

OMB Circular A-110: Amended for Freedom of Information Act (FOIA) Access to Research Data

Purpose:

The purpose of this document is to provide the campuses with corporate guidance for implementing the amended OMB Circular A-110. Circular A-110 was revised to provide public access to research data, under certain circumstances, through the Freedom of Information Act (FOIA). Campuses should use this guidance to understand the basic scope of the amendment, develop implementation and communication plans, and to inform principal investigators about the potential impact on their research data. In summary, this document provides guidance on these topics:

- effective date and applicability
- agency implementation
- campus and central office contacts
- definitions
- technology transfer implications
- scientific discretion exclusions
- cost reimbursement
- FAQs
- references

Effective Date and Applicability:

The effective date of the amended Circular A-110 is November 8, 1999. *The amendment applies to*:

- new and competing continuation awards made after the effective date.
- research data first produced in a project that is supported exclusively with federal funds, or in a project with both federal and non-federal support.
- research data cited publicly and officially by a federal agency in support of an action that has the force and effect of law (e.g., regulations, administrative orders).

The amendment does not apply to:

- research data collected under contracts because contract data can be accessed through FOIA (independent of Circular A-110) if the data is in the possession of a federal agency.
- note: for research data already available to the public through an archive or other source, requestors will be referred directly to the public source.

Agency Implementation:

The federal agencies need to implement the Circular A-110 amendment into their individual code of regulations. This implementation and codification will take time. It is important to note

that until an agency codifies the Circular amendment, FOIA requests for the release/disclosure of research data do not need to be fulfilled.

Campus and Central Office Contacts:

• For the campus, the RF recommends the campus (e.g., sponsored research office) be the initial point-of-contact for principal investigators that have

questions concerning the Circular A-110 amendment. Campuses should inform principal investigators that they should not respond directly to any

request for the release/disclosure of research data. Principal investigators should be advised to inform the sponsored research office of any requests

they receive directly.

• For central office, the RF recommends the campus contact Christopher J. Hanifin, Esq., Acting Vice President for Legal Affairs and General Counsel at Central Office for clarification, guidance, and assistance with requests for the release/disclosure of research data. Chris can be reached by phone at

518-434-7045, by fax at 518-434-8352, or by e-mail at christopher.hanifin@rfsuny.org.

Definitions:

The primary definitions included in the amended Circular A-110 are *research data* and *published*.

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

Research data does not include, for example, preliminary analyses, drafts of scientific papers, or plans for future research. The complete list of

exclusions is in NIH's Guidance to Grantees, it is available at:

https://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm

• *Published* is defined as research findings that are published in a peer-reviewed scientific or technical journal, or when a federal agency publicly and

officially cites the research findings in support of an agency action that has the force and effect of law.

Technology Transfer Implications:

The final amendment did not provide quite the assurance educational institutions wanted. However, the Circular A-110 amendment does exclude "trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, *or similar information which is protected under law*."

Scientific Discretion Exclusions:

Principal investigators may apply individual scientific discretion in reviewing research data prior to release/disclosure - in addition to the usual FOIA exemptions. The sponsored research office should carefully review the agency regulation codification of the Circular A-110 amendment for the scientific discretion "exclusion option" prior to releasing any data.

Cost Reimbursement:

Educational institutions need to gain experience in complying with FOIA requests for the release/disclosure of research data - especially with the methods for cost reimbursement. Guidance for cost reimbursement will be developed once the campuses and central office become familiar with the release/disclosure of data.

FAQs:

This is a sample of some grantee frequently asked questions. The questions are developed from NIH guidance and other sources, and the answers have been tailored slightly to stress certain impact areas for the campuses.

Q: How should telephone calls requesting research data under the Circular A-110 amendment be handled?

A: Principal investigators should contact the sponsored research office before releasing/disclosing research data. Investigators certainly are free to share their research data if they choose, however caution is advised - especially with respect to data related to the special protection areas (e.g., human/animal subjects, hazardous materials, recombinant DNA molecules), and application of the scientific discretion option.

Q: How might research data become subject to release/disclosure?

A: A requestor can ask the funding agency to obtain the research data. All requests for the release/disclosure of data must meet the requirements of the Circular A-110 amendment. The funding agency will contact the grantee institution and request the research data. Data that meets the definitions and requirements must be released to the funding agency within a "reasonable time". The agency will screen the research data, apply any of the applicable FOIA exemptions, and release the qualifying data to the requestor.

Q: What happens if an institution refuses or fails to comply?

A: Refusal or failure to comply with a request would be viewed as a material failure, and the agency would initiate appropriate enforcement action(s). Enforcement actions could result in withholding future support, or imposing additional restrictive award terms and conditions to the entire grantee institution.

Q: Do Certificates of Confidentiality protect against a request for research data under FOIA or the Circular 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 and the Circular A-110 amendment.

Q: Besides archiving, what other areas should be considered?

A: How to structure and design informed consent statements and other human subject procedures are areas for consideration, especially for IRB's (Institutional Review Boards) – given the potential for wider use of research data collected under an award.

Q: How long is research data required to be stored after a project is completed?

A: Research data must be stored for 3 years after submission of the final financial status report, unless the institutional policy for records establishes longer retention periods. It should be noted that FOIA requests for the release of research data can be made in accordance with the retention time periods in the institutions records policy. For example, if an institution's records policy establishes a 10-year retention, those records are accessible for release/disclosure under a FOIA request.

Q: What happens if the principal investigator has moved?

A: It is important to remember that research grants are awarded to institutions, not to individuals. The FOIA office at the federal agency will send the request for research data to the grantee institution's sponsored research office, and will copy the principal investigator. The FOIA office will work with the grantee institution to locate the principal investigator to fulfill the request for the data.

Q: Can data collected under a training grant be requested under the Circular A-110 amendment?

A: Maybe - this is a complex issue. Fellowships are awarded to individuals not institutions, and data collected under fellowship grants may be exempted. If data collected under a training grant awarded to an institution of higher education, a hospital, or other non-profit institution; are published and are cited in a regulation, the data would be accessible under the Circular 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 Circular A-110 amendment.

References

These are several electronic sources for background, and additional information and guidance on the Circular A-110 amendment. Circular A-110 amendment, Federal Register final rule (64 FR 54926, October 8, 1999):

- <u>https://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=1999_register&docid=99-26264-filed</u>
 NIH Guidance to Grantees and Applicants, December 14, 1999:
- https://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm

Note: This is NIH guidance only, agency implementation and codification is expected early in 2000.