



Alpha Clinic

## City of Hope Alpha Clinic

### Clinical Trial Application

Applications can be submitted to the Alpha Clinic at any stage of development (use contact below)

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**1. RESEARCH PROPOSAL TYPE** (please check what applies):

- Hematopoietic stem or stem/progenitor cells
- CAR T cells
- Neural Stem Cells
- Other \_\_\_\_\_

**2. TITLE OF CLINICAL TRIAL** (IRB #, if available):

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**3. PRINCIPAL INVESTIGATOR:** \_\_\_\_\_

DEPARTMENT: \_\_\_\_\_

PHONE NUMBER: \_\_\_\_\_

CO-INVESTIGATORS (*list name, degree, and department*):

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_



6. DURATION OF PROJECT: \_\_\_\_\_ YEARS

Approximate Start Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Approximate End Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

IND # (if applicable): \_\_\_\_\_ Date IND filed: \_\_\_\_\_

TOTAL NUMBER OF PATIENTS: \_\_\_\_\_

**IMPORTANT: THE FOLLOWING SERVICES ARE PROVIDED BY THE ALPHA CLINIC TO ACCELERATE DELIVERY OF THE CELL THERAPY IN YOUR STUDY**

Please check which services you request:

- a. Monitoring of informed consent procedures.....
- b. Assistance with patient navigation and support.....
- c. Scheduling of protocol-specific procedures.....
- d. Infusion of cellular product in the Alpha Clinic .....
- e. Biospecimen collection, shipping, and follow-up of protocol-specific correlative studies .....
- f. Assistance with regulatory submissions .....
- g. Coordination of data entry and management of regulatory documents .....

7. PROTOCOL-SPECIFIC PROCEDURES (please check all applicable below):

- Stem cell mobilization
- Apheresis
- Preparative regimen before cell therapy infusion
- Cell therapy infusion
- Monitoring post cell therapy infusion
- Biospecimen collection for correlative studies
- Other.....

8. IF STUDY INCLUDES CORRELATIVE STUDIES, PLEASE CHECK REQUIREMENTS:

- Serum/plasma specimen collection
- Bone marrow aspirate/biopsy
- Peripheral blood mononuclear cells
- Pharmacokinetics, specimen collection, processing, storage
- Other.....

**9. SPECIAL PROTOCOL REQUIREMENTS:**

Please list below any special equipment, SOPs, and/or personnel training needed for your protocol:

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**10. RADIOISOTOPES:**  **NO**       **YES** *If yes, you will be asked to provide the Radiation Safety Committee approval letter before the study is implemented into the Alpha Clinic.*

**11. RECOMBINANT DNA STUDIES**  **NO**       **YES** *If yes, you will be asked to provide the IBC approval letter and NIH RAC outcome letter before the study is implemented into the Alpha Clinic.*

**12. WHAT IS THE FUNDING SOURCE FOR THIS PROJECT?**

- 1) \_\_\_\_\_ CIRM; CIRM grant no. \_\_\_\_\_
- 2) \_\_\_\_\_ NIH; NIH contract or grant no. \_\_\_\_\_
- 3) \_\_\_\_\_ Industry; source and clinical trials agreement date \_\_\_\_\_
- 4) \_\_\_\_\_ Other Extramural Grant; source name and no. \_\_\_\_\_
- 5) \_\_\_\_\_ Other; please state \_\_\_\_\_
- 6) \_\_\_\_\_ None

**Has Clinical Trials Finance Office (CTFO) reviewed your protocol?**  **NO**       **YES** *(If yes, you will be asked to provide CTFO outcome letter before Alpha Clinic trial implementation)*

\_\_\_\_\_  
signature: PRINCIPAL INVESTIGATOR

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
DATE

**PI Contact Information** (please include phone and email)

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## NOTE TO INVESTIGATOR

Protocol # \_\_\_\_\_ was approved at the meeting of the Alpha Clinic Leadership Council on \_\_\_\_\_ . Please contact the Alpha Clinic office to discuss study implementation.

It is very important to acknowledge the City of Hope Alpha Clinic support in any publications or presentations that include results performed utilizing Alpha Clinic facilities and/or services. Please use the following format for this acknowledgement:

**This research was performed in the CIRM Alpha Stem Cell Clinics Network and made possible by a grant from the California Institute for Regenerative Medicine (Grant Number AC1-07659). The contents of this publication are solely the responsibility of the authors and do not necessarily represent the official views of CIRM or any other agency of the State of California.**

Proof of productivity is extremely important for continued funding of the City of Hope Alpha Clinic. We appreciate your cooperation. Thank you.