USAID
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United States Agency for International Development

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Research Policy

Draft

Date
Washington, DC

Summary

USAID-supported research reflects the Agency's mission to support the national interests of the United States by promoting sustainable development through programs that foster broad-based economic growth, democracy, environment, food security, and health. Research to identify, test, improve and adapt solutions to priority problems in developing countries is of central importance to the Agency's mission. High quality research allows USAID to develop, test, refine and evaluate the acceptability and cost-effectiveness of new and improved products, tools, approaches and interventions that focus on the key concerns of developing countries. Research also helps inform policy, strategic direction of programs, and overcome barriers to implementation in developing country settings. USAID's research investments strengthen the evidence-base for development and aim to:

- Enable scientific **discovery** and technological **innovation** to improve the well-being of people and nations by offering sustainable solutions to key development challenges;
- Understand the myriad social, cultural and contextual factors that impact use of research results;
- Develop innovative strategies and approaches to encourage **technology transfer and incorporation of research results into practice;**
- Foster host-country **capacity** to conduct research; and
- Promote open access to research results through **knowledge management.**

The purpose of this policy is to consolidate, in one convenient reference, existing policies of particular relevance to the design and management of research activities. It also fills important policy gaps where the Automated Directives System (ADS) is incomplete, especially on subjects such as scientific peer review, quality standards for research plans and reports, open data, measuring the impact of research, and handling potential conflicts of interest in publication. While avoiding restating the ADS, the policy also explains and references existing policies on matters that frequently arise in the conduct of research. Additionally, the policy contains useful templates and tools for research activity managers and their implementing partners as well as guidance on how Bureaus should organize to provide support to the field to enable the policy to be implemented even when the research activity manager is not familiar with scientific methods and approaches.

DRAFT

Abbreviations

ADS	Automated Directives System
AERA	American Educational Research Association
AO	Agreement Officer
AOR	Agreement Officer's Representative
APHIS	Animal and Plant Health Inspection Service
APS	Annual Program Statement
BEO	Bureau Environmental Officer
CE	Categorical exclusion
CFR	Code of Federal Regulations
CHSO	Cognizant Human Subjects Officer
CIO	Chief Information Officer
CO	Contracting Officer
COI	Conflict of Interest
CONSORT	Consolidated Standards of Reporting Trials
COR	Contracting Officer's Representative
DEC	Development Experience Clearinghouse
DHHS	Department of Health and Human Services
EA	Environmental Assessment
EO	Environmental Officer
ERC	Ethical Review Committee
FACTS	Foreign Assistance Coordination and Tracking System
FWA	Federal Wide Assurance
GC	General Counsel
IEE	Initial Environmental Examination
IP	Intellectual Property
IPR	Intellectual Property Rights
IRB	Institutional Review Board
LPA	Legislative and Public Affairs
M&E	Monitoring and Evaluation
NRC	National Research Council
OHRP	Office of Human Research Protections
OMB	Office of Management and Budget
OSTP	Office of Science and Technology Policy
PSC	Personal Services Contractor
REO	Regional Environmental Officer
RFA	Request for Applications
RFP	Request for Proposals
TA	Technical Advisor
TEC	Technical Evaluation Committee
TREND	Transparent Reporting of Evaluations with Non-randomized Designs
USDA	United States Department of Agriculture
USDH	United States Direct Hire
USG	United States Government

DRAFT

Contents

Summary 2
Abbreviations 1
1. Introduction 3
2. Quality Standards in Research 5
Guidelines for research plans 5
Guidelines for peer review 6
Influential scientific, financial or statistical information 9
3. Ethical Standards in Research 10
Protection of human subjects 10
Care of laboratory animals 12
Research misconduct 12
4. Reporting Standards in Research 13
Standards for research reports 13
Progress reports 13
Research tracking 13
Assessing research contributions 14
5. Designing research activities 14
Setting research priorities 14
Promoting competition 14
Gender considerations 15
Environmental considerations 16
Intellectual property considerations 16
Capacity development 17
Open access to data 18
6. Supporting Scientific & Technical Excellence among USAID Staff 19
Publication 19
Conference Attendance 22
7. Annexes 24
Annex A - Research Plan Template 24
Annex B - Template for research reports 28
Annex C -- Checklist for Environmental Consequences 33
Annex D – iEdison Intellectual Property Reporting Guidelines 36

DRAFT

1. Introduction

USAID-supported research reflects the Agency's mission to support the national interests of the United States by promoting sustainable development through programs that foster broad-based economic growth, democracy, environment, food security, and health. Research to identify, test, improve and adapt solutions to priority problems in developing countries is of central importance to the Agency's mission. High quality research allows USAID to develop, test, refine and evaluate the acceptability and cost-effectiveness of new and improved products, tools, approaches and interventions that focus on the key concerns of developing countries. Research also helps inform policy, strategic direction of programs, and overcome barriers to implementation in developing country settings. USAID's research investments strengthen the evidence-base for development and aim to:

- Respond to host-country needs and priorities;
- Enable scientific discovery and technological innovation to improve the well-being of people and nations by offering sustainable solutions to key development challenges;
- Understand the myriad social, cultural and contextual factors that influence the use of research results;
- Develop innovative strategies and approaches to encourage technology transfer, adoption, incorporation of research results into practice, and scale up;
- Foster host-country capacity to conduct research and practice evidence-based policy making;
- Support the introduction of evidence-based research into programs;
- Promote open access to research results through knowledge management; and
- Harness research and science to meet the development needs of men and women, girls and boys, as well as vulnerable groups such as persons with disabilities, indigenous people, ethnic minorities, and communities affected by conflict and extreme poverty.

USAID supports research intended to discover and develop solutions to specific development challenges. The term *research* (as defined by the Office of Management and Budget) refers to systematic and creative activities undertaken to increase the knowledge base, including understanding of humankind, culture, environment, and society, and the application of this knowledge base to devise new interventions. Being hypothesis-driven, testable, and independently replicable are typical qualities of the research process.

While the scope of research, and thus this Research Policy, is not absolute, in general *research* includes:

- Experiments;
- Observational studies;
- Operations and implementation research;
- Qualitative research;
- Population-based surveys that provide data for e.g. global results monitoring, small area variation analyses and cross-national comparisons and analyses;
- Impact evaluations; and
- Product development activities.

Research generally does **not** include:

- Routine product safety and/or quality monitoring and testing and other types of

DRAFT

quality assurance and improvement activities;
- Performance evaluations;
- Routine program/project monitoring;
- Geographic mapping and earth observations;
- Assessments done for the purpose of program/project design or that contribute to strategy development; and
- Training activities for scientific and technical personnel.

Overlap exists between research and data-driven evaluation. Many of the principles and procedures outlined in this policy may be useful for USAID staff and implementing partners who conduct rigorous evaluations – particularly impact evaluations.

Several key principles guide all aspects of USAID-supported research. These are:

Quality – USAID supports high quality research through scientific peer review and stakeholder review of the research at all appropriate stages from proposal to report.

Oversight – USAID maintains an appropriate scientific and technical staff to ensure responsible management and oversight of research.

Coordination – Research activities are coordinated internally (within Bureaus, Regional Bureaus and Missions) and externally (among implementing agencies, other agencies of the USG, and among other donors) to ensure efficiency, avoid duplication, and maximize the impact of resources.

Ethics – Research must meet sound ethical standards of accountability and social responsibility. Research will be conducted according to the highest scientific and professional standards of integrity. Research involving human subjects or laboratory animals will conform to relevant standards designed for their protection and to all applicable US and host-country regulations related to environmental safety.

Equity – Research must meet the highest standards of equity in access to research funds, participation in research, benefits from research findings, and safety in research efforts. Issues of gender equity are of special concern. Assessment of equity in research programs will include concern for ethnic and racial minorities and other disadvantaged and underrepresented groups.

Participation – Where appropriate, local, informed participation (e.g. through community consultation, advisory bodies or other approaches) will help guide all aspects of research from identifying the problem, to conducting the research and analysis, to incorporating the findings into strategies, policies and programs that lead to scale up and impact on development objectives.

Support – for short and long term research – not all research activities can be completed within a five-year time horizon allowed by most cooperative agreements and contracts. Strategic efforts that require a longer time horizon will be protected where appropriate.[1]

[1] Most USAID research is funded under assistance mechanisms. Section 635(h) of the Foreign Assistance Act states that a grant or cooperative agreement may not run at any time for more than five years. As long as this is the case, USAID may extend the agreement. If the scope and purpose of the research requires more time for completion, the award recipient may be evaluated before the end of the initial five year period of performance. If the recipient is making acceptable progress toward achieving the specifications in the Program Description, and continuation of the program is determined by the agreement officer (AO) to be in the best interests of the government, the recipient will be authorized in writing by the AO to continue for an additional period of performance not to exceed five years for a total of 10 years in

2. Quality Standards in Research

Sound development programming relies on scientific evidence. Strong evidence enables policy-makers and program planners to make decisions that ultimately improve practice and affect development outcomes. Research must be of sufficient quality to generate evidence that is credible, reliable and valid. In other words, quality research is a precursor to quality evidence.

