Clear Form

UCI 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: Is the study authored by a UCI Investigator? ☐ Yes ☐ No Will this be a multi-site study? ☐ Yes ☐ No ☐ To be determined Did this study originate from basic science at UCI? ☐ Yes ☐ No	**If National (NCTN) or Industrial study:** Did the PI provide input on the study design? ☐ Yes ☐ No Did this study originate from basic science at UCI? ☐ Yes ☐ No

Describe the scientific interest:

☐ Modification in established therapy ☐ FDA-approved agent in another indication ☐ Conducted under IND
☐ Early phase trial ☐ Early phase with novel agent/high impact/potential practice changing trial
Other/Explanation:

Describe authorship opportunity: *(i.e. authorship if lead/high accrual, etc.)*	**Does this study require Team L involvement for inpatient/PPCU Services?** If yes, please present this protocol at Heme DOT. ☐ Yes ☐ 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)*

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)*
If yes, please submit protocol with DOT application if available or present a summary of companion study (purpose, target accrual, etc) to DOT meeting.

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:** The design and implementation of these clinical research studies is controlled by the pharmaceutical company

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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. Based on 1988-2017 death master files; accessed Nov 21, 2021.

- **Breast Cancer:** Significantly higher incidence in OC vs CA, and higher incidence and mortality among Non-Hispanic Whites in OC vs CA
- **Cervical Cancer:** Significantly higher incidence among Hispanics/Latinos than Non-Hispanic Whites in OC vs CA, and higher mortality among Hispanics/Latinos than other ethnic/racial groups in OC vs CA
- **Liver Cancer:** Significantly higher incidence and mortality among Asians/Pacific Islanders and Hispanics/Latinos than Non-Hispanic Whites in OC vs CA
- **Lung Cancer:** Increasing incidence among Asians/Pacific Islanders, and higher mortality among Non-Hispanic Whites than other ethnic/racial groups in OC vs CA
- **Melanoma:** Higher incidence and mortality among Non-Hispanic White females than other ethnic/racial groups in OC vs CA; significantly higher incidence among Non-Hispanic White males and Hispanics/Latinos males in OC vs CA
- **Ovarian Cancer:** Significantly higher incidence among Non-Hispanic Whites and Asians/Pacific Islanders in OC vs CA, and higher mortality among Non-Hispanic Whites than other racial/ethnic groups in OC vs CA
- **Prostate Cancer:** Leading cause of cancer incidence, and second leading cause of cancer mortality among males in OC. Significantly higher incidence and mortality among Blacks in CA, and significantly lower 5-year survival among Blacks and Asian Pacific Islanders in CA.
- **Stomach Cancer:** Significantly higher incidence and mortality among Hispanics/Latinos and Asians/Pacific Islanders than Non-Hispanic Whites in OC vs CA
- **Testis Cancer:** Significantly increasing trends in incidence and mortality among Hispanics/Latinos compared to all other groups in CA