Cancer Therapy Evaluation Program (CTEP)  
Investigational Drug Branch (IDB)  
Externship Fellow Program

Charles Kunos, M.D., Ph.D.  
Percy Ivy, M.D.  
Jeffrey Moscow, M.D.
<table>
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<tr>
<th>Program Offering</th>
<th>CTEP Investigation Drug Branch (IDB) Externship Program</th>
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<tr>
<td>Program Description</td>
<td>Whether you are a part of the National Cancer Institute’s scientific or clinical oncology communities, your ability to communicate effectively to patients, clinical research peers, pharmaceutical partners, and your research team is critical to your success. The CTEP IDB externship program is an up to 4-week highly interactive experience offering mentorship and best practices for improving formal communication with CTEP and its clinical oncology development and trial stakeholders. Using Letter of Intent (LOI) or concept trial reviews as well as medical officer group dynamics and one-on-one coaching feedback, this CTEP externship program provides participants the skills for impactful presentations and the insights to craft your own competitive LOIs or concepts.</td>
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<td>Who Should Participate</td>
<td>Medical or Radiation Oncology Fellows, or Junior Oncology Faculty (&lt;7 years from final oncology training)</td>
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<td>Program Cost</td>
<td>No Charge</td>
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<td>Program Date(s) &amp; Location</td>
<td>Up to 4-week rotations</td>
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<td>NCI Shady Grove, Room 5W 440, 442</td>
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<td>Registration Information</td>
<td>Advanced registration for this externship is required and space is limited to 4 /calendar month.</td>
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<td>Registration Contact</td>
<td>Charles Kunos, MD, PhD</td>
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<td>Medical Officer and Coordinator, Investigational Therapeutics &amp; Radiation</td>
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<td>Investigational Drug Branch, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis</td>
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<td>National Cancer Institute, National Institutes of Health</td>
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<td>9609 Medical Center Drive, Room 5W-506</td>
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<td>Rockville, MD 20850</td>
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<td>(E): <a href="mailto:charles.kunos@nih.gov">charles.kunos@nih.gov</a></td>
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Mission Statement

Cancer Therapy Evaluation Program (CTEP)
The Cancer Therapy Evaluation Program (CTEP) is a branch of the U.S. National Cancer Institute with the explicit goal:

“To improve the lives of cancer patients by finding better ways to treat, control and cure cancer”

CTEP supports a national program of cancer research by:

1) Interacting with the Pharmaceutical Industry and NIH researchers to bring interesting new agents to experienced US investigators to conduct trials

2) encouraging high-quality research which addresses critical clinical questions while seeking to better answer translational questions which inform about molecular targets and mechanisms of drug effects

3) beginning to develop and run clinical trials using TEAM Science (with clinician scientists, translational scientists and basic scientists)

4) ensuring the safety of clinical trial subjects

5) partnering with the FDA
• A program designed by CTEP to provide both American and foreign fellows or early career investigators with intense advanced training in all aspects of drug development, particularly in early drug clinical development.
74 fellows from National Cancer Institute cancer centers and partners

26 U.S. sites: Johns Hopkins (9), Ohio State (6), Mayo Clinic (5), Washington Hospital Center (5), Memorial Sloan Kettering (4), Yale (3), Thomas Jefferson (2), Columbia (2), Georgetown (2), MD Anderson (2), Case Western Reserve (1), Moffitt (1), Cornell (1), Baylor (1), Westchester (1), Pittsburgh (1), Maryland (1), U of Utah (1), U of Colorado (1), Cincinnati (1), U of Kentucky (1), Rutgers (1), U of California-San Diego, Vanderbilt (1), Northwestern (1), NCI Pediatric Oncology Branch (1), NCI Clinical Center (3)

15 Foreign sites: Japan (6), Taiwan (1), Belgium (1), S. Korea (2), China (2), Canada (1), Nigeria (2)
Address the analysis of tumor and other tissues for pathway activation or biomarker

Comment on whether patient assigned to trial based on tumor molecular characterization

Consider frequency of patient monitoring

Question if there is a post-treatment molecular re-analysis for response/resistance

CTEP: Externship Expectations

- Externship Participants:
  - Involved in day-to-day operations
  - Review LOIs or concepts at collaboration with medical officers [right panels]
  - Present LOIs or concepts at IDB or Protocol Review Committee (PRC) meetings
  - Familiarize themselves with NCI branches and resources
  - Learn the thought processes involved in a clinical development plan for competitive LOIs or concepts
  - IF desired, work on a research project of choice, in collaboration with medical officers

* Comment on clinical data:
  - Clinical response
  - PK
  - Functional imaging
  - Tumor and normal tissue PD markers

Are there non-clinical models for targets?

Is translational research planned with clinical models:
- Sequencing
- Methylation
- FISH
- IHC
- Expression array
- 72 active agents under cooperative research and development agreement (CRADA)

CTEP: Externship Expectations

Meeting Participation Opportunities:

- **Monday:** Pharmaceutical company presentations; Disease-specific Working Groups
- **Tuesday:** Project Team or Unsolicited LOI teleconferences between CTEP & Investigators
- **Wednesday:** Investigational Drug Branch meeting (LOI review); Clinical Investigations Branch meeting (concept review)
- **Thursday:** Protocol Review Committee meeting (LOI/concept review); Biomarker Review Committee meeting
- **Friday:** Pharmacodynamic Working Group meeting; Disease-specific Working Groups
• Please contact Dr. Charles Kunos at: charles.kunos@nih.gov

• Provide your availability and preference for the month you want to be at CTEP; foreign fellows must allow 6 months for processing paper work

• State your major career objectives and your specific interests in oncology

• Attach a current curriculum vitae

• Explain how you heard about the fellowship program, and who referred you, if appropriate