Interim Research Terms and Conditions for Grants and Cooperative Agreements Awarded by EPA's Office of Research and Development (December 2014)

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OMB Uniform Guidance

Overview

The EPA interim research terms and conditions apply to research grants and cooperative agreements awarded by the Office of Research and Development. The interim research terms and conditions will not apply to research centers, conferences, training projects, fellowships, or awards made as part of the People, Prosperity, and the Planet (P3) program.

EPA implementation of the research terms and conditions includes the applicable EPA general terms and conditions.

1. General. As a result of this agreement, the recipient agrees to provide to EPA's Office of Research and Development (ORD) annual progress reports with associated summaries, and a final report with an executive summary along with a copy of any papers resulting from the research conducted.

A. Annual Progress Reports. The recipient agrees to submit annual progress reports to the EPA Project Officer within 90 calendar days after the end of each reporting period. If the agreement was partially funded, so that an additional increment of funding is to be provided, EPA may elect to not provide further funding until the recipient has submitted the required annual progress report. EPA may withhold payment if progress reports are not submitted by the due date. In addition, if EPA determines that the recipient has not made sufficient progress toward completing its research, EPA may terminate the assistance agreement. Sufficient progress is demonstrated by the grantee meeting the project schedule and milestones described in the approved research plan to the maximum extent practicable, while taking into account any extenuating factors that may have delayed progress. The reporting period begins at the project start date, or, for subsequent years, on the annual anniversary of the start date. The reports should generally not exceed five 81/2 X 11 pages, exclusive of the summary discussed below.

These reports shall include:

(1) Brief statements covering work status, work progress, preliminary data, results, and evaluations made during the reporting period, including a comparison of actual accomplishments with the goals and objectives (outputs/outcomes) for the period. Address difficulties you have encountered (or might encounter) in carrying out this project and remedial actions (to be) taken. If the goals of the project have not changed from the original application, state this. If these have been modified, provide the revised goals and discuss the reason for the

modification. Discuss any problems, delays, or adverse conditions which may materially impair the ability to meet the results (outputs/outcomes) specified in the application. If the work includes human subjects research, provide the status of required approvals [Institutional Review Board (IRB) and EPA Human Subjects Research Review Official (HSRRO) final approval]. Where appropriate, provide the date the annual IRB approval materials and/or approved IRB amendment materials were sent to the Project Officer.

(2) A discussion of any absence or changes of key personnel involved in the project.

(3) A discussion of expenditures to date along with an explanation of any costs which are significantly higher or lower than originally estimated. Revised budget information will be required under this agreement if any significant changes in the size or scope of the project or in the originally-negotiated total estimated costs are anticipated for the project period.

(4) Statements addressing how the quality assurance requirements of 2 CFR 1500.11 and the agreement are being met, especially focusing on the system in place that assures the quality of environmental measurements, data generation and use.

(5) Results (outputs/outcomes) to date, emphasizing findings and their significance to the field, their relationship to the general goals of the award, their relevance to the agency's mission, and their potential practical applications.

(6) Assurance that research misconduct has not occurred during the reporting period. EPA defines research misconduct as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results [65 FR 76262.1], or ordering, advising or suggesting that subordinates engage in research misconduct.

(7) Planned activity for the subsequent reporting period, including a description of equipment, techniques, and materials to be used or evaluated. If the work includes human subjects research, provide information on upcoming IRB approvals/renewals/amendments and any materials to be submitted for EPA HSRRO review.

(8) Publications arising from this project. Copies of publications and reprints which have not previously been submitted to the agency should be enclosed with the report.
The publication list should be cumulative of previous Annual Reports.

(9) In addition, the recipient agrees to submit annual report summaries with each annual progress report for posting on the Internet. These will be placed on EPA/ORD website(s). EPA will not alter the content of a summary without consultation with the principal investigator(s).

The summary should be submitted in the following format:

EPA Assistance Agreement Annual Report Summary (1-2 pages)

Period Covered by the Report:

Date of Report:
EPA Agreement Number:
Title:
Investigators:
Institution:
Research Category:
Project Period:
Objective of Research:
Progress Summary/Accomplishments (Outputs/Outcomes):
Publications/Presentations:
Future Activities:
Supplemental Keywords:
Relevant Websites:

B. Final Report. The recipient agrees to submit a final report to the EPA project officer (PO) within 90 calendar days after the expiration of the project period. The project officer may require clarifications of the final report before the report is considered acceptable. Although there are no page restrictions on the final report (other than on the executive summary below), EPA does not expect a final report of great length. However, this document shall include a discussion of:

(1) Project activities over the entire period of funding, describing the recipient's achievements with respect to the stated project goals and objectives (outputs/outcomes).

