

**National Cancer Institute (NCI)
National Cancer Advisory Board (NCAB)
ad hoc Subcommittee on Experimental Therapeutics**

**Virtual Meeting
2 September 2026
9:30 a.m.–10:12 a.m. EDT**

SUMMARY

Subcommittee Members

Dr. Richard J. Boxer, Chair
Dr. Rose Aurigemma, Executive Secretary
Dr. Nilofer S. Azad
Dr. Callisia N. Clarke (absent)

Ms. Julie Papanek Grant (absent)
Dr. Amy B. Heimberger
Dr. Kimberly Stegmaier
Dr. Ashani T. Weeraratna (absent)

Other Participants

Dr. Jessica Calzola, NCI
Dr. John D. Carpten, Chair, NCAB
Dr. James H. Doroshow, NCI
Dr. Gary L. Ellison, NCI
Dr. Anthony Letai, Director, NCI
Ms. Amber Lowery, NCI
Dr. Douglas R. Lowy, NCI
Mr. Ricardo Rawle, NCI

Dr. George Sigounas, NCI
Dr. Shamala Srinivas, NCI
Dr. Fred K. Tabung, NCAB
Dr. Sundar Venkatachalam, NCI
Dr. Brigitte Widemann, NCI
Dr. Karen M. Winkfield, NCAB
Dr. Amanda Cennname, The Scientific
Consulting Group, Inc., Rapporteur

Welcome and Opening Remarks

Dr. Richard J. Boxer, Clinical Professor, David Geffen School of Medicine, University of California, Los Angeles

Dr. Richard Boxer, Subcommittee Chair, welcomed participants to the NCAB *ad hoc* Subcommittee on Experimental Therapeutics (Subcommittee) meeting and noted that the Subcommittee had not met for approximately 2 years. He explained that changes in funding priorities and programmatic focus had interrupted previous plans to convene discussions among government, academic, and other scientific partners regarding emerging opportunities in experimental therapeutics. Dr. Boxer voiced support for resuming regular Subcommittee meetings.

Briefing on Current Areas of Interest in Experimental Therapeutics

Dr. Rose Aurigemma, Associate Director, Developmental Therapeutics Program (DTP), Division of Cancer Treatment and Diagnosis (DCTD), NCI

Dr. Rose Aurigemma, Subcommittee Executive Secretary, provided an overview of two areas of current interest within experimental therapeutics: (1) the development of new approach methodologies (NAMs) to reduce reliance on animal testing and (2) the implementation of NIH Highlighted Topics as a mechanism for communicating research priorities to the extramural community.

New Approach Methodologies

Dr. Aurigemma described NIH-wide efforts to reduce animal testing in drug development, including support for alternative methodologies (e.g., organoid-based models, advanced *in vitro* assays). Recent developments include the launch of the NIH Standardized Organoid Modeling (SOM) Center at the

Frederick National Laboratory for Cancer Research, which is developing standardized, reproducible organoid models representing normal human tissues for broad use across NIH and the research community.

Ongoing work within DCTD includes the development of *in vitro* toxicology assays for evaluating candidate therapeutics. Dr. Aurigemma highlighted examples of these efforts, which include cardiovascular safety assays using human induced pluripotent stem cell–derived cardiomyocytes and organoids, as well as platforms for evaluating on-target/off-tumor and off-target toxicities associated with chimeric antigen receptor T-cell therapies.

NCI’s Patient-Derived Models Repository contains more than 900 clinically characterized tumor models and supports efforts in drug discovery and development. Current activities include the use of well-characterized patient-derived organoids in high-throughput drug screening platforms to identify new therapeutic agents and drug combinations.

Dr. Aurigemma emphasized that widespread adoption of NAMs will require extensive validation to demonstrate reproducibility, robustness, and predictive value. Future integration of these data with artificial intelligence approaches could improve prediction of therapeutic efficacy and toxicity.

