RFA 13-01 Appendix D: NIH Collaborations

For this RFA, NIH will consider two types of collaborations with CIRM-funded researchers:

1. CIRM will fund California researchers in collaborations with NIH intramural investigators, who will be supported in accordance with NIH processes and regulations. NIH intramural investigators could collaborate with CIRM-funded investigators on various aspects of preclinical research, or a Phase I, Phase I/II or Phase II clinical trial. By collaborating with an intramural investigator at NIH, a CIRM-funded investigator could access NIH research resources for screening, formulation, and clinical trial capabilities.

2. Access to NIH resources. Examples are provided below. (These examples relate to multiple stages of research, so some may not be appropriate for this RFA.)

    a. NIH can arrange for CIRM-funded researchers to engage with the NIH Clinical Center or other specialized facilities or resources. For example:

        The NIH Clinical Center could provide training to CIRM investigators through one of the Clinical Center's many clinical investigator training or visiting fellowship programs.

        A CIRM funded investigator may apply to use the special equipment or facilities at the NIH Clinical Center, which could provide opportunities for investigators that may not be possible in their home institutions and which do not involve conducting human studies in the NIH Clinical Center. If selected, such an individual would be eligible to be appointed as a Guest Researcher.

    b. H9 and H14 cGMP grade seed bank and matched research grade

    c. Engineered reporters in the same lines for preclinical animal studies

    d. Access to Drug Master File (DMF) for manufacture of H9 and H14 derived products should you choose one of NIH's providers

    e. Same as above with iPSC lines that are integration free and sourced from appropriate banks

    f. Enabling international coordination with clinical partners

    g. Coordinating a multicenter clinical trial or licensing deals with companies

    h. Helping develop the potency and efficacy assays common for the manufacturing process or disease target

    i. Providing standards and reference controls for their efforts including animal models, etc.

j. TALENS designed with FTO for expressing a missing gene

k. Other Engineering tools

l. Coordinated access to NCATS funding program

m. Screening opportunities through the molecular library program

n. Access to panels of lines that are being generated related to specific diseases

In order to explore possibilities for NIH collaboration with your proposed project, contact Megan Laycock, Program Manager, NIH Center for Regenerative Medicine at mailto:megan.laycock@nih.gov or 301-594-7827.

It is NOT necessary to arrange the collaboration prior to submitting your CIRM Letter of Intent.