

Ethical Stem Cells: Back to Basics

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The California Institute for Regenerative Medicine's (CIRM) <u>initial round of grants</u> for 2014 provides an interesting perspective on a pattern of research funding that has emerged at CIRM in recent years.

That pattern, as several analyses done by the Lozier Institute of CIRM's grant making reveal (here and here), shows a discernible trend away from funding ethically contentious human embryonic stem cell research (hESCR) and somatic cell nuclear transfer (SCNT, i.e. human cloning for research) and increased funding for ethically non-controversial adult stem cell research and other alternatives to hESCR.

Nor is CIRM alone in this movement towards favoring non-hESCR (here, and here). But what makes this development even more significant in CIRM's case is that the Institute was established by voter referendum for the very purpose of giving priority to funding for hESCR.

CIRM's most recent round of grants in January of this year again shows that, operationally at least, funding for hESCR is no longer a governing priority there.

The grants fall under the category of "Basic Biology." In announcing the awards, CIRM explained that they "go to researchers trying to advance the field by tackling significant, unresolved issues in human stem cell biology." This is in contrast to most of the grants CIRM has awarded in recent years, which favored projects not just because they utilized hESCs, but rather because they were judged to have the greatest promise to reach clinical trials in the shortest time frame feasible. A growing majority of these grants have gone to non-hESCR projects.

On the other hand, as their name implies, Basic Biology grants are intended to support more immediate research into the workings of stem cells, with clinical trials a more distant goal. As Jonathan Thomas, Chair of CIRM's governing board, noted, "Only by this deeper understanding at the basic level can we hope to advance research at more advanced levels."

The Basic Biology grants announced on January 29 were the fifth round of such grants since the initial ones awarded in 2009. Of 24 grants awarded, 13 went to non-hESCR projects for a total of \$12.3 million. Eight grants went to research using hESCs alone for a total of \$8.7 million (the remaining six projects utilized both embryonic and non-embryonic stem cells). Thus, of the money awarded to projects using hESCs alone, or that were non-hESCR alone, the non-embryonic amounted to 58%, hESCR 42%.

While in this latest round of grants the gap between funding for non-embryonic and hESCR is not as great as seen in other grant categories, the purpose of the grants



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must be taken into account. When the purpose of the grants was clinical/translational (i.e., leading to clinical trials as quickly as possible), nonhESCR projects have been clearly preferred for funding over those utilizing hESCs. However, when reaching clinical trials is a more distant concern – as in the category of Basic Biology grants -- there is more leeway to fund hESCR, though still to a lesser extent than the alternatives. Nonetheless, it is noteworthy that even in the area of basic stem cell science, adult and other non-hESCR avenues of research are now receiving the greater share of the funding.

A look at previous grants awarded under the Basic Biology category is instructive.

The first round of basic biology grants was in two parts, the first part awarded in August, 2009. Twelve projects received funding; four projects involved non-hESCs alone while two involved hESCs alone; the remaining six projects used both hESCs and non-hESCs.

The second part, awarded in April, 2010, went to 16 projects total. Only three grants went to projects using non-hESCs alone, while projects using hESCs alone were more than double, at seven (one of these projects was for SCNT). The remaining six projects used both non-hESCs and hESCs.

Thus, combining both parts of this initial two-part grant, out of 28 grants awarded, seven went to projects using non-hESCs alone (the fewest out of the total); nine went to projects using hESCs alone and 12 went to projects using both non-hESCs and hESCs.

The third round of Basic Biology grants, in May, 2011, marks a noticeable turnabout. Of 27 projects selected, the number of grants to non-hESCR projects and hESCR projects was almost equal, with non-hESCR projects slightly ahead at 13 (totaling \$20.2 million) and hESCR projects receiving 12 grants (totaling \$16.1 million). Of these 25 grants (the remaining two grants went to projects using both non-hESCs and hESCs), 55% percent of the funding went to non-hESCR and 45% to hESCR.

The fourth round of basic biology grants shows a dramatic increase in the proportion of awards going to non-hESCR projects. Of 28 grants awarded, seven went to projects using hESCs alone; more than double that amount - 17 - went to projects using non-hESCs (the remaining four grants were for projects using both hESCs and non-hESCs). Of the total amount of dollars awarded to projects using non-hESCs alone or to projects using hESCs alone, \$7.7 million, or 25%, went to hESCR projects, while projects using non-hESCs alone received \$23.2 million, or 75%.



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This fourth round of grants marks, so far, the highwater mark in the portion of dollars going to projects using non-hESCs alone awarded under the Basic Biology category; nonetheless, since 2011 the amount of money awarded such projects has consistently outpaced the amounts awarded to projects using hESCS alone.

CIRM's pattern of grant-making, at least since 2009, has shown that research using ethically non-contentious adult stem cell research and other alternatives to hESCR is now seen as holding the most potential to actually lead to clinical trials and therapies in the short term.

And now, as the last several rounds of Basic Biology grants show, such research would also appear to hold the most therapeutic potential in the long term as well.