US Government Mandates for Clinical and Translational Research

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Abstract

This commentary is germane for clinical and translational researchers. Basic scientists may face different obstacles to developing their research careers. Over the past several years, the federal government has seen reductions in funding for extramural research. It seems that under the adverse economic forecasts, things are going to get worse. It might seem logical for the federal government to stretch whatever limited resources exist, by asking the institutions to cost-share greater fractions of the actual research costs, and as an incentive, avoid the imposition of unfunded mandates. But alas, although well intended, there have been expensive requirements imposed by the government, making it difficult for investigators and institutions to adequately fund and conduct their research and for scientific journals to maintain paying subscribers. Five prominent and costly changes, which are the focus of this commentary are (1) HIPAA, (2) ClinicalTrials.gov, (3) Clinical and Translational Science Awards, (4) Upcoming rule changes for IRBs, and (5) PubMedCentral, each of which will be discussed in the ensuing paragraphs. Clin Trans Sci 2012; Volume 5: 83–84

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HIPAA (Health Insurance Portability and Accountability Act)

The cost effectiveness of HIPAA has never been thoroughly studied. At the University of Florida, annual training is required, costing hundreds of thousands of dollars each year in lost work time. This seems ironic as typical board certification is done every 5–10 years. An unintended consequence is that fear of HIPAA violations can impede opportunities for informal hallway interactions amongst practitioners, ultimately adversely affecting patients. Privacy concerns are common sense, and the overwhelming proportion of us understood their importance and applied appropriate protections long before HIPAA was introduced. We found few studies that looked at costs and benefits. Wolf and Bennett¹ initially found a 73% decrease in their ability to recruit patients pre versus post initiation of HIPAA, but they were able to recover, albeit with considerable added effort. O'Herron et al.² concluded that HIPAA impeded medical record and database research and increased the workload to get such studies through their IRBs. Gunter³ estimated in 2002 that HIPAA would have a \$3 billion financial impact on the US economy over a 10-year period. The logical challenge to the federal government is to either discontinue it or prove by systematic review that HIPAA is cost effective.

ClinicalTrials.gov

While it is commendable to have a trials registry, a new requirement under consideration is that trials opened after March 1, 2012 (exact date as yet unknown), will have to provide patient level de-identified information from their definitive analyses. Ultimately, this responsibility will fall upon the shoulders of the institutional biostatisticians and informational technology (IT) staff. Responsibilities for compliance will be borne by the institution as a whole, whereas at present, data sharing is decentralized. This makes a large difference and adds greatly to the cost, since a common data format for diverse types of data will need to be built. This will also lead to costly edicts from the central institutional administration upon researchers as to how to maintain their data. In addition, if these clinical trial data are made public, without a data use agreement with the owners of the data, there will be rogue analyses of the data, with misinterpretations potentially appearing on the WWW, and possibly leading to adverse medical

consequences for WWW readers. As a case in point, even though only summary information was available, Mr. Mike Adams <http://www.naturalnews.com/021976.html> and Dr. Suzy Cohen <http://dearpharmacist.com/?p=1038> misinterpreted results in the antioxidant trial of Cook et al.⁴ Gullible readers might have discontinued their statins or blood pressure medication in favor of unproven antioxidants.

Clinical and Translational Science Awards (CTSA)

When the initial requests for applications for CTSAAs were released, the idea was that General Clinical Research Centers (GCRCs) would be phased out, and that a much broader research infrastructure would be established within CTSA-funded centers. For those applicants who had a funded GCRC, they were told that if successful, their CTSA award would be substantially higher to accommodate the broader mission. Institutions took up the challenge and offered considerable cost sharing in their applications. But the NIH did not come through with its part, and in effect, funded CTSAAs at similar levels that they funded GCRCs. For example, the University of Florida actually was awarded slightly fewer dollars in its first year as a CTSA, than the combined initial notice of award for its GCRC and K30 programs would have provided for that year. For a perspective on the first 2 years of CTSAAs, see Morrison,⁵ especially where she talks about major reductions from the initial notice of award to the actual award in their year 02.

Institutional Review Board (IRB) Rule Changes

At present, the federal government is obtaining input on new rules that will have a major impact on how IRBs operate. If adopted in their present form, these rules would have cost implications as well as potentially impede the ability to do research. Perhaps the most costly element is that IRBs will be charged with enforcing data security. This duty traditionally is a joint responsibility of the institutional IT department and privacy office. IRBs generally are not well positioned to assume this role. Whatever national IRB rules are set up for electronic data security, each institution's IT department will have its own rules that are likely to be substantially different and better justified by local conditions. This mandate

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would add to the personnel costs for both the IRB and investigators, who will now need to answer to two authorities on data security. Another item under consideration is whether biologic specimens should be considered to be protected health information (PHI). Since they contain DNA, they potentially have information that could link the patient's identity and disease condition, making it in theory PHI. Such a decision would render tissue-banking research on legacy samples virtually impossible, leading to the effective loss of treasured public health resources.

PubMedCentral

The NIH has issued an edict that all articles that are at least in part supported by NIH be jointly published in PubMedCentral. This can place authors in a legally difficult position, as the journal, not the author owns the rights to the paper. It is, therefore, up to the journal to determine whether or not to put the article in PubMedCentral. This can be harmful to the journal's bottom line, since if all of their articles are so published, even if a year later, subscriptions would suffer. This government mandate on struggling journals could also lead to major increases in page charges. Finally, such a requirement could hinder young investigators from getting their studies published, and thereby contribute to publication bias. PubMed registration plus a documented request to publish in PubMedCentral seems to be a reasonable compromise on this requirement.

Concluding Discussion

Federally funded research is under greater public scrutiny than ever, and hence the Department of Health Education and Welfare (DHEW) employees have to stay on good terms with congress. The research community needs to work closely with these federal employees, assisting them to understand and minimize bureaucratic institutional burdens to success. For its part, DHEW

has to foster good will with the research institutions through cooperation over intimidation. Fines and penalties for many types of HIPAA violations and incomplete compliance to ClinicalTrials.gov requirements are far out of line with the true economic damage. For example, the University of Florida was threatened with two \$10,000 per day fines over noncompliance with summary data by ClinicalTrials.gov for two perfectly registered trials that closed in 2005. Summary data requirements were supposed to apply only to trials that opened much later. Lastly, our greatest fear is that instead of clinical and translational research being a wonderful intellectual challenge for our young investigators, it will become so stifling and underfunded that retention of these scholars, the life blood of every academic institution, will become impossible.

Conflict of Interest

None.

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