August 16, 2017

Carrie Wolinetz, Ph.D.
Associate Director for Science Policy
National Institutes of Health

William Riley, Ph.D.
Associate Director for Behavioral and Social Sciences Research
National Institutes of Health

Dear Drs. Wolinetz and Riley,

The Association for Research in Vision and Ophthalmology (www.arvo.org) would like to register its concern about the NIH Definition of Clinical Trials.

Our members' research, much of it funded by NEI, encompasses a broad range of eye and vision science, from basic to clinical to translational. Many member scientists conduct basic research, using humans as experimental observers. These studies are not 'clinical trials' in the conventional usage and common understanding of the term; but the new NIH definition could put that label on a substantial body of work in our field.

It was stated in the recent article in Science (*NIH redefines clinical trials, attracting critics; 21 July 2017; sciencemag.org*), that NIH is working to clarify the scope of the definition. In doing so, we request that the definition of intervention type be an emphasis in such clarification. The current definition of manipulation of the subject or subject's environment is too broad in that it encompasses activities such as measuring physiologic responses to viewing different images. As a potential example, a clinical researcher may be examining the effect of using a new type of visual stimulus on the metabolic rate of certain retinal cells. In this scenario, the researcher would be using human subjects, potentially randomizing or otherwise assigning them to different stimulus patterns and measuring the subsequent metabolic rates. If the current definition is used, this type of study could be considered a clinical trial.

We echo concerns expressed by others that classifying basic human research as clinical trials can confuse the public about the nature of trials and that the additional studies categorized as trials will place additional and undue burden on NIH oversight, on researchers and their institutions, as this new ruling will not only impact established research groups but student projects. We also share concern that the grant review process will be significantly disrupted by the requirement that beginning with the January 25, 2018 grant due dates, all applications proposing clinical trials must be submitted through a FOA designated specifically for clinical trials.

On behalf of ARVO leadership, I thank you for your time and attention to this critical issue.

Sincerely,

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