The National Research Council (NRC) describes quality research as having the following characteristics.[2] Quality research:

- Poses a significant, important question that can be investigated empirically and that contributes to the knowledge base.
- Tests questions that are linked to theory or conceptual underpinnings.
- Applies methods that best address the research questions of interest.
- Bases research on clear chains of inferential reasoning supported and justified by complete coverage of the relevant literature.
- Provides the necessary information to reproduce or replicate the study.
- Ensures that the study design, methods and procedures are sufficiently transparent.
- Ensures an independent, balanced and objective approach to the research.
- Provides sufficient description of the sample, the intervention and comparison groups.
- Uses appropriate and reliable conceptualization and measurement of variables.
- Evaluates alternative explanations for findings.
- Assesses the possible impact of systematic bias.
- Submits research to the peer review process.
- Adheres to quality standards of reporting.

While there is no specific set of factors that will ensure quality research, the more research studies are aligned with these characteristics, the higher the quality of research is likely to be. Based on these characteristics, the following procedures should guide research funded in whole or in part by USAID.

Guidelines for research plans

A well written research plan (sometimes referred to as a protocol) facilitates quality research results. All research requires a detailed research plan prior to approval of the use of USAID funds.

Regardless of discipline, the main elements of a research plan are similar. Research plans usually include: an abstract; study objectives, questions to be answered or hypotheses to be tested; rationale and significance of the study; concise review of previous work in the scholarly or gray literature with full citations; a methodology section that includes study design, population, sample size and statistical power, subject selection, data collection and measurement methods; statistical analyses planned; and strategies for data management and dissemination to the public. Research plans also specify project management, personnel roles and responsibilities, data handling, ethical considerations (protections of human subjects and/or animals); budget; timeline, personal

accordance with a mutually agreed upon budget. For reference see USAID ADS 303.3.14 and ADS 303.6.5 at: and also 22 CFR 226.25.

[2] Shavelson RJ, Towne L (Eds) Scientific Research in Education. Washington DC: National Research Council National Academy Press, 2002.

DRAFT

qualifications to carry out the research; and partners (local and international).

As previously noted, objectivity is a key principle of quality research, and is essential if USAID research is to have credibility and impact within the larger scientific and development communities. This implies that the roles of "investigator" and "implementer" should be separate whenever possible and practical. In other words, organizations that have developed and will be in the process of implementing a new intervention or approach should not also test and verify its efficacy or effectiveness. Instead, research on the feasibility of an intervention or approach should be conducted by another organization that would be seen as objective and not have an inherent bias or conflict of interest (COI).

USAID employs different models of funding research which determine whether a research plan is developed prior to, or after an award is made. In some instances, USAID competitively awards grants, cooperative agreements or contracts for single studies or a discreet set of research and related activities focused on a single topic or question. For this type of award, the research plan should be developed as part of the application/bid submitted to USAID for funding and, if awarded, would become the technical description of the project in the award document.

In other cases, USAID awards larger projects to research organizations or consortia of partners to conduct multiple studies and related activities (e.g., translation activities to encourage the uptake and implementation of research findings, activities focused on gaining regulatory approval for drugs, agricultural products and other technologies, activities to increase capacity of host country partners to conduct research, and activities to address knowledge management challenges). For such projects, it would be impractical to expect research plans to be developed pre-award. Instead, research plans must be developed post-award for each study planned. In such cases, the research plan is considered an extension of the (approved) work plan and subject to substantial involvement.

Consequently, each research plan must be approved by the A/COR before the research can commence. Language to this effect should be included in the substantial involvement section of any cooperative agreement that will conduct research.

Operating units must develop and provide implementing partners clear guidelines on the preparation of research plans for submission to USAID. Annex A provides an example generic template that could be adapted to the specific requirements of each operating unit or program. For randomized clinical trials refer to the Standard Protocol Items: in the Recommendations for International Trials (SPIRIT Guidelines).

Guidelines for peer review

Scientific peer review is central to the integrity of the research enterprise. It is an accepted standard practice for United States Government (USG) agencies that fund and conduct research. Peer review must be used to evaluate the scientific and technical merits of research plans submitted to USAID and influential scientific, financial and statistical information disseminated by the Federal Government.

Definitions

Scientific peer review involves the review of research proposals or research plans by scientific experts who have in-depth expertise in the topic of the research and who do not

DRAFT

have a COI. The reviewers are usually active researchers and therefore qualified "peers" of the investigators in the subject matter of the research. "External" reviewers are typically not employed by the same organization as investigators of the research being proposed and are not directly involved in the financial sponsorship of the research. "Internal" reviewers are scientific or program experts on the staff of USAID.

Aims and scope

The aims of scientific peer review are to assess the quality of the science; to provide constructive feedback to investigators to enable them to clarify any outstanding questions and strengthen the design of the study; and to make sure the research proposed is in keeping with the overall goals and priorities of the award. Scientific peer review may assess whether:

- Investigators adequately describe the likely contribution the study will make to the overall goals of the award and to the development goals of the Agency;
- Investigators clearly describe the intervention so that it could be replicated and brought to scale if it proves successful;
- Investigators summarize and build upon research reported in the literature;
- The costs of an intervention, product or technology would not prohibit implementation at scale in developing countries;
- The study methodology is sufficiently rigorous;
- The plans for data sharing, knowledge transfer, host-country investigator capacity development, and knowledge management are adequate and clearly explained;
- Appropriate steps are taken for protection of human subjects and animal welfare; and
- Budget and timeline are reasonable and aligned with the work proposed.

Additionally, because of the nature of development-related research, a good peer review process should seek feedback from implementers and communities of practice whenever possible.

While all research plans require scientific peer review, they do not necessarily require the same level of scrutiny. For example, a small operations research study not intended to generalize beyond the specific setting in which it is conducted would not require the same level of scrutiny as a large, field trial testing a new crop variation or a randomized clinical trial of a new vaccine. Simple, direct follow-ons to an existing research plan or the geographic expansion of a previously reviewed research project typically do not require a complete second, scientific peer review. In other words, one model of peer review is not appropriate for all situations. The type of research activity should determine the level and extensiveness of scientific peer review required. Some illustrative factors to consider when deciding the level and extensiveness of external scientific peer review may be:

- Possible risks and benefits to humans, livestock, or the environment;
- Vulnerability of populations to be enrolled as study subjects (e.g. pregnant women, minor children, prisoners; refugees, etc.);
- The overall study budget – large investments may require additional scrutiny;
- Whether the intervention or technology under study could have unintended uses or consequences including potential dual use;

DRAFT

- Whether the study results will likely lead to sweeping policy changes globally; and
- Whether there is likely to be political, economic or social implications of the research that would result in challenges based on the study's methodologies or conclusions.

Conduct of the review

Investigators are usually "blind" to the identities of the peer reviewers and sometimes peer reviewers are blind to the identity of the investigator(s) in an effort to encourage unbiased assessment in the review process.

In instances where an award would be for a single study or body of work around a particular, focused question, scientific peer review must be employed **pre-award** as a part of the technical evaluation. In such cases the application or proposal must describe the research plan in sufficient detail to allow peer reviewers to assess its scientific and technical merit.

In keeping with USG procurement regulations, external scientific peer reviewers may participate on a technical evaluation committee (TEC) as long as they have no real or perceived COI extending beyond a material or financial nature.[3] However, the majority of reviewers on a TEC must be USAID staff regardless of hiring mechanism. External scientific reviewers selected as peer reviewers must be recognized scientific or technical subject matter experts and should also have expertise in the cultural or programmatic context in which a project will be carried out. Experts may be drawn from academia, other research and technical organizations, United Nations agencies, other Federal agencies, non-governmental organizations, or from the private sector among other organizations.

In certain instances, such as when the research involves intellectual property, for example, reviewers must sign a non-disclosure agreement. It is generally advisable to seek reviews from experts in statistical methods and as appropriate, laboratory procedure when the research being proposed relies on highly specialized methods or practices.

In instances where research plans will be developed **post-award**, e.g. for projects designed to conduct multiple studies over time in response to demands and requests from the field or headquarters and where it would be impractical or impossible to develop research plans pre-award, scientific peer review must be used to evaluate the research plans upon submission to USAID and no funds may be spent on the research activity (except for preparation work) until the review is complete. A summary of the review process and findings must become part of the official project file.

USAID scientific and technical experts may serve as reviewers, but to the maximum extent practical, peer reviewers should be external to USAID and to the investigator's organization. The number of reviewers largely depends on the complexity of the research and the need to seek fairness and balance in the review.

[3] A COI in regulatory language includes situations when: [1] A member of the TEC works for or has any other financial interest (including being an unpaid member of a Board of Directors) in the organization that submits an application for TEC review; [2] His or her spouse/partner or minor child works for or has any other financial interest in the organization that submits an application for the TEC review; [3] An organization or entity in which the TEC member serves as an officer, director, trustee, general partner, or employee has a financial interest in the application under review. This includes situations where the TEC member is negotiating for one of the positions noted herein and is serving as an unpaid member of the organization or entity's board of directors; and [4] The TEC member is an employee of an external organization (e.g. technical advisors in AIDS, child survival, infectious diseases, population, basic education) participating in the review of a potential competitor's proposal which allows him/her access to financial or other data that may be competitively useful to the reviewer's organization.

