Historical Analysis of Ownership & Publication Rights in Government Contracts for Health Services Research

July 2007
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<tr>
<th>Year</th>
<th>Government</th>
<th>Foundation</th>
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Introduction
In December 2005, AcademyHealth’s Board of Directors approved the formation of an exploratory committee to examine the impact of funders’ restrictions on the publication of health services research. The action was taken in response to concerns that researchers have expressed regarding funders’ attempts to exert undue influence over the content of research as a condition of publication, whether in peer-reviewed journals or otherwise. Indeed, 13 percent of respondents in AcademyHealth’s annual member survey stated that within the preceding 5 years, they had experienced problems with content restrictions in the case of government-funded research, with a lower rate reported in the case of privately sponsored research. Nine percent of respondents reported foregoing government funding because of restrictive contracts, again with a lower reported rate in the case of privately sponsored research. Where industry-sponsored research is concerned, control over content may be more customary, thereby accounting for lower “experienced problems” and “foregone” rates. This does not explain the differences between government and foundation funders, however.

Survey Question: In the past 5 years, have you or your institution foregone funding because of overly restrictive contracts and/or grant clauses by a potential funder?

Figure 1

Survey Question: In the past 5 years, have you experienced problems with funders related to the prior review, editing and/or approval of your research results for publication or other dissemination?

Figure 2

These results, in addition to anecdotal evidence from members, fueled the creation of the exploratory committee, which was charged with investigating the problem and developing recommendations.

Background and Methods
This analysis, prepared for the exploratory committee, focused on federal government-funded research for several reasons. The first is the greater availability of data to analyze as a result of public access to RFPs, data-use documents, and other legal documents governing eligibility for funding and access to data. The second was the greater presence of reported problems among AcademyHealth members.

The third reason for this focus is the presence of special legal considerations where government funding of research is concerned, particularly where the recipient of research funding is an academic institution, as opposed to a “work-for-hire” firm undertaking special tasks for the government. Under broad principles of contract law, a contract between two parties is binding if they agree to its terms. At the same time, and as discussed below, American jurisprudence traditionally has granted universities special legal
status as a public domain for academic freedom under the First Amendment of the United States Constitution. In other words, the first amendment restricts the ability of government to curtail free speech where the speaker is a university, even where the funding for the “speech” is from the government and would otherwise represent “work for hire” tasks. Because of the special legal significance assigned to government contracts with universities under the First Amendment, we focused our efforts on these contracts.

Although this special significance also attaches to contracts for state governments, it would be unmanageable to tackle state conduct in all 50 states. While anecdotal evidence suggests similar problems may occur under some state contracts, focus here is federal. The research entities that are the basis of our focus are academic institutions and private contractors to the extent that they sub-contract with academic institutions.

Because of the legal nature of the documents to be examined and the landscape against which the question of content restraint arises, this effort was undertaken by two lawyers experienced in research, supported by a law student. These staff members supplemented legal research techniques with unstructured, open-ended interviews with a range of respondents.

The legal document review began by examining requests for proposals (“RFPs”) publicly available through government Web sites. Staff conducted legal research into federal regulations and standards that govern the government contracting processes, known as federal acquisition regulations (FAR) as well as critical federal judicial decisions relevant to constraints on speech in academic settings.

Staff also conducted extensive interviews with contracting officers at a range of institutions represented by AcademyHealth members. These university officials represent a dozen institutions selected because of the presence of AcademyHealth members, as well as extensive federal government research experience. The appointed AcademyHealth committee supplemented this research with a roundtable discussion at the 2006 AcademyHealth Annual Research Meeting (ARM) in order to obtain input from members on these issues. (See Appendix A for a detailed account of this session). This roundtable led to an expansion of original efforts to include the presence of content restrictions in data use agreements, and was followed by additional interviews with government contracting officers and private sector consulting organizations.

All interviews were conducted in accordance with IRB requirements of the George Washington University. Being cognizant of ongoing relationships between funders and universities, we assured the university contracting officers that their names and the institutions would remain confidential. The government contracting officer names and agencies remain confidential as well. We conducted one confidential interview with a researcher from a non-profit research center.

**Findings**

**Overall**

Our interviews with university officials suggest that on a widespread basis, universities have experienced increased problems with content restrictions over the past five years. Our findings suggest that several factors may be at work:

- Increasing government custom and culture of controlling the flow of even non-classified information.
- Basic misinterpretation of authorizing legislation, misconstruing limits on disclosure related to privacy or security with authority to control content flow.
- Misapplication of specific FAR provisions.
- Lack of awareness of changes and amendments to FAR that have explicitly recognized the right of universities to engage in free speech in government funded research.
- Use of “sensitive but unclassified” (“SBU”) clauses in connection with unclassified data, as a means to justify heightened scrutiny and review of research.

**Findings from Legal Research**

Our legal research focused on pertinent case law relevant to government contracts with universities that fall under FAR, FAR provisions and amendments, approximately 40 RFPs governed by FAR from publicly available Web sites, along with actual contracts and data use agreements (DUAs) provided to us by interviewees.
Government Contracting and the FAR

Government contracting is a highly regulated aspect of contract law that follows uniform policies and procedures. The acquisition of supplies and services by all government agencies is governed by the FAR. The FAR provisions were developed to assist the government in contracting for timely, high value products and services, while maintaining the public’s trust and fulfilling public policy objectives.

The FAR govern all government contracts, which are used when the agency’s purpose is to acquire goods or services for the direct benefit or use of the Federal government. Government contracts are distinguishable from grants and cooperative agreements, which are broader agreements that are used either to transfer a thing of value to a state or local government or to promote a broader national interest. The government agency is generally involved in a more “hands-on” manner in the case of contracts than in grants or cooperative agreements and FAR governed contracts encompass “work-for-hire” agreements that use private contractors do carry out government activities. Some agencies have created supplements to the FAR. For example, the Department of Defense has promulgated the “DFARS,” the Defense Federal Acquisition Regulation Supplement. Health and Human Services (HHS) also supplements FAR.

It has been recommended that FAR be required for all healthcare organizations given the large volume of money spent on the industry; government grants to healthcare industries have exceeded $1 trillion/year. Currently, however, the FAR only apply to government contracts and not to research grants or cooperative agreements in the healthcare industry. Other regulations, such as Office of Management and Budget (OMB) circulars, apply to grants and cooperative agreements.

First Amendment Jurisprudence, Universities & Academic Freedom

The First Amendment provides for broad protections against government intrusion upon free speech, imposing a high standard of proof on official efforts to limit free speech and restrict what can enter the “marketplace of ideas.” In particular, any attempt to place a prior restraint on speech, that is, to restrict an idea before it has had a chance to enter a public forum, is presumptively unconstitutional.

In situations in which government provides funds aimed at achieving a specific policy goal or message, the Supreme Court has afforded the government broad leeway to show preference for specific policies and to subsidize favored viewpoints. In the controlling case on this issue, Rust v. Sullivan, the Supreme Court upheld an HHS regulation (known as the Gag rule) that prohibited recipients of Title X family planning funds from engaging in abortion counseling activities with federal funding. The Rust holding reaches broadly, stating that “The Government can, without violating the Constitution, selectively fund a program to encourage certain activities it believes to be in the public interest, without at the same time funding an alternative program which seeks to deal with the problem in another way.” Thus the government enjoys the power to make decisions on how to allocate federal resources, regardless of whether the allocation decisions include viewpoint regulations.

At the same time, in upholding the restriction at issue in Rust, the Court explicitly found that the government was not restricting speech in traditionally open forums, and specifically mentioned universities as one such open forum. Significantly, the Court stated, “we have recognized that the university is a traditional sphere of free expression so fundamental to the functioning of our society that the Government’s ability to control speech within that sphere by means of conditions attached to the expenditure of Government funds is restricted by vagueness and overbreadth doctrines of the First Amendment.”

While Rust is the controlling Supreme Court precedent on this topic, a federal district (trial) court in the influential Federal Circuit had occasion in 1991 to rule on a specific case of attempted prior restraint against a university. In Board of Trustees of Leland Stanford Junior University v. Sullivan, the court struck down application of certain provisions of the HHS/FAR (“HHSAR”) to university research as unconstitutional under the First Amendment. A copy of the Stanford decision is included in Appendix B.

Although a federal trial level court normally would not be controlling case law, in 2005, HHS revised the HHSAR to acquiesce to the Stanford decision, meaning that its principal holding striking down prior restraint in a university research context
was explicitly to be honored. Although Stanford focused on a contract between the government and a university, the government presumably could not condition a university’s subcontracting rights on its willingness to forego freedom of speech. The thrust of the decision therefore would carry over to situations where a university is a subcontractor to another entity who holds the prime contract.

The HHSAR revision was published in the Federal Register on January 3, 2005. The relevant pages of the federal register from January 3, 2005 can be found in Appendix C.

Requests for Proposals
Our review of over 40 RFPs available on public and government websites (such as agency websites and www.fedbizopps.gov), revealed that most RFPs did not expressly restrict publication or disclosure of data. Several recent RFPs, however, indicate that one or more HHS agencies have started to include restrictive language in RFPs. Appendix E contains a sample of the restrictive language found in these recent RFPs.

Contracts
Some of our interviewees from universities allowed us to examine their contracts. A number contain problematic clauses in light of Stanford. Some of the more problematic clauses in HHS contracts include the “confidentiality of information” clause (HHSAR 352.224-70), and the “rights in data – special works clause” (FAR clause 52.227-14). The confidentiality of information clause was modified in 2005 in response to the Stanford decision, as discussed above. The modifications to this clause are reflected in Appendix D. The “rights in data – special works” clause grants to the government the right to control data generated by contractors. The text of this clause, which is not addressed in the 2005 Federal Register rule, is included in Appendix D as well. It creates an absolute restriction on the publication or dissemination of this data. Interviews with contracting officers revealed that this clause has been used more frequently in contracts for basic science and research over the past few years, and some university contracting officers believe it has been inappropriately applied. University contracting officers generally attempt to have this clause removed or modified if it appears in a contract for health services research.

In addition to these FAR/HHSAR provisions, some university contracting officers have noted the appearance of unique clauses in contracts with HHS agencies. For example, some HHS agencies have crafted special clauses restricting the use and publication of data and analyses generated by contractors. Other clauses restrict the use of the agency logo or other information identifying the agency as the source of funding for the research if information is published without the agency’s review and approval.

Data Use Agreements
During the roundtable discussion in Seattle, members addressed concerns that clauses restricting publication and disclosure of data might be contained in data use agreements. Accordingly, after the June meeting in Seattle, we reviewed several data use agreements provided to us by some of the university contracting officers we interviewed for this effort. We were able to review three such agreements. In addition, one of the authors of this analysis had occasion to negotiate a DUA with an HHS agency during the preparation of this report. Her experiences are described here.

