

2. Research is reviewed by the IRB in accordance with the limited IRB review as described 34 CFR 97.104(d)(2)(iii); or

3. Research that is part of the IRB-approved study that has progressed to the point that it involves only one or both of the following:

i. data analysis, including analysis of identifiable private information or identifiable biospecimens, or

ii. accessing follow-up clinical data from interventions that subjects would undergo as part of clinical care.

(1) For each activity under this contract that requires continuing review, the Contractor shall submit an annual written representation to the CO or COR stating whether research activities have been reviewed and approved by the IRB within the previous 12 months. The Contractor may use the form titled "U.S. Department of Health and Human Services (HHS) Subpart C Certification Form" for this representation. For multi-institutional projects, the Contractor shall provide this representation on its behalf and on behalf of any subcontractor engaged in research activities for which continuing IRB reviews are required.

(2) If the IRB disapproves, suspends, terminates, or requires modification of any research activities under this contract, the Contractor shall immediately notify the CO in writing of the IRB's action.

(e) The Contractor shall bear full responsibility for performing, as safely as is feasible, all activities under this contract involving the use of human subjects and for complying with all applicable regulations and requirements concerning human subjects. Neither the Contractor, subcontractor, agents of the Contractor, or employees of the Contractor, nor any person, organization, institution, or group of any kind involved in the performance of such activities under this contract, shall be deemed to constitute an agent or employee of the Department or of the Federal government with respect to such activities. The Contractor agrees to discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent contractor without imputing liability on the part of the Government for the acts of the Contractor, subcontractor, or their employees.

(f) Upon discovery of any noncompliance with any of the requirements or standards as stated in this clause, the Contractor shall correct such noncompliance as soon as practicable, typically no later than 1 business day. If the CO determines, in consultation with the Protection of Human Subjects Coordinator, Office of Acquisition, Grants, and Risk Management, Office of Finance and Operations, or the sponsoring office, that the Contractor is not in compliance with the requirements or standards stated in this

clause, the CO may suspend work under this contract, in whole or in part, until it is determined that the Contractor has corrected such noncompliance and the CO authorizes the continuation of work.

1. Initial notice of suspension. The initial notice of suspension under this clause may be communicated orally or in writing by the CO.

2. Notice of suspension of work. The CO shall provide written notice of suspension of work under this clause. The notice shall contain the following:

a. The effective date of suspension of work.

b. The requirements and/or standards for which the Contractor is out of compliance.

c. Any special instructions for the suspension of work.

3. Authorization to resume work. If the CO determines that the noncompliance has been remedied and it is in the best interest of the Government, the CO may authorize work to resume under the contract. The CO will provide written notice to the Contractor of such authorization.

(g) Non-compliance with the requirements or standards as stated in this clause may result in the Government termination of this contract for default, in full or in part, in accordance with FAR 49.401. Such termination may be in lieu of or in addition to suspension of work under the contract. Nothing herein shall be construed to limit the Government's right to terminate the contract for failure to fully comply with such requirements or standards.

(h) The Regulations, and related information on the protection of human research subjects, can be found on the Department's protection of human subjects in research website: <https://www2.ed.gov/about/offices/list/ocfo/humansub.html>.

Contractors may also contact the following office to obtain information about the regulations for the protection of human subjects and related policies and guidelines: Protection of Human Subjects Coordinator, U.S. Department of Education Office of Finance and Operations, Office of Acquisition, Grants, and Risk Management, 400 Maryland Avenue SW, Washington, DC 20202-4331. Email: HumanSubjectsResearch@ed.gov.

(End of clause)

3452.224-73 Protection of student privacy in compliance with FERPA.

As prescribed in 3424.704, insert the following clause in solicitations and contracts:

PROTECTION OF STUDENT PRIVACY IN COMPLIANCE WITH FERPA (OCT 2023)

(a) Pursuant to the Family Educational Rights and Privacy Act (FERPA), 20 U.S.C.

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1232g, and its implementing regulations, 34 CFR part 99, the Department designates the Contractor to serve as an authorized representative of the Secretary of Education, solely for the purpose of carrying out an audit or evaluation of federally supported education programs, the enforcement or compliance with Federal legal requirements that relate to federally supported education programs, or conducting a study for or on behalf of the Department, to develop, validate, or administer predictive tests, administer student aid programs, or improve instruction, as specified in the statement of work, the schedule, and other similar documents to the contract.

(b) The Contractor shall collect or receive access to the following personally identifiable information from student education records that is protected by FERPA: [specify the PII from student education records to be collected or accessed by the Contractor, as identified by the requiring activity] (collectively, the PII).

(c) The Contractor shall only use the PII to meet the purpose set forth in paragraph (a) of this clause and for the activity, scope, and duration specified in the statement of work, the schedule, and other similar documents to the contract. Prior to collecting or receiving access to the PII, the Contractor shall establish policies and procedures, consistent with FERPA and other Federal confidentiality and privacy provisions, to protect the PII from further disclosure (except back to the Department) and unauthorized use, including limiting use of the PII to only authorized representatives with legitimate interests in the purpose set forth in paragraph (a) of this clause.

(d) To the extent required to ensure the Contractor's compliance with the provisions of FERPA and other Federal provisions, the Contractor shall afford the Department and its authorized agents access to all of the facilities, installations, technical capabilities, operations, documentation, records, databases, policies, procedures, and systems of the Contractor and any subcontractor.

(e) The Contractor shall limit access to the PII to the Contractor's personnel who require the PII to satisfy the Contractor's obligations under the contract.

(f) If the Contractor collects or receives access to the PII to conduct a study for, or on behalf of, an educational agency or institution, then the Contractor shall conduct such study in a manner that does not permit personal identification of parents and students by anyone other than representatives of the Contractor, or subcontractors, with legitimate interests in the study.

(g) Once the purpose for which the PII was collected or accessed is fully satisfied, the Contractor shall notify the Department immediately and seek the Department's in-

struction and authorization regarding destruction of the PII in accordance with law.

(h) If the Contractor subcontracts any of the contract work requiring collection or access to the PII, then the Contractor shall include this clause (including this paragraph (h)) in any such subcontract and, further, the Contractor shall ensure that subcontractors at any tier comply with all terms, conditions, and obligations imposed on the Contractor herein and under FERPA.

(i) Violation by a subcontractor of any provision set forth in this clause will be attributed to the Contractor.

(End of clause)

3452.227-70 Publication and publicity.

As prescribed in 3427.409, insert the following clause in all solicitations and contracts other than purchase orders:

PUBLICATION AND PUBLICITY (MAR 2011)

(a) Unless otherwise specified in this contract, the contractor is encouraged to publish and otherwise promote the results of its work under this contract. A copy of each article or work submitted by the contractor for publication shall be promptly sent to the contracting officer's representative. The contractor shall also inform the representative when the article or work is published and furnish a copy in the published form.

(b) The contractor shall acknowledge the support of the Department of Education in publicizing the work under this contract in any medium. This acknowledgement shall read substantially as follows:

"This project has been funded at least in part with Federal funds from the U.S. Department of Education under contract number [Insert number]. The content of this publication does not necessarily reflect the views or policies of the U.S. Department of Education nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government."

(End of clause)

3452.227-71 Advertising of awards.

As prescribed in 3427.409, insert the following clause in all solicitations and contracts other than purchase orders:

ADVERTISING OF AWARDS (MAR 2011)

The contractor agrees not to refer to awards issued by, or products or services delivered to, the Department of Education in commercial advertising in such a manner as to state or imply that the product or service