DRAFT

Various models have been used to ensure efficiency. For example, USAID has contracted with an external agency (e.g. the National Science Foundation and National Academies of Science) to help organize panels of scientific peer reviewers; some research projects include a technical advisory group (TAG) of scientific and program experts who meet routinely to discuss priority issues and critique proposed research; or A/CORs recruit external scientific peer reviewers themselves and handle all aspects of the review.

Decision and implementation authorities

USAID's Bureaus and Missions that fund research must have written standard operating procedures and expectations for the conduct scientific peer review. Decisions related to how these standards apply and how extensive the review of a given research plan should be rest with A/CORs and their technical advisors (TA) provided they have sufficient scientific expertise. Likewise, the decision for how best to organize and manage the scientific peer review process rests with USAID staff: either the chair of the TEC if the review is to occur pre-award; or with the A/COR and/or technical advisor(s) if the review occurs post-award.

In the case of post-award reviews, USAID staff oversee the process of identifying external and internal peer reviewers, referee any conflicting opinions among reviewers, provide anonymous reviewers' comments and other feedback to the investigators, and work with investigators to make sure essential changes that need to be made to the research plan are incorporated in a timely manner. A/CORs and TAs may seek advice from point persons to be designated within USAID/ Washington Bureaus who have the expertise and scientific background to help guide the review process and answer questions related to ethics, research methodology, statistical analysis, questionnaire design, scientific sampling and other issues.

Alternatively, Bureaus and Missions (or operating units) may choose to stand up a research committee of staff members with training and experience in the conduct of research. Such committees perform the functions as outlined above on behalf of the A/CORs. Such committees can help determine if an activity should be considered research, evaluation or other type of analytical work, assist the A/COR in understanding and implementing the research policy, and promote efficient use of time and division of labor when the operating unit only occasionally supports research.

Influential scientific, financial or statistical information

The Office of Management and Budget (OMB) has issued guidelines for ensuring the quality and objectivity of information disseminated by Federal agencies.[4] OMB requires federal agencies to submit all influential scientific information to peer review before the information is publically disseminated.

OMB defines 'scientific information' as "factual inputs, data, models, analyses, technical information or scientific assessments related to such disciplines as the behavioral and social science, public health and medical sciences, life and earth sciences, engineering or physical sciences." OMB defines 'influential scientific information' as "scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions". OMB defines 'highly influential scientific assessments' as "a subset of

[4] OMB Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Dissemination by Federal Agencies, Final Guidelines 2/22/2002

influential scientific information. A scientific assessment is an evaluation of a body of scientific or technical knowledge that typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information."

The OMB government-wide information quality guidelines are required by the Data Quality Act (2001). A peer review bulletin issued in 2004 details guidelines for peer review of influential scientific information and applies more stringent peer review requirements to highly influential scientific assessments.

Agencies must undertake a peer review of influential scientific information before they disseminate the information to the public. Peer review is not the same as public comment. Different types of peer review are appropriate for different types of information products, and agencies are granted under the OMB guidelines discretion to weigh the benefits and costs of using a particular peer review mechanism for a particular information product. The USAID specific policy directive states that scientific or statistical original or supporting data must be developed using sound statistical and research methods. Any information that could be "influential" (i.e. will have or does have a clear and substantial impact on important public policies or important private sector decisions" must be subjected to rigorous, unbiased scientific peer review. The policy may be found here – USAID ADS Chapter 578

For further information see:
OMB Memo: Final Information Quality Bulletin for Peer Review, Revised Information Quality Bulletin for Peer Review, and OMB Information Quality Guidelines

3. Ethical Standards in Research

Protection of human subjects

Along with many other agencies of the U.S. government, USAID has adopted the Common Federal Policy for Protection of Human Subjects in Research (the "Common Rule") – see 22 CFR part 225. The Common Rule describes the various functions and processes needed to ensure human subjects protection (including informed consent procedures, special protections for minors and other vulnerable populations, and exemptions), defines relevant terminology and concepts, and specifies how and when the rules apply in different circumstances.

Additionally, USAID has a guidance document entitled Protection of Human Subjects in Research Supported by USAID: A Mandatory Reference for ADS Chapter 200. This guidance describes how the Common Rule is implemented and interpreted by USAID and is intended to help USAID and implementing partner staff to understand and apply the Common Rule when supporting or conducting research involving human subjects.

The guidance document discusses:

- The basic principles of human subjects protection;
- Definitions, interpretation, and guidance regarding certain terms and concepts in the Common Rule;
- How the Common Rule is applied in various research locations;
- When alternative protection procedures may be acceptable;
- How to apply the Common Rule to various types of research and research-related activities;

DRAFT

- How to balance protections with the burden of implementing them;
- The right for USAID officials to access research records; and
- Compliance with the Common Rule and providing assurance.

These USAID regulations and the guidance help address common questions such as 'When is an activity considered research?', and 'When are human subjects involved?' A/CORs, TAs, and Mission staff have a first-line responsibility to assess the applicability of the USAID regulations to a particular research project and to ensure that organizations receiving USAID funds adhere to these regulations. A/CORs for USAID projects that include research involving human subjects should, therefore, be knowledgeable about these regulations, and a standard provision requiring recipients of USAID funding to comply with these regulations should be included in all relevant grants, contracts, and cooperative agreements. USAID also has an Agency-wide Cognizant Human Subjects Officer (CHSO), designated by the Bureau for Global Health, who can address questions and provide further guidance. Ultimate Agency authority for decisions regarding human subjects' protection has been delegated to the CHSO. Note that although the regulations often appear to be more readily applicable to biomedical research, they are applicable to all research involving human subjects, including social science and behavioral studies.

As part of its key provisions, the Common Rule requires that research involving human subjects be reviewed by a properly constituted ethical review committee (ERC) or institutional review board (IRB, which is most common in U.S.). Criteria for the proper constitution and function of an IRB are included in the Common Rule and USAID recipients subject to these regulations must formally certify that they will comply with these criteria. Many research institutions (in the US and abroad) certify their compliance by filing a Federal-Wide Assurance (FWA) with the Office of Human Research Protections (OHRP) at the Department of Health and Human Services (DHHS). Alternative assurance provisions can sometimes be acceptable for USAID but are rarely used.

The FWA is the institution's commitment to meet requirements regarding, for example, the frequency of IRB reviews, record keeping, and the composition of the IRB. The latter must ensure adequate technical expertise, community representation[5], knowledge of local conditions, and the absence of COIs. In most cases, recipients of USAID funds for research involving human subjects will have an appropriate IRB with an FWA at their own institution or at the institution of a sub-recipient or collaborator that is implementing the research. Research with multiple collaborators and sites may often involve more than one IRB review, and inclusion of a local IRB review in countries where research is conducted is preferred. Many USG agencies also maintain their own IRBs to supplement or duplicate the IRBs of the recipient institutions. USAID does not maintain its own IRB. This does not diminish the importance of protecting human subjects, but clarifies the roles of USAID and the recipient institutions, and may sometimes expedite the timely start of research that ultimately increases the benefit to human subjects and the communities where research is conducted and applied. In all cases, all parties involved must be fully committed to

[5] Special provision may need to be made for adequate community representation in low literacy or non-majority language communities. This also applies to obtaining individual informed consent for participation in research.

ensuring the ethical conduct of research involving human subjects.

Some IRBs, or the institution or agency with which they are associated, may request a fee for services. These are typically such as the initial and annual reviews, or the review of protocol changes. Such fees may be justified when used to cover reasonable IRB operating costs. Fees which are clearly in excess of reasonable operating costs, or which appear to be intended to generate large profits beyond the reasonable administrative costs (e.g. fees calculated as a percentage of the study budget) should be questioned and in no case should such fees be allowed to compromise the impartial and independent ethical review of any research involving human subjects. When the request for such fees appears to be unreasonable and unjustified, selection of alternative sites is advised. USAID staff and implementing partners are advised to consult the Agency CHSO if in doubt as to whether IRB fees reflect reasonable administrative costs.

Since the welfare of human subjects is a matter of USAID concern, research processes, procedures, and results may be independently reviewed and inspected by A/CORs, as well as other Agency staff, consultants, and advisory groups. The Standard Provision regarding human subject protection in agreements, grants, and contracts should specify that such access will be allowed and that the informed consent documents for human subjects should include the possibility of such reviews by USAID and its consultants.

Care of laboratory animals

Awards that anticipate using animals in research must contain the standard provision found in the ADS]. The provision notes that award recipients must comply with relevant Public Laws governing animal welfare; register with the Secretary of Agriculture; and furnish evidence of such registration to the Agreement or Contract Officer (A/CO) before undertaking the research.

To insure compliance it is recommended that a copy of the registration be furnished to the A/COR for the official file. The provision also specifies that the recipient must acquire animals used in research under the award only from dealers licensed by the Secretary of Agriculture, or from exempted sources. Recipients must adhere to the principles enunciated in the Guide for Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animals Resources, National Academy of Sciences - National Research Council (NAS-NRC), and in the United States Department of Agriculture's (USDA) regulations and standards issued under the Public Laws referenced above.

The recipient may request registration of the recipient's facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which the recipient's research facility is located. The location of the appropriate APHIS Regional Office as well as information concerning this program may be obtained by contacting the Senior Staff Office, Animal Care Staff, USDA/APHIS, 4700 River Road, Unit 84, Riverdale, MD 20737-1234.

