? Or wait for them to be reported to you?
- How would you like the invention information reported to you?
 - Every institution has a different template.
 - Create your own with the questions you need answered to turn around for your stakeholders.
 - More business related and commercialization plans if the goal is revenue?
 - More scientific or patient-focused questions to use for fundraising appeals or demonstrate foundation impact?

Is it worth it?

- BCRF has never received any royalty.
- Hours spent developing the policy in 2013?
- Each year BCRF spends at least 5 hours/week in August and September negotiating policies plus added administrative time for each unique policy.
- BCRF is currently negotiating a policy with a single institution for over 3 months.
 - This has caused several grants to be delayed in activation.
- BCRF passively received a handful of invention notification each year which are largely briefly reviewed and filed.