One of the agreements examined contains clauses guarding the confidentiality of the information contained in the data set, including agency review and approval in order to ensure that no breach of confidentiality has occurred. The DUA contains no prior restraint on content.

Another DUA includes FAR clause 52.227-14, “Rights in Data – Special Works,” one of the problematic clauses that has appeared in other government contracts for health services research. This DUA includes a provision requiring the contractor to provide proposed publications using the data for review and comment. Although the clause does not require agency approval of the draft, it allows the agency two months to comment and suggest changes. It also requires written notification to the agency that the publication maintains privacy and confidentiality of the individuals whose information is supplied by the DUA, ensures the quality of statistical and analytical work, and ensures that the information was used expressly for the purposes for which it was supplied. This notice is required prior to publication. If the agency and the researcher do not agree prior to publication, the researcher must include a statement disclaiming agency endorsement of the work.

The third DUA that we reviewed does not contain specific FAR or HHSAR references, but contains numerous provisions establishing the right of the
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Our information gathering also included an
informational interview with the Council on
Governmental Relations (COGR). COGR, in a
joint project with the Association of American
Universities (AAU), produced a report,
“Restrictions on Research Awards: Troublesome
Clauses,” which addresses the fact that
universities across the country have reported a
significant increase in sponsors including award
language that either restricts the dissemination of research results or the use of foreign nationals
without prior approval on certain research projects. The report can be found at http://www.
cogr.edu/docs/TroublesomeClauses.DOC.

Finally, we conducted interviews with three
government contracting officers.

University Contracting Officers: The contracting
officers with whom we spoke uniformly
confirmed that publication restrictions in
government contracts are a chronic problem
and generally a “deal-breaker” for universities.
As part of the negotiation process with federal
agencies, contracting officers are generally open
to approving contract language which provides
for a specified review and comment period (e.g.
30, 60 or 90 days). However, they will not accept
contract provisions that require “prior approval”
by the government before the university
researcher is permitted to publish results. One
modification to this position occurs in the case
of multi-site research. Universities will often
agree to a delay in publication to allow all sites to
complete their work.

In addition to serving as the prime contractor,
universities often serve as subcontractors on
government-sponsored research projects.
Restrictive clauses in contracts between the
prime and the government agency flow down
to the university subcontractor; the university
typically has no direct negotiating leverage with
the agency. A prime contractor may be more
restrictive with a subcontractor, but not less.
The contracting officers explained that whether
they are serving as a prime or subcontractor on
a project, restrictions on publication rights are
unacceptable.
Like universities, non-profit research centers face the same contract negotiation challenges as universities. In addition to using restrictive contract language, government funders use long review delays to stall publications. The funders may also delay a publication by making repeated requests for additional analyses, which eventually cause the findings to become stale. One researcher noted that government funders may also announce conclusions from a study, which are not entirely consistent with the actual findings. Researchers are then placed in the awkward position of deciding whether to challenge their funder.

Consulting Firms: Consulting firms generally enter into “work for hire” contracts with the government. Under such arrangements, the government agency sets the publication parameters. These firms understand that they have no leverage to challenge restrictive clauses. Accordingly they generate findings that may never become public—that fact is understood from the start. The consulting/private agencies know that to the extent a federal agency is “testing the waters” with a politically charged piece of research, there is a greater likelihood that no findings will be published.

In those instances in which a consulting/private firm’s bid for a federally-funded contract includes a university as a subcontractor, negotiations change. Many universities “draw a line in the sand” and refuse to consider any publication restrictions. Other universities may, for financial reasons, be willing to find an acceptable common ground within the contract parameters. The consulting/private firms find themselves accepting or declining contracts based on university rules.

Government Contracting Officials: The government generally awards large blanket contracts, known as indefinite duration, indefinite quantity (“IDIQ”) contracts. Government officials noted that universities are generally treated the same as businesses when they bid on contracts, although they recognized the unique situation with respect to publication. One government official noted that the government tends to use contracts instead of grants when it seeks more control. Budget constraints also dictate the funding vehicle. At least one government official noted the disclosure and publication of research results is a sensitive issue under the current administration. The government has received negative feedback from university researchers for using clauses that restrict publication such as FAR clause 52.227-17, “Rights in data – special works” (not covered by the 2005 notice). One agency has recently revised its contracting process as a result of complaints from universities regarding publication restrictions. Under the new process, research is classified as “policy sensitive” or “not policy sensitive,” with the former receiving a rigorous review and approval and the latter receiving notice and comment within a reasonable period of time.

Interview Results: Key Themes

1. Culture/Custom

The general consensus of those we spoke with is that less federal funding is being awarded through grants and more is being awarded though contracts, which allows government agencies to impose greater restraints. Researchers who became accustomed to greater freedoms in a grant environment are resistant to contract-based limitations.

There is a general sense that government agencies are becoming increasingly inflexible regarding a researcher’s publication rights. With more limited research funds available, this places the universities in a difficult negotiating position.

We heard that “every funder has an answer they want” and funding agencies want contractors to be discreet. Yet, researchers question the validity of federal agencies acting more like corporate funders in what is becoming a more prescriptive environment. The increased politicization of federal agencies seems to be shaping the research environment and fostering a contract-heavy procurement process.

2. Misinterpretation of authorizing legislation

University contracting officers pointed out that in its aggressive use of contracting powers, some government counterparts misinterpret the Public Health Service Act. Some government contracting officers contend that in order to
comply with their authorizing legislation, they must review and approve products produced with federal funding to ensure quality. The scientific community would argue that quality is maintained through the peer-review process and through timely publication.

3. Misapplication of FAR provisions

Some government contracts contain blanket prohibitions for limited needs. Government contracting officers often insert boilerplate clauses without fully understanding the purpose behind the research. For example, restrictive language on publishing may be included when the real intent of the agency is to protect human subjects. University contracting officers find that confusion can arise when their government counterparts are unfamiliar with the “science” behind a project.

During the negotiation process, these misapplications of FAR provisions may be identified, but are only corrected if the government contracting officer is open to examining the underlying purpose behind the contract clauses and the appropriateness of their use vis-à-vis the specific project. When contracting “by the book” is not appropriate for the underlying project, the contracting officer may need input from the Principal Investigator to clarify the structure of the research study.

4. Lack of knowledge of revisions to HHSAR, lack of institutional knowledge by contracting officers

The contract provisions originating with an HHS-based agency that are associated with the release of information are largely governed by HHSAR, the agency’s supplement to the FAR. HHSAR 352.224-70, created in 1984, addresses Confidentiality of Information. This provision has been particularly problematic for university contracting officers because of its prohibition on the release of a researcher’s findings if the results are of such a nature that premature release would cause injury to the public health. University contracting officers were able to temper this broad prohibition by invoking an additional section of the regulation, which provided that parties to the contract could specify the subject matter covered by the prohibitions. Therefore, if the government agency refused to delete the clause, the university could specify the subject matter that would fall within its parameters. In 2005, universities received even more relief when HHSAR 352.224-70 was revised to eliminate the prohibition dealing with threats to public safety.

The challenge for university contracting officers is negotiating with government counterparts who do not have historical knowledge of applicable regulations, or revisions to HHSAR.

5. Sensitive But Unclassified (SBU)

Another means to restrict disclosure and publication rights for federally-funded research is use of “sensitive but unclassified” (“SBU”) secrecy clauses. SBU is not well-defined in federal regulations, and the phrase is made more vague by the fact that not all agencies use this exact term. Some agencies will use phrases such as “for official use only” instead. The result of this label is a limitation or restriction on the disclosure and publication of the results of research.

Scientists in the mid-1980s opposed the use of SBU secrecy clauses. “The presidents of Stanford, Caltech, and MIT jointly informed the White House in early April 1984 that their universities would refuse to conduct certain kinds of sensitive, but unclassified, scientific research for the Pentagon if DOD reviewers were given the power to restrict the publication of findings.” In addition to infringing on academic freedom, inclusion of SBU clauses is at odds with the national security policy which calls for an open policy for unclassified fundamental research.

Our literature review indicated that SBU is a category that appears in research for the Department of Defense or other research related to national security. Our interviews, however, revealed that SBU is also used within HHS. One interviewee’s agency recently revamped its process for awarding IDIQ contracts. The interviewee explained that in response to complaints about the contracting process, and specifically in response to complaints about publication restrictions and lengthy notice and comment periods, the agency had developed a classification process. The new IDIQ’s classify task orders into “policy sensitive”
and “not policy sensitive,” with separate review processes for each. Any task orders involving research that the agency deems “policy sensitive” must undergo agency approval prior to publication and disclosure, but task orders that are not policy sensitive can be published after a reasonable period of notice and comment. The interviewee indicated that the agency had received positive feedback on this revised process, although only a handful of contracts have been awarded under this new process. The interviewee indicated that the agency had worked with its general counsel’s office to develop and implement this new process. Significantly, the determination as to what is policy sensitive is an ad-hoc determination, made at the program level.

Discussion
This study focused on federal limits applied to research conducted by Universities working under contract. It is not possible, without significant funding, to review all forms of restriction by both public and private funders to all types of entities at all levels of government. We examined university research and federal contractual restrictions because judicial policy—explicitly recognized by at least one federal cabinet department—suggests that there are real limits to what conditions the government can attach to its funded research. Where a contract involves the acquisition of data by academic researchers, rather than funding of the research itself, the case for broadly recognized rights would appear to be even stronger.

Our recommendations to the exploratory committee are as follows:

1. Applying the 2005 Federal Register intent to all restrictive clauses: The problems with rights in data clause negotiations suggest that the spirit of the Federal Register notice should go beyond confidentiality clauses and should be applied to all clauses in contracts, whether DUAs or funded research. The government can properly claim the right, in our view, to take steps to ensure that prior to publication, confidentiality and privacy restrictions have been honored. This right though needs to be bounded by strict timelines in order to keep from degenerating into a prior restraint de facto.

2. Encouraging review and comment rights: The federal government may wish to encourage review and comment rights, particularly where it considers data SBU, and researchers might be wise to honor such requests, if properly time-bound. Federal officials’ comments can be exceedingly valuable if obtained in a timely fashion prior to publication.

3. Eliminating SBU from the health services research lexicon: No one really knows what this means and the federal government continues to use a subjective (and thus potentially unconstitutional) test. HSR data simply are not the type of data that are sensitive in our view. They might sometimes be embarrassing, but cost, quality, safety, and access issues in health care simply are not “sensitive.”

4. Drafting sample clauses: AcademyHealth should consider the development of sample clauses applicable to privacy, confidentiality, and rights in data, that would meet government needs without crossing the boundaries of legality.

5. Facilitating discussion among federal contract officers and University officers: Everyone we spoke with asked for clarification. AcademyHealth might consider training university officers on this topic at the ARM and sponsoring a daylong special session with the government to explore the issues as they apply to health services research.