Research misconduct

Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- **Fabrication** - is making up data or results and recording or reporting them.
- **Falsification -** is manipulating research materials, equipment, or processes, or

changing, omitting, changing or omitting data or results such that the research is not accurately represented in the research record.

- **Plagiarism -** is appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research misconduct does not include honest error, differences of opinion or data cleaning and interpolation according to established criteria.

Federal agencies and research institutions are partners who share responsibility for the integrity of the research process. USAID staff who conduct or manage research activities should be aware of and uphold the policies and principles outlined in the USAID Scientific Integrity Policy and ensure that their implementing partners are also aware of the policy. The USAID Scientific Integrity Policy may be found here.

4. Reporting Standards in Research

Standards for research reports

Clear, transparent reporting and documentation helps ensure correct interpretation of research results and will enable USAID to assist Missions and governments to more readily access valuable information for decision-making. As an illustrative example, the template provided in Annex B can be used as a guide for the structure of research reports to USAID. It is based on the CONSORT Guideline, TREND (Transparent Reporting of Evaluations with Non-randomized Designs) and the Standards for Reporting on Empirical Social Science Research in AERA Publications adapted primarily for reporting results of implementation research.[6]

Progress reports

Implementing partners are required to submit routine progress reports in accordance with 22CFR226.25, 51 and 91. Most A/CORs require these reports quarterly along with reports of financial status. A/CORs should also engage with implementing partners, as appropriate, through e.g., periodic technical discussions, management reviews and site visits.

Implementing partners are generally required to submit a performance monitoring plan with indicators to enable monitoring and reporting of progress. Evaluations should be planned and conducted in accordance with the USAID Policy on Monitoring and Evaluation (see ADS Chapter 203 Assessing and Learning).

Research tracking

The USAID Development Experience Clearinghouse (DEC) houses all final documentation and products from USAID and USAID-funded activities. All research reports, publications (including those publish after the project has ended) and additional documentation from research must be submitted to the DEC upon completion.

Many research and project/program investment tracking systems already exist within USAID. These should be built upon or modified as needed for the purposes of tracking research (for example: FACTS Info, the Performance Planning Report, the Evaluation Registry and the DEC). Additionally, Bureaus have databases designed to track investments in research that are designed to meet specific

[6] Link to: CONSORT Guideline
Link to: The TREND Statement
Link to: AERA Standards for Reporting

needs of the program and its unique reporting requirements.

Assessing research contributions

Simple indicators that capture USAID's contribution to scientific knowledge should include:

- Number of publications in scientific journals by USAID staff and implementing partners;
- Number of new technologies developed with USAID funding;
- Number of patents and patents pending on USAID-supported products, inventions and pharmaceuticals and related processes.

Qualitative indicators may be used to assess the impact of research such as "Policy or programmatic changes made as a result of research".

Online search and retrieval tools such as Web of Science™ may be used to track accessibility of research findings. Web of Science™ can track publications by sources of funding, author and affiliation, and the number of times articles are cited by other authors. Implementing partners must credit USAID as the source (or one source) of funding in the papers they publish, including those published after the end date of the award, so that USAID investments in research can be tracked.

5. Designing research activities

Setting research priorities

Research is an integral component of USAID's sustainable development programming. Research priorities within a given topic or sector will reflect USAID's strategic goals in a given area. Compared with the magnitude and scope of research needs in international development issues, USAID has limited resources to bring to bear. Thus, the degree of the Agency's support for and involvement in a particular research activity may vary: the Agency may be the leading supporter of research; it may share that leadership with other donors; it may only participate in an effort which others are leading; or it may just observe rather than support the effort.

The operating unit is responsible for selecting topics for investigation and for guiding the degree of Agency involvement and allocation of resources to research. Operating units are responsible for making sure investments in research are not inappropriately redundant or duplicative with other donor supported research or with previous investments in research. Once a commitment is made to fund research, operating units should make every effort feasible and practical to support the research to completion. The factors to be considered not only in initiating research but in decisions to continue funding ongoing efforts may, for example, include:

- Relevance to USAID's strategic priorities and to Missions' identified needs.
- The potential contribution of research toward meeting those priorities and identified needs compared to other strategic investments.
- Comparative advantage of USAID support as a unique or important donor.
- The magnitude of the problem warrants investment in finding solutions. Significant factors include, but are not necessarily limited to: numbers of people affected; geographic area affected; and economic impact.
- There is a reasonable likelihood that research will produce useful knowledge or understanding, feasible interventions or approaches, or innovative technology(ies) amenable to adoption and scale up within a reasonable time.

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Promoting competition

It is critical to ensure that requests for applications (RFAs), requests for proposals (RFPs) and annual program statements (APSs) for projects designed to conduct research provide a clear outline of how the application or proposal should be structured and what content to include. This helps ensure fairness and transparency in the technical review process and encourages competition. If prospective applicants or bidders not familiar with USAID processes have clear and specific guidance on how to construct an application or bid, then the evaluation is less likely to be biased in favor of applicants/bidders with more familiarity with the standards expected by TECs. Operating units that fund research must develop specific guidance and job aids (such as templates and checklists) to aid design teams responsible for writing RFAs and RFPs for projects that include research.

Such guidance would include detailed instructions to applicants/bidders on the elements related to research they are expected to address in their submission to USAID. Examples of such elements include:

- Expectations of the research capacity of the applicant/bidder organization;
- Research background and qualifications of the project director, key staff and implementation team;
- Previous publications and other scholarly work;
- Previous research conducted in developing country settings;
- Key research issues to be addressed with USAID funds;
- Expected results by the conclusion of the project (e.g. questions answered, research results taken to scale, new technologies developed and tested, good manufacturing process certifications, drugs registered with stringent regulatory authorities and host country governments, patents registered, etc.).

Many projects designed to implement programs or provide technical assistance to countries may include a research component. Such projects should also include in the RFA, RFP or APS similar instructions and evaluation criteria specific to assessing competence in conducting research. Key staff may not be required to have training and background in conducting research but the project should clearly indicate how they will access such expertise. Likewise the applicant/bidder should indicate what research would likely be conducted and how it would contribute to the overall objectives and aims of the project.

Gender considerations

USAID investments support gender equality and equitable opportunities for males and females to benefit from and participate in research both at home and abroad. Gender should be considered in all areas of the research process:

- Gender analysis should be carried out to influence project design to ensure that it explicitly addresses any disparities and includes actions to reduce inequalities revealed;
- Incorporating gender considerations when applicable into research designs, e.g., in the framing of research questions that address gender gaps, appropriate methods for gathering data from both males and females, presenting sex-disaggregated data and findings etc.;
- Incorporating gender considerations when applicable into the technical evaluation criteria of research RFAs and RFPs and

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balancing the gender composition of technical evaluation committees;
- Ensuring gender balance in the membership of research oversight bodies such as technical advisory groups;
- Ensuring that the dissemination of research findings engages beneficiaries and diverse stakeholders in the use/application of research to promote gender equality.

Additionally, a need exists for reflexivity in analyzing development data – understanding ones relationship to both the research and the research process and the impact gender may have on either. For additional information see: USAID Policy on Gender Equality and Female Empowerment and ADS Chapter 205: Integrating Gender Equality and Female Empowerment in USAID's Program Cycle.

Environmental considerations

Research funded by USAID must undergo an initial environmental examination (IEE) pursuant to 22 CFR 216 prior to making any award notifications. These pre-award checks help to ensure that the activity's environmental consequences are considered in the award process and that high quality standards are in place in programs supported by USAID. One can apply for a categorical exclusion (CE) for research activities. Many CEs exist – those that may apply to research are listed below:

- Research activities that may have an effect on the physical and natural environment but will not have a significant effect as a result of limited scope, carefully controlled nature and effective monitoring;
- Controlled experimentation exclusively for the purpose of research and field evaluation which are confined to small areas and carefully monitored;
- Analyses, studies, academic or research workshops and meetings; and
- Studies, projects or programs intended to develop the capability of recipient countries to engage in development planning, except to the extent designed to result in activities directly affecting the environment (such as construction of facilities, etc.).

Environmental Officers (EO) are responsible for verifying the degree to which CEs can be applied to specific research activities. However, EOs may not be familiar with the research topic and scientific literature on the topic. Therefore the A/COR must assist the EO in flagging any potential detrimental impacts on the natural and human environment that might result from the research activity and what measures are planned to mitigate the impact. Additional screenings may be necessary for projects working in certain technical or geographic areas that are particularly vulnerable or environmentally sensitive. For additional information see ADS Policy 204 and USAID Environmental Compliance Tools.

Intellectual property considerations

Research awards may include more complex intellectual property (IP) issues than other USAID awards. Such issues involve IP that is used in the award, which may belong to the implementing partner or to a third party, as well as IP that is developed under the award. USAID may also have an interest in how such IP is used after an award has ended. The standard terms under both contracts and assistance awards generally allow the implementing partner the primary rights to the IP, while providing USAID with a broad license to use the IP.

It is critical to consider IP issues in program design and funding decisions, prior to award, so

that appropriate clauses can be included in the award. Where the IP issues are complex, Operating Units should consider an IP Management Plan addressing the IP implicated.