Highlighted Topics

Dr. Aurigemma described NIH’s new Highlighted Topics initiative, which is intended to communicate high-priority research areas to the research community. The initiative provides a mechanism for NIH institutes, centers, and offices to identify strategic areas of interest and encourage investigator-initiated applications in those fields.

Dr. Aurigemma described an example of a recent NCI Highlighted Topic titled “Next-Generation Cellular Immunotherapy: Reprogramming Immune Cells Within the Body.” Several additional Highlighted Topics are in development, including “Advancing Treatment Options Using Targeted Degradation Technologies,” “Integrating Immune Aging Research to Improve Therapeutic Outcomes,” and “Natural Product Discovery and Development for Disease Prevention, Interception, and Treatment.” Dr. Aurigemma encouraged Subcommittee members to consider additional Highlighted Topics that could be published in the future.

Group Discussion

Dr. Boxer and Subcommittee

Dr. John Carpten, NCAB Chair, asked whether the SOM Center would consider donor diversity across the lifespan. Dr. Kimberly Stegmaier also emphasized the importance of including pediatric populations in future organoid efforts. Dr. Aurigemma acknowledged that representation of pediatric, adult, and geriatric populations will be an important consideration as the program expands.

Dr. Stegmaier suggested expanding work on genetically modified organoid models to support toxicity assessments. She also recommended broadening the pending degrader-focused Highlighted Topic to include other bifunctional therapeutic technologies. Dr. Sundar Venkatachalam noted that DCTD is already exploring related approaches beyond degraders and expects additional developments in this area.

Dr. Amy Heimberger observed that organoid systems have significant potential for evaluating chemotherapeutic and targeted agents but currently provide limited ability to model interactions between tumors and the immune system. She suggested developing approaches that better represent the immune–tumor interface, including the incorporation of matched immune-cell populations.

Dr. Heimberger also underscored the importance of comparing the predictive value of organoid systems and animal models for clinical outcomes. Dr. Aurigemma noted that efforts are underway to incorporate immune components into tumor organoid systems and expand the development of models that can better evaluate immunotherapeutic responses.

Dr. Anthony Letai, NCI Director, expressed optimism about the future potential of *ex vivo* systems to evaluate immunotherapies and noted that previous comparisons between patient-derived xenograft models and *ex vivo* approaches have demonstrated encouraging concordance. He also noted that NCI plans to publish guidance encouraging investigators to identify relevant Highlighted Topics in grant applications to facilitate tracking and evaluation.

Dr. Heimberger noted that aged animal models can be prohibitively expensive for investigators and suggested exploring ways to facilitate access to aged rodent resources. Dr. Aurigemma remarked that resources supported by the National Institute on Aging may offer a more accessible alternative for researchers pursuing studies in this area.

Participants also discussed methods for tracking the uptake of Highlighted Topics. Dr. Venkatachalam suggested that the Center for Scientific Review could potentially implement mechanisms to identify and track applications associated with specific Highlighted Topics. Dr. Letai noted that NIH has previously explored this approach and agreed that such tracking would be valuable.

Dr. Nilofer Azad emphasized the need for improved communication about the many resources available through NCI and NIH, noting that investigators are often unaware of existing tools and services. She suggested creating more centralized and accessible mechanisms for investigators, particularly junior clinical researchers, to learn about available resources and collaborations.

Dr. Aurigemma described ongoing efforts to modernize and consolidate NCI's web presence and highlighted existing consultation services that connect investigators with NCI staff and resources. Dr. Letai agreed on the importance of this point and suggested that more intuitive search tools, potentially incorporating large language model technologies, could help investigators identify relevant information.

Dr. Boxer asked about the impact of recent policy and funding changes on NCI staff. Dr. Aurigemma acknowledged that staff have experienced substantial organizational changes but commended their adaptability and commitment to supporting the extramural community during this period of transition.

Closing Remarks and Adjournment

Dr. Boxer expressed appreciation to the participants for their engagement during the discussion. He adjourned the meeting at 10:12 a.m. EDT.

Dr. Richard J. Boxer
Chair

Date

Dr. Rose Aurigemma
Executive Secretary

Date