

The California Research and Cures Initiative

Framing the Role of Public Stakeholders

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CRCI

- ◆ Codified stem cell research as a constitutional right of the people of California'
- ◆ Created a hybrid public/private scientific research institution (CIRM)



QuickTime™ and a
TIFF (Uncompressed) decompressor
are needed to see this picture.

A system of regulation requires not only regulators and the regulated, but also stakeholders, i.e. people and groups interested in the outcome or operation of the regulated entity

- ◆ There is a formal system for incorporating stakeholders in “traditional” regulatory process: the “note and comment” period required under the rules of regulation, at both federal and state levels.
- ◆ Modern technology has generated new outlets for expression --
 - advocacy organizations, the media and, now the Internet.
- ◆ In this environment, and despite political and philosophical differences, stakeholders more easily can demand a concrete and verifiable role in decision-making

So.....Who Are the Stakeholders?

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Proposition 71 contemplated three types of Stakeholder/Beneficiaries

- ◆ Patient beneficiaries, who may benefit from therapeutic discoveries;
- ◆ The California workforce, by generating new jobs in biotechnology;
- ◆ The California treasury, from new sources of taxable revenue in the biotechnology field and a lowered cost of chronic conditions, such as diabetes, on state health budgets.

In the relatively brief period between the initial decision to place a stem cell initiative on the ballot, and the present time, there have been several distinct operational phases, and varying types and involvement of stakeholders

Phase 1: Campaign

- ◆ The “Yes on Proposition 71” campaign set out the framework of the political process, and, for many, tied the “yes” campaign to a referendum on the federal stem cell research policy.

Phase 2: Primary Organization

Following the passage of the initiative, as the organizational identity of the CIRM emerged, new stakeholders emerged and some existing stakeholders began to play different roles, many of which focused on organizational transparency

This phase has also generated a new type of stakeholder not previously contemplated

Phase 3: Secondary Organization

With the basic organizational structure in place, the CIRM's activities shifted to external operational policies -- most critically,

- (1) Intellectual property and ownership of CRCI-generated material;
- (2) Guidelines for the ethical conduct of research;
- (3) Design of the research program

We are now in a phase where diverse new and old stakeholders are jockeying for attention -- from the public, from the CIRM and through the political process

- (1) How have stakeholders' identity and roles changed over the fifteen months of the CIRM's existence?**
- (2) How have stakeholder perspectives informed the CIRM's formulation of its internal processes of social control:
 - basic governing structure,**
 - internal (CIRM) policies -- e.g. institutional oversight, conflict of interest, "open meeting" procedures, document accessibility****

How Have Stakeholder Perspectives Affected the CIRM's Responses to External Forces of Social Control?

- ◆ **Litigation:**
 - ◆ “Moral” argument against stem cell research;
 - ◆ “Procedural” argument against constitutionality of Proposition 71;
- ◆ **Funding mechanism: legitimacy of tax free public bond funding;**
- ◆ **Competition: Competing stem cell research in other states and outside US - alternative models of governance and oversight**

(4) How have stakeholder perspectives affected the CIRM's dual roles as a funding body and ethical oversight arbiter?

- ◆ Each set of stakeholders also brings to the table a unique perspective on a regulatory framework;
- ◆ There has been an effort to develop new procedural forms of oversight; most notably the emergence of a new kind of IRB-like entity (the ESCRO or SCRO);
- ◆ The key difference between the “traditional” IRB and the “new” ESCRO, at the present time, is the reaching back of the form of the object -- the embryo, oocyte, the egg--and not just a specific person.

WHO ARE THESE “NEW” STAKEHOLDERS?

- ◆ Donor Stakeholders (varying degrees of consent)
(may have consented to “some kind of research” in a general way at the time of donation):
 - ◆ Egg donors
 - ◆ Oocyte donors
 - ◆ Sperm donors
 - ◆ “Down-the-line” donors:
 - ◆ “New generation” donors (from same biologic material;
 - ◆ “Syndicated” donors (same biologic product - 5,10,20,50 yrs out)

- ◆ **“Down-the line” research subjects, including but not limited to ultimate “patients” (10 yrs, 20 yrs, 50+ yrs.,???)**
- ◆ **Private sector stakeholders**
- ◆ **Researcher stakeholders**
- ◆ **Government regulators**
- ◆ **Politicians**
- ◆ **“Black Marketeers”**

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WITH
STEM CELLS
WE CAN GROW
JUST ABOUT
ANYTHING...

