

# Presidential Address: Research Ownership, Communication of Results, and Threats to Objectivity in Client- Driven Research

*Charles E. Metcalf*

A disturbing saga of suppression of research results came to public light in April 1996 [see King, 1996]. The story began in 1987, when a university pharmacy professor accepted a contract from a pharmaceutical company to test a brand-name thyroid drug (produced by the company) against three less expensive (one brand-name, two generic) alternatives. The professor signed a contract that specified the research protocol and experimental design in detail. The contract also included a confidentiality provision prohibiting publication of the results without client permission.

The results submitted in 1990 turned out to be “unfavorable” to the company: The study concluded that the four drug preparations were “bioequivalent,” despite the much higher cost of the company’s formulation. The company responded by: (1) waging a 4-year campaign to discredit the study; (2) denying the professor permission to publish by invoking the confidentiality clause in the contract, forcing the professor to withdraw a *Journal of the American Medical Association (JAMA)* article 12 days before its scheduled publication in 1995; and (3) publishing the company’s interpretation of the data, without acknowledgment of the original study, in a journal supported in part by the company [see Rennie, 1997].

“Justice” finally prevailed, some 7 years after the study’s completion, under the pressure of adverse publicity [see Altman, 1997a, 1997b; Sternberg, 1997]. The original article was recently published in *JAMA* after the company withdrew its objections. The study utilized a randomized, four-way crossover trial with a completed sample size of 22; the published article had seven authors [see Dong et al., 1997].

Although this saga involves an extreme compounding of several events in a single study funded by the pharmaceutical industry, elements of the story are common to the broader domain of policy research. Individuals and institutions conducting client-funded research encounter contractual restrictions on their right to disseminate results, and they may face pressure—often subtle—to alter the interpretation of their findings or the content of their reports. These restrictions and pressures may be present whether the client is a private firm, government agency, or foundation.

Most broad discussions of the communication and exchange of research results implicitly presume that the researcher owns his or her research results, and therefore is free to control the dissemination process. Discussions couched in terms of “academic freedom” involve the preservation of these rights. However, much policy research—especially that related to evaluating the impacts of public programs on their target populations—is conducted by private research organizations on a contractual basis for government organizations or, with increasing frequency, for foundations. Furthermore, the researcher’s status as *employee* of the research organization is an additional factor in his or her right to disseminate results. The contractual basis of client-driven research and the employee status of researchers can have major influences on the ownership, content, and dissemination of policy research findings. This article explores some of these influences in the contract research world.

I begin by examining how issues of research ownership create important distinctions between client-driven and self-directed research. The focus is on the researcher’s ability to control the content and dissemination of research reports. I then turn to how these issues are resolved for policy research conducted under contract to the federal government, extending the discussion to research conducted for private organizations or foundations. Finally, the relationship between the researcher and his or her employing institution is examined.

#### SELF-DIRECTED VERSUS CLIENT-DRIVEN RESEARCH: ISSUES OF OWNERSHIP

Some commonly accepted rules exist for communicating findings from self-directed, scholarly research and for judging the credibility of those findings. First, the researcher owns the research product (but not necessarily the data used to produce it) and is free to choose both the forum and content for disseminating the results. Of course, various forums may impose rules on papers accepted for publication (for example, peer review and transfer of copyright rights), but the researcher is free to shop around for a suitable publication venue.

Second, broadly accepted professional standards for scholarly research require that the data underlying the research must be available to others, and that the methods must be sufficiently documented to permit replication of results by others. With these standards, other scholars have the opportunity to replicate a researcher’s results and have access to the same data to permit analyses from other perspectives.

These standards promote both the quality and the objectivity of reported research findings. Objectivity and choice of research methods and activities may be colored by tenure requirements, funding requirements, peer pressure, and the like, but the researcher retains ultimate power over his or her actions through ownership of the research. Furthermore, *the basic guardian of both quality and objectivity in the conventional world of scholarly research is the required openness to the examination of others. If you do not adhere to this rule, your research is presumptively not credible.*

#### Ownership Rules for Client-Driven (Contract) Research

Some definitions are in order here. First, by *contract research*, I exclude *grants*, which leave ownership rights more clearly in the hands of researchers. Second,

I consider *research* as work leading to a concrete report that could be presented to a third party as evidence, and I exclude *consulting*, which implies a confidential advisory relationship between expert and client, from research. This line between research and consulting is often blurred; I return to this distinction later when discussing private clients.

