University of California
Office of the President

Senior Vice President—
Business and Finance

Research Administration Office

Memo
Operating Guidance

No. 00-02

March 22, 2000

CONTRACT AND GRANT OFFICERS (CAMPUS AND LAB)*
VICE CHANCELLORS--RESEARCH
INFORMATION PRACTICES COORDINATORS

Subject: OMB Circular A-110 Revision: Release of Research Data Requested by the Public under Federal Grants via Federal Freedom of Information Act Procedures

Purpose

This Memo provides guidance about implementing the requirements of the A-110 final rule issued by OMB in the Federal Register on October 8, 1999 regarding release of research data, and the Agency common rule issued in the Federal Register on March 16, 2000. The Agency common rule simply incorporates the Final Rule issued by OMB in Agency Codes of Federal Regulations without Agency supplement regarding their respective operational implementation

This Memo finalizes and replaces Interim Contract and Grant Memo No. 99-08 issued December 20, 1999.

NIH did issue important Agency operational implementation and guidance on December 14, 1999 on the www: http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm, hardcopy enclosed. This Memo relies on the NIH Guidance and generalizes its practical applicability to all Federal Agencies, since there is no equivalent from other Agencies at this time.

Please submit questions or issues to RAO as they arise so we can develop a coordinated UC implementation. RAO will work closely with OP Office of Research, Allison Rosenberg, and Information Practices Coordinator Ross Smith in Office of General Counsel.

Background

Senator Shelby included a provision in Public Law 105-277 which directed "OMB to amend Section___.36, Intangible Property, of Circular A-110 to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act (FOIA).

OMB published the Final Revision to A-110 to implement Public Law 105-277 in the Federal Register dated October 8, 1999. A copy may also be obtained from: www.whitehouse.gov/OMB/fedreg/a110-finalnotice.html

*Note: The addressees above represent the standard distribution of Contract and Grant Memos. Additional addressees, if any, may be added based on the subject of the Memo. See cc's.

It is important to note that "OMB recognizes the importance of ensuring that the revised Circular does not interfere with the traditional scientific process." This is reflected in the care with which definitions were developed.

Guidance

The NIH guidance, including the Q & A, is quite comprehensive and well thought out. There will be additional questions and issues as the implementation unfolds for NIH, other Federal Agencies and UC.

The NIH guidance is limited to releases under the Federal Freedom of Information Act (FOIA). The University is also subject to the California Public Records Act (CPRA). If a request from the public is for research data that are (1) first produced in a project that is supported in whole or in part with Federal funds, and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law, then the procedures in the NIH guidance should be followed, whether or not the requestor cited the FOIA or the CPRA. If the request is for data that do not meet the above criteria, it should be processed under the CPRA.

University Responsibilities

a. University Coordination Points

The University has Information Practices Act (IPA) Coordinators on each campus are responsible for handling requests from the public pursuant to the California Public Records Act. It is recommended that IPA Coordinators be assigned the responsibility for handling/coordinating requests for release of research data from Federal agencies pursuant to the A-110 revision.

The NIH guidance provides for NIH to send copies of the request to the Sponsored Research Office and the principal investigator. We recommend that a copy of the notice be sent by the campus Sponsored Research Office to the campus IPA Coordinator upon receipt.

a. University Screening.

Incoming requests from Federal agencies should be screened by the University using the same criteria used for Federal screening as described in the NIH guidance. If the Agency request does not provide the information required or the request is invalid, the IPA Coordinator should go back to the Agency to obtain the information before it is forwarded to the Department.

b. Responsibility to define and provide research data.

- The responsibility for responding to the agency request rests with the University. However, the University's ability to respond, depends, in major part, on the availability of the PI who performed the research, and the availability of the research data.

- The PI who performed the research under the Federal grant is responsible for determining: the scope of the incoming request, the research data within the scope, what data is within the A-110

definition of research data, whether the publication criteria specified by A-110 have been met, the location of the data, and arranging for the copying of the data. If there is more than one PI on one or more UC campuses, or subawards to non-UC research entities, these PIs may have to be identified and contacted as well.