6. Exploring the issue at the state level: It is evident from our discussions that state government conduct in a prior restraint context poses an equally important matter of concern.

7. Privately funded Research: The legal situation for publication restrictions in work funded by not-for-profit and for profit entities differs from that for government. From the perspective of users of research findings, these differences may be less clear, yet such restrictions may differentially affect how research is interpreted and evaluated. If the goal of our efforts with respect to publicly supported research is to achieve an “influence free” standard, we should offer a mechanism whereby private funders can write contracts and...
grants that meet such a standard. Model language and expectations would also be helpful.

During the special session held at the ARM (see Appendix A), participants also made suggestions for additional action AcademyHealth might consider taking in support of publication freedom:

**Educational Primer**
While some universities have developed an in-house expertise at negotiating federal contracts, other universities and other non-university-based settings, which negotiate fewer contracts, are less adept at this process. These organizations would benefit from an educational primer which outlines common pitfalls that are encountered during a contract negotiation, including processes to reach a satisfactory agreement. The primer could also address challenges that may arise during the course of the research project and at the point of publication. The primer might be structured for a variety of users (researcher, university, funder, prime contractor, subcontractor). The primer should include restrictions that can also appear in DUAs.

**Policy**
AcademyHealth might consider adopting a policy statement supporting a set of best practices in contract negotiation. The policy might also support a set forth best practices related to the review and comment process for draft manuscripts and DUAs.

**Model Language**
Participants at the AcademyHealth ARM suggested that AcademyHealth develop model contract language based on language which has proven successful in ensuring publication freedom.

We have not tested what the response to model language would be from federal agencies. Some policymakers may reject it, while others might find it to be a helpful platform from which to negotiate. Similarly, while universities competing for federal dollars may not want to adopt uniform contract language, they too might find model language to be helpful in the negotiation process.

Finally, we might further explore the following:

**Collaborations**
During the course of our interviews, we learned of two entities which may serve as natural partners in our effort to address publication restrictions.

- **Federal Demonstration Partnership (FDP)** - The FDP is a cooperative initiative among 10 federal agencies and 98 institutional recipients of federal funds that meets 3 times each year. The purpose of FDP is to reduce the administrative burdens associated with research grants and contracts. For more information on this initiative, see http://thefdp.org.

- **Council on Government Relations (COGR)** - COGR is an association of research universities. Its primary function is to provide advice and information to its membership and to make certain that federal agencies understand academic operations and the impact of proposed regulations on colleges and universities. COGR helps to develop policies and practices that fairly reflect the mutual interests and separate obligations of federal agencies and universities in research and graduate education. For more information, see http://www.cogr.edu.

**Legislation**
AcademyHealth could work with its advocacy arm, the Coalition for Health Services Research, and others interested in scientific research, to reach out to policymakers in an effort to clarify relevant authorizing and appropriations statutes. The Coalition might develop strategies to encourage more broad-ranging changes in governmental practice and custom where control of research output is concerned.

AcademyHealth and/or the Coalition might consider how it could support two relevant pieces of legislation:

- **Federal Research Public Access Act of 2006, S. 2695** - On May 2, 2006, Senators Cornyn and Lieberman introduced the “Federal Research Public Access Act of 2006,” S. 2695. The purpose of this Act is, “To provide for Federal agencies to develop public access policies relating to research conducted by employees of that agency or from funds administered by that agency.”
Congressional Record reveals that the impetus of this bill is to provide better value to American taxpayers by increasing their access to federally-funded research. The bill requires all agencies to develop public access policies and to deposit articles that result from federally-funded research in free, publicly-accessible archives within six months of publication. In this way, the Congress can ensure that Americans do not have to pay twice to see the results of the research funded with tax dollars. At least 48 universities have expressed their support for the legislation.

- Bill to Protect Scientific Integrity in Federal Research and Policymaking, S. 1358—In June 2005, Senator Dick Durbin (D-IL) introduced a “Bill to Protect Scientific Integrity in Federal Research and Policymaking,” S. 1358. This bill prohibits federal employees: (1) from tampering with the conduct of federally-funded scientific research or analysis, (2) from censoring findings of such research or analysis, or (3) from directing the dissemination of scientific information known by the directing employee to be false or misleading. Representative Henry Waxman (D-CA) introduced a similar bill, H.R. 839, in February 2005. The bill is currently under consideration by the Senate Committee on Homeland Security and Governmental Affairs.

Appendices
A. Summary of Annual Research Meeting Roundtable Discussion, June 26, 2006
C. Federal Register, Notice of HHSAR Amendments—January 3, 2005
D. Specific FAR Clauses: HHSAR 352.224-70 “Confidentiality of Information” (including January 3, 2005 revisions) & FAR 52.227-14 “Rights in Data—Special Works”
E. Sample restrictive language included in RFPs

Endnotes
1. The First Amendment states, “Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.”
2. Agreements with private funders thus would not raise the same issues because courts will enforce the terms agreed to by the parties. There is no caselaw suggesting special legal requirements that private entities must follow with respect to the First Amendment. Our interviews with private sector firms were relevant to shed light on situations where private entities enter into subcontracts with universities, thus raising legal issues under the First Amendment.
3. The First Amendment applies to the states via the Fourteenth Amendment.
4. Over the course of this research, one of the three authors has had occasion to negotiate a DUA. Her experience is described herein.
5. 48 C.F.R. Ch. 1.
7. Id. at 193.
8. Id. at 200.
9. 773 F. Supp. 472 (D.D.C. 1991). For government restrictions of speech to be constitutional, the restrictions must be narrowly tailored to a compelling government interest. The Stanford court held that the regulations promulgated by HHS were vague and overly broad, and thus an unconstitutional restraint on free speech. Id. at 447.
11. We do not comment on the propriety of applying such a clause in the context of publication of basic science research.
12. A unique entity is the Institute of Medicine. The IOM is a 501(c)(3) private entity with a Congressional charter to advise the government. It is exempt from the Federal Advisory Committee Act. Each President signs an Executive Order providing that the IOM does not compete for contracts. The majority of IOM support comes from federal agencies. Contracts between the IOM and federal agencies specify a statement of work, but the IOM maintains copyright and ownership rights to all information generated under the contracts. Draft reports are not provided to the sponsor for review. While the government agency may receive a courtesy copy of a report in advance of the public, the report is final and is released without sponsor input. Government sponsors are not permitted to speak at an IOM news conference.
14. Executive Order 12,350 states that “it is the policy of this Administration that, to the maximum extent possible, the products of fundamental research remain unrestricted. . . . No restriction may be placed upon the conduct or reporting of federally funded fundamental research that has not received national security classification. . . .” Although drafted before the events of September 11, 2001, this National Security Decision Directive 189 (“NSDD-189”), was reaffirmed by all subsequent administrations, including that of current president George W. Bush. In November 2001, Condoleezza Rice, then National Security Advisor to the President stated that “The key to maintaining U.S. technological preeminence is to encourage open and collaborative basic research. . . .[t]he policy on the transfer of scientific, technical, and engineering information set forth in NSDD-189 shall remain in effect, and we will ensure that this policy is followed.” (Claus, R.L, Space-Based Fundamental Research and the ITAR: A Study in Vagueness, Overbreadth, and Prior Restraint, 2 Santa Clara Journal International 1 2004.)
15. Other Executive Orders have expressly stated that basic scientific research cannot be classified if it does not clearly relate to the national security. See Exec. Order No. 12958, 60 Fed. Reg. 19,825 (Apr. 20, 1995). This encompasses health services research.
On June 26, 2006, members of the Exploratory Committee held a Roundtable Discussion at AcademyHealth’s Annual Research Meeting. The focus of the session was how best to balance the expectations, rights and obligations of sponsors and researchers in the context of contract-funded and grant-funded research.

The Session was moderated by Tom Rice (UCLA) and panelists included: Sara Rosenbaum (George Washington University), Robert Berenson (The Urban Institute), Douglas Kamerow (RTI International; US Editor, BMJ), Harold S. Luft (University of California, San Francisco), and Vincent Mor (Brown University).

**Panelist Perspectives**

At the start of the session, each panelist outlined their perspective on the issue of funder restrictions. Rosenbaum explained that the Exploratory Committee is in its evidence-gathering phase. She noted that private funders can exercise their own prerogative. Government funders, when making contract awards, are governed by the Federal Acquisition Regulations (FAR). She noted that universities enjoy a unique protection based on the 1991 Stanford case. Institutions, such as RTI and RAND face broad policy questions when dealing with government funders and their contract become complicated when university subcontracts are involved. Rosenbaum highlighted four problematic areas, which the participants were encouraged to address during the session, including ideas of solutions:

Luft noted that increasingly, government contract provisions are becoming problematic. He cited the Betty Dong case in which UCLA refused to defend its research in a government contract dispute. Luft said that increasingly, government contract language is being written broadly and universities continue to try and narrow that language. Moreover, when government contracting officers do not understand the underlying research, contract clauses can be particularly problematic. Moreover, the variation in research projects necessitates variation in contracting language. Mor pointed to past problems associated with restraints in Data Use Agreements, although he noted that the CMS structure seems to have improved.

Kamerow pointed to drug companies as “straw men.” He noted that the government’s problematic restraints are moving closer toward drug company-type restraints. RTI works primarily on research contracts. He finds that the questions around prior restraint arise in a variety of ways and vary from agency to agency, from contract to contract, and from contracting officer to contracting officer. Ten years ago, Kamerow worked in AHRQ’s Evidence-based Practice Program. Generally, the practice centers conducted AHRQ-funded work were required to submit products to the agency for review and approval. AHRQ argued that the review and approval process was necessary to maintain quality. He noted that they were also “seeking to get glory for AHRQ” and also because of the content of some of the products. Kamerow noted that they did receive pushback from grantees, which was generally resolved. He offered that a solution to the issue may be to develop model language which includes a specific period for review, with an “escape clause” which allow the researcher to publish, if the period for review has pass with no action, without the agency’s name.

In his role as U.S. editor of BMJ, Kamerow explained that if a manuscript is “watered down” before it reaches the journal, there is not good way for the editors to determine what changes may have been made.