Finally, I also define *contract research* to relate to a situation in which the client wants an objective answer, not “research” to support a predetermined position. Both the *client* and the *researcher* often confuse or are conflicted over this distinction. For example:

- Litigation and advocacy clients may seek “truth,” and perhaps only use it when it supports their maintained position.
- Policy clients may seek objective analysis, but they may be swayed by implicit commitment to a proposed policy or existing program, or by the political sensitivities of particular results.
- Researchers who have built up policy perspectives over time may be swayed in their interpretation of evidence. (This risk applies equally to academic and contract research.)

For contract research, the researcher and his or her employing institution are collecting data and conducting research on an issue defined and paid for by a client. In this environment, two questions must be answered: (1) Who owns the research product? and (2) Who controls the content and the dissemination of the research product? These questions are typically defined by the contract, and the rights no longer lie intrinsically with the institution nor, by extension, with the researchers it employs to conduct the research.<sup>1</sup>

In this contract research world, the client has a clearer power over what the researcher does and says; the researcher no longer has the protection that the presumptive right of ownership provides. This relationship raises several questions that must be confronted:

- How does the researcher preserve his or her principles of objectivity—and control over research content—in such an environment, given potential pressure on the content of research and on the mode of dissemination?
- How does the researcher engage in the free communication of research methods and results so essential to the advancement of knowledge (to say nothing of professional reputations) if the client is able to control or influence the process?
- How are these issues reconciled with the client’s interests?

## CONTRACT RESEARCH FOR THE FEDERAL GOVERNMENT

This section addresses questions about the relationship between the buyer and producer of research in the context of contract research for the federal government.<sup>2</sup> First, I summarize the typical project sequence, from competitive

<sup>1</sup> The final section of this article discusses the distinction between the researcher and the employing research institution.

<sup>2</sup> Contracts that can be defined more accurately as consulting services are excluded from this discussion, as is research covered by security restrictions.

procurement through final report, and then I describe the typical procedures for communicating results from research projects conducted under government contract. After providing some examples of how pressure can be exerted in this environment on the content and release of reports, I discuss protections in the system that can help safeguard the objective communication of results. Finally, I speculate on some potential effects of the federal contract research environment on the choice of research methods.

### A Typical Project Chronology

In order to identify dissemination rights and points of access to information, it may be useful to view a contract research project as consisting of a competitive procurement process, an active contract phase, and contract completion.

In the competitive procurement process, the government announces a request for proposals (RFP) and makes it publicly available. The RFP includes a statement of the research problem, specifies the work to be conducted, and identifies the criteria for contract award. After contract award, the public can obtain both the contract document (which includes a statement of the work to be conducted) and the winning proposal by submitting a Freedom of Information Act (FOIA) request. It is common practice for research organizations that lose a bid to request copies of the winning proposal. Although the winning organization has some ability to protect certain portions of its proposal as proprietary, this FOIA procedure allows research organizations to make some limited comparison of proposed research methods.

During the active contract phase, there are strong restrictions on the release of information to the external research and policy communities. First, data collected during the project are subject to confidentiality protections and can only be used for the express purposes of the contract. Second, works in progress and “internal working documents” are confidential and may not be disseminated except with client authorization. These materials are not subject to FOIA requests.<sup>3</sup>

For large-scale demonstrations and major evaluations, the period of restricted flow of research information is extensive, and contracts lasting 5 years or longer are not uncommon. In these longer term projects, most agencies have procedures for review, clearance, and public release of interim reports. In the early income maintenance experiments of the 1960s and 1970s, contracts typically guaranteed that researchers could release reports after a 60- to 90-day waiting period.<sup>4</sup> Current federal contracts tend to be far more restrictive, with no automatic dissemination rights before the contract ends.

