

## Compliance Today – June 2019

# Anticipatory surveillance complements traditional research compliance monitoring and auditing

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Anticipatory surveillance of media, a new approach to detecting and preventing research noncompliance at our institution, was developed in response to reports of unapproved research.

### Impact of undetected or unreported unethical research

Why conduct surveillance? Without appropriate institutional oversight to ensure compliance with laws, regulations, and basic ethical principles,<sup>[1], [2], [3], [4]</sup> unapproved research can have serious, negative implications for human and animal research subjects, researchers acting as agents of their institutions, the funding agencies that support research, and sometimes the credibility of an entire field of research. Medical journals and watchdog groups have reported on unethical research and clinical trials, including some involving HIV and other infectious diseases, throughout the 1990s and into the present day.<sup>[5], [6]</sup>

In 2013, a researcher at a US university conducted an unapproved test of a herpes vaccine on human subjects in a hotel room; he later expanded the trial to St. Kitts where the vaccine was tested on more than 20 persons. Some subjects experienced adverse reactions, but these events went unreported because this trial was not conducted according to regulations. Neither the government of St. Kitts nor the university that employed the researcher claimed to have approved of, or had any knowledge of, these activities. However, the researcher had a patent for the technology, which was assigned to the university and licensed to a startup company.<sup>[7], [8]</sup> These unapproved trials resulted in federal investigations of both the company sponsor and the university and are now the subject of lawsuits brought by at least three participants against the company that licensed the patent and sponsored the St. Kitts trials.<sup>[9]</sup>

### Can this happen here? Can we prevent it?

When most reporting came from medical journals and watchdog groups, there was often a delay between the event(s) and report(s). Institutions could not help but be reactionary to these reports unless they had some form of advance warning. The combination of a delay between the event and reporting it, and having some advance warning, occasionally allowed institutions the opportunity to formulate a response plan, but the response was still reactionary.

It is no longer primarily medical journals and watchdog groups reporting on unethical or unapproved research. Under-reporting of clinical trial results and adverse events in both clinical research and medical treatment settings have become fodder for online blogs and social media forums dedicated to discussing these subjects.<sup>[10], [11]</sup> Subjects discussed on these forums are often subsequently reported in popular mainstream media outlets.

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With the almost instantaneous transmission of information that occurs now, advance warning is less likely and a proactive approach has become more important. We asked whether regular and systematic surveillance of media could assist in detecting unapproved research at our institution.

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