USAID should strive to ensure that IP is addressed in a manner consistent with the development mission of USAID, which includes consideration of scale up and legal access to new products, technologies, and approaches by target beneficiaries. The use of research results for development impact will often depend upon access to pre-existing IP and upon how the rights to project-generated IP would be shared, protected, priced and licensed, or released into the public domain. For example, factors that might be relevant in the design of an activity include:

- The specific allocation of rights to project-derived IP among institutions, including both the rights to revenues from the IP and the rights to control licensing of the IP, as well as equitable consideration of developing-country partners on shared project awards;
- How the IP rights would be protected (without exposing developing-country partners to loss of rights if they cannot afford high costs to register or defend the IP);
- Description and treatment of any preexisting IP or patents pending that could affect the use of the project's results, as well as other forms of property such as copyrights, breeders' rights to plant varieties or hybrids, genetic resources, etc.;
- The specific mechanism(s) by which affordable legal access to project data, products and technologies by target end-users in developing countries would be ensured; and
- How commercial licensing would be handled if needed to ensure accessibility and affordability including, for example, benchmarks or price, time, or geographic limitations to exclusive licenses.

22 CFR 226 provides the standard IP clause for US organizations under assistance, and the Standard Provisions for Non-US Non-Government Organizations provides the standard IP clause for non-US organizations under assistance. For contracts, 48 CFR 52.227-14 provides the standard IP clause. USAID policy on this may be found at ADS 318.

All federal grantees and contractors must report on activities involving disposition of IP rights resulting from federally funded research. Implementing partners must report inventions, patents and licenses that have resulted from federal funding through the Interagency Edison (iEdison.gov) system. This database also provides USAID A/CORs and A/COs information useful in overseeing compliance with federal reporting regulations for IP. Annex D provides a summary of the reporting requirements.

Capacity development

Capacity development refers to a process of change in which people and organizations improve their potential to design, manage, support and conduct research and to engage with stakeholders to ensure that research is used to inform policy and evidence-based practice. The process of change occurs at individual level to improve individual competencies, and at organizational level to improve the functions and processes to support and manage research e.g.: human resources management; grants management support services; and infrastructure such as libraries,

internet bandwidth, laboratories, and other facilities required to conduct research.

Capacity development is not simply a training process but rather an application process wherein individuals and their organizations take ownership to build skills and organizational systems that ultimately puts them on par intellectually and managerially with counterpart investigators and research organizations in donor countries. This requires a deliberate rather than passive process of setting goals for capacity development in research (even modest ones), planning with developing country partners, and monitoring benchmarks toward achieving these goals.

The emphasis on capacity development in research builds upon a strong USAID policy on human and institutional capacity development to improve the impact and sustainability of all Agency development assistance programs and is further reinforced by the USAID Forward Implementation and Procurement Reform Initiative. Thus, USAID's research activities, to the maximum extent possible, should:

- Enable a country-led approach to identify research priorities;
- Build capacity development activities into research studies;
- Encourage USAID implementing partners to engage local research partners through sub-awards to assist in the planning and conduct of all aspects of research studies;
- Increase direct partnerships and relationships with developing country researchers and research organizations to conduct all aspects of research studies;
- Ensure that developing country researchers receive credit for contributions they make on research studies through, e.g., authorship and acknowledgement on reports and published papers;
- Involve from the beginning and throughout the research process country stakeholders best placed to benefit from, and act upon, the research findings. Standing up technical advisory groups made up of country-level stakeholders who engage in framing research questions, interpreting cultural context and language, and discussions of how to best use findings for policy change, advocacy and program strengthening is strongly encouraged.

Additionally, partnerships with host country governments, private sector entities and other donors including other USG agencies to leverage support, expertise and funding for capacity development should be assessed and considered when planning and setting development goals for capacity development in research.

Open access to data

Improving the accessibility of USAID-funded data can bring the Agency, its partners, and other stakeholders a deeper and more up-to-date understanding of development challenges, which in turn will help USAID and others design, manage, and evaluate development programs more effectively. By making USAID data available through user-friendly platforms in machine-readable formats, host countries, scientists, and communities can propel research forward in solving complex development problems.

Executive Order 13642, issued by the President on May 9, 2013 calls for making open and machine readable the new default for government information. In addition to operational and program related data, this

DRAFT

order applies to data generated in as part of research activities.

Results of research (including published and unpublished manuscripts, and their underlying data) for which 50 percent or more of its funding comes from USAID, once secured of any concerns related to privacy, security, or other principled exceptions, must be made publicly accessible online for search, retrieval, analysis, and application. Manuscripts must be uploaded to dec.usaid.gov, and underlying data must be uploaded to www.usaid.gov/data in accordance with the instructions provided at each website to comply with this requirement.

As noted previously, federally funded scientific research is subject to a more rigorous peer review process than other types of data before it can be made available to the public. To facilitate this review process and in recognition of time lags associated with publication in peer reviewed journals, research data may be temporarily withheld from public release (embargoed) pending completion of the review process. Specifically, research results may be embargoed for up to twelve months following the end of the award. In the event that the award supporting the research ends prior to the end of the embargo period, the manuscript must be submitted to the DEC, and the data must be submitted to the DDL where it will be held until the conclusion of the embargo period. **The only allotted exception** regards the association of the information with a publisher's copyright. If a paper has been confirmed for publication before the above deadline, i.e. twelve months after the end of the initial grant, and that publication has a copyright restriction, then an additional twelve-month embargo will be held on the research following the date of publication. *See USAID's Public Access Plan for additional information concerning copyright and embargo periods.*

6. Supporting Scientific and Technical Excellence among USAID Staff

Publication

USAID staff are encouraged to publish scientific and technical papers and other scholarly work. Publishing scientific and technical work is a useful means of sharing important innovations, research, and experience with the international community and provides staff opportunities to continually develop and demonstrate scientific and technical expertise. Publishing can further the Agency's development goals by advancing knowledge, disseminating best practices, and providing staff growth and professional satisfaction. Provided writing and publishing is aligned with the scope of staff members' job duties, they may be afforded opportunities during regular business hours to write and publish, conduct secondary data analyses, and keep up-to-date with the scientific and technical literature. USAID staff in supervisory roles should also raise awareness about the policies related to authorship and ensure their staff members are adhering to the principles outlined in this document.

The following policy applies to publications of official USAID concern, intended for submission to scientific and technical, peer reviewed

DRAFT

periodicals and books (including electronic publications). For other types of publications refer to ADS 558 for guidance on review, submission and approval processes.

A publication is of official USAID concern when:

- The author represents him/herself as affiliated with USAID, whether the staff member is a direct or non-direct hire;
- The subject matter of the publication is directly or indirectly related to work conducted by USAID;
- When work was conducted prior to employment or affiliation, but publication will occur during employment or affiliation; and
- When work was conducted during employment or affiliation, but publication is sought after conclusion of employment or affiliation.

To be an author, USAID staff **must** meet the following three criteria:

- Meet the international standards for authorship;
- Have no COI; and
- Have the work reviewed by his/her Assistant Administrator (AA)/Mission Director or designee prior to submission.

Meeting standards for authorship

USAID staff are directed to adhere to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals when determining if they qualify for authorship. As outlined in those requirements, authorship credit is based on the following conditions, all of which must be met:

- Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
- Drafting the product or revising it critically for important intellectual content; and
- Final approval of the version to be published.

All persons designated as authors **must** meet all these qualifications and all those who qualify must be listed. Acquisition of funding, general supervision or oversight of researchers/authors or review and approval of an information product, by themselves, do not justify authorship. Each author should have participated sufficiently in the work to take public responsibility for the integrity of the work as a whole.

The order of authorship should be a joint decision among co-authors. If authorship is attributed to a group, all members of the group who are named as authors should fully meet the criteria for authorship. Group members who do not meet the criteria should not be listed as an author, but may, with their permission, be listed elsewhere (e.g. in an acknowledgement). Co-authors must always be informed before listing them on a publication. The above principles should be applied when assessing criteria for authorship and no person shall be listed as a co-author merely by virtue of his or her position in the organization.

Conflicts of interest

USAID staff must avoid real or perceived COI.

Journal/Publisher Requirement: USAID staff must adhere to the COI requirements for the journals in which they intend to publish. These requirements often include the disclosure of relevant financial interests, activities, relationships, and affiliations.

DRAFT

Publishing with an Implementing Partner: Co-authoring publications with implementing partners, where a staff member has budgetary or technical oversight for the work done that led to the publication, is a situation with potential for COI, calling for particular care and oversight. To reduce the potential for a COI and to avoid potential misunderstandings with the implementing partner, transparency and documentation is essential. **Under such circumstance where a staff member wishes to participate as a co-author on a potential future publication for which he/she has such budgetary or technical oversight, the budget and technical oversight for the work done that will lead to the publication must be reviewed and approved by a USAID employee in a supervisory role to the USAID staff co-author, for example, the team leader or immediate supervisor.** It is recommended that USAID staff planning to co-author with an implementing partner clarify in writing with the implementing partner the roles of the parties conducting the work.[7]

Staff members are strongly encouraged to consult the Office of the General Counsel with any questions.

