Dear Dr Collins

I am writing to emphasize the importance of Dr James Pekar's email, included below. I have also just sent these concerns to Mike Lauer and Lawrence Tabak about the expanded definition of clinical trials.

First, a note: I am very strongly sympathetic to the goals of increasing transparency and replicability in science. I view this as a strong priority for my field, and many others, and would be a very enthusiastic advocate for using the power of the NIH to achieve these goals. I have read Mike's papers on the topic, and I fully agree with the motivations. But the current situation with the revised definitions is not an effective solution.

Now, as you know, NIH has just released yet another revised list of case studies to show how to apply this expanded definition. Unfortunately, the re-revised case studies for fMRI, 18a, b and c, are even more mystifying.

Case 18A involves participants (at different ages) who do working memory tasks and brain scans to assess the association of these measures over time; and is NOT a clinical trial.
Case 18B involves participants (from different clinical groups) who do cognitive tasks, behavioral tasks, or presentation of stimuli while undergoing a brain scan to assess brain activity, compare this activity between groups; and is NOT a clinical trial.
Case 18C involves participants (from different clinical groups) who do a gambling task, to compare the effects of wins and losses on brain function. This IS a clinical trial.

So now all cognitive neuroscientists are tasked — on pain of very serious penalties — with trying to figure out what the relevant difference is supposed to be, between 18c and the other two? The questions and answers on the website are not illuminating. 18A and 18B involve "prospective assignment to experimental conditions hypothesized to affect brain function." ALL cognitive tasks, behavioral tasks, and presentation of stimuli affect brain function. 18A and 18B are also designed to learn about how the brain responds to different stimuli in different groups; and involve brain function as an outcome. Thus, the implication is that there is something more inherently clinical about a "gambling task" with wins and losses than a cognitive, behavioral, or working memory task, or the otherwise unspecified "presentation of stimuli".

I hope it is clear that this distinction is highly arbitrary, and has no continuity with any practice either historically or by any other institute.

This situation is frankly embarrassing for American science. Please help create the space and motivation to resolve it.

Sincerely

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