**Session Discussion**

Before the roundtable discussion commenced, the participants were asked to identify themselves and their organizations. Represented at the session were individuals from: University of Washington, Brandeis, UCLA, Kaiser Commission, AHRQ, Kaiser Northwest, Lovelace Clinic Foundation, BCBS MN, RTI International, GWU, CDC, University of Kentucky, Oncology Research Society, Boston VA and Thompson MedStat.
A question was raised about the role of journals in soliciting disclosures about contributions made to journal manuscripts. Arnie Epstein noted that the *New England Journal of Medicine* raises questions about sources of funding. The journal is working on revising its existing disclosure statement. Luft noted that this particular problem came to light when the UCSF tobacco documents became public and it was not disclosed that Phillip Morris employees were co-authors on papers. Luft said that *HSR* will soon roll out a new author/disclosure form, similar to the form used by *Journal of the American Medical Association*. The *HSR* form will require authors to disclose whether sponsors or other organizations contributed to the manuscript, including any review/approve requirements. The disclosure will be required at the time manuscripts are accepted for publication, not at the time of submission. However, the authors will see the form requirement at the time of submission. Kamerow noted that *BMJ*’s position is that transparency goes a long way toward resolving the issue of funder influence. However, he does not believe the journal asks for information about any prior approval process associated with submitted manuscripts.

Bill Marder from MedStat noted that they collaborate with researchers at AHRQ. The “review and comment” requirement is part of the collaboration process. There is a somewhat different issue if “review and approval” is required, especially if journals ask for disclosure of manuscript contributors.

One participant who has conducted some federal agency-sponsored work noted that if findings are not consistent with the agency’s agenda, or if the funder disagrees with the findings, they do not want to be named as the funding agency. This could put researchers in a difficult position if they are required by journals to disclose the sponsor’s name. A way to address this dilemma is to add a disclaimer that the work is the author’s and does not represent the views of the government agency.

Another participant noted that “review” varies from agency to agency. Editing, developing statistical strategies, etc. may go beyond the purview of the funder. A “review” may lead to months of delay in getting the work out. Such delay is more frequent when the funder is a close collaborator.

Often universities are well-protected. Other organizations do not have expertise in-house. AcademyHealth might consider developing model contract language to deal with a variety of situations and covering both offerors and awardees. Researchers are placed in a difficult position when work is completed, review by the funding agency is completed, but the product is not released from the agency. Negotiating contracts and resolving publication prohibitions includes a whole series of landmines. It can be the “battle of the boilerplates.”

Federal agencies seem to be funneling funds through small businesses. Some university faculty are responding by developing their own small businesses and accepting work outside of the university setting. This scenario is becoming more common as both universities and government funders are holding firm to the position that they own the data. Faculty are caught in the middle.

If AcademyHealth develops model language and the government agencies are not interested in adopting it, what else can we do? There has to be an “out” in any model language. If the funding agency refuses to approve publication, the researcher could publish without identifying the sponsor or indicate that the findings do not represent the views of the government.

Developing model language would be a useful exercise if it is consistent with the intent of funders, but some funders will continue to resist complete freedom to publish. AcademyHealth might develop a policy position which provides that research funded by public monies should be widely disseminated.

AcademyHealth could develop model contract language which includes multiple options. Or, it could develop a set of good practices. Journal editors could develop a practice to inquire of authors whether they followed the AcademyHealth “set of good practices.” The set of good practices or statement of principles or policy statement could articulate what the technical contract language is trying to accomplish.

It may be useful to gather intelligence from co-authors from government agencies. If publication is restricted, is it because they are
concerned about the quality of the research; are they concerned about pleasing a higher authority at the agency; do they want to assure Congressional funding for a particular issue? We need to better understand the motivations behind the groups who are putting up the roadblocks. There simply needs to be a greater understanding of the underlying issues.

On the issue of authorship, some journals require the rights are responsibilities of each author—detailing each person who had input into a manuscript. Luft pointed out that as an editor, he has no concern about what level of input a funder had, as long as it clearly disclosed. Kamerow agreed, noting that at the BMJ, the issue is one of “contribution.” Did the funder contribute substantially to the manuscript.

AcademyHealth might consider developing an educational Primer which describes the issues that are likely to arise in contract negotiations. The Primer could be developed with an eye toward multiple perspectives (researcher, lawyer, PI, funder). The Primer could help to dispel the current misunderstanding and/or lack of information about publication rights.

Data use agreements remain high for some researchers as a problematic issue—can you use data after you have completed the initial work?

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APPENDIX A—Continued

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APPENDIX B

Appeals Filed by Pro Se Appellant Rodney Stitch in the United States Court of Appeals for the District of Columbia Circuit

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The BOARD OF TRUSTEES OF the LELAND STANFORD JUNIOR UNIVERSITY, Plaintiff,  
v.  
Louis SULLIVAN, M.D., Secretary, Health and Human Services, et al., Defendants.  

Civ. A. No. 90–2656(HHG).  
United States District Court, District of Columbia.  

University sought declaratory judgment that confidentiality clause in research contract was unconstitutional and injunction requiring government to re-award contract to university. The District Court, Harold H. Greene, J., held that: (1) confidentiality clause violated First Amendment, and (2) appropriate remedy was to award contract to disappointed party without additional round of procurement proceedings.  

Summary judgment entered for plaintiff.  

1. Constitutional Law ==90.1(1)  
United States ==66  
Confidentiality clause in public research contract to be awarded by National Heart, Lung, and Blood Institute of National Institutes of Health for study of artificial heart device violated First Amendment; clause required researchers to give government advance notice of their intent to publish preliminary findings and allowed government’s contracting officer to block publication and was impossibly vague. U.S.C.A. Const.Amend. 1.  

2. Constitutional Law ==90(1)  
Prior restraints are permitted only in exceptional cases. U.S.C.A. Const.Amend. 1.
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4. Constitutional Law 90.1(1)
First Amendment protects scientific expression and debate just as it protects political and artistic expression. U.S.C.A. Const.Amend. 1.

5. United States 64.60(5)
It was appropriate for district court to order that public research contract be awarded by a part of the Department of Health and Human Services to disappointed party without additional round of procurement proceedings after it was found that confidentiality clause in contract violated First Amendment. U.S.C.A. Const.Amend. 1.


OPINION

HAROLD H. GREENE, District Judge.

The principal legal issue in this lawsuit—the extent to which the government may curtail the speech of a recipient of a government grant—is related to that which was recently resolved by the Supreme Court in Rust v. Sullivan, — U.S. —, 111 S.Ct. 1759, 114 L.Ed.2d 233 (1991), a case involving abortion counseling in family planning clinics. This Court has carefully considered that decision as well as other, prior appellate law dealing with the issue in question and, in the context of pending motions for summary judgment, it is resolving the dispute in favor of plaintiff Stanford University.

I

In August 1989 the National Heart, Lung, and Blood Institute (Institute) of the National Institutes of Health issued a notice that it planned to award contracts for a five-year research project on an artificial heart device. The research was to be conducted at two separate academic institutions, each of which was to receive a government grant of approximately $1.5 million. The notice indicated that the contract might include a clause known as the Confidentiality of Information Clause (confidentiality clause) which would require researchers to obtain government approval before publishing or otherwise publicly discussing preliminary research results. In October 1989 Dr. Philip Oyer, a professor of cardiovascular surgery at Stanford Medical School, submitted a proposal on behalf of Stanford in response to the notice. Stanford’s proposal objected to several provisions of the notice, particularly the confidentiality clause, and ultimately, when Stanford and the government could not agree with respect to the clause, the government withdrew the contract from Stanford and awarded it elsewhere.3
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Stanford argues that the confidentiality clause constitutes an illegal prior restraint and an unconstitutional condition on a government benefit. The relief requested is a declaratory judgment that this clause is unconstitutional and an injunction requiring the Institute to re-award the contract to Stanford.

II

1. The confidentiality clause requires researchers to give the government advance notice of their intent to publish preliminary findings, and it allows the government’s contracting officer to block such publication. More specifically, under the clause, a researcher must give forty-five days advance notice that he plans to publish preliminary findings. If the contracting officer objects to the publication, the researcher may file a written claim with him, and the contracting officer then has an additional sixty days in which to decide that claim. The contracting officer’s ultimate decision is final and binding (except that the researcher may file suit in court). See 48 C.F.R. § 52.223-1.

2, 3. It is well established that under the law this procedure constitutes a prior restraint on speech in that it allows the government to suppress the dissemination of information in advance of publication, not yet begun the human trials of the artificial heart device. The government agrees that a resolution of this case in favor of Stanford would not significantly injure St. Louis University or any other third party.

4. Stanford also argues that the clause was not authorized by statute, but the Court rejects that claim. While there is no statute specifically authorizing the actions taken or contemplated by the Institute, there is broad contracting authority which is adequate to constitute statutory sanction for the actions taken by the Institute. 42 U.S.C. § 241(a)(7).

5. The information subjected to this prior government approval is defined as: information which might require special consideration with regard to the timing of its disclosure may derive from studies or research, during which public disclosure of preliminary unvalidated findings could create erroneous conclusions which might threaten public health or safety if acted upon. 48 C.F.R. § 352.224-70(f). The information is also referred to as “findings . . . which have the possibility of adverse effects on the public or the Federal agency.” 48 C.F.R. § 352.224-70(f).

6. The confidentiality clause further prohibits disclosure of personal information about individual participants in the research study as well as of proprietary information. 48 C.F.R. § 352.224(a). Stanford does not contest the government’s restrictions on these two types of confidential information, and they are not at issue in this lawsuit.

7. It is immaterial that the restraint does not last forever. Even a restraint of speech for a limited period is inconsistent with the First Amendment. See, e.g., New York Times Co. v. United States, 403 U.S. 713, 91 S.Ct. 2140, 29 L.Ed.2d 822 (1971).
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Cite as 773 F.3d. 472 (D.C.Cir.: 1991)

The defendants now concede that the government could not impose the kind of restraint contemplated by the regulation on scientists whose research is not paid for by a government grant or contract. The question before the Court therefore is whether the grant of public funds takes the present situation out of the category of impermissible suppression of speech.

III

Prior to the issuance by the Supreme Court of the Rust decision earlier this year, the law regarding speech-type restrictions attached to government grants was less than clear. Although there were factual differences among the cases which could be, and were, cited as responsible for the particular results reached in the various cases, it has become increasingly difficult to discern a principled rule applicable to all the various situations.

Among the principal decisions in recent years upholding the constitutionality of speech-type restrictions accompanying particular contracts or subsidies are Regan v. Taxation Without Representation (TWR), 461 U.S. 540, 103 S.Ct. 1997, 76 L.Ed.2d 129 (1983); Cammarano v. United States, 358 U.S. 498, 79 S.Ct. 524, 3 L.Ed.2d 462 (1959); DKT Memorial Fund Ltd. v. Agency for

8. Transcript of July 12, 1991 Hearing at 52. Further, although at one stage of this litigation defendant appeared to contend to the contrary, Opposition to Summary Judgment at 5 n. 4, this case does not involve commercial speech. Stanford seeks to engage in five years of research, not to "propose a commercial transaction." Board of Trustees of State Univ. of N.Y. v. Fox, 492 U.S. 469, 473, 109 S.Ct. 3028, 3031, 106 L.Ed.2d 388 (1989). Defendants later conceded this point. Transcript of July 12, 1991 Hearing at 39.