Internal review prior to submission

USAID staff must have their AA/Mission Director, or their designees review the work prior to submitting the publication. The purpose of this review is to:

- Provide constructive feedback and ensure the quality of the presentation;
- Identify any sensitive issues and develop a plan for how these will be handled pre- or post- publication; and
- Provide guidance on how best to disseminate the information to key audiences.

Additionally, it is advisable to ask a direct line supervisor and the communications point person in one's Office/Mission to review prior to requesting AA review.

Throughout the internal review process, the principles outlined in the USAID Scientific Integrity Policy must be upheld. In particular, direct line supervisors, AAs/Mission Directors or their designees and communications point persons must not suppress or alter the meaning and/or veracity of scientific and technical findings through the review and editing processes.

Disclaimer statements

USAID staff must include, except in circumstances described below with regard to employment status at the time of research and publication, the following disclaimer in publications they author: "The views and opinions expressed in this paper are those of the authors and not necessarily the views and opinions of the United States Agency for International Development."

For work published while employed at USAID but researched prior to joining the Agency, the following disclaimer should be used: "[NAME] was not at USAID when the research for the current paper was conducted. The views and opinions expressed in this paper are those of the authors and not necessarily the views and opinions of the United States Agency for International Development."

For work published after an employee leaves the Agency, but that was conducted while employed by USAID, the following disclaimer

[7] Additionally, if the implementing partner intends to use USAID funds to publish, this must be approved by the C/OR.

should be used: "[NAME] was employed by USAID when the research for the current paper was conducted. The views and opinions expressed in this paper are those of the authors and not necessarily the views and opinions of the United States Agency for International Development."

If in doubt about which disclaimer to use, seek guidance or advice from LPA.

Copyright

According to United States copyright law, works created by federal employees (generally, USDHs and PSCs) as part of their official duties cannot be copyrighted in the United States. Section 105 of the Copyright Act (17 U.S.C. §105) reads as follows:

"Copyright protection under this title is not available for any work of the United States Government, but the United States Government is not precluded from receiving and holding copyrights transferred to it by assignment, bequest, or otherwise."

Section 101 of the Copyright Act defines a work of the United States Government as follows: "A 'work of the United States Government' is a work prepared by an officer or employee of the Unites States Government as part of that person's official duties."

In practice, journals typically will include a section in the publisher's agreement where the federal employee can indicate their employment status or that the work was supported under a United States Government contract. If this option is not available, or if there are any other questions about copyright, please contact the Office of the General Counsel.

Compensation

As described in ADS 558.3.3, USAID staff must not accept compensation or fees for material written as a matter of official business, as prohibited by statute.

Dissemination

USAID staff must provide the Bureau for Legislative and Public Affairs (LPA) a copy of the galley proofs and a summary of the most notable findings once the work is accepted for publication. USAID staff are strongly encouraged to work with LPA and their Bureau/Mission communications point people to develop a dissemination plan for the findings so that they reach intended audiences. USAID staff must upload their publication to the DEC upon publication.

Conference Attendance

Opportunities to engage in scientific exchange at scientific and technical conferences are limited for USAID scientists and technical experts, particularly those in direct hire positions. Opportunities are limited by: tight budgets and restrictive requirements for travel approval e.g. the need to obtain a waiver if more than three people plan to attend the same conference. New OMB directives to federal agencies further restricted travel budgets in general and conference attendance in particular.[8] In response to concerns about the new policy raised by the scientific community within and outside the federal government, OMB working with the Office of Science and Technology Policy (OSTP) issued a Controller Alert in May 2013 that states:

As each agency reviews its travel and conference-related activities, it is critical for each agency to continue to recognize the important role that mission-related travel and conferences can often play in Government

[8] OMB Memorandum M-12-12

operations. Given the unique travel and conference needs of each agency, there are circumstances in which physical collocation is necessary to complete the mission. These circumstances may include, but are not limited to, collaborations in the scientific community… [and]

In addition, bringing together federal employees at a single location – such as for program reviews or technical evaluations, presentation of scientific findings, oversight boards or advisory group meetings, international engagements, and standards-setting committees – may be the most efficient and cost-effective means for reviewing Government-sponsored efforts, issues or challenges. Several agencies rely on meetings with industry and academic colleagues to drive innovation and ensure continued advancement in related fields.[9]

USAID, as a leader in development, relies on robust scientific and technical exchange among scientists and technical experts inside and outside the agency to ensure that USAID staff remain current with the latest developments in their respective fields. Without scientific and technical exchange, USAID scientists and technical experts will have their ability to function in a global innovation community reduced. Attendance at scientific and technical conferences and technical meetings has important benefits for the Agency that must be taken into account in decisions about travel and conference attendance.

Conference attendance:

- Affords USAID scientific and technical staff an avenue to advance research findings that have a critical impact on development;
- Enables USAID scientific and technical staff to remain current with the latest scientific developments through networking and scientific exchange;
- Offers efficient ways to avoid duplication or unnecessary assessments in program design, for example, it enables one to determine what other donors are already funding;
- Creates incentives for USAID scientific and technical staff to make scholarly activities a high priority of their work; and
- Provides visibility so that USAID is seen as a leader in science and research on par with other agencies of the USG.

Such factors must be taken into account by Missions and Bureaus when prioritizing travel and conference attendance. When such justifications can be met, conference attendance travel/funding should be given high priority.

[9] Holdren, JP. Memorandum for NSTC Committee and Subcommittees, Implementation of Federal Travel and Conference Policies with Respect to Scientific and Technical Conferences, August 5, 2012.

7. Annexes

Annex A - Research Plan Template

Overview

Research funded by USAID must undergo rigorous scientific, technical and ethical review. These guidelines outline the minimum standards for USAID-sponsored research. Since Implementing Partners have varying levels of research expertise, these guidelines should be used at the discretion of the Agreement Officer Representative (AOR) and Technical Advisor(s) (TA).

Preparing a Research Plan

Note: Not every research plan will need to include every item described in this guidance. Select those that apply.

Identifying Information: Identify the principal investigator, the study team, their respective institutional affiliations, and provide contact information. Provide the agreement name or number. Title the research plan in a way that summarizes the main idea under investigation. The title should be able to stand alone as a description of the study. Number pages sequentially. As research plans undergo many revisions, it is essential to provide the version date of the plan to be reviewed.

Overview: Provide a brief overview of the study, its main objectives and rationale, countries and settings where the work will take place, population(s) of interest, and the expected applicability of the study findings. Explain the scientific importance of the study.

Literature review: The literature review should provide a synopsis of the current state of knowledge on the topic under study. Discuss the key issues or gaps that this proposed research will address. Include citations (either numerical or by author and date) in the text with full references listed in the bibliography or references section.

Study objectives: List the objectives, specific aims, study questions or hypotheses the study will answer.

Design: Describe the study design. Explain its appropriateness to the project and to the objectives/questions previously outlined. Describe how the study design helps diminish sources of bias.

Study Population: Define the population from which the sample will be drawn (e.g. if the study involves humans subjects describe the population in terms of age, ethnicity, socioeconomic status, gender, risk status or vulnerability, geographic location or catchment area, etc.). Discuss what population inferences will be made.

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- Case definitions: When appropriate, provide a description of an illness/ condition, sign(s)/symptom(s) or health event which define whether study participants have a condition under study.

- Participant inclusion criteria: Describe conditions or characteristics applicable to the identification and selection of participants. Describe the conditions necessary for eligible persons to be enrolled in the study.

- Participant exclusion criteria: Describe the characteristics that would disqualify otherwise eligible participants from the study. Provide a justification for excluding a subpopulation.

Sampling plan: Provide detail about how the sample will be identified and selected and how participants will be assigned to comparison groups.

- Describe the sample, e.g., convenience, population-based, or systematically chosen for a particular purpose.
- Describe procedures for sampling.
- State the unit(s) of analysis.
- Estimate the required sample size. Provide power calculations for significance testing when appropriate.
- Describe how participants will be enrolled (e.g. the manner in which they will be contacted, screened and registered in the study) and how they will be assigned to comparison groups. In studies where randomization is used, describe these processes in detail including whether participants and researchers will be blinded and procedures to ensure that randomization resulted in comparable groups. If group level or aggregate information will be collected (e.g. from focus groups), explain how the groups will be formed or what procedures will be followed to enroll participants in the groups.

Variables: Define the independent, intervening and dependent variables. Describe any study instruments or methods to be used to collect data or construct variables and measures including evaluations of the instrument's reliability and validity or the sensitivity and specificity of a diagnostic test or other measure. Discuss all sources of data used to construct variables (e.g. medical records, health information management systems, census data, etc.). Provide a description and background information on any drugs, seed/crops, technologies, devices, interventions, tools and approaches to be tested or employed in the research.

Data handling and collection: Provide detail on data collection procedures, methods to maximize response rates, how losses to follow up will be tracked and what procedures will be used to minimize losses to follow up. Discuss how the investigators will monitor data collection in the field to ensure quality and consistency. Describe how those responsible for data collection will be trained and monitored. Discuss data entry and cleaning and procedures for ongoing data management and quality assurance. Describe how data will be stored and document the procedures utilized to preserve confidentiality during transmission, use and storage of data and the names of persons responsible for

data stewardship. Describe the final disposition of records, data, computer files, specimens and other materials at the end of the study. Discuss plans for any sub-awards. Identified local and international partners participating in the research and describe their roles and responsibilities.