Once the research project and its associated contract are completed, the balance of power for research dissemination shifts dramatically. Data collected for the study typically become available to other researchers, with restrictions to protect confidentiality of respondents or individual records. After the final report for the project is accepted by the client and the contract is completed, the report and other formal project deliverables can be obtained through FOIA requests. *Regardless of internal contract restrictions, the contractor has the im-*

<sup>3</sup> These materials are subject to subpoena in litigation, however, and may be subject to FOIA requests after contract completion.

<sup>4</sup> In fact, in the early experiments, the client sometimes wanted to trumpet early results that appeared favorable, while the researchers wanted to drag their feet “until the final results were in.”

*plicit nonexclusive right to request its own report under the FOIA, and to release it freely without restriction.*

Thus, while the government owns the research products it purchases through contract, the FOIA protects the researcher's right to disseminate his or her results—and, indeed, the right of anyone else to disseminate the results.

### Typical Procedures for Communicating Results

Most government research projects are undertaken by the client with the presumption that the results will contribute to policy formation and debate. I have found a research-friendly environment to be the rule rather than the exception in most federal agencies that engage in contract research. Indeed, the whole concept of the government commissioning research to guide public policy, with the understanding that the research will ultimately be freely available, may be unique to the United States.<sup>5</sup>

Typically, the contractor and client collaborate in distributing a research report under the client's auspices, with full acknowledgment of the contractor and of individual report authors. Once the client is given the "scoop" for first release, the contractor is usually free to distribute additional copies of the report as it sees fit. In addition, the client often facilitates tailoring of additional reports aimed toward journal publication and conference presentation. Often, however, conference papers based on projects in progress must withhold results that have not yet been released by the client. As a result, what a researcher is free to say is frequently restricted, and there have been numerous cases of contractor sanction for premature release of results.

The client usually has little power over what the contractor eventually releases but does exercise considerable power over the timing of release. The control over the acceptance of contract deliverables and the timing of their release is where the client wields its "ownership power." *This control is also the client's main weapon in influencing the content of research reports. Depending on perspective and the specifics of each case, this is variously interpreted as ensuring the quality of the research or as "bending" content in ways that may threaten objectivity.*

### Pressure on the Content and Release of Reports

In 1993, Mathematica Policy Research (MPR) completed a study of the National School Lunch Program under contract to the U.S. Department of Agriculture (USDA). The study concluded that school lunches met their objective of providing at least one third of the recommended daily allowances of key nutrients, but that they also contained fat levels exceeding dietary guidelines [Burghardt and Devaney, 1993, 1995]. In the portions of the MPR report comparing the dietary intake of school lunch participants and nonparticipants, the program appeared to have a stronger effect on increasing fat intake than on increasing nutrient intake. Furthermore, analyses that attempted to correct for selection bias eliminated most measured effects on nutrient intake but preserved the fat intake result.

<sup>5</sup> I am the coauthor of at least one paper for a Canadian province which, if I were to release it unilaterally, would subject me to charges of treason against the queen.

During the intense debate between MPR and USDA staff over the interpretation and presentation of these results, a subcontractor to MPR leaked the evidence of high fat content to a senior USDA official—in clear violation of contract protocol—elevating the prominence of that result in subsequent policy discussions.

In portions of the MPR report comparing participant and nonparticipant dietary intake, USDA staff wanted MPR researchers to report only comparisons that were based on least-square regressions and not those that attempted to correct for selection bias. This pressure came despite the researchers' conclusion that the corrected results represented their best estimate of program impacts. (The results with selection bias corrections were "less favorable" to the client and had higher reported standard errors of estimate, as is universally true of methodologies that correct for selection bias.) The USDA staff—in a written "past performance" report intended to influence MPR's future receipt of federal contracts—later criticized MPR staff for revealing these selection bias results in a meeting with senior USDA officials.<sup>6</sup>

Sometimes, the review period before a report is released is when the research findings can have their maximum influence on the policy process, out of the eyes of public scrutiny. In late 1974, Congress enacted two temporary programs in response to continued high unemployment: the Federal Supplemental Benefits Program (FSB), which provided further benefits to unemployed workers who had exhausted their initial unemployment insurance (UI) entitlements; and Special Unemployment Assistance (SUA), which made benefits available to unemployed workers whose previous employment had not been covered under regular UI.<sup>7</sup> In 1976, MPR surveyed participants in the two programs, using the results to form the basis for a report that Congress mandated from the secretary of labor.