Equally unpersuasive is the defendants’ claim that, inasmuch as the government could have hired scientists as employees, a diminution of the free speech rights of scientists affiliated with a university receiving government monies is less offensive to the law than it might otherwise be. Id. at 6 n. 5. Even assuming that the premise is correct, that kind of an argument could be made with respect to almost any activity, and its acceptance would in practice erode First Amendment freedoms on the widest scale.

9. There are, to be sure, some significant factual differences among the cases. For example, TWR and Cammarano involved tax preferences;
rights of these medical workers and that it is therefore valid. That of course is the law and this Court, like all lower courts, is bound thereby. There are, however, two bases upon which, under the Rust Court's own language, the Rust result does not follow here.

First. The Supreme Court made a sharp distinction in Rust between the denial of a benefit to an individual on account of his speech or expression (which is constitutionally prohibited) and an insistence that public funds be spent for the program purposes for which they were authorized (which the Constitution allows). Said the Court:

The Secretary’s regulations do not force the Title X grantee to give up abortion-related speech; they merely require that the grantee keep such activities separate and distinct from Title X activities. Title X expressly distinguishes between a Title X grantee and a Title X project . . . The Title X grantee can continue to perform abortions, provide abortion-related services, and engage in abortion advocacy; it simply is required to conduct these activities through programs that are separate and independent from the project that receives Title X funds.

In contrast, our “unconstitutional conditions” cases involve situations in which the government has placed a condition on the recipient of the subsidy rather than on a particular program or service, thus effectively prohibiting the recipient from engaging in the protected conduct outside the scope of the federally-funded program.

111 S.Ct. at 1774 (emphasis in original) (citations omitted).

11. It may be that Stanford University and all those affiliated with it are under a like prohibition. Transcript of July 12, 1991 Hearing at 28.

12. The ban on discussing unvalidated findings may last longer than the five-year contract period, for if the government considers results to be “preliminary” and “unvalidated,” it could bar publication even after the contract is over.

13. Defendants’ ban on preliminary reporting could not validly be defended on the basis that it is tied to the heart research program rather than the researchers, for the latter, as noted, would be precluded from speaking or publish-
BOARD OF TR. OF LELAND STANFORD UN. v. SULLIVAN

Cite as 773 F.Supp. 472 (D.D.C. 1991)

versity is a traditional sphere of free expression so fundamental to the functioning of our society that the Government's ability to control speech within that sphere by means of conditions attached to the expenditure of Government funds is restricted by the vagueness and overbreadth doctrines of the First Amendment." This explicit exception to the broader ruling in Rust is directly on point here. The plaintiff is of course a university. The subject of this lawsuit is the very free expression that the Rust Court held to be so important for the functioning of American society that it may be curtailed through conditions attached to grants or contracts only if these conditions are not vague or overbroad. Yet, the conditions imposed by the defendants are plainly in that category.

The regulations permit the contracting officer to prevent Stanford from issuing "preliminary unvalidated findings" that "could create erroneous conclusions which might threaten public health or safety if acted upon," or that might have "adverse effects on . . . the Federal agency." 48 C.F.R. § 352.224-70. In the view of this Court, these standards are impermissibly vague. Under what circumstances are preliminary findings regarded as "validated"? Who will decide whether the conclusions drawn by Stanford are erroneous—the non-scientist contracting officer? What is meant by the phrase that a report "could" create erroneous conclusions? How would it be determined that such a conclusion "might threaten public health or safety," and to what degree of certainty would there have to be a threat to public health and safety? What kind of a threat? What would be regarded as an adverse effect "on the Federal agency?" Would such an effect have to be concrete, financial, reputational, or of some other nature? To pose these questions, and others that could be asked, is to reveal the vagueness of the standards.

There is the related problem of the chilling effect of these vague and overbroad conditions. It is impossible for a grantee such as Stanford and its chief researcher Dr. Oyer to know what might be regarded as a violation of these amorphous standards. Because of the vagueness and subjectivity of the administrative regulation, a responsible grantee could be certain of not being in violation only if it refrained from publishing any preliminary findings not endorsed by the contracting officer. Thus, the qualifying phrases referred to above are not likely to effect any real diminution of the otherwise unfettered authority of the contracting officer, and no prudent grantee is likely to publish that which the contracting officer has not cleared even if the reasons for the refusal to clear appear to be wholly invalid. In sum, this case fits snugly in the "free expression at a university" category that Rust carved out and their availability will be strictly controlled under the research regime. And of course there is not the slightest reason to believe that the Stanford scientists—who are not in the business of selling patent medicines—will be making fraudulent claims when they publish learned articles on artificial heart research.

Defendants' stated goal of protecting prospective patients from unwarranted hope (that might result from the issuance of preliminary findings by Stanford scientists not screened in advance by a government contracting officer), id. at 10, constitutes a strange and attenuated way of protecting health and safety. Neither these defendants nor any other public officials have statutory or other authority to regulate citizens' hopes.

16. In fact, defendants' claim that the condition is designed to protect public health and safety, Opposition to Summary Judgment at 5 n. 4, is also off the mark. Defendants point to cases in which government agencies tried to protect members of the public from false claims by commercial purveyors of medicine and therapies. But no such public health hazard is posed in this case if only because only twenty of the artificial heart devices will be made available,
of its general ruling on speech conditions attached to grants.

IV

Defendants' approach to this case is that, since public funds will be expended on the artificial heart research at issue here, the burden is on plaintiff Stanford University to explain why and under what circumstances it should be relieved of the obligation to submit its publications on this subject to the government for its prior approval. That approach views the issue from the wrong end of the telescope.

Stanford University, a premier academic institution, engaged in significant scientific and medical research for the benefit of the American people, is not ipso facto compelled under the law to surrender its free speech rights and those of its scientific researchers to a "contracting officer" merely because a regulation issued by defendants so directs. There exists, after all, the First Amendment to the Constitution, the supreme law of the land, which protects those very rights.

The Supreme Court decided in Rust v. Sullivan that when the government grants money to an institution or a program, it may under certain circumstances condition that grant upon curtailment of the program participants' rights under the First Amendment. Defendants' argument in this case is that that decision is applicable to government grants and contracts generally, without substantial limitation. The

18. All it would take to transform the potential into reality would be a regulation similar to the one promulgated by the defendants here, and a somewhat plausible rationale. See Chevron v. National Resources Defense Council, Inc., 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984).

19. That is not to say that all the various departments and agencies of the government may be expected to rush out at once to curtail the free speech rights of those with whom they deal. But establishment of the principle that such action can pass constitutional muster is sure to be implemented, and it is bound to have increasingly wide negative effects on a free society, as the legality of censorship accompanying federal monies becomes more and more common and thus more and more deeply ingrained in the fabric of government and society.

Rust decision opened the door to government review and suppression of speech and publication in areas which had theretofore been widely thought immune from such intrusion; the government's position in this case, if endorsed by the courts, would take that door off its hinges.

That position must be viewed in the context of the fact that few large-scale endeavors are today not supported, directly or indirectly, by government funds—from the health care of senior citizens, to farm subsidies, to the construction of weaponry, to name but a few of the most obvious. Defendants' proposal would, at least potentially, subordinate the free speech rights of the participants in the programs receiving such federal monies to the government's wishes. To put it another way, if the Supreme Court decision were to be given the scope and breadth defendants advocate in this case, the result would be an invitation to government censorship wherever public funds flow, and acceptance by the courts of defendants' position would thus present an enormous threat to the First Amendment rights of American citizens 18 and to a free society.20

This Court, like all lower courts, is of course bound by the Rust decision. But for the reasons stated, the Court will not, without explicit appellate direction, further narrow the speech and expression rights of citizens and organizations, or subject to government censorship the publications of institutions of higher learning and others engaged in legitimate research. No such

20. Defendants' position also conflicts with the trend in this country, as well as elsewhere, to allow citizens and organizations to speak and otherwise to operate without intrusive official direction. Even in the Soviet Union, where Joseph Stalin at one time decided what could be published and by whom, the dead hand of government control of scientific research and publication is apparently no more.

21. In Rust, in a holding reminiscent in its detail of Miranda v. Arizona, 384 U.S. 436, 86 S.Ct. 1602, 16 L.Ed.2d 694 (1966), the Supreme Court even upheld a regulatory requirement that prescribed in so many words what the physicians and nurses in family planning clinics must say when asked by a woman patient about abortions.
appellate direction has been given; on the contrary, as explained above, "must" is consistent with a decision to allow Stanford to use its own judgment on when and what to publish, notwithstanding that its research is supported with federal funds. The Court will accordingly issue an injunction which will have the effect of prohibiting defendants from interfering with the university's freedom to publish.

V

[5] What remains to be decided is what relief is appropriate. Defendants argue that their Department should be given the opportunity "to resolicit the contract following appropriate procurement procedures." Motion to Dismiss at 32. However, it is plain that the contract would have remained with Stanford but for the illegal confidentiality clause. Under these circumstances, a court may order that the contract be awarded to the disappointed party without an additional round of procurement proceedings. Delta Data Systems Corp. v. Webster, 744 F.2d 197, 204 (D.C.Cir.1984). The judgment being issued contemporaneously herewith therefore so provides.

ORDER

Upon consideration of plaintiff's motions for a preliminary injunction and for summary judgment; defendants' motion for summary judgment; the oppositions, replies, and supplemental memoranda; the hearing on the motions; and the entire record herein; it is this 26th day of September, 1991, in accordance with the Opinion issued contemporaneously herewith

ORDERED that defendants' motion for summary judgment be and it is hereby denied; and it is further

ORDERED that plaintiff's motion for summary judgment be and it is hereby granted; and it is further

ORDERED that judgment be and it is hereby entered in favor of plaintiff; and it is further

ORDERED that the Secretary of Health and Human Services shall award to Stanford University Contract No. N01-HV-08110, a contract involving a left ventricular heart system or device, without including a provision requiring the approval of a contracting officer or other government official prior to publication or discussion of preliminary research results.

UNITED STATES of America, Plaintiff,
v.
Rahnaun A. WILKERSON, Defendant.
Crim. No. 90-369.
United States District Court,
District of Columbia.

Defendant pled guilty to possession with intent to distribute narcotics and using or carrying a firearm in relation to a drug trafficking crime. In sentencing defendant, the District Court, Sporkin, J., held that: (1) statutory exposure on narcotics offense would be based on the 4.9 grams of drugs weighed in court's presence at court's request due to fact that amount of drugs reported as evidence was slightly over five gram line, and (2) imprisonment for term of 97 months, followed by placement on conditional supervised release for term of six years, was appropriate.

Order accordingly.

