

## 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](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 of 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 10<sup>th</sup> 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.