(2) Complete details of all technical aspects of the project--both negative and positive--the recipient's findings, conclusions, and results, including the associated quality assurance results.

(3) An evaluation of (a) the technical effectiveness and economic feasibility of the methods or techniques investigated or demonstrated, if applicable and (b) an explanation of how the research adds to the understanding of or solutions for environmental problems or is otherwise of benefit to the environment and human health. This discussion should be a minimum of one paragraph long and written in terms understandable by the educated layman.

(4) Publications arising from this project. Copies of publications and reprints which have not previously been submitted to the agency should be enclosed with the report.
The publication list should be cumulative of previous Annual Reports.

(5) For projects involving computer modeling, if requested by the PO, the recipient agrees to provide the following information with the final report:

a. Model description, key assumptions, version, source and intended use;
b. Performance criteria for the model related to the intended use;
c. Test results to demonstrate the model performance criteria were met (e.g., code verification, sensitivity analyses, history matching with lab or field data, as appropriate);
d. Theory behind the model, expressed in non-mathematical terms;
e. Mathematics to be used, including formulas and calculation methods;

f. Whether or not the theory and mathematical algorithms were peer reviewed, and, if so, include a summary of theoretical strengths and weaknesses;
g. Number and uncertainty associated with parameters (how data was selected/obtained and assessed to assure it met requirements, or, documentation of the weakness due to known uncertainty and variability);
h. Input data requirements and how data will be selected/obtained and later assessed to assure it met requirements, or, documentation of the weakness due to known uncertainty and variability;
i. Hardware requirements; and
j. Documentation (e.g., users' guide, journal publications, model code).

(6) In addition, the recipient agrees to submit an Executive Summary with the final report for posting on the internet. This will be placed on EPA/ORD website(s) along with a list of publications. EPA will not alter the content of a summary without consultation with the Principal Investigator(s). Note: the recipient need not create this summary if the final report is ten pages or less, and is suitable for inclusion in the EPA website.

The summary should be submitted in the following format:

EPA Assistance Agreement Final Report Executive Summary (3-5 pages)

Period covered by the report:
Date of final report:
EPA agreement number:
Title:
Investigators:
Institution:
Research category:
Project period:
Objective of research:
Summary of findings (outputs/outcomes):
Publications/Presentations:
Supplemental keywords: (do not duplicate terms used in progress summary)
Relevant websites:

2. Form of Reports. The recipient agrees to provide final and annual reports and associated summaries in an electronic format. The electronic versions shall be submitted in PC format, using commonly available word processing software or PDF. When requested by the Project Officer, these reports shall also be submitted in hardcopy format.

A. Annual Meeting Attendance. The Principal Investigator(s) will attend annual EPA Research Grants Seminars (otherwise known as progress reviews or all-investigators meetings) if requested by EPA, to present and discuss the project. Per EPA instructions, expenses for travel to these meetings have been provided within the funding for this agreement.

3. Publications and/or other public release of results.

A. The grant recipient agrees that any reports, documents, publications or other publically available materials supported by this assistance agreement shall contain the following statement:

"This publication [article] was developed under Assistance Agreement No._____ awarded by the U.S. Environmental Protection Agency to [name of recipient]. It has not been formally reviewed by EPA. The views expressed in this document are solely those of [name of recipient or names of authors] and do not necessarily reflect those of the agency. EPA does not endorse any products or commercial services mentioned in this publication."

The Lead/Contact principal investigator is responsible for ensuring that all members of the project team comply with these acknowledgement requirements.

B. Additionally, the above acknowledgement language should be included in any presentations, posters, websites, and media interviews.

C. The recipient is strongly encouraged to continue to notify the Project Officer of any papers that are published based on the research under the agreement. EPA intends to post references to all publications resulting from the agreement on the EPA website.

D. The recipient agrees to submit one copy of each peer reviewed journal article(s) resulting from this research, in addition to the final technical report.

