02/04/2011

<u>Programmatic Terms and Conditions</u> <u>for Centers and Consortia</u>

1. Advisory Committee

a. The Center Director will establish and maintain a **Science Advisory Committee** (SAC). EPA recommends that the SAC consist of approximately five to seven individuals who are experts in technical fields related to the goals of the Center. The function of this Committee is to assist in evaluating the merit, value and contribution of research projects, and the relevance and importance of individual organizational elements to accomplishing the overall goals of the Center. The Committee will elect a chair and vice-chair from among its members. The EPA Project Officer will serve as a non-voting observer. The SAC must meet at least once a year to discuss progress of Center activities unless a different schedule is approved by the EPA. The Center Director must maintain records of any decisions he or she proposes which deviate from the recommendations of the SAC.

b. The committee must have an appropriate balance of members from academia, industry, environmental organizations, and governmental entities, representing a range of opinions and environmental disciplines.

2. <u>Reporting</u>

a. **Overview.** The recipient agrees to provide EPA's Project Officer *annual Center progress reports* with associated *annual research project summaries*, and a *final Center report* with *final project summaries*, along with a copy of, or reference for, any papers resulting from the research conducted. Requirements for the content of reports and summaries are stated below. Any detail specific to this Center in addition to those below may be established by the Project Officer and negotiated with the Center Director in advance, provided the frequency of reporting is not more than quarterly.

b. **Annual Center 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. 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 milestones described in the 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. Annual reports should discuss

the activities of the *Center as a whole*. These reports shall include:

(1) A discussion of the research performed during the reporting period and results (outputs/outcomes) that have been generated.

(2) A discussion on difficulties the Center has (or might) encountered in carrying out its mission, and remedial actions (to be) taken. If the goals/hypotheses of any project funded under this Center have been modified from the original application, provide the revised goals and discuss the reason for the change. A discussion of any problems, delays, or adverse conditions which may materially impair the ability to meet the results (outputs/outcomes) specified in the application.

(3) A discussion of any absence or changes of key personnel involved in the individual projects or Center management.

(4) A discussion of expenditures to date and an explanation of any costs which are significantly higher or lower than originally estimated.

(5) A discussion of how the quality assurance requirements of the following are being met: (1) 40 C.F.R. Part 30.54 or 40 C.F.R. Part 31.45; (2) G-1 STAR, *Guidance on Satisfying EPA Quality System Requirements for STAR Grants* (for individual projects), and (3) this agreement. For more information on quality assurance see http://epa.gov/ncer/guidance/ga.html.

(6) Planned activities for the subsequent reporting period.

(7) 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.

c. Annual Project Summaries. For *each* project funded under this grant, an annual project summary must be submitted with the annual Center progress report. These will be placed on the EPA/NCER website. EPA will not alter the content of a summary without consultation with the Principal Investigator(s). The summary should be submitted in the format shown in *Attachment A* and need not be more than two pages.

d. **Final Center Report**. The recipient agrees to submit a final report to the EPA Project Officer 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 accepted. These reports shall include:

(1) A discussion of the accomplishments/activities (outputs/outcomes) of the Center during the entire period of funding, describing achievements with respect to the mission of the Center, and incorporating quality assurance considerations.

(2) Details of any significant technical aspects of funded projects (both negative and positive) not included in the final *project* summaries.

(3) An evaluation of (a) the technical effectiveness and economic feasibility of the methods or techniques investigated and (b) an explanation of how the funded research adds to the understanding of or solutions for environmental problems, or is otherwise of benefit to the environment and human health, 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).

e. **Final Project Summaries.** The recipient agrees to submit project summaries for each funded research study with the final Center report. Summaries will be placed on the EPA/NCER website along with a list of publications. EPA will not alter the content of a summary without consultation with the Principal Investigator(s). Each summary should be submitted in the format shown in *Attachment B*, recommended at three to five pages.

f. **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.

3. <u>Human Subjects</u> (if applicable)

Should the Center support human subjects research under this assistance agreement, the following requirements apply:

a. 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: (1) copies of all documents upon which the IRB(s) with jurisdiction based their approval(s) or exemption determination(s) and (2) copies of the IRB approval or exemption determination letter(s). The project officer will forward these to the HSRRO for review and approval, which must be obtained in writing before the research can begin.

