Appendix: Review Criteria From Recent CIRM RFAs

RFA 07-05 New Cell Lines Awards

It is the intent of the New Cell Lines Awards to support the development of human stem cell lines that are pluripotent, i.e., cell lines that can differentiate into derivatives of all three germ layers, the ectoderm, mesoderm, and endoderm. Applications will be evaluated in primarily two areas: the Significance and Innovation of the project, and the Design and Feasibility of the Research Plan.

A. Significance and Innovation

- The proposed methods or the cell lines that will be derived contribute to solving an important problem in stem cell biology.
- The proposed concept and approach are original and innovative.
- The proposed research, if successful, will significantly move the field forward, either scientifically or medically.

B. Design and Feasibility of the Research Plan

- The proposed research is carefully designed to give meaningful results.
- The rationale that derived cell lines will be pluripotent is convincing.
- The criteria used to confirm pluripotency of derived cell lines are sufficient.
- Potential difficulties are acknowledged, and alternative plans are provided should the proposed strategies fail.
- The preliminary data are compelling and supportive of the proposed concepts, hypotheses and approaches.
- The aims of the research can be reasonably achieved within the proposed timeframe.
- The PI and key personnel have the training and experience to conduct the proposed work.
- Evidence of prior success and track record supports the qualification of the PI to derive the new cell lines as proposed.

RFA 08-02 Tools and Technologies Awards

The purpose of the Tools and Technologies Awards is to support the development and evaluation of innovative tools and technologies that will overcome current road blocks in basic, translational and clinical stem cell research. Applications will be evaluated primarily in three areas: 1) impact of the research to overcome current road blocks and advance the stem cell field, 2) design and feasibility of the research plan, and 3) qualifications of the Principal Investigator and the research team.

A. Impact

- The proposed tools and/or technologies contribute to overcoming a significant road block in stem cell biology.

- The proposed tools and/or technologies research will significantly impact existing concepts or methods and drive the stem cell field forward, either scientifically or towards clinical application.

B. Design and Feasibility of the Research Plan

- The rationale for the development and testing of a novel tool and/or technology is convincing.
- The proposed research is carefully designed to give meaningful results.
- Potential difficulties are acknowledged, and alternative plans are provided should the proposed strategies fail.
- The aims of the research can be reasonably achieved within the proposed timeframe.
- The milestones stated are well described, scientifically justified and provide a quantitative assessment of research outcome(s).
- The scope of the proposed work justifies the timeline and the proposed project budget.
- For those applications addressing further development of an existing tool or technology, the preliminary data are compelling and supportive of the proposed concepts, hypotheses and approaches.

RFA 08-05 Early Translational Research Awards

CIRM intends the Early Translational Research Awards to support research that will lead to development candidates or overcome current bottlenecks to advancement of novel cell therapies to the clinic. CIRM will instruct reviewers to prioritize applications focused on the identification of a development candidate. CIRM will target at least 50% of awards to this category. In the bottleneck category, CIRM will ask the reviewers to prioritize applications that target cell therapy, particularly cell therapies derived from human pluripotent stem cells; or, that utilize stem cells to develop better, more predictive disease models. Applications will be evaluated in four areas: (1) scientific basis, rationale and impact of the proposed research; (2) design and feasibility of the research plan to either identify a development candidate or eliminate a bottleneck; (3) the qualifications and track record of the PI and key team members of the research team; and 4) collaborations, resources and environment.

A. Scientific Basis, Rationale and Impact

For applications focused on research leading to a development candidate:

- There is strong supportive evidence for the proposed research.
- Human stem cells are necessary or advantageous to the proposed research compared to other approaches.
- The proposed research leads to a development candidate that addresses an unmet medical need.

- The proposed research leads to a development candidate that, if successfully developed and commercialized, would have a significant impact on disease, injury or medical practice.

For applications focused on bottlenecks:

- There is strong supportive evidence for the proposed research.
- The proposed approach to address the bottleneck is based on a scientifically justifiable hypothesis.
- The proposed research addresses a critical bottleneck to the advancement of effective, novel cell therapies to the clinic.
- CIRM is particularly interested in proposals for research that will overcome bottlenecks to the advancement of human pluripotent cell-derived therapies to the clinic. CIRM will instruct reviewers to give special consideration to such proposals.
- The proposed research utilizes human stem cells to develop better, more predictive disease models to foster the advancement of better candidates to clinical testing.

B. Design and Feasibility of the Research Plan

For applications focused on a development candidate:

- The target profile for the proposed development candidate is appropriate and is achievable.
- The research plan is well designed to result in a development candidate. The plan adequately addresses all necessary activities to enable a development candidate for subsequent consideration for preclinical development. The plan identifies interim milestones, acknowledges potential problems, and suggests alternative approaches should the proposed primary approaches fail.
- There are preliminary or other supporting data for the proposed development candidate and for successful application of the technologies/methodologies proposed to achieve the development candidate.
- The proposed timeline shows key research activities and highlights interim milestones. The timeline and interim milestones are appropriate, feasible and technically sound. The goal of a development candidate can be reasonably achieved within the proposed period.

For applications addressing a bottleneck:

- Success criteria are established for assessing whether the bottleneck has been overcome. The success criteria are quantitative, well described, meaningful, and scientifically justified.
- The proposed research is carefully designed to give meaningful results and achieve the success criteria.
- Potential difficulties are acknowledged, and alternatives are provided should the proposed primary approaches fail.

- The preliminary data are compelling and supportive of the proposed concepts, hypotheses and approaches.
- The proposed timeline shows key research activities and highlights interim milestones. The timeline and interim milestones are appropriate, feasible and technically sound. The aims of the research and achieving the success criteria can be reasonably met within the allocated period.

C. Qualifications of the Principal Investigator and Research Team

- The PI and key members of the research team have the training and experience to conduct the proposed research.
- The PI has a record of achievement that supports his/her qualifications to conduct and lead the translational research as proposed.
- For those proposals addressing a development candidate, the PI has access to experts or has assembled advisors who can provide expert advice on challenges to achieving a viable development candidate suitable for further development. These may include clinician(s) expert in the disease area of interest, regulatory expert, a project manager and/or other consultants
- The PI and key members of the research team are committing sufficient effort to the proposed research to maximize timely achievement of the research goals. CIRM will instruct reviewers to give added consideration to the PI's qualifications where the PI commits effort in excess of 10% to the proposed research.
- The PI has developed a budget that is appropriate for the proposed research.

D. Collaborations, Resources and Environment

- Critical resources to the success of the project are available through: 1) the applicant institution; 2) advisors, consultants or subcontractors; or 3) collaborations including public-private collaborations or collaborative funding opportunities.
- Any proposed collaboration is critical and integral to the success of the research.
- The environment facilitates the interactions that enhance the probability of success of the proposed research.
- There is adequate evidence of institutional support for the PI and for translational research.