Clear Form

UC Irvine Chao Family Comprehensive Cancer Center

# DOT-TB Feasibility Application

All hypothesis-driven, cancer-related clinical research must undergo review by the applicable Disease Oriented Team (DOT) or Tumor Board (TB). Submit this completed form and the protocol or synopsis to CancerCenter_Committees1@hs.uci.edu.

## GENERAL INFORMATION

| | |
|---|---|
| **Reviewing Committee:** Select one | **Protocol ID:** |
| **Principal Investigator:** | |
| **Sub-Investigators:** | |
| **Concept/Study Title:** | |

**Study Source:** (*see study source definitions on following page)* Select one

| | |
|---|---|
| **If Institutional or Externally Peer-Reviewed study:**<br>Is the study authored by a UCI Investigator?<br>☐ Yes ☐ No<br>Is this a multi-site study?<br>☐ Yes ☐ No ☐ To be determined<br>Did this study originate from basic science at UCI?<br>☐ Yes ☐ No | **If National or Industry study:**<br>Did the PI provide input on the study design?<br>☐ Yes ☐ No<br>Did this study originate from basic science at UCI?<br>☐ Yes ☐ No |
| **Describe authorship opportunity**: *(i.e. authorship if high accrual, steering committee involvement, etc.)* | **Are there potential patients on a waitlist?**<br>☐ Yes, how many? ☐ No |

## ACCRUAL POTENTIAL

| | | |
|---|---|---|
| **Expected UCI Accrual:** | | **Target Accrual Justification** *(e.g. Cancer Registry data):* |
| **Max UCI Participants to be Consented:** | | |
| **Projected Accrual End Date:** | | |

**List Competing Studies:** *(e.g. studies that enroll an overlapping patient population, both active and in pipeline) Refer to the Cancer Center website for updated DOT-specific treatment landscapes: https://cancer.uci.edu/clinical-trials-flowcharts*

**Does the study have a companion study?** ☐ Yes ☐ No *(e.g. studies enrolling patients from a prior study under a new protocol, such as a long-term follow-up safety study after completion of a cellular therapy trial)*

**Describe the potential to accrue underrepresented patients (e.g. women, racial/ethnic minorities, etc.) in CFCCC's catchment area to this trial and if the disease under study disproportionately affects racial/minority populations.** (*See geographical and racial/ethnic disparities data below)*

**Study Sources Definitions**

Per NCI P30 Cancer Center Support Grant DT4

- **National:** NCI National Clinical Trials Network (NCTN) and other NIH-supported National Trial Networks
- **Externally Peer-Reviewed:** R01s, SPORES, U01s, U10s, P01s, CTEP, or any other clinical research study mechanism supported by the NIH or an approved peer-reviewed funding organization
- **Institutional**: In-house clinical research studies authored or co-authored by Cancer Center (CC) investigators and undergoing scientific peer review solely by the Protocol Review and Monitoring System of the CC. The CC investigator has primary responsibility for conceptualizing, designing and implementing the clinical research study and reporting results. It is acceptable for industry and other entities to provide support (e.g., drug, device, other funding), but the trial should clearly be the intellectual product of the center investigator. This category may also include: **1)** Institutional studies authored and implemented by investigators at another Center; or **2)** Multi-Institutional studies authored and implemented by investigators at your Center
- **Industrial:** A pharmaceutical company controls the design and implementation of these clinical research studies.

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**Disparities in CFCCC Catchment Area (Orange County) Cancer Incidence**

Courtesy of the CFCCC Office of Community Outreach and Engagement
Source: California Cancer Registry

- **Breast:** Higher incidence in Orange County, mortality not decreasing for Hispanic women
- **Colorectal:** Increasing early onset incidence & mortality, especially in Hispanics
- **Leukemia:** Increasing incidence & mortality (female) in Hispanics
- **Liver:** Increasing incidence & mortality in Hispanics (e.g. fatty liver disease)
- **Lung:** Increasing incidence & mortality in Asian & Hispanic males
- **Melanoma:** Higher and increasing incidence in Hispanics & Whites, higher mortality for Whites
- **Prostate:** Higher incidence & mortality in Asians
- **Stomach:** Increasing incidence & mortality (male) in Asians, lower survival in Hispanics