1. Drugs and Narcotics <=133

In prosecution for possession with intent to distribute narcotics where amount of drugs reported as evidence was slightly over five gram line, it was proper to order counsel to bring expert and scale before court so that drugs could be weighed; amount of drugs implicated was significant factor when sentencing defendant, insofar as statutory minimum sentence of five
APPENDIX C: Federal Register, Notice of HHSAR Amendments – January 3, 2005

Federal Register /Vol. 70, No. 1/Monday, January 3, 2005/Rules and Regulations


§ 73.673 [Amended]

4. Section 73.673 is amended by removing and reserving paragraph (b).

5. Section 73.3526 is amended by revising paragraph (e)(11)(iii) to read as follows:

§ 73.3526 Local public inspection file of commercial stations.

(e) * * *

(11) * * *

(iii) Children’s television programming reports. For commercial TV broadcast stations, both analog and digital, on a quarterly basis, a completed Children’s Television Programming Report (“Report”), on FCC Form 398, reflecting efforts made by the licensee during the preceding quarter, and efforts planned for the next quarter, to serve the educational and informational needs of children. The Report for each quarter is to be placed in the public inspection file by the tenth day of the succeeding calendar quarter. By this date, a copy of the Report for each quarter is also to be filed electronically with the FCC. The Report shall identify the licensee’s educational and informational programming efforts, including programs aired by the station that are specifically designed to serve the educational and informational needs of children, and it shall explain how programs identified as Core Programming meet the definition set forth in § 73.671(c). The Report shall include the name of the individual at the station responsible for collecting comments on the station’s compliance with the Children’s Television Act, and it shall be separated from other materials in the public inspection file. The Report shall also identify the program guide publishers to which information regarding the licensee’s educational and informational programming was provided as required in § 73.673, as well as the station’s license renewal date. These Reports shall be retained in the public inspection file until final action has been taken on the station’s next license renewal application. Licensees shall publicize in an appropriate manner the existence and location of these Reports. * * * * *

PART 76—MULTICHANNEL VIDEO AND CABLE TELEVISION SERVICE

6. The authority citation for part 76 continues to read as follows:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

48 CFR Chapter 3

Acquisition Regulation

AGENCY: Department of Health and Human Services (HHS).
FOR FURTHER INFORMATION CONTACT:
Tracey Mock, Office of Acquisition Management and Policy, telephone (202) 205–4430, e-mail: Tracey.Mock@hhs.gov.

SUPPLEMENTARY INFORMATION:

A. Background

The Department emphasizes that it is not making significant amendments to the existing HHSAR. The amendments being made to the HHSAR concern internal procedural matters which are administrative in nature, and will not have a major effect on the general public or on contractors or offerors supporting the Department. The majority of the amendments concern HHS organizational title changes resulting from reorganizations, such as the Health Care Financing Administration (HCFA) being renamed the Centers for Medicare & Medicaid Services by the Secretary of Health and Human Services in June 2001.

B. Regulatory Flexibility Act

The Department of Health and Human Services certifies this document will not impose any new requirements. Therefore, no regulatory flexibility statement has been prepared. Since this rule does not impose any new requirements, there are no regulatory flexibilities to be analyzed.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the changes to the HHSAR do not impose any record keeping or information collection requirements that require approval by the Office of Management and Budget under 44 U.S.C. 3501, et seq. Existing approvals cited in 48 CFR 301.106 remain in effect. The provisions of this regulation are issued under 5 U.S.C. 301; 40 U.S.C. 486 (c).


Government procurement.

Ed Sohnag,
Assistant Secretary for Administration and Management.

Accordingly, 48 CFR chapter 3, parts 302, 303, 304, 306, 307, 317, 324, 333, and 352 are amended as follows:

1. The authority citation for 48 CFR chapter 3, parts 302, 303, 304, 306, 307, 317, 324, 333, 334, and 352 continues to read as follows:


CHAPTER 3—[AMENDED]

2. 48 CFR chapter 3 is amended by—

a. Removing “Assistant Secretary for Management and Budget” and adding “Assistant Secretary for Administration and Management” in its place each time it appears;

b. Removing “Administration for Children and Families” each time it appears;

c. Removing “Health Care Financing Administration” and adding “Centers for Medicare & Medicaid Services” in its place each time it appears;

d. Removing “Director, Office of Acquisition Management and Policy” in its place each time it appears;

e. Removing “AGF” each time it appears;

f. Removing “HCFA” and adding “CMS” in its place each time it appears;

g. Removing “ASMB” and adding “ASAAM” in its place each time it appears;

h. Removing “DASGAM” and adding “Director, OAMP” in its place each time it appears;

i. Removing “OAM” and adding “Division of Acquisition Policy (DAP)” in its place each time it appears.

PART 302—DEFINITIONS OF WORDS AND TERMS

302.101 [Amended]

3. Amend section 302.101 in the definition of Head of the Contracting Agency (HCA) by removing “FDA—Director, Policy, Evaluation and Support Staff, Office of Facilities, Acquisition and Central Services” and adding “FDA—Director, Office of Acquisitions & Grant Services” in its place.

PART 303—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

4. Add section 303.104–7 to read as follows:

303.104–7 Violations or possible violations of the Procurement Integrity Act.

(a)(1) The contracting officer’s determination that a reported violation or possible violation of the statutory prohibitions has no impact on the pending award or selection of a contractor must be submitted through appropriate channels, along with supporting documentation, to the Head of Contracting Activity (HCA) for review and approval of the determination awarding a contract.

(2) The contracting officer’s determination that a reported violation or possible violation of the statutory prohibitions has an impact on the pending award or selection of a contractor must be referred through channels, along with all related information available, to the HCA (if the HCA is an SES) or to another SES official designated by the OpDiv. That individual will—

(i) Refer the matter immediately to the Office of Acquisition Management and Policy (OAMP). Assistant Secretary for Administration and Management, Office of the Secretary for review, which may consult with the Office of General Counsel (OGC) and the Office of Inspector General (OIG), as appropriate; and

(ii) Determine the action to be taken on the procurement in accordance with FAR 3.104–7(c) and (d). The HCA shall obtain the approval or concurrence of the OAMP before proceeding with the action.

(b) The individual in paragraph (a)(2) of this section acts as the agency head designee with respect to actions taken under the FAR clause 52.203–10, Price or Fee Adjustment for Illegal or Improper Authority.

PART 304—ADMINISTRATIVE MATTERS

5. Revise paragraph (b) of Section 304.7001 to read as follows:

304.7001 Numbering acquisitions.

(a) * * *

(b) Numbering system for contracts. All contracts which require numbering (paragraphs (a)(1) through (3) of this section) shall be assigned a number consisting of the following:

(1) The three digit identification code of the Department (HHS);

(2) A one digit alphabetic identification code of the servicing agency:

O Office of the Secretary
P Program Support Center
M Centers for Medicare & Medicaid Services
F Food and Drug Administration


PART 306—COMPETITION REQUIREMENTS

306.501 [Amended]

6.8. Amend section 306.501 by:

(a) Removing “FDA—Director, Office of Facilities, Acquisition, and Central Services” and adding “FDA—Chief, Office of Shared Services” in its place;

(b) By removing “HCFA—Director, Office of Internal Customer Support” and adding “CMS—Chief Operating Officer”—in its place;

(c) By removing “NIH—(R&D) Director, Office of Extramural Research (Other than R&D)—Director, Office of Intramural Research” and adding “NIH—Senior Advisor for Policy, Office of Extramural Research (R&D) and Senior Advisor to the Deputy Director for Intramural Research (Other than R&D)” in its place.

PART 307—ACQUISITION PLANNING

9. Redesignate paragraph (a)(3) as (a)(4) and add new paragraph (a)(5) to section 307.170–2 to read as follows:

307.170–2 Training course prerequisites.

(a) * * *

(3) Project Officers on HHS projects for which HHS or OMB requires an Exhibit 300 [under OMB Circular A–11, part 7] must successfully complete either HHS’ “Early Warning Project Management System Workshop” or an equivalent Earned Value Management course (see paragraph 307.170(c)).

307.7105 [Amended]

10. In section 307.7105, revise the last sentence of paragraph (a)(6) to read as follows:

307.7105 Format and content.

(a) * * *

(6) * * * Efforts to identify set-aside possibilities, e.g., (b), HUBZone, veteran-owned, service-disabled veteran-owned, and small business, and efforts to identify sources such as small disadvantaged and women-owned small businesses must be documented.

* * * * *
PART 352—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

Subpart 352.2—Texts of Provisions and Clauses

352.224–70 [Amended]

17. In section 352.224–70, remove paragraphs (b) and (f) and redesignate paragraph (c) as (b), paragraph (d) as (c), paragraph (e) as (f), paragraph (g) as (e), paragraph (h) as (f), and paragraph (i) as (g).

352.270–8 [Amended]

18–20. Amend section 352.270–8 in paragraph (a) by removing “Office of Protection from Research Risks (OPRR), National Institutes of Health,” and adding “Office for Human Research Protections (OHRP)” in its place; amend the last sentence of paragraph (d) in section 352.270–8 by removing “National Institutes of Health” and replacing with “OpDiv”; and remove the last sentence of paragraph (e) in section 352.270–8 and add “The contracting officer will direct the offeror/contractor to the OHRP IRB Registration and Assurance Filing website, found at http://www.hhs.gov/ohrp/ or to the physical address if the offeror/contractor cannot access the Internet. HHS regulations for the protection of human subjects may be found at: http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfR46_01.html” in its place.

352.270–9 [Amended]

21–22. Amend section 352.270–9 by removing the heading in paragraph (a) reading “Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects (Sep. 1985)” and adding “Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (Revised 1986, Reprinted 2000)” in its place; and amend section 352.270–9 by removing in the undesignated paragraph under the heading “Office for Protection from Research Risks (OPRR),” and adding “Office of Laboratory Animal Welfare (OLAW)” in its place.

23. Add new section 352.333–7001, to read as follows:

352.333–7001 Choice of Law (Overseas).

As prescribed in 333.215–70, use the following clause:

Choice of Law (Overseas)

This contract shall be construed and interpreted in accordance with the substantive laws of the United States of America. By the execution of this contract, the contractor expressly agrees to waive any rights to invoke the jurisdiction of local national courts where this contract is performed and agrees to accept the exclusive jurisdiction of the United States Armed Services Board of Contract Appeals and the United States Court of Federal Claims for hearing and determination of any and all disputes that may arise under the Disputes clause of this contract.

[FR Doc. 04–27697 Filed 12–30–04; 8:45 am]

DEPARTMENT OF AGRICULTURE
Office of Procurement and Property Management


RIN 0599-AA11

Agriculture Acquisition Regulation: Miscellaneous Amendments (AGAR Case 2004–01)

AGENCY: Office of Procurement and Property Management, USDA.

ACTION: Direct final rule.