Following the initial approvals indicated above, the recipient must provide, as part of the annual report(s), evidence of continuing review and approval of the research by the IRB(s) with jurisdiction, as required by 40 CFR 26.109(e).

b. Files for all projects involving human subjects must be kept by an individual within the Center who is charged by the Center Director with the responsibility of securing, approving, and recording IRB approvals.

4. **Quality Assurance/Quality Control Program**

a. The recipient must provide acceptable quality assurance and quality control documentation to the EPA Project Officer within 60 days of the acceptance of this agreement. Acceptable documentation will be a Quality Management Plan (QMP). A QMP is a detailed policy statement describing the management and technical activities necessary to plan, implement and assess the effectiveness of the Quality Assurance (QA) system and Quality Control (QC) operations within the Center. For guidance on writing a QMP for NCER, see http://epa.gov/ncer/guidance/guidanceqmps0607.pdf. If additional guidance is needed, see the EPA's full guidance on QMPs at http://www.epa.gov/quality/qmps.html.

b. The Center Director will designate one individual within the organization to serve as Quality Assurance Manager (QAM) for the Center. This individual is responsible for implementing the Center's quality system and coordinating the QA/QC activities within the Center. The QAM must keep complete files on all quality documentation for the Center (e.g. QMP for the Center, various QA/QC plans for each project, audit records, etc.).

5. Publications, Abstracts and/or Other Public Release of Results

a. EPA encourages the independent publication of the results of its extramural research in appropriate scientific journals. Any journal article so published, however, must contain acknowledgement of the appropriate grant number and the following statement: "This publication was made possible by USEPA grant (number). Its contents are solely the responsibility of the grantee and do not necessarily represent the official views of the USEPA. Further, USEPA does not endorse the purchase of any commercial products or services mentioned in the publication."

The Center Director is responsible for ensuring that all members of the project team comply with these acknowledgement requirements.

b. Additionally, an acknowledgment of EPA support should be included on presentations, posters, Web pages, and stated during all 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/NCER 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.

6. <u>Peer Reviews</u>

a. EPA may elect to undertake periodic **independent peer evaluations** of the Center. At least 60 days notice will be provided before any such review is conducted. It is expected that the Center Director will cooperate fully with the peer review teams.

b. When required, an **activity status statement** must be submitted to the EPA Project Officer describing how the recommendations by any peer review have been implemented. This applies to peer reviews conducted by EPA before the award or during performance. The Center Director and EPA Project Officer will agree on the date the statement is due and the specific recommendations that must be addressed.

7. Other Recipient Responsibilities

a. The Center Director and other appropriate Center personnel must attend an **annual meeting** with EPA personnel. The date and location of this annual meeting will be set by the EPA Project Officer, in consultation with the Center Director. The SAC chair is also requested to participate in this annual meeting.

b. No institution may be added to or subtracted from the Center without the express written concurrence of the EPA Project Officer.

c. The Center Director should devote 50% (or specify, if this sentence is necessary) of his or her time to manage the Center effectively.

d. 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.

e. **Full funding of projects at award.** NCER's policy is that where projects are awarded that are supported by EPA funds, adequate funds must be set aside by the Center at the initiation of each project, in order to ensure completion without additional funding. This requirement may be met totally by EPA funds, or by supplemental funding that has been committed by or is anticipated from other sources. While this may limit the number of projects which may be started at any given time, it enables the Center to focus its efforts and assure that each project will be pursued to completion.

f. In accordance with 40 CFR 30.25(f), the recipient may initiate a one-time no-cost extension 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 40 CFR 30.25(f), 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 thirty 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.

g. **Program Income.** Program income is "gross income received by the grantee or subgrantee directly generated by a grant supported activity, or earned only as a result of the grant agreement during the grant period." Sources of program income include fees for services performed under the agreement, such as registration at conferences, and proceeds from sales of publications developed with assistance funds. If program income is generated under this agreement, the recipient will allocate the income by adding it to funds committed to the agreement (i.e., roll the funds back into the research effort).

h. **Light Refreshments and Meals.** Unless the event(s) are specified in the approved workplan, the recipient agrees to obtain prior approval from EPA for the use of grant funds for light refreshments and meals served at meetings, conferences, training workshops, and outreach activities (events). The recipient must send requests for approval to the EPA Project Officer and include:

- (1) An estimated budget and description for the light refreshments, meals, and/or beverages to be served at the event(s);
- (2) A description of the purpose, agenda, location, length and timing for the event.