The draft report written by MPR concluded that, for the SUA program, 60 percent of all beneficiaries lost their jobs because of seasonal layoffs, and 55 percent of all beneficiaries had been school employees. More than three fourths of the unemployed school workers had returned to their pre-UI jobs prior to the survey. When MPR briefed congressional staff on the preliminary results, MPR's conclusion that a majority of SUA beneficiaries were seasonal workers was labeled "irresponsible," presumably because the staff did not want to see the program publicly characterized as a seasonal program primarily for the benefit of school workers. Shortly thereafter, however, the SUA program was modified to exclude school employees with a "reasonable assurance" of a return to work. By the time the MPR report was publicly released, its most politically sensitive conclusions referred to program features that had already been changed [Corson et al., 1977]. In addition, the MPR report was released as an independent study, rather than as the congressionally mandated report from the secretary of labor.

### **Protections in the System**

There are a number of protections in the system that allow research institutions to safeguard their objectivity and the ability of their professional staff to com-

<sup>6</sup> This discussion reflects confidential interactions with the client that I would not normally be free to divulge. However, portions of what transpired appear in the past performance report, obtained by MPR in April 1997 pursuant to a FOIA request.

<sup>7</sup> Both programs were temporary and are no longer in existence.

municate their research findings. First, we have already stressed the importance of the ultimate availability of research reports to the public, time delays notwithstanding. Second, most large-scale studies engage advisory panels and other forms of peer review at both the design and report stages. Thus, external scrutiny often carries over into the extended period during which release of research results is restricted.

Third, although a client may refuse to accept a report that does not meet contract requirements and may require the researcher to respond to review comments, *the client is not free to alter the content of the report*. This fact was highlighted in a celebrated case arising out of a 6-year evaluation of the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). The evaluation was funded by the USDA and conducted by Research Triangle Institute. The project was plagued with difficulties, including numerous delays and a client-mandated removal of the project's initial principal investigator. Before publishing the final report on the project in 1986, the USDA deleted the original chapter and executive summaries of the contractor's report, replacing them with a "compendium of results" written by the USDA staff. In response to a congressional request to investigate the resulting controversy, the U.S. General Accounting Office (U.S. GAO) issued a report in 1990 that publicly chastened the agency and labeled the substitute compendium as "misleading" [U.S. GAO, 1990]. In its comments on the U.S. GAO report, the USDA announced a new policy of stating its objections to contractor reports in a separate cover letter, rather than altering the text (p. 54, letter from Ann Chadwick, acting assistant secretary for the Food and Consumer Service, to John W. Harman, U.S. GAO, July 12, 1989).

In the case of my own institution, MPR insists on review rights for all final copy (made more difficult by the electronic transmission of reports). It also subjects all reports to internal quality assurance procedures that, among other things, are sensitive to client pressures on report content.<sup>8</sup>

Finally, in contract research for the federal government, the definition of "client" can be a powerful influence on the behavior of a research institution intent on long-term survival. If we define the client to be the current administration, the contractor and often the contract outlive the current client. For contract research institutions that regard themselves as doing policy research for a sequence of clients with differing policy agendas, the institutions' reputation for objectivity (as well as the quality of their work) is their primary currency in maintaining their longevity. This strength tends to provide the ability to withstand short-term pressures placed on report content, sometimes at the expense of short-term damage to the institution.

