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July 9, 2020

California Institute for Regenerative Medicine (CIRM)
1999 Harrison Street, Suite 1650
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To the ICOC Members:

I have submitted a more detailed request for supplemental funding on CIRM COVID-11775, and a separate itemized budget has been sent to D. Kearney. Here is a short summary of the request for discussion at your meeting tomorrow.

CLIN2COVID19-11775: Evaluation and Characterization of SARS-CoV-2 Antibody in Convalescent Volunteer Plasma Donors for Potential Therapeutic Use

Background. This CIRM award supports the ability of clinical sites, especially those in medically underserved areas, to assess COVID-19 convalescent plasma (CCP), and it provides a research testing of CCP for correlates of SARS-CoV-2 neutralization, treatment, and clinical outcome. With the initial funding, start-up activities were initiated with establishment of a website (covidplasmastudy.com) and Covid-19 antibody assays. Since 72% of all Covid-19 cases are in Southern California, our strategy has been to identify hot-spots of infection in four regions with the goal of setting up assistance to these areas as MD coordinator sites. These are Orange/San Bernardino/Riverside Counties (Zone 1), San Diego/Imperial Counties (Zone 2), and Ventura/Santa Barbara Counties (Zone 3), and LA County (Zone 4). This is still in process as we set up the interactions with these sites.

Purpose of Supplemental Funding. The problems identified to date relate to getting help to the areas of COVID-19 surge, and certain aspects of implementation of efforts were not anticipated in the original application. The prospective donors derive from clinical sites where the needs vary with the different types of medical services provided, and, thus, some sites have the ability to link with our program to process CCP donors and provide plasma treatment while others can send us candidate donors but do not treat COVID-19 patients. The more rural the clinical sites, where MDs are so busy with the COVID-19 surge, new staff is needed to engage in a plasma program. Importantly, payment for travel of the blood collection sites and for the collection of CCP can be limiting, and additional funds are necessary to obtain the CCP needed. This supplemental grant will provide funds that allow us to better address each of these problems and assure that the main goal of treatment of COVID-19 patients with CCP is accomplished.

Specific Aspects Provided with the Supplemental Funding. A supplementary budget has been requested that will provide an additional \$175,000 to support the needs of the COVID-19 plasma program at UCI. This will permit reimbursement of donors for travel to blood draw sites, payment to its collection site for plasmapheresis, and, most importantly, support of coordinating staff in specific sites of ethnic diversity (see details on original application). UCI is in position to bringing CCP as a therapeutic to underserved areas. Its outreach program extends from the Vietnamese and Chinese communities in Orange County and to the predominantly Hispanic groups in Riverside and San Bernardino Counties. Also, using an existing UCI-UCR collaboration, a plan is in place for outreach to the native American Communities in Riverside and San Bernardino county. UCI has extensive experience in outreach and sero-prevalence studies and is working with the Orange County Department of Health to access our Chinese, Vietnamese and Hispanic communities. The goal is to reach the Covid-19 positives in these populations and bring them into the study where they can be evaluated as donors, thus increasing the availability of convalescence plasma as treatment.

The additional \$75,000 requested in the supplement will provide funds for support of activity in Zone 3, a predominantly Hispanic region with which we have been working to assist with CCP treatment and data collection. A portion of these funds will help with managing and enhancing the support for the main recruitment tool, the study website, and clinical research coordination for the local MDs to further assure that we can effectively reach underserved areas. Thank you for your consideration.

Sincerely,

A handwritten signature in blue ink, appearing to read 'John A. Zaia', with a long horizontal line extending to the right from the end of the signature.

John A. Zaia, M.D.
Aaron D. and Edith Miller Chair in Gene Therapy
Director, Center for Gene Therapy
Hematological Malignancy and Stem Cell Transplantation Institute