Dear Dr. Riley;

The Vision Sciences Society (http://www.visionsciences.org) would like to register its concern about the NIH Definition of Clinical Trials.

VSS is an organization of scientists who are interested in the functional aspects of vision. Our member’s research, much of it funded by NEI, encompasses the breadth of topics in modern vision science, from visual coding to perception, recognition and the visual control of action, as well as the recent development of new methodologies from cognitive psychology, computer vision and neuroimaging. Most of this work is basic research, using humans as experimental observers. It provides fundamental data that can be applied to health-related issues from diagnosis and treatment of ocular and nervous system disorders to driving safety and medical image perception. These studies are not ‘clinical trials’ in the normal understanding of that term but the new NIH definition could put that label on a substantial body of work in our field. The purpose of our research is to shed light on normal visual processing. While the results may influence future studies with clinical populations, they are not yet at the stage of influencing patient care. Clinical trials on the other hand, are designed to yield their main conclusions about the health benefit of a treatment (or intervention) or the diagnostic efficacy of a test in assessing a medically important aspect of health. Before we can understand the health benefits of a treatment, we need to understand how visual processing occurs in normal populations.

We believe that broad use of this definition would produce multiple negative effects:

1. There is important clinical work in vision science. Some of this work leads to clinical trials of the sort listed on public-facing sites such as [clinicaltrials.gov](http://clinicaltrials.gov). Classifying basic human research as clinical trials can confuse the public about the nature of the clinical trials. Note that we are not opposed to scientific openness. The public has a right to know what the NIH is funding, but defining clinical trials too broadly does not advance that goal.

2. Diluting the clinical trials databases with studies that are not clinical trial will make it less likely that members of the public will be able to find and enroll in true clinical trials.

3. Because the public will not appreciate the subtleties of the new definition of ‘clinical trial’, this will hold the researchers and the NIH up to public ridicule for claiming to be doing ‘clinical trials’ of matters that are clearly not clinical issues.

4. This will dilute NIH oversight of real clinical trials that should be monitored.

5. This will add to the bureaucratic burden for researchers and their institutions

6. We have a particular interest in researchers at smaller institutions that may not have administrative support to guide researchers through the increased burden.

7. Grant review will be significantly disrupted by the requirement that “clinical trial” grants must be reviewed by study sections that review “clinical trials”.

The Society urges you to seek clarification of the definition. We trust that a clarification would limit the definition of clinical trials to a sensible subset of NIH research.

Sincerely,

Vision Science Society Board of Directors

Eli Brenner, David Brainard, Lynne Kiorpes, Jeff Schall, Preeti Verghese, Andrew Watson, Mike Webster, Laurie Wilcox, Jeremy Wolfe