### Effects on Research Methods

The nature of the contract research environment has had, in my judgment, some significant effects on research methods. For example, there is an increased tendency for researchers and clients to agree explicitly, in advance, on the research methodology and the scope of reports, even to the point of pre-specifying details such as table formats. This process protects the client from

<sup>8</sup> This procedure is designed to protect the quality and objectivity of reports from the perspective of the institution. It can also have the effect of restricting the perceived right of the study director or of individual researchers to control report content.

a broad range of undue surprises. It also protects the researcher by providing less “wobble room” for the client when the chips fall where they may. (It also inhibits interactive research inquiries, a possible detrimental effect.)

This environment has also contributed to the ongoing debate over the use of experimental versus nonexperimental methodologies for evaluating policy impacts. In particular, nonexperimental methodologies leave more room for subjective judgment in the choice of analytic method, increasing the size of the battleground for debates over report content. For example, empirical estimates that correct for selection bias tend to be more complicated to defend, to have much larger standard errors of estimate, and to lead to different potential policy implications than results based on standard multiple regression. Thus, the researcher may be in the position of defending results that, in his or her judgment, are closer to the truth but look less reliable and are possibly less favorable to the client’s position. As a result, the trend toward experimental methodologies has picked up momentum. With these methodologies, rightly or wrongly, results can be reported more on a “what you see is what you get” basis.

### CONTRACT RESEARCH FOR PRIVATE CLIENTS AND FOUNDATIONS

Typically, private clients are more explicit about their ownership of purchased research products, and there is no contractor protection equivalent to the FOIA. However, when private clients want to use research results as evidence in some external forum, they may view themselves as purchasing *both* a research product *and* the research institution’s reputation for quality and objectivity. The institution, in turn, can only sustain its credibility if it retains some control over how its research products are communicated to the outside world. Therefore, negotiating the terms under which research reports are to be publicly released becomes a crucial element of the contract.

Mathematica Policy Research (MPR) has conducted a limited amount of research for private clients that stipulate research reports must remain confidential unless permission for public release is granted. In these circumstances, MPR has imposed a limited form of protection by requiring a contract clause stating that, if the client references the research in any manner or releases any portion of it, *the entire report as submitted by MPR must be released*. Although this approach yields to a client right of “no dissemination,” it protects against the risk of misrepresentation and its potential effect on the institution’s standards of objectivity.

This approach has been justifiably criticized for permitting clients to select which studies to release based on outcome, thus producing a biased set of public information. For example, consider a hypothetical private organization that conducts demonstrations of a training program in ten locations and contracts for ten separate studies of program effectiveness. Suppose further that the program impact is positive in five of the ten locations. Even if each study, taken separately, meets all accepted standards of quality and objectivity, the reported pattern of evidence is clearly distorted if the client is free to release only the five studies pertaining to the successful sites.

As highlighted at the beginning of this article, this debate is being waged in studies for the pharmaceutical industry, which has come under attack for withholding unfavorable evidence. There is some indication that the industry is moving toward a policy of permitting investigators to publish results without



prior company approval, in the wake of public scrutiny of this controversy [see, for example, *Journal of the American Medical Association*, 1997].

Many—perhaps most—universities refuse to accept contract research that restricts researchers' publication rights. In contrast, is it possible for private sector research institutions *both* to work for clients on a confidential basis *and* to retain the protections of objectivity that only unrestricted publication rights would appear to guarantee? I believe that the answer is yes, *but only if clients cede the right to condition publication decisions on study results*. One approach would be for research institutions to require clients to choose between two alternative contractual relationships:

- A confidential consulting relationship, where the research is to be used only for internal purposes, not as third-party evidence.
- A research contract to generate evidence for influencing third parties, with public release of results regardless of study outcome.

Many private clients may have difficulty accepting these conditions.<sup>9</sup> However, clients are increasingly aware that, if they wish to commission research with the imprimatur of objectivity and credibility, they must accept the necessity of open availability of research findings regardless of how the results come out. Despite some powerful impediments to this process, I believe the trend is clearly in this direction.