SUMMARY: The Department of Agriculture (USDA) is publishing technical amendments to the Agriculture Acquisition Regulation (AGAR) as a final rule. We use the direct final rule process to make non-controversial changes to the AGAR. We are amending the AGAR to update organizational references to USDA components; to update citations to statutes and to Executive Orders; to update or clarify internal procedures; and to reflect changes in the Federal Acquisition Regulation through Federal Acquisition Circular 2001–24.

DATES: This rule will be effective on April 4, 2005, unless we receive written adverse comments or written notice of intent to submit adverse comments on or before February 2, 2005. If adverse comments are received, USDA will publish a timely withdrawal of the rule in the Federal Register.

ADDRESSES: Please submit any adverse comments, or a notice of intent to submit adverse comments, identified by AGAR Case 2004–01 or Regulatory Information Number (RIN) 0599–AA11, by any of the following methods:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

• E-mail: joe.daragan@usda.gov.

Include AGAR Case 2004–01 or RIN 0599–AA11 in the subject line of the message.

• Fax: (202) 720–8972.

• Mail: U.S. Department of Agriculture, Office of Procurement and Property Management, Procurement Policy Division, STOP 9303, 1400 Independence Avenue, SW., Washington, DC 20250–9303.

• Hand Delivery/Courier: U.S. Department of Agriculture, Office of Procurement and Property Management, Procurement Policy Division, Reporter’s Building, 300 7th Street, SW., Room 310A, Washington, DC 20204.

All submissions received must include the agency name and AGAR Case number or RIN for this rulemaking. All comments received will be posted without change to http://www.usda.gov/procurement/policy/agar.htm including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Joseph J. Daragon, (202) 720–5729.

SUPPLEMENTARY INFORMATION:

I. Background

The AGAR implements the Federal Acquisition Regulation (FAR) (48 CFR ch. 1) where further implementation is needed, and supplements the FAR when coverage is needed for subject matter not covered by the FAR. The AGAR is being revised to reflect changes in the FAR made by Federal Acquisition Circulares (FACs) 97–02 through 2001–24 and to implement changes in USDA delegated authorities and internal procedures since October 2001. In this rulemaking document, USDA is making corrections to the AGAR as a direct final rule, since the corrections are non-controversial and unlikely to generate adverse comment. The corrections are clerical or procedural in nature and do not affect the public.

Rules that an agency believes are noncontroversial and unlikely to result in adverse comments may be published in the Federal Register as direct final rules. The Office of Procurement and Property Management published a policy statement in the Federal Register (63 FR 9158, February 24, 1998) notifying the public of its intent to use direct final rulemaking in appropriate circumstances.
(a) Definitions.
“Data,” as used in this clause, means recorded information regardless of form or the medium on which it may be recorded. The term includes technical data and computer software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing or management information.

“Unlimited rights,” as used in this clause, means the right of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose whatsoever, and to have or permit others to do so.

(b) Allocation of Rights.
(i) The Government shall have—
(ii) Unlimited rights in all data delivered under this contract, and in all data first produced in the performance of this contract, except as provided in paragraph (c) of this clause for copyright.
(iii) The right to limit exercise of claim to copyright in data first produced in the performance of this contract, and to obtain assignment of copyright in such data, in accordance with paragraph (c)(1) of this clause.
(iv) The right to limit the release and use of certain data in accordance with paragraph (d) of this clause.

(c) Copyright.
(i) The Contractor agrees not to assert, establish, or authorize others to assert or establish, any claim to copyright subsisting in any data first produced in the performance of this contract without prior written permission of the Contracting Officer. When claim to copyright is made, the Contractor shall affix the appropriate copyright notice of 17 U.S.C. 401 or 402 and acknowledgment of Government sponsorship (including contract number) to such data when delivered to the Government, as well as when the data are published or deposited for registration as a published work in the U.S. Copyright Office. The Contractor grants to the Government, and others acting on its behalf, a paid-up nonexclusive, irrevocable, worldwide license for all such data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the Government.
(ii) If the Government desires to obtain copyright in data first produced in the performance of this contract and permission has not been granted as set forth in subdivision (c)(1)(i) of this clause, the Contracting Officer may direct the Contractor to establish, or authorize the establishment of, claim to copyright in such data and to assign, or obtain the assignment of, such copyright to the Government or its designated assignee.

(d) Release and use restrictions. Except as otherwise specifically provided for in this contract, the Contractor shall not, without prior written permission of the Contracting Officer, incorporate in data delivered under this contract any data not first produced in the performance of this contract and which contain the copyright notice of 17 U.S.C. 401 or 402, unless the Contractor identifies such data and grants to the Government, or acquires on its behalf, a license of the same scope as set forth in paragraph (c)(1) of this clause.

(e) Indemnity. The Contractor shall indemnify the Government and its officers, agents, and employees acting for the Government against any liability, including costs and expenses, incurred as the result of the violation of trade secrets, copyrights, or right of privacy or publicity, arising out of the creation, delivery, publication, or use of any data furnished under this contract; or any libelous or other unlawful matter contained in such data. The provisions of this paragraph do not apply unless the Government provides notice to the Contractor as soon as practicable of any claim or suit, affords the Contractor an opportunity under applicable laws, rules, or regulations to participate in the defense thereof, and obtains the Contractor’s consent to the settlement of
any suit or claim other than as required by final decree of a court of competent jurisdiction; nor do these provisions apply to material furnished to the Contractor by the Government and incorporated in data to which this clause applies.

HHSAR 352.224-70 Confidentiality of Information. (Apr. 1984)

Note: the January 2005 revision deleted paragraphs (b) and (f).

(a) Confidential information, as used in this clause, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

(b) In addition to the types of confidential information described in paragraph (a) of this clause, information which might require special consideration with regard to the timing of its disclosure may derive from studies or research, during which public disclosure of preliminary unvalidated findings could create erroneous conclusions which might threaten public health or safety if acted upon. (deleted Jan. 3, 2005)

(c) The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the “Disputes” clause.

(d) If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

(e) Confidential information, as defined in paragraph (a) of this clause, that is information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization, shall not be disclosed without the prior written consent of the individual, institution, or organization.

(f) Written advance notice of at least 45 days will be provided to the Contracting Officer of the Contractor’s intent to release findings of studies or research, which have the possibility of adverse effects on the public or the Federal agency, as described in paragraph (b) of this clause. If the Contracting Officer does not pose any objections in writing within the 45-day period, the Contractor may proceed with disclosure. Disagreements not resolved by the Contractor and the Contracting Officer will be settled pursuant to the “Disputes” clause. (deleted Jan. 3, 2005)

(g) Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this clause, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

(h) Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

(i) The provisions of paragraph (e) of this clause shall not apply when the information is subject to conflicting or overlapping provisions in other Federal, State or local laws.
Appendix E: Sampling of Critical Language from Requests for Proposal (RFP’s)

PART I - THE SCHEDULE
Request for Proposal

SECTION A - SOLICITATION FORM
No. AHRQ-04-0005
Date Issued: March 15, 2004
Date Due: May 17, 2004
Time Due: 1:00 p.m. local time

SECTION H - SPECIAL CONTRACT REQUIREMENTS

H.1 DATA CONFIDENTIALITY AND SECURITY

(a) This contract entails accessing, processing, and storing data on individuals and organizations that is covered by one or more of the following:

• AHRQ’s system of records number 09-35-0002 published in the Federal Register (Vol. 63, No. 40, March 2, 1998, pp. 10231),
• the FEDERAL AGREEMENT FOR RELEASE OF DATA WITH INDIVIDUAL IDENTIFIERS contained as Appendix F-2 of the HCFA Data Release Policy Guide,
• Appendix III of OMB Circular A-130, or
• Section 903(c) of the Public Health Service Act (42 U.S.C. 299a-1(c)), or

(b) The contractor agrees to provide security, processing, storage, and disposal systems and safeguards sufficient to meet the requirements of the above laws, agreement, and system of records. Additionally, the systems and safeguards shall comply with the HDC Mainframe Users Guide, the NIH Computer Center Users Guide, and the Department of Health and Human Services Automated Information Systems Security Program Handbook, Release 2.0.

(c) The Contractor and his professional staff will take steps to ensure that the intent of this section is enforced at all times through appropriate qualifications standards for all personnel working on this project and through adequate training and quality assurance procedures.

H.2 RESTRICTIONS ON PUBLICATION AND DISSEMINATION OF MATERIAL DERIVED FROM WORK PERFORMED UNDER THIS CONTRACT

Section 903(c) of the Public Health Service Act (PHS Act), 42 U.S.C. 299a-1, states in part that "No information, if the establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under this title, may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented...to its use for such other purpose. Such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented...to its publication or release in other form."

To ensure compliance with these requirements and to fulfill the mandate of 923(b)(1) of the PHS Act, 42 U.S.C. 299c-2(b)(1), to assure that statistics developed with AHRQ support are of high quality, comprehensive, timely, and adequately analyzed, except as otherwise provided in this contract, the Agency for Healthcare Research and Quality (AHRQ) must, prior to dissemination by the contractor, review all reports, presentations, or other disclosures that contain information, statistics, analytical material, or any other material, which is based on or derived from work performed under this contract. Accordingly:

(a) Except as provided in H.1(c), (e), and H.2(d), the contractor will not publish, have published, or otherwise disseminate any material resulting or derived from the work performed for AHRQ-funded research, except in accordance with the terms or conditions required by the Project Officer or until AHRQ has published the results of the research.

(b) AHRQ will, within three months of the receipt of any proposed publication, presentation, or any other disclosure of materials derived from information collected or produced for a particular task order, use best effort to review the proposed report, presentation, or other text to assure that (1) identifiable information is being used for the purpose for which it was supplied; (2) the privacy of individuals supplying the information or described in it is
not violated; and (3) the quality of statistical work meets the statutory standards cited above.

(c) Except as provided in H.1 (e), in the event no written conditions or approval are received from the Project Officer by the end of the three month period following submission of a request (that is accompanied by the proposed text) to publish a report or to make a presentation or other disclosure of material derived from work performed for AHRQ-funded research, the contractor may publish, present, or otherwise disclose this material subject to the restrictions of Section 903(c). However, the contractor must print prominently on the report or any portion of it which is released, or state prior to any oral or other disclosure of material derived from work performed under this contract, the following disclaimer:

"THIS REPORT (or other appropriate description of publication) HAS NOT BEEN APPROVED BY THE AGENCY FOR HEALTHCARE RESEARCH AND QUALITY"

(d) Whether or not written approval of the Project Officer is received, the contractor must:

• print the following statement prominently on written reports or other forms of recorded data derived from work performed under this contract which is to be released; or
• preceding any presentation or other oral disclosure of such material make the following statement:

"IDENTIFIABLE INFORMATION ON WHICH THIS REPORT, PRESENTATION, OR OTHER FORM OF DISCLOSURE IS BASED, IS CONFIDENTIAL AND PROTECTED BY FEDERAL LAW, SECTION 903(c) OF THE PUBLIC HEALTH SERVICE ACT, 42 U.S.C. 299a-1(c). ANY IDENTIFIABLE INFORMATION THAT IS KNOWINGLY DISCLOSED IS DISCLOSED SOLELY FOR THE PURPOSE FOR WHICH IT HAS BEEN SUPPLIED. NO IDENTIFIABLE INFORMATION ABOUT ANY INDIVIDUAL SUPPLYING THE INFORMATION OR DESCRIBED IN IT WILL BE KNOWINGLY DISCLOSED EXCEPT WITH THE PRIOR CONSENT OF THAT INDIVIDUAL."