Handling unexpected or adverse events: Describe the types of adverse events that might be encountered and how study personnel will be trained to react. Describe methods that will be used to track adverse reactions and their potential impact on the study.

Analysis plan: Discuss potential sources of bias and possible analytic approaches to avoid drawing erroneous conclusions (e.g. stratification, statistical adjustment). Discuss statistical packages to be used for the data analysis.

Ethical Considerations: Along with many other Federal Agencies, USAID has adopted the Common Federal Policy for Protection of Human Subjects in research (often called the "Common Rule") – see 22 CFR 225 (Annex B, part 1). The Common Rule describes the various functions and processes needed to ensure human subjects protection, defines relevant terminology and concepts, and specifies how and when the rules apply in different circumstances.

USAID also has the following guidance document (Agency reference, Annex B, part 2) which aids project management by further explaining the underlying principles and their application in various situations. This guidance is intended to help AORs and TAs, Mission staff, and Implementing Partners or recipients to understand and apply the USAID regulations when supporting or conducting research involving human subjects. See section ___ of the Research Policy for further information.

Note: Not every study requires IRB review and approval. Determine in advance whether the study would be exempt.

Budget: Provide a detailed budget for the study. Identify all sources of funding.

Timeline: Provide a detailed timeline for all phases of the study. We encourage the use of Gantt charts for project management.

Dissemination and knowledge transfer: Describe plans for disseminating the findings of the study to relevant stakeholders and target audiences. Define effective communications channels and best formats for presenting the information. Describe how the research will be used to influence practice or policy. Discuss plans for publications, reports and presentations. List any products, including inventions and patents that may be derived from the study. State to whom the data belong and any rights and limitations to access that exist for data analyses and publications.

Note: The results and findings of federally funded research are required to be made available to the public. Publication and other forms of knowledge dissemination/transfer should be built into the activity from the outset.

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Additional considerations:

- Gender: Undertake an analysis of the gender implications of the study. This should include consideration of e.g. involvement of women and girls as stakeholders and participants, how women and girls might stand to benefit from the study, rationale for exclusion from the study population, and differences in biological or social risks associated with gender.
- Environment: Undertake an analysis of the environmental implications of the study. Pay particular attention to disposal of medical waste.
- Plans for sub-awards: Discuss plans for sub-awards, how awardees will be identified, the scope and purpose of the sub-award in the context of the study and the estimated dollar amount and duration of the sub-award.
- Identify the implementing partner(s): Care should be taken to differentiate the roles of researchers from implementers to promote objectivity in research and avoid a major potential source of bias. Identify who will implement the intervention under study and how they will be trained.

Annexes/Appendices: Include

- Study consent forms
- Data collection forms and other study materials
- Institutional review board (IRB) approval letters
- Disclosures of any real or potential conflicts of interest.

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Annex B - Template for research reports

Administration

Heading	Elements
Study name	Study name and any abbreviation. If the study is a clinical trial the title should reflect that. Project name and number
Investigators	Names and institutions of investigators Indicate the principal Investigator Name of contact person and address for correspondence including e-mail address
Study countries	Provide the names of the countries where the research took place.
Ethics	Provide names of institutional review boards (IRB) that reviewed and approved the research. If research was exempt from IRB review indicate this and the reason for the exemption
Funding	Indicate sources of funding
Oversight committees	Provide the name of the committee, data safety monitoring board (DSMB), technical advisory group (TAG), or other oversight body if applicable, and the names of the chairs and the names of the committee members and their institutional affiliations
Abstract	Provide a brief abstract describing the research. Use a structured format. The abstract should include: • Introduction • Methods • Results • Discussion
Key words	Provide up to eight keywords that reflect the content of the report. Avoid use of abbreviations.

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Problem Formulation

Heading	Elements
Background/introduction	Provide a concise statement of the purpose and scope of the study. • Explain why the topic is important if this is not obvious. • Summarize previous research on the topic. Include citations of both published and gray literature. • Explain why previous work is not sufficient. Indicate how this study fills gaps in existing knowledge, addresses unresolved issues, overcomes shortcomings of previous research or contributes to new knowledge. • If appropriate, provide the conceptual framework or theoretical underpinnings of the study and rationale for it. • If appropriate, provide the rationale for the methodological orientation of the study. • If appropriate, provide the rationale for the groups studied. • Describe the context of the study in detail to provide information relevant to how the findings may or may not be applicable to other settings.
Objectives	Primary study objective, question, or hypothesis Secondary study objective(s), question(s), or hypothesis(es)

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Methods

Heading	Elements
Design	• Describe the study design and comparison groups (if any).
Sampling	• Describe the population under study and the rationale for choosing this population if not obvious. • Describe the sampling frame used. • Describe the type of sample drawn (e.g. simple random, stratified, systematic, probability-proportional-to-size, purposeful, snowball, etc.), the methodology used, and the rationale. • Describe how the sample size needed for statistical testing was calculated. Include power calculations. • Describe any non-participation or non-inclusion among sample approached and document reasons.
Sources of data and methods of data collection	• Describe all sources of data used. • Describe how instruments were developed and attach all instruments used in data collection. • Describe the unit(s) of analysis. • Describe in detail how, where, when and by whom data were collected and how field settings or timing may have influenced data collected in that context.
Variables and measures	• Describe any standard measures or instruments used and provide information on their reliability and validity. • If new measures or indexes were developed (e.g. through data reduction techniques), sufficient detail should be provided to make clear how the variables were constructed and how their reliability and validity was assessed. • When transcripts of recordings or notes are used, the method to classify/code response categories or characterize actions should be clearly described.
Data analysis	• Describe the procedures used for analysis including software packages. • Describe the analytic techniques/test statistics used. • For qualitative studies, describe how data were organized into analytic categories and how any constructed analytic concepts/domains have been used, if applicable.

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Results and Conclusions

Heading	Elements
Issues in data collection	• Disclose any issues that arose in data collection and processing (e.g. missing data, losses to follow up, violations of statistical assumptions, possible sources of bias etc.) and how these were handled in cleaning and data analysis. • Describe the quality of data sources such as clinic records and the context of their use.
Presentation of results	• Use tables and graphs to summarize information. In general, tables are better than graphs for giving structured numeric information, whereas graphs are better for indicating trends and making broad comparisons or showing relationships. Tables and graphs should, ideally, be self-explanatory. The reader should be able to understand them without detailed reference to the text. The title should be informative, and rows and columns of tables or axes of graphs should be clearly labeled. The source of data should be given at the bottom. • For each statistical result there should be included a measure of the relation between variables (e.g. odds ratio, regression coefficient), an index of uncertainty (e.g. confidence interval), and a qualitative judgment as to the importance of the finding. • For qualitative analyses, describe the processes throughout data collection of identifying categories of events, actions, subgroups of people, or other substantive categories by which data were organized and patterns of observations identified. The process of developing descriptions, claims and interpretations should be clearly described and illustrated. Evidence to support each claim should be presented. Practices used to develop and enhance the evidence for each claim should be described including the search for disconfirming evidence and alternative interpretations. Interpretive commentary should

DRAFT

	provide a deeper understanding of the claims – e.g. how and why the patterns described may have occurred; how they relate to one another; how they support or challenge theory and findings from previous research. Use direct quotations from informants to illustrate points made. • Report unexpected findings and how that affected analysis.
Presentation of conclusions	• Summarize the main findings and their interpretation, clearly linking them to the purpose/hypothesis of the study presented above. • Indicate alternative explanations for the findings and any possible sources of bias. • Indicate to whom the results in this context may be generalized, or the limits to generalization. • Discuss how the results might be applied in practice as well as the policy and program implications.
Ethical considerations	• State which institutional review boards approved the study or if the study was deemed exempt. • Report research results in a way that honors consent agreements with human subjects and any other agreements with respect to gaining access to research sites, data or materials. • Include statements about potential conflicts of interest.
Dissemination of findings	• Discuss how findings were shared with the research population and other key stakeholders.

DRAFT

Annex C -- Checklist for Environmental Consequences

Check appropriate column as Yes (Y), Maybe (M), No (N) or Beneficial (B). Briefly explain Y, M and B checks in next Section, "Explanations". A "Y" response does not necessarily indicate a significant effect, but rather an issue that requires focused consideration.