- If the PI who performed the research is unavailable, then the responsibility falls on the Department Chair to prepare the response. This assumes the research data is available to the Department. If the PI has transferred to another institution, and has taken the research data with him/her, the request from the agency should be returned to the Agency with information as to how to locate the PI.

- If the research data cannot be found, the FOIA and CPRA requires that a diligent search be done and a good faith effort be made to comply.

- Research data refers to raw data. In making decisions about what is required to be provided, the obligation is limited to providing the raw data. There is no obligation to create a new document which arranges, organizes, documents, or indexes the data.

c. Estimating costs.

The Department is also responsible for developing a cost assessment to respond to the agency request. NIH guidance states that information will be provided in the near future about estimating costs. Section - __ .36 (d)(1) states in part: "If the Federal awarding agency obtains the research data solely in response to a FOIA request, the agency may charge the requester a reasonable fee equaling the full incremental cost of obtaining the research data. This fee should reflect costs incurred by the agency, the recipient, and applicable subrecipients. This fee is in addition to any fees the agency may assess under the FOIA (5 U.S.C. 552(a)(4)(A))." The University's experience in responding to requests under the CPRA will be considered together with NIH guidance. Please consult with the campus IPA Coordinator if costs need to be estimated.

Please note the NIH guidance provides for the University to submit a cost estimate to the Federal agency, for approval by the public requestor, before the University is obligated to incur the expense and effort to collect and make the research data available.

d. Record retention.

A-110 requires financial records supporting charges to grants to be retained for "a period of three years from the date of submission of the final expenditure report" under the grant. However, the Federal right of access to records is "not limited to the required retention period (three years) but shall last as long as the records are retained. " So research data must be retained for a minimum of three years, and if kept longer, is required to be provided in response to public requests as long it is retained.

Questions regarding the interpretation of the A-110 data release requirement may be referred to the Campus IPA Coordinator, Campus Vice Chancellor for Research, or OP Research Administration Office, OP Vice Provost for Research, and Office of General Counsel.

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Cancel: C&G Memo 99-08

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Enclosure

cc: Executive Director Bennett
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To NIH Grantees and Applicants: Notice Of Amendment To A-110

Introduction

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access under some circumstances to research data through the Freedom of Information Act (FOIA). The effective date of the revised Circular is November 8, 1999; the guidance that NIH will impose on grantees will be effective pending publication of revised 45 CFR 74, which is expected in early 2000. Amended A-110 is applicable to new and competing continuation awards made after that date. It is important for grantees to understand the basic scope of this amendment and to plan for implementation. NIH encourages sharing of research data. Nothing in the A110 amendment should affect ongoing data sharing plans.

The revised circular applies to data that are (1) first produced in a project that is supported in whole or in part with Federal funds, and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law.

The guidance presented below explains how access would be achieved when a request is made under this amendment. We will use the News Flash page of the NIH web site to update information as we gain experience with the implementation process. (See http://www.nih.gov/grants/news.htm

Below we provide additional information related to this amendment on:

- Applicability
- Definitions
- Overview of Process
- Frequently Asked Questions (FAQs)

To see the full text of the A-110 amendment, see Federal Register, Volume 64(195) at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=1999_register&docid=99-26264-filed

Applicability:

The amendment to OMB Circular A-110 applies only to data produced with Federal support that are cited publicly and officially by a Federal agency in support of an action that has the force and effect of law.

Agency actions that have the force and effect of law include:

- Regulations
- Administrative orders

This amendment applies to data that are first produced in a project that is supported exclusively with Federal funds or in a project with both Federal and non-Federal support.

The amendment applies only to data first produced under a competing award issued after the effective date.

It applies to data collected by institutions of higher education, hospitals, and non-profit institutions that

receive grants and other financial assistance provided by Federal agencies.

