

## Report on Research Compliance Volume 17, Number 4. March 26, 2020

### From Remote Oversight to Wind-Downs: Research Struggles in the Time of COVID-19

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“In an effort to minimize the risk of contracting or spreading COVID-19 in human participant research interactions and to preserve personal protective equipment for clinical care, the university is placing temporary restrictions on human subjects research effective Saturday, March 14, and continuing through Friday, May 1.”<sup>[1]</sup>

So began the note from the University of Michigan (U-M) Office of the Vice President for Research, posted over the second weekend in March, a message that reflected the rapidly changing environment surrounding the coronavirus outbreak and the need to consider the sometimes competing needs of patients and research subjects—not to mention the desire to keep staff healthy. The announcement included that the May 1 date would be reevaluated.

Indeed, U-M later updated that note with one that sounded more urgent: “The university encourages you to develop a research Continuity of Operations Plan by the end of this week (Friday, March 20). Consider how the work of your groups could be slowed for the coming weeks to be prepared for a reduction in operations, and what steps you would follow if the work had to be placed on hold with short notice. The planning you do now will support the long-term success of our laboratories and research groups.”<sup>[2]</sup>

In a subsequent post on March 21, U-M noted that regardless of all the other changes, “our research support units (Research and Sponsored Projects, Technology Transfer, Research Ethics & Compliance, Consulting for Statistics, Computing & Analytics Research, etc.) remain operational.”<sup>[3]</sup>

As the outbreak that first took hold in China and Europe began to spread in the last month to the United States, U-M and other universities took immediate and, in most cases, unprecedented steps, often in concert with their institutional review boards (IRBs). As U-M demonstrated, research compliance officials kept working, usually at home, their days a blur of conference calls, emails, video meetings and regular checks of agency websites to get the latest guidance.

Some actions were inevitable based on requirements from local governments and state officials, but often preceded those mandates.

For example, on March 2, New York University (NYU) Langone Health banned “all domestic and international work-related travel and attendance at outside business and academic meetings, conferences, etc. for at least the next 60 days.” This decision was two weeks or more ahead of widespread travel bans.

Near the end of the month, many organizations were forced to consider shuttering research labs because government agencies began telling the public they had to stay home unless they worked in “essential” positions or businesses. At a minimum, ongoing studies were transitioning, whenever possible, to remote monitoring or oversight of trials.

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