



October 27, 2023

The Honorable Bill Cassidy
Health, Education, Labor, and Pensions Committee
United States Senate
455 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Ranking Member Cassidy,

The American College of Radiology (ACR) - a professional association representing more than 41,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, offers the below considerations to your office's request for information regarding modernizing the National Institutes of Health (NIH).

ACR has historically been a leader in the radiology clinical trial space, helping to develop and implement new prevention, diagnosis, and treatment approaches at a faster pace for a variety of diseases and disorders. Support for the NIH and our national research infrastructure allows for the continued advancement of scientific discoveries and breakthroughs, improving the lives of patients with a wide spectrum of diseases and disorders, many of whom depend on radiology and imaging tools for prevention, diagnosis, and treatment of disease. ACR encourages increasing NIH, and other health agencies, capacities in areas such as imaging and radiology science, artificial intelligence, engineering, and computational processing, to provide numerous opportunities across the biomedical research spectrum. ACR is proud to have contributed to the success of advancing imaging practices through clinical research on a variety of NIH funded clinical trials, including those conducted by the National Cancer Institute (NCI), and is an active partner and collaborator in this space.

Increasing the Pace of Science

Overarching Questions

3. In your view, what would be the appropriate balance between basic, translational, and clinical research at NIH? How can NIH continue to prioritize truly fundamental research while improving outcomes for translational and clinical projects?
 - Basic, translational, and clinical research are all important priorities and function interdependently to ultimately benefit patient care. We note an unmet need with respect to certain types of translational research – for example real-world outcomes, economics and policy research are particularly critical for moving science to everyday practice, and broad, equitable access. Currently, there is insufficient funding for translational research outside of the private sector, which creates opportunities for bias in the information used for decision making.
6. What lessons can be learned from individual NIH Institutes and Centers (ICs) related to the conduct of clinical research? How can clinical trials be conducted more efficiently



and effectively? What types of trials should NIH conduct, and what types are more appropriate for industry to undertake?

- The ACR is a long-standing partner in NIH clinical trials, specifically, NCI sponsored clinical trials. The infrastructure supporting NCI-sponsored clinical trials could be more efficient and effective by adopting the following suggested changes.
 - The NIH should consider a streamlined approach for clinical application reviews, including the design and approval processes. The specific IC-sponsored leadership should be included in the initial stages of a trial review, to reduce burden on NIH staff and streamline this process. IC specific staff should be involved in helping with design studies early in the process, to increase efficiency, address any budgetary and funding interests, and quicken the launch of trials.
 - The NIH should consider a focus on studies that employ an observational model to collect Real-World-Evidence. This would allow for the automated collection of data from Electronic Health Records for populations not accounted for in randomized clinical trials. Data collection efforts on the use of drugs and devices would create rich data sets that would allow for hypothesis generation, and the training and testing of potential Artificial Intelligence (AI) software and AI-enabled healthcare products. One example of a vehicle to achieve the collection of Real-World-Evidence, are clinical registries, such as the ACR National Clinical Imaging Research Registry (ANCIRR). ANCIRR collects images and clinical data from multiple practice settings, enabling researchers to address complex scientific questions and produce results applicable across various care settings, geographic locations, and populations.
 - Biospecimens collected during clinical trials for future research purposes should be accessible to the study trial teams, ideally during the trials, or within a short interval of the study closure. Clinical trials frequently collect biospecimen, such as blood and buccal smears, to potentially enable a deeper understanding of why some treatments fail in subsets of the patient population being studied (different racial and ethnic groups, people with certain genetic variants, etc.) Often those specimens are difficult to access and there are delays in using them.
 - There should be a focus on the mandatory component of data sharing in all NIH studies, after publication of the primary study results. Due to underfunding, researchers struggle to make data available, because it requires substantial work and time after the study funding has lapsed. These datasets could be valuable for the development and testing of new diagnostic and therapeutic tools, including AI algorithms. In addition, consideration should be given to sequestering some of this data for use by the Food and Drug Administration and other federal agencies to validate AI algorithms. Datasets are not valuable without appropriate data dictionaries and annotations of imaging and other data. All of this requires a budget to accomplish, which is frequently not part of the budget for the primary research study.



Extramural Research Program

2. How do academic institutions typically fund the salaries of extramural investigators? What benefits and challenges come with this approach? How could this practice be reformed to better support the biomedical research workforce and ensure that NIH dollars, on a per project basis, accurately reflect the time commitments of each investigator and staff member?
 - Physician-scientists are integral to developing innovations with a clear pathway from bench to bedside. The NIH cap interferes with the ability to recruit and retain physician-scientist in numerous ways. Academic departments need to fund a competitive salary above the NIH salary cap to support physician-scientists, typically through clinical revenue. Salaries may be lowered to reduce the departmental need to “fund the gap” discouraging physicians from pursuing NIH research funding, and physician-scientists from remaining scientists, with an increased pressure to revenue generating patient care activities. Although less severe, non-physician scientists, particularly senior scientists, are also exposed to considerations of the “cap gap.” A recommended solution is to increase the cap and to adjust it for inflation annually, as the current system is not sustainable.¹

Thank you for your consideration of these suggestions. Please do not hesitate to contact me or ACR staff, Gloria Romanelli, JD, Senior Director of Regulatory Affairs at gromanelli@acr.org or Katie Grady, Government Affairs Director at kgrady@acr.org, with any questions.

Sincerely,

William T. Thorwarth Jr. MD, FACR
Chief Executive Officer

¹ Williams CS, Rathmell WK, Carethers JM, Harper DM, Lo YMD, Ratcliffe PJ, Zaidi M. A global view of the aspiring physician-scientist. *Elife*. 2022 Sep 13;11:e79738. doi: 10.7554/eLife.79738. PMID: 36098684; PMCID: PMC9470153.