

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:	Protocol ID:
Principal Investigator:	
Sub-Investigators:	
Concept/Study Title:	
Study Source: (see study source definitions on following page)	

<p>If Institutional or Externally Peer-Reviewed study:</p> <p>Is the study authored by a UCI Investigator? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Will this be a multi-site study? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> To be determined</p> <p>Did this study originate from basic science at UCI? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>If National (NCTN) or Industrial study:</p> <p>Did the PI provide input on the study design? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Did this study originate from basic science at UCI? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>
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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.)

ACCRUAL POTENTIAL

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

List Competing Studies:
(i.e. studies that enroll an overlapping patient population, both active and in pipeline)

Describe the potential to accrue underrepresented patients (i.e. 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, SP0RES, 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

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 1988-2015 death master files; accessed Jan 25, 2019.

- **Breast Cancer:** Higher incidence in OC vs CA, increasing mortality rate, higher incidence among Hispanics/Latinos in OC vs CA
- **Cervical Cancer:** Higher incidence among Hispanics/Latinos than other ethnic/racial groups
- **Liver Cancer:** Higher incidence among Asians/Pacific Islanders and Hispanics/Latinos than Non-Hispanic Whites, higher incidence and mortality rate among Asians/Pacific Islanders in OC than Asians/Pacific Islanders in CA
- **Lung Cancer:** Higher incidence in OC vs CA, increasing incidence among Asians/Pacific Islanders, higher mortality rate among Asians/Pacific Islanders in OC vs CA
- **Melanoma:** Higher incidence and mortality rates among Non-Hispanic Whites in OC vs CA, higher incidence among Hispanics/Latinos in OC vs CA, increasing incidence in these groups
- **Ovarian Cancer:** Higher mortality rate in OC vs CA, increasing incidence among Asians/Pacific Islanders
- **Stomach Cancer:** Higher incidence and mortality rates among Hispanics/Latinos and Asians/Pacific Islanders vs Non-Hispanic Whites, higher incidence among Hispanics/Latinos in OC vs CA, higher mortality rate among Asians/Pacific Islanders in OC vs CA