4. Other recipient responsibilities.

Subject to the limitations in 2 CFR 200.308, without prior written approval from EPA the recipient may initiate a one-time no-cost of this project of up to 12 months by notifying EPA in writing, with the supporting reasons and revised project period end date, at least ten calendar days before the project period end date specified in the award agreement. Notwithstanding 2 CFR 200.308, if the extension causes the project period to exceed five years or is in addition to a previously requested one-time no-cost extension of this project, the extension should be requested at least 75 calendar days in advance of the project period end date and approved by EPA. These approvals are necessary due to EPA Office of Research and Development policy.

5. Foreign Travel

No foreign travel will be funded by this agreement without prior written approval of the EPA. The recipient agrees to notify the EPA Project Officer at least 60 days before any proposed foreign travel to allow the EPA sufficient time to obtain the appropriate clearances. The recipient understands that funds awarded under this assistance agreement may not be used for international activities unless prior written notification is received from the EPA Project Officer that the international activities have been approved by EPA's Office of International and Tribal Affairs. For purposes of this condition, international activities include any foreign travel paid for with EPA funds. In addition, the recipient understands that all foreign travel must comply with the Fly America Act. All travel must be on U.S. air carriers certificated under 49 U.S.C. Section 1371, to the extent that service by such carriers is available even if foreign air carrier costs are less than the American Carrier.

6. Human Subjects

No research involving human subjects will be conducted under this agreement without prior written approval of the EPA to proceed with that research. The recipient agrees to comply with all applicable provisions of EPA Regulation 40 CFR 26 (Protection of Human Subjects). This includes, at Subpart A, the Basic Federal Policy for the Protection of Human Research Subjects, also known as the Common Rule. It also includes, at Subparts B, C, and D, prohibitions and additional protections for children, nursing women, pregnant women, and fetuses in research conducted or supported by EPA.

The recipient further agrees to comply with EPA's procedures for oversight of the recipient's compliance with 40 CFR 26, as given in EPA Order 1000.17 Change A1 (Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research). As per this order, no human subject may be involved in any research conducted under this assistance agreement, including recruitment, until the research has been approved or determined to be exempt by the EPA Human Subjects Research Review Official (HSRRO) after review of the approval or exemption determination of the Institutional Review Board(s) (IRB(s)) with jurisdiction over the research under 40 CFR 26. For HSRRO approval, the recipient must forward to the Project Officer: (1) copies of all documents upon which the IRB(s) with jurisdiction based their approval(s) or exemption determination(s), (2) copies of the IRB approval or exemption determination letter(s), (3) copy of the IRB-approved consent forms and subject recruitment materials, if applicable, and (4) copies of all supplementary IRB correspondence.

Following the initial approvals indicated above, the recipient must, as part of the annual report(s), provide evidence of continuing review and approval of the research by the IRB(s) with jurisdiction, as required by 40 CFR 26.109(e). Materials submitted to the IRB(s) for their continuing review and approval are to be provided to the Project Officer upon IRB approval. During the course of the research, investigators must promptly report any unanticipated problems involving risk to subjects or others according to requirements set forth by the IRB. Additionally, investigators are to comply with guidance the EPA HSRRO may provide regarding routine human subjects research monitoring and reporting of unanticipated problems.

7. Research Misconduct

In accordance with 2 CFR 200.328, the recipient agrees to notify the EPA Project Officer in writing about research misconduct involving research activities that are supported in whole or in part with EPA funds under this project. EPA defines research misconduct as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results [65 FR 76262. I], or ordering, advising or suggesting that subordinates engage in research misconduct. The recipient agrees to:

(1) Immediately notify the EPA Project Officer who will then inform the EPA Office of Inspector General (OIG) if, at any time, an allegation of research misconduct falls into one of the categories listed below:

A. Public health or safety is at risk.
B. Agency resources or interests are threatened.
C. Circumstances where research activities should be suspended.
D. There is a reasonable indication of possible violations of civil or criminal law.
E. Federal action is required to protect the interests of those involved in the investigation.
F. The research entity believes that the inquiry or investigation may be made public prematurely so that appropriate steps can be taken to safeguard evidence and protect the rights of those involved.
G. Circumstances where the research community or public should be informed. [65 FR 76263.III]

(2) Report other allegations to the OIG when they have conducted an inquiry and determined that there is sufficient evidence to proceed with an investigation. [65 FR 76263. III]