#### Foundations as Research Clients

Historically, foundations have been major funders of grants to researchers and research institutions, where publication rights automatically reside with the grant recipients. In recent years, however, foundations have increasingly utilized contract research and data collection to support their own public policy initiatives. I have found that foundations, as relatively new clients for contract research, are potentially as risky as other private clients in terms of the threats to researcher-controlled dissemination of results, for a number of reasons.

First, foundations tend to hold strong views about ownership of research and dissemination rights, leading to intense negotiations regarding contractor rights in these areas. Second, foundation research is often tied to initiatives with strong institutional commitment to their success, and weak commitment to objective evaluations of the impacts of these initiatives by conventional research standards. In my experience, foundations want to retain as much control as possible over dissemination, *not* to inhibit the release of unfavorable findings, but to promote the success of their initiatives, often with little sympathy for researchers' "qualifications" of results. Perhaps because of their long history of funding grant research, however, foundations that fund contract research have been fairly quick to embrace the principle of researchers' publication rights.

#### A NOTE ON RESEARCHERS' PUBLICATION RIGHTS IN PRIVATE RESEARCH ORGANIZATIONS

With regard to publication rights, the relationship between researchers and their employers in private organizations is parallel in many ways to the rela-

<sup>9</sup> This approach poses problems, especially when research is being conducted for a lawyer to use in litigation, where representation of the client is the lawyer's paramount concern.

tionship between research organizations and private clients. The institution views itself as the “owner of record” of the reports produced by the researchers it employs under contract for clients, except as constrained by contract. At the same time, the institution’s reputation is based on researchers whose professional standing derives from their ability to publish their research. To my knowledge, most private research organizations attribute the authorship of research documents to individual researchers and maximize authors’ publication rights, subject to the realities of the contract research environment.

In addition to restrictions imposed by clients, research institutions feel obligated to exercise some control over researcher activities at both the funding proposal and the contract stages. Unlike grant proposals submitted by academic researchers, proposals for contract funding commit the research organization—if awarded the contract—to fulfill the clients’ stated research requirements, to conform to the institution’s quality standards, and to conduct the research within the contract’s financial terms. Proposal documents are subject to technical, budgetary, and contractual review to ensure that these conditions are met. Although the organization’s research staff produces and reviews the technical content of proposals, the institution regards these proposals as proprietary, with the contributing researchers having no formal ownership rights.

During the execution of a research contract, individual researchers direct the design and content of research activities on behalf of the organization and the commitments that it made during the proposal and that it specified in the contract. Research institutions typically protect their quality standards and commitments to their clients by establishing a review process for both the research design and subsequent research reports produced by individual researchers. This process focuses both on quality and compliance with contract requirements. Unlike the refereeing process associated with scholarly journals—which leaves a researcher free to seek out alternative dissemination venues—a research institution usually requires a report to meet organizational standards before the report is submitted to the client.

After a contract ends, or after a client clears a report (during the course of a longer term contract), most policy research organizations encourage researchers to publish the results of their research. Furthermore, many organizations support professional research activities beyond what is covered explicitly by the contract. The organization and the researcher benefit mutually from the enhancement of professional reputations that results. Institutions monitor researchers’ publication activities from two perspectives: (1) to ensure that contract restrictions, such as those that apply to the use of data, are not being violated; and (2) to confirm that publishers’ copyright releases do not infringe on institutional or client prerogatives. Otherwise, in practice, the right of researchers in private research institutions to disseminate research results through conference participation and publication is comparable to that held by researchers in academic institutions.<sup>10</sup>

For the most part, I believe that private research organizations engaged in contract research on public policy issues have done a credible job of fostering an open research environment for their professional staff. They have done so despite the threats to objectivity and to the unrestricted dissemination of re-

<sup>10</sup> However, an incident was brought to my attention in which a researcher was allegedly required by his employing institution to withdraw a paper from the 1996 APPAM research conference, apparently for institution reasons rather than client requirements.

search results often inherent in a contract research setting. Fostering this open environment is of ultimate benefit to clients, because it is crucial to the provision of the objective and credible research that they desire.

*CHARLES E. METCALF is President of Mathematica Policy Research, Inc. (MPR). He served as President of APPAM from 1996 to 1997.*

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