It does not apply to data collected by commercial organizations.
It does not apply to most data collected by State and local governments.

It applies to new and competing continuation awards that are made after the effective date of the amendment. This is to say, it applies to Type 1 and Type 2 grants (i.e., new and competing continuations) as well as Type 3 (competitive supplements) awards made after the effective date. It does not apply to Type 5 (i.e., non-competing continuations) awards. Amended A-110 does not apply to data collected under contracts, but contract data can be accessed through FOIA (independent of A-110) if in the possession of a government agency.

For data that are already available to the public through an archive or other source, requestors will be referred directly to the public source.

Definitions:

The term, **Research Data,** is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings.

It does not include:

- preliminary analyses
- drafts of scientific papers
- plans for future research
- peer reviews
- communications with colleagues
- physical objects (e.g., laboratory samples, audio tapes, video tapes)
- trade secrets
- commercial information
- materials necessary to be held confidential by a researcher until publication in a peer-reviewed journal
- information which is protected under the law (e.g., intellectual property)
- personnel and medical files and similar files, the disclosure of which would constitute unwarranted invasion of personal privacy
- information that could be used to identify a particular person in a research study.

Published is defined as when either:

a. research findings are published in a peer-reviewed scientific or technical journal; OR
b. a Federal agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law.

Overview of Process:

- The requestor prepares a FOIA request. The request must include:
    - The specific regulation or administrative order citing the data being requested;
    - The publication cited in the regulation or administrative order;

- The grant number under which the data were produced;
  (Information on grants, including grant numbers, is available on the NIH web site in CRISP)
- A specific description of the data being sought;
- A statement that the data are being requested under the amendment to Circular A-110 (45 CFR 74.36).

- NIH asks the requestor to send the request to the FOIA coordinator for the NIH Institute or Center (IC) funding the grant. A list of IC FOIA coordinators is provided on the NIH FOIA web page. (See http://www.nih.gov/od/foia/index.htm)
- The FOIA coordinator for the funding IC processes the request.
- The FOIA coordinator notifies the funding IC's grants management office and sends a letter to the Office of Sponsored Research at the grantee institution with a copy to the Principal Investigator notifying them about the request. Included with that letter will be guidance provided by the NIH FOIA office on how to

  respond to this request.
- If the data are already available to the public through an archive or other source, the A-110 amendment allows the FOIA coordinator to direct the requestor to the public source. And the process stops here.
- However, if the data are not publicly available, the process continues as follows.
- The amendment to A-110 provides for a reasonable fee to cover costs incurred in responding to the request. The fee will include both the costs to the NIH and the costs incurred by the grantee institution, which will be accounted for separately. To accomplish this, the FOIA coordinator:

  - Asks the grantee institution to estimate cost of providing the data; and
  - Tells the requestor the estimated cost of producing the data.
  - If the requester has a history of not paying for costs related to either FOIA or A-110 or if the estimated cost is greater than $250, then prepayment will be requested.

- Under the A-110 amendment, the grantee institution and the investigator are required to provide data that are consistent with the definition of research data (see definitions above) and deemed responsive to the request.
- Prior to sending the data to the appropriate NIH FOIA coordinator, the grantee institution and the investigator redact the data to remove personal identifiers and other information in accordance with amended A-110 definitions (see above) and FOIA procedures.
- The grantee institution transmits the data to the FOIA coordinator of the funding IC along with an accounting of all associated costs.
  NIH will develop guidance on how to estimate associated costs.
- The FOIA coordinator and a knowledgeable program official from the funding IC review the submitted data.
- The FOIA coordinator responds to the requestor, issues a final invoice for the fees, and transmits the data.

Frequently Asked Questions:

Q: For the past five years, an NIH-supported study has been collecting data on traffic-related deaths. In June, 1999, this study was cited in a federal regulation. Can the underlying data be requested under the A-110 amendment?