(3) An estimated number of participants in the event and a description of their roles.

Recipients may address questions about whether costs for light refreshments, and meals for events are allowable to the recipient's EPA Project Officer. However, the Agency Award Official or Grant Management Officer will make final determinations on allowability.

Note: U.S. General Services Administration regulations define light refreshments for morning, afternoon or evening breaks to include, but not be limited to, coffee, tea, milk, juice, soft drinks, donuts, bagels, fruit, pretzels, cookies, chips, or muffins. (41 CFR 301-74.11)

i. Solicitation of Research Projects (if applicable)

(1) At least once per year (based on the availability of funds) the Center Director will solicit for technical proposals or pre-proposals for general research within all institutions of the Center, indicating subject areas of interest. The focus of these solicitations, the conditions of submission, and distribution policy are to be based on the recommendations of the SAC, and the solicitations will be reviewed by this Committee. Proposals and pre-proposals will be evaluated by the appropriate Committee members for technical quality and relevance to the Center's mission. The Center Director will select proposals for funding based on the recommendations of the SAC and the availability of research funds.

(2) It is an objective of this award to fund projects recommended by the SAC. Per term and condition 1.a, the Center Director must maintain records of any decisions he or she proposes which deviate from the recommendations of the SAC.

(3) The Center agrees to conduct subaward competition(s) consistent with the EPA negotiated work plan for this assistance agreement.

8. <u>Quarterly Project Progress Reports (if applicable)</u>

NCER has restricted statutory authority to fund certain types of research. Therefore, the Project Officer must review proposed projects. The purpose of the PO review is not to influence the type of research to be funded by the Center, but to advise the Director of which projects may not legally be supported with EPA funds, and recognize those that do fall under EPA's authorities. Consequently, in accordance with 40 CFR 30.51(d), the recipient agrees to provide the following:

a. A description of each new research project approved to be initiated since the last quarter, in the form of:

- (1) An abstract or summary description; and
- (2) A full project description (project narrative).

b. A budget in the format shown at: <u>http://epa.gov/ncer/rfa/forms/index.html</u>. One summary budget sheet in this format must be provided for all expenses estimated for the Center through the end of the project period. This summary budget will show all expenses anticipated for *running the Center* in the appropriate budget categories, with one total for all expenses associated with *projects* being funded by the Center included in the "Other" category. A separate budget sheet should be provided for each project to support the total shown in the "Other" category.

c. A discussion of the circumstances in which the Center Director disagreed with the SAC.

d. Any of the aforementioned requirements may be waived by the PO in writing.

9. <u>Cooperative Agreements</u> (if applicable)

a. EPA investigators from the EPA's [insert lab/division] may be substantially involved in specified individual projects. The nature of these interactions is set forth below.

Name, Lab/Division	Project Title	Research Contribution
1. [individual, specific location]	1.	1. [a sentence or phrases stating what the EPA PI will be responsible for]
2.	2.	2.

b. When a change in the individuals involved or the nature of the interactions is anticipated, the recipient agrees to provide notification to the Project Officer 30 calendar days in advance by updating this table.

Attachment A

NCER Assistance Agreement Annual Project Summary

Period Covered by the Report: Date of Report: EPA Agreement Number: Center Name: Project Title: Investigator(s): Institution(s) of PI(s): Research Category: Project Period: Objective of Research: Progress Summary/Accomplishments (Outputs/Outcomes): Publications/Presentations: Future Activities: Supplemental Keywords: Relevant Web Sites:

Attachment B

NCER Assistance Agreement Final Project Summary

Period Covered by the Report: Date of Final Report: EPA Agreement Number: Center Name: Project Title: Investigator(s): Institution(s) of PI(s): Research Category: Project Period: Objective of Research: Summary of Findings (Outputs/Outcomes): Publications/Presentations: Supplemental Keywords: Relevant Web Sites: