

From: **COGR Administrator** <administrator@cogr.edu>
Date: Wed, Jan 24, 2018 at 9:40 AM
Subject: Revisions to the NIH Clinical Trial Case Studies
To: COGR LISTSERV <COGRLISTSERV@cogr.edu>

Dear COGR Members,

We have previously reported that COGR, AAMC, AAU and APLU sent a [letter](#) to Dr. Michael Lauer, NIH Deputy Director for Extramural Research, on September 17, 2017, expressing concern that NIH's definition of "clinical trial" has been significantly expanded through the set of case studies published by the agency in the summer of 2017. Associations have had subsequent exchanges with Dr. Lauer on this topic, including discussions on alternative reporting structures for basic health research involving human subjects.

Yesterday the Federation of Associations in Behavioral and Brain Sciences (FABBS) provided an [update](#) on progress that has been made with respect to the NIH clinical trial case studies and on January 22, a [dialogue](#) on this topic between Jeremy Wolfe, immediate past president of FABBS, and Mike Lauer addressing related concerns that have been raised by the community was published in Nature Human Behaviour. The article provides information and clarifications that should be helpful to investigators.

As indicated in the FABBS blog, case study 18 (a-f) has been revised such that there does not appear to be anything in 18 that would suggest that basic health research involving fMRI is a clinical trial. This would appear to include fMRI research involving manipulations that result in transient changes to physiology or behavior with no therapeutic intent. Further, case studies 24 and 26, which have been of concern, have been removed from the website and could potentially be under revision. We remain concerned about other case studies that capture basic health research, including case studies 9 and 14 as highlighted in our letter, and those that continue to occupy grey areas and further stretch the boundaries of what has traditionally been defined as a clinical trial. COGR will continue its dialogue with NIH and other associations and societies engaged on this issue and seek further revisions as necessary. In the meantime, investigators should continue to consult the case studies. As indicated in Nature article, those uncertain of whether their research meets the definition of a clinical trial should reach out to their program officer and NIH will uphold that opinion.

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