A: No. Only data collected under grants awarded after the effective date of the amendment are

affected.

Q: How should telephone calls requesting data under the A-110 amendment be handled?
A: All investigators are free to share their data if they so choose. In doing so, all parties should be aware of the need to adhere to human subjects protections, including the >protection of confidentiality. However, when a request will be addressed through amended A-110, the caller should be referred to the FOIA office at the funding NIH Institute or Center.

Q: Do Certificates of Confidentiality protect against a request for data under FOIA or the A-110 amendment?
A: No. A Certificate of Confidentiality protects identifying information of subjects. It does not exempt the entire data set. However, it should be noted that identifying information is also protected under FOIA as well as under the A-110 amendment.

Q: Are data collected under an SBIR or STTR accessible through the A-110 amendment?
A: No, commercial organizations are exempted.

Q: What happens if a FOIA request is made for data that are available to the public in an archive?
A: The FOIA officer will refer the requester to the archive where the data are available.

Q: I am an investigator working on a topic that is often cited in regulations. Therefore, I would like to plan to archive the data to be collected in my next project. Can I request funding in the application to archive the resulting data?
A: Yes. You should describe the archiving plan in the study design and include information about this in the budget justification section of the application.

Q: Besides archiving, what other things should I be thinking about?
A: You may also want to think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

Q: How long does NIH require data to be stored after a project is completed?
A: For three years after the submission of the financial status report.

Q: Does that mean that data are only accessible for three years after the close out of the grant?
A: No. If an investigator or grantee institution chooses to keep records longer than three years, then they must be made available in response to a request under the A-110 amendment.

Q: What happens if the PI has moved?
A: Research grants are awarded to Institutions, not individuals. The FOIA office will send the request for data to the Office of Sponsored Research at the grantee institution and will send a copy to the PI. The FOIA office will work with the grantee institution to locate PI and to fulfill the request for data.

Q: What happens if either the investigator or grantee institution refuses to comply with the request?
A: This would be viewed as a material failure to comply with the terms and conditions of award, and NIH would initiate appropriate enforcement action. This could result in withholding of future support or imposing additional restrictive terms and conditions of award to the grantee institution.

Q: A research project has just received a very small amount of support from the NIH as well as a much larger award from a private foundation. Thus, the data will be produced with the combined

support. Would the data be accessible under the A-110 amendment?
A: Yes. As long as the data collection occurred with some Federal support, regardless of level or amount, the grantee institution would be required to provide those data.

Q: Can data collected under a training grant be requested under the A-110 amendment?
A: This is a complex issue, and so the answer is maybe. Fellowships are awarded to individuals, not institutions. Therefore, data collected under fellowship grants may be exempted. If data are collected under a training grant awarded to an institution of higher education, hospital, or other non-profit institution, are published, and are cited in a regulation, the data would be accessible under the A-110 amendment. If a trainee works on a research project that is not Federally funded, the data associated with that non-Federal award could not be requested under the amendment to A-110.

Q: A competing continuation for a longitudinal study will be renewed after the effective date or the A-110 amendment. This will pay for years 9 through 12 of data collection. Are the data collected in years 1 through 8 accessible under this amendment?
A: No. The only data that are accessible are those collected under the award issued after the effective date of the A-110 amendment.

Q: The State Health Department received a grant to study emphysema. Are the resulting data accessible under amended A-110?
A: If the State Health Department collected those data, they are not accessible under this specific provision. However, if the State Health Department contracted data collection to an institution of higher education or other non-profit organization, then the data would be accessible.

Q: An abstract was published in the Report of 10th Annual Meeting of Snail Physiologists and cited in a Federal regulation. Are those data accessible under amended A-110?
A: It depends. If the abstract is based on preliminary analyses (as abstracts often are), then the data would be excluded since they do not fit the amended A-110 definition of research data. However, if the abstract is not based on preliminary analyses and is cited by a Federal agency in a regulation, then the data may be accessible.

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