(e) In cases where the Contracting Officer has given written notice that the Government intends to retain all rights in any particular data produced under this contract, the contractor shall have no right without prior written permission of the Contracting Officer to publish any of those data or analyses based on those data, depending on the scope of the Contracting Officer’s notice.

(f) Whenever data or analyses are to be developed by a subcontractor under this contract, the contractor must include the terms of H.1 (a), (b), (c), (d) and (e) in the subcontract, without substantive alteration, and with a prohibition on the subcontractor engaging in further assignment of its obligations to the contractor. No clause may be included to diminish the Government’s restriction on publication and dissemination of work or material derived from work performed under this contract.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration
Office of Administration & Financial Management
Room 13A-19, Parklawn Building
5600 Fishers Lane
Rockville, MD 20857-5600

May 11, 2006

SECTION H - SPECIAL CONTRACT REQUIREMENTS

H.1. RIGHTS TO DATA

The contractor shall be prohibited from publishing or disseminating data or information associated with the records. All records will be maintained in a secured area and during non work hours locked with no access except for authorized personnel.

H.2. CLEARANCE/PRODUCTION OF INFORMATION PRODUCTS/SERVICES

a. DHHS/Office of the Assistant Secretary for Public Affairs requires clearance for any external publication, audiovisual, exhibit, or public affairs
service produced for or by Health Resources and Services Administration (HRSA) through this contract as a deliverable (an external publication is one of which 50 copies or more are to distributed outside HHS). This clearance, which takes approximately four (4) weeks, is obtained by the Project Officer through HRSA’s Office of Communications.

b. It is the policy of HHS and HRSA that HHS must be prominently and dominantly identified as the primary publisher/producer, to include use of the HHS logo, on all communication materials, including those produced by Contractors (This requirement may be satisfied by displaying the HHS logo on the back cover of a publication). The HRSA logo must be displayed in a position of prominence second only to HHS as the identifier on all communication materials produced on behalf of HRSA, whether by Agency staff, Contractors, or other entities. Communication materials are any and all documents and presentations intended for audiences outside the Agency, including but not limited to:

- Fact sheets, newsletters, brochures, flyers
- Press releases, advisories, other media materials, Internet publications
- Exhibits, posters
- Summaries, monographs, proceedings
- Slides, overhead transparencies, posters
- Audio and videotapes, films

Internal Publications (not more than 50 copies are to be distributed outside HHS) are exempt from this requirement. Where appropriate, the words Division of …, Office…, Bureau…, etc. shall be included below the HRSA logo. Only the Agency Administrator may grant an exception to the policy. Title 44 of the U.S. Code requires that the printing of any publication developed under this contract shall be done by the Government Printing Office. Printing shall be coordinated through the Project Officer.

OMB clearance must be obtained if you intend to survey or interview more than nine (9) people outside of HRSA and/or the Department, including grantees.

SECTION I - CONTRACT CLAUSES

I.1. HHSAR 352.224-70 CONFIDENTIALITY OF INFORMATION (APR 1984)

(a) Confidential information, as used in this clause, includes (1) information or data of a personal nature about an individual, or (2) proprietary information or data submitted by or pertaining to an institution or organization.

(b) In addition to the types of confidential information described in (a)(1) and (2) above, information which might require special consideration with regard to the timing of its disclosure may derive from studies or research, during which public disclosure of preliminary invalidated findings could create erroneous conclusions which might threaten public health or safety if acted upon.

(c) The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential.

Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the “Disputes” clause.

(d) If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

(e) Confidential information, as defined in (a)(1) and (2) above, that is information or data of a personal nature about an individual, proprietary information or data submitted by or pertaining to an institution or organization, shall not be disclosed without the prior written consent of the individual, institution or organization.
(f) Written advance notice of at least 45 days will be provided to the Contracting Officer of the Contractor’s intent to release findings of studies or research, which have the possibility of adverse effects on the public or the Federal agency, as described in (b) above. If the Contracting Officer does not pose any objections in writing within the 45-day period, the Contractor may proceed with disclosure. Disagreements not resolved by the Contractor and the Contracting Officer will be settled pursuant to the “Disputes” clause.

(g) Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this clause, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

(h) Contracting Officer determinations will reflect the results of internal coordination with appropriate program and legal officials.

(i) The provisions of paragraph (e) of this clause shall not apply when the information is subject to conflicting or overlapping provisions in other Federal, State or local laws.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Substance Abuse and Mental Health Services Administration
Division of Contracts Management, OPS
Choke Cherry Road, Room 7-1051
Rockville, MD 20857

Date Issued: May 12, 2006
Date Due: June 12, 2006
Questions Due: May 24, 2006
Intent Notice Due: May 24, 2006
Time Due: 3:00 pm, Local Time

The Substance Abuse and Mental Health Services Administration (SAMHSA), Division of Contracts Management (DCM), invites you to submit a proposal in accordance with the requirements of Request for Proposals (RFP) No. 280-06-0150 for the project entitled “National Resource Center on Homelessness (NRCH)”. The North American Industry Classification System (NAICS) code for this acquisition is 541990.

H.3. PRIVACY ACT

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties. The Contractor shall ensure that each Contractor employee knows the prescribed Rules of Conduct and each Contractor employee knows that he/she can be subject to criminal penalties for violation of the Privacy Act.

The Privacy Act System of Records applicable to this project is 09-30-0049. This document is incorporated into this contract as Attachment 11 in Section J.

The Privacy Act is applicable to the records kept by the Contractor on paying honorarium and/or per diem to Consultants. The Contractor shall destroy these records in accordance with the provisions of the Privacy Act after contract closeout has occurred and the accounting record retention requirements of the Internal Revenue Service and the General Accounting Office have been met.

H.12. OWNERSHIP OF MATERIALS AND DISPOSITION OF DATA

All information and materials including data developed under this contract are the property of the government and shall be delivered as part of the deliverables under the contract. No information developed under this contract shall be released by the contractor without the written permission of the government.

Where automated databases are developed, maintained or regularly updated by the contractor, the Government maintains ownership of all software, manuals, data, data processing, user documentation and any other materials developed by the contractor to manage it. Any software developed to manage or enhance these data must be fully documented and the documentation provided to the Government. Any required transfer of the data will be effected in such a way that the database will be immediately available without interruption.
H.19. OMB CLEARANCE

The Contractor shall not collect or record any information calling for answers to identical questions from more than nine (9) persons or organizations. This approval must be obtained before expenditure of funds or public contacts for the actual acquisition of the information. This applies to questionnaires, electronic transmission requirements, etc., regardless of whether the information collection occurs by mail, person or telephone interview or group interviews (e.g., focus groups). It does not matter whether the response is voluntary or mandatory. Information collection may begin only after the Contracting Officer notifies the Contractor in writing that OMB clearance has been obtained.

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Acquisition and Grants Group
Division of Beneficiary Support Contracts

Date: May 9, 2006

To: All Potential Offerors

Subject: Medicare Consumer Assessments of Healthcare Providers Survey (CAHPS)
Solicitation No. RFP-CMS-2006-0009

H.2 352.224-7 Confidentiality of Information (APR 1984)

a. Confidential information, as used in this clause, mean (1) information or data of a personal nature about an individual, or (2) proprietary information or data submitted by or pertaining to an institution or organization.

b. In addition to the types of confidential information described in a. (1) and (2) above, information which might require special consideration with regard to the timing of its disclosure may derive from studies or research, during which public disclosure of preliminary invalidated findings could create erroneous conclusions which might threaten public health or safety if acted upon.

c. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

d. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

e. Confidential information, as defined in a. (1) and (2) above, that is information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization, shall not be disclosed without the prior written consent of the individual, institution, or organization.

f. Written advance notice of at least 45 days will be provided to the Contracting Officer of the Contractor's intent to release findings of studies or research, which have the possibility of adverse effects on the public or the Federal agency, as described in b. above. If the Contracting Officer does not pose any objections in writing within the 45-day period, the Contractor may proceed with disclosure. Disagreements not resolved by the Contractor and the Contracting Officer will be settled pursuant to the "Disputes" clause.

g. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this clause, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

h. Contracting Officer determinations will reflect the results of internal coordination with appropriate program and legal officials.
i. The provisions of paragraph e. of this clause shall not apply when the information is subject to conflicting or overlapping provisions in other Federal, State or local laws.

H.10 Restrictions on the use of Information

The access to and use of data/information under this contract shall be in accordance with FAR clause 52.224-2, Privacy Act.

Any Contractor personnel, consultant, or subcontractor employee having access to Privacy Act covered data/information shall be required to execute a “Statement of Understanding.”

FAR clause 52.224-2, Privacy Act:

PRIVACY ACT (APR 1984)

(a) The Contractor agrees to--

(1) Comply with the Privacy Act of 1974 (the Act) and the agency rules and regulations issued under the Act in the design, development, or operation of any system of records on individuals to accomplish an agency function when the contract specifically identifies--

(i) The systems of records; and

(ii) The design, development, or operation work that the contractor is to perform);

(2) Include the Privacy Act notification contained in this contract in every solicitation and resulting subcontract and in every subcontract awarded without a solicitation, when the work statement in the proposed subcontract requires the design, development, or operation of a system of records on individuals that is subject to the Act; and

(3) Include this clause, including this subparagraph (3), in all subcontracts awarded under this contract which requires the design, development, or operation of such a system of records.

(b) In the event of violations of the Act, a civil action may be brought against the agency involved when the violation concerns the design, development, or operation of a system of records on individuals to accomplish an agency function, and criminal penalties may be imposed upon the officers or employees of the agency when the violation concerns the operation of a system of records on individuals to accomplish an agency function. For purposes of the Act, when the contract is for the operation of a system of records on individuals to accomplish an agency function, the Contractor and any employee of the Contractor is considered to be an employee of the agency.

(c)(1) "Operation of a system of records," as used in this clause, means performance of any of the activities associated with maintaining the system of records, including the collection, use, and dissemination of records.

(2) "Record," as used in this clause, means any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, education, financial transactions, medical history, and criminal or employment history and that contains the person's name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a fingerprint or voiceprint or a photograph.

(3) "System of records on individuals," as used in this clause means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.