

January 13, 2012

Robert A. Star, MD
Director of the Kidney, Urologic, and Hematologic Diseases Division
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Building 2 DEM, Room 625
6707 Democracy Boulevard
Bethesda, Maryland 20892

Re: Strategies for Allocation of Available Resources to Various Grant Funding Mechanisms

Dear Dr. Star:

On behalf of the American Society of Nephrology and the 13,000 members the society represents, I want to thank you for soliciting ASN to propose strategies for allocation of available resources to various grant funding mechanisms. You specifically asked for advice on three issues: protection of the R01 “payline”; balance between funding large budget projects vs. investigator-initiated R01s; and approaches to preserve innovation without destroying incremental science that spawns innovation. We have carefully considered these issues.

ASN understands that, including the across-the-board cuts, FY 2012 funding for NIH was slightly reduced from FY 2011 in the omnibus budget bill. ASN further recognizes the likelihood of additional, possibly more significant, cuts to future NIH budgets, and that NIDDK will need to make difficult decisions about how to allocate decreasing grant dollars across funding mechanisms. ASN shares NIDDK’s commitment to advancing research and improving treatment for kidney disease patients, and agrees with the need to carefully consider approaches to this issue.

ASN believes the investigator-initiated R01 grants should remain the primary source of funding for fundamental, translational, and clinical science in kidney research, and recommends NIDDK continue to primarily protect the R01 payline. However, the R01 payline will need to be flexible, allowing the payline to float to accommodate “worthy big science projects,” broadly defined as initiatives that require multi-investigator mechanisms of funding for implementation and have a reasonable likelihood of producing high impact results. The extent that the payline is allowed to drop would need to be determined empirically, assessing the effects of small decreases on the trainee and new investigator pipeline and loss of established labs. While the loss of any investigators is regretful, ASN believes the NIDDK needs to have flexibility to allow it to preserve innovation and progress in kidney biology and disease research. While ASN represents the entire kidney investigative community and does not believe it would be appropriate to propose specific projects for funding, the society suggests the following criteria to determine whether investments in large projects would be worth the tradeoff of a lower R01 payline:

1. Projects that use human samples or data for discovery-based science to generate data for hypothesis generation and address questions of disease mechanism and clinical

utility (e.g., surrogate markers for clinically meaningful endpoints and biomarkers to subset patients for adaptive trial design).

2. Projects that facilitate additional sample collection and storage (not supported by the parent study) from ongoing, well-designed clinical trials, including studies initiated by Pharma that could be supported through public-private partnerships. ASN anticipates that “big science projects” would propose use of these samples as described in point “1” or could be ancillary studies as described in “5” below.
3. Clinical trials supported by a strong evidence base, the results of which would impact practice and unlikely be funded by Pharma.
4. Projects supported by NIDDK funding mechanisms should promote efficient use of data by being open or transparent, encouraging projects with a data management plan that facilitates use by outside investigators.
5. Ancillary projects that build on the "big science" infrastructure, which would protect the R01 payline but promote collaboration and force/promote network building and interactions.
6. Continue funding flexibility to support young investigators receiving R01s, even if they miss the payline, by giving program staff discretion to fund them above the payline.
7. Use funds that become available with a floating R01 payline to support innovative projects that have not fared well in the traditional review process. Program staff should obtain advice on these initiatives from NIDDK Council and other experts.
8. ASN supports the efforts of KUH to disseminate information on the scope and focus of projects that will be of interest to the Patient-Centered Outcomes Research Institute (PCORI), which will provide a new source of dollars to support kidney disease research.

ASN welcomes the opportunity to discuss these recommendations with you further. Please contact ASN Manager of Policy and Government Affairs Rachel Shaffer at (202) 640-4659 with any questions. Thank you again for seeking out ASN’s suggestions. The society is committed to serving the nephrology community, and ensuring research dollars are well spent is a central focus of our work.

Sincerely,

A handwritten signature in black ink, appearing to read "Ronald J. Falk". The signature is fluid and cursive, with a large initial "R" and "F".

Ronald J. Falk, MD, FASN
President