



Compliance TODAY

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Roy Snell



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VOLUME 20, ISSUE 12

by Michael J. Tuteur and Torrey K. Young

That ‘hot’ research project may land your lab in hot water

- » The False Claims Act is a potent source of potential liability for research laboratories that use federal funding.
- » Financial violations are relatively easy to uncover and, with the potential for treble damages, both the government and private whistleblowers have incentives to find them.
- » The most common mistake is failing to comply with time-and-effort rules that require grant recipients to account for researcher hours and other resources expended on each project.
- » Compliance can be unwieldy given multiple simultaneous projects in the typical lab, but don’t succumb to the temptation to make up numbers that won’t bear scrutiny.
- » The best solution is to enlist everyone from entry-level researchers to principal investigators in the task of personally verifying time-and-effort data and complying with the requirements of institutional auditors

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Most busy scientific research laboratories have a spectrum of projects underway at any given time. Some projects are producing exciting results, and others seem to be heading nowhere. Why not shift personnel from the losers to the winners?

Here’s one big reason: The government is watching. And unless you’re careful, simply moving a couple of post-docs from one project to another can generate False Claims Act (FCA) liabilities up to three times the amount of money the government thinks it was shortchanged.¹

Counting the hours

National Institutes of Health requirements give research institutions leeway on how they account for work funded by federal grants, but

they demand consistency and good record-keeping in exchange. Although this may make veteran principal investigators (PIs) grumble, keeping track of lab members’ hours is just one of the essential compliance duties research institutions must enforce, as both the Department of Justice and profit-motivated whistleblower lawyers place increasing scrutiny on research spending. The institutions that get this right will find not only are they protecting themselves against FCA liability over minor things like accounting for time and effort, but they’re also increasing the odds of uncovering major problems like falsification of data and plagiarism.

Too many scientists treat grants as money to be spent as they see fit, and subordinates may have no idea how much of their time is supposed to be allocated to a single project as defined by the grant award. That can be a problem, as most government grant awards specify the amount of time team members must spend on the project being funded.² The commitment of time is not expressed in terms of hours, however, but typically as



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a percentage of total effort. A nonchalant approach to time-and-effort reporting can quickly lead to trouble in a big lab where the PI has a dozen post-docs and various other research fellows, graduate students, interns, and support personnel, all working on a variety of projects.

Time and again we've seen situations where nobody is really watching these percentage commitments, especially when one grant turns out to be exciting and another looks like a dud. Without consulting the institution or others managing the sponsored research, the PI shifts resources to the popular grant. This may make sense from a scientific perspective, but it can create unexpected liability if the other grants are ignored or reporting is not adjusted. The government even pursues cases against institutions that have labs assigning researchers to mundane tasks when they are supposed to be receiving training under training grants.

A more foolproof system would require lab employees to punch a time clock or account for the hours spent on each project as they incur them, like lawyers, but that would be unwieldy and potentially inhibit the flow of work among multiple simultaneous research projects.

A culture of accountability

A better approach is to instill a culture of accountability from the most junior lab assistant on up to the most senior PI. Auditors can tell when people are on vacation, or when the lab is dark, and can match that information with time-and-effort records. Consequently, every lab employee must be trained to think a little bit like an auditor, conscious always of the need to properly account for the work performed on each project so the certification process is accurate and holds up under scrutiny. That could entail making each lab member personally certify the percentage of

time and effort they spend on each project, with the PI as well as the institution's contract managers and audit team checking for compliance; or that could mean making the PIs have internal lab meetings, data management systems, and ways of appropriately assessing the time and effort that each lab member has spent on a project before certifying, in addition to checks at higher levels of the institution.

Don't think this task can be fulfilled by certifying hours according to a predetermined budget. Government investigators and private lawyers who specialize in whistleblower suits know labs don't operate that way. Work can ebb and flow, often in dramatic ways, depending on the status of an experiment or research project. So a researcher can quite legitimately attest to performing a burst of activity on one project and doing nothing on the other for a short amount of time. Most importantly, certifications should represent work as it was actually performed, not necessarily how it was planned at the outset of the project.

It is relatively easy for the government to determine if the time-and-effort rules have been violated. One of the most effective methods is to interview lab employees to see if they can substantiate time-and-effort certifications. Auditors also look for suspicious signs, such as wholesale shifts in effort from one project to another. A zero in the effort column could be a red flag triggering further investigation.

Fortunately, it's also relatively easy for institutions to put controls in place. Compliance starts with making sure lab employees are trained to keep their eyes open and ask questions. The audit team must be involved, and PIs must be required to cooperate with the office that reviews grant applications and time-and-effort reports. Those reports also must be sent out and collected on a timely basis. Another red flag is untimely submission of effort certifications, because the ability to accurately certify time

and effort diminishes if significant amount of time has passed.

Expect pushback from some researchers. They may not understand how easy it is to stumble into a very expensive FCA claim—or how easy their actions are to detect. From the government’s perspective, these are easier cases as compared to scientific misconduct cases that require an expert’s analysis of the science. With a time-and-effort case, the allegation is that the lab obtained money by making direct representations it didn’t fulfill. The reported settlements and case decisions include some very big awards, often larger than pure scientific misconduct cases. The labs in question may be performing very good science, but if they fail to comply with their time-and-effort commitments, they risk very substantial monetary and reputational liability.³

Conclusion

In this era of publish or perish, researchers are pushing harder than ever to generate results that will catch the attention of journal editors and push their labs to the front of the line in the next grant cycle. Yet that determination can’t be allowed to override compliance on time-and-effort regulations. All it takes is one disgruntled post-doc with a hankering for a bounty to call some private lawyers who specialize in this sort of case to file a whistleblower claim. In that event, the PI can expect to spend some serious time and effort in an unwelcome and unexpected legal process. ☹

1. U.S. Department of Justice: “False Claims Act: A Primer” Available at <https://bit.ly/1Sckpg1>
2. National Institutes of Health, Policy & Compliance: “FAQ Usage of Person Months” Revised February 20, 2013. Available at <https://bit.ly/2R2WeoD>
3. U.S. Department of Justice, press release: “University of Florida Agrees to Pay \$19.875 Million to Settle False Claims Act Allegations” November 20, 2015. Available at <https://bit.ly/2J5vUar>

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