Y. M. N or B

1. Earth Resources

   a. grading, trenching, or excavation in cubic meters or hectare ___

   b. geologic hazards (faults, landslides, liquefaction, un-engineered fill, etc.) ___

   c. contaminated soils or ground water on the site ___

   d. offsite overburden/waste disposal or borrow pits required in cubic meters or tons ___

   e. loss of high-quality farmlands in hectares ___

2. Agricultural and Agrochemical

   a. impacts of inputs such as seeds and fertilizers ___

   b. impact of production process on human health and environment ___

   c. other adverse impacts ___

3. Industries

   a. impacts of run-off and run-on water ___

   b. impact of farming such as intensification or extensification ___

   c. impact of other factors ___

4. Air Quality

   a. substantial increase in onsite air pollutant emissions (construction/operation) ___

   b. violation of applicable air pollutant emissions or ambient concentration standards ___

   c. substantial increase in vehicle traffic during construction or operation ___

   d. Demolition or blasting for construction __

   e. substantial increase in odor during construction or operation ___

   f. substantial alteration of microclimate ___

5. Water Resources and Quality

DRAFT

a. river, stream or lake onsite or within 30 meters of construction ___

b. withdrawals from or discharges to surface or ground water ___

c. excavation or placing of fill, removing gravel from, a river, stream or lake ___

d. onsite storage of liquid fuels or hazardous materials in bulk quantities ___

6. Cultural Resources

a. prehistoric, historic, or paleontological resources within 30 meters of construction ___

b. site/facility with unique cultural or ethnic values ___

7. Biological Resources

a. vegetation removal or construction in wetlands or riparian areas in hectare ___

b. use of pesticides/rodenticides, insecticides, or herbicides in hectare ___

c. Construction in or adjacent to a designated wildlife refuge ___

8. Planning and Land Use

a. potential conflict with adjacent land uses ___

b. non-compliance with existing codes, plans, permits or design factors ___

c. construction in national park or designated recreational area ___

d. create substantially annoying source of light or glare ___

e. relocation of >10 individuals for +6 months ___

f. interrupt necessary utility or municipal service > 10 individuals for +6 months ___

g. substantial loss of inefficient use of mineral or non-renewable resources ___

h. increase existing noise levels >5 decibels for +3 months ___

9. Traffic, Transportation and Circulation

a. increase vehicle trips >20% or cause substantial congestion ___

b. design features cause or contribute to safety hazards ___

c. inadequate access or emergency access for anticipated volume of people or traffic ___

10. Hazards

a. substantially increase risk of fire, explosion, or hazardous chemical release ___

b. bulk quantities of hazardous materials or fuels stored on site +3 months ___

DRAFT

c. create or substantially contribute to human health hazard ___

11. Other Issues (to be used for categories not captured under1 through 10 above)

a. Substantial adverse impact ___

b. Adverse impact ___

c. Minimal impact ___

B. EXPLANATION OF ENVIRONMENTAL CONSEQUENCES: explain Y, M and B responses

C. RECOMMENDED ACTION (Highlight Appropriate Action):

1. The project has no potential for substantial adverse environmental effects. No further environmental review is required.
2. The project has little potential for substantial adverse environmental effects; however the recommended mitigation measures will be developed and incorporated in the project design and/or construction, operation and maintenance phases. No further environmental review is required.
3. The project has substantial but mitigatable adverse environmental effects and required measures to mitigate environmental effects. Mitigation and Monitoring (M&M) Plan must be developed and approved by the BEO and/or REO prior to implementation. M&M Plan is to be attached to the Scope of Work.
4. The project has potentially substantial adverse environmental effects, but requires more analysis to form a conclusion. A Scoping Statement must be prepared and be submitted to the BEO for approval. Following BEO approval an Environmental Assessment (EA) will be conducted. Project may not be implemented until the BEO approves the final EA.
5. The project has potentially substantial adverse environmental effects, and revisions to the project design or location or the development of new alternatives is required.
6. The project has substantial and unmitigable adverse environmental effects. Mitigation is insufficient to eliminate these effects and alternatives are not feasible. The project is not recommended for funding.

D. IDENTIFIED SIGNIFICANT ENVIRONMENTAL IMPACTS (including physical, biological and social), if any: (Use ER tools such as Leopold Matrix to identify significant environmental impacts)

E. RECOMMENDED MITIGATION MEASURES (includes Public Participation in case of all types of community and infrastructure projects).

DRAFT

Annex D – iEdison Intellectual Property Reporting Guidelines

Extramural Invention Reporting Compliance Responsibilities Electronic (iEdison) and Paper Mechanisms				
Action	When	Discussion	37 CFR Reference	Comparison Paper vs. iEdison
Employee Agreement to Disclose All Inventions: The agreement to be obtained by the grantee/contractor organization is that the employee will abide by the terms of the patent rights clause.	At time of employment -- term of employment.	Grantee/contractor organizations must have policies in place regarding ownership of intellectual property, including conflict of interest issues.	401.14(f)(2)	
Invention Report: The grantee/contractor must submit a report of any "subject" invention. The report must identify inventor(s), federal agency(ies) grant or contract number(s), and date of any public disclosure. Date of submission establishes time frames for all future actions. Must be complete in technical detail. The report should be directed to the lead agency. The term "subject invention" means any invention of a grantee or contractor	Within 2 months of inventor's initial report to the grantee/contractor organization.	There is no single format for disclosing the invention to the government. The communication should include: the title of the invention, date of any public disclosure, names of all inventors, source(s) of federal funding (i.e. grant or contract number), a written description of the invention in technical detail. The invention disclosure should ideally be signed by the inventor(s): at the very least signed by a grantee/contractor institutional official.	401.14(a)(2) 401.14(c)(1)	Submission of the invention report may be done electronically by uploading either a PDF, TIFF, or text file through iEdison. Alternatively the document can be faxed to the lead agency, or submitted through U.S. mail.

organization conceived or first actually reduced to practice in the performance of work under a federal funding agreement (grant, cooperative agreement, contract).				
Rights to Inventions on Subcontracts: Subcontractors retain rights to their subject inventions.	Same reporting responsibilities, obligations and time frames as prime grantee/contractor organization.	Prime grantee/contractor organization cannot require ownership of subcontractor's subject invention(s).	401.14(g)(1) 401.14(g)(2)	Invention disclosure, confirmatory license, and proof of government support clause may be submitted electronically through iEdison.
Election of Title to Invention: Grantee/contractor organization must notify the federal agency sponsor that it will retain ownership of invention and take steps to commercialize the invention.	Within 2 years of reporting the invention to the lead federal agency sponsor. (If disclosed publicly, this period is decreased.)		401.14(b) 401.14(c)(2) 401.14(f)(1)	Election of title handled electronically using iEdison, otherwise a signed paper document is required.
Confirmatory license: The grantee/contractor organization must provide a nonexclusive, nontransferable, irrevocable, paid-up license for the government to	Commensurate with report of any initial patent filing, unless the invention is being licensed as an unpatented biological		401.14(f)(1)	Submission of the confirmatory license may be done electronically by uploading either a PDF or TIFF file through iEdison. Alternatively the signed document can be faxed to the lead agency, or submitted through

practice or have the invention practiced on its behalf throughout the world.	material or research tool.			U.S. mail. See http://iedison.gov/iEdison/license.jsp
Nonelection of Title to Invention: Grantee/contractor organization must notify the federal sponsor that it will not retain ownership of an invention.	Within 2 years of reporting to federal agency sponsor. (If disclosed publicly, this period is decreased.)	Effectively a waiver to the government. After further review the federal agency sponsor may elect title on behalf of the government. Title does not actually vest with the government until government elects to retain title.	401.14(c)(2) 401.14(d)	Handled electronically through iEdison, otherwise a signed hard-copy request is required.
Assignment of Invention Rights to the Inventor: The inventor may request assignment of invention rights. Agencies support requests of this type to variously. In all cases, documentation is required when a grantee/contractor organization waives rights to the invention and the inventor(s) wishes to retain the invention rights.	At the time the grantee/contractor organization elects not to pursue title and the inventor requests rights in the invention.	First, the grantee/contractor organization must elect not to retain rights in the invention. Second, the inventor must request the assignment of rights, agree to all terms associated with invention reporting as detailed in 37 CFR 401, and must pursue commercialization of the invention through patent filing or licensing as a research tool. Specific procedures for any agency should be determined prior to initiating the request. For NIH, see inventor certification.	401.14(k)(1) non-profits	This status can be indicated using iEdison; all other issues (such as outstanding required documents) should be resolved prior to proceeding further. Paper receipt (via fax) of inventor certification signed by each inventor and organizational official.
Initial Patent	Within 1 year	Time frame may vary	401.14(c)(3)	All filing data can be

Application: The grantee/contractor must inform the government of the initial patent application that related to any subject invention. The patent application must include a government support clause.	after election of title, unless there is an extension.	if invention becomes public. The term initial patent application means a nonprovisional U.S. national application for patent as defined in 37 CFR 1.9(a)(3). The notification must include the patent application number and filing date assigned by the USPTO. A copy of the full application is not required.	401.2(n)	submitted via iEdison. Evidence of inclusion of government support clause may be submitted electronically as either a PDF or TIFF file through iEdison. Alternatively, a hard copy may be submitted via fax or U.S. mail.
Assignment to Third Party: Documentation necessary when a grantee/contractor wishes to assign invention rights to third party. If the grantee/contractor is a non-profit, the government must approve the assignment. For profit or small business grantee/contractors do not need to seek approval. If the rights are assigned, new rights holder assumes the same reporting responsibilities as the grantee/contractor organization.		If assignment approved, third party must pursue commercialization of the invention through patent filing or (for NIH) licensing of the invention as a research tool. Specific procedures to request third party assignment may vary between agencies. Consult lead agency prior to initiating request.	401.14(k) for non-profits. Note the distinction between small businesses and non-profit organizations.	Extent of information available about this process varies according to agency. Consult agency links on the iEdison Home Page.

Issued Patent: Grantee/contractor must provide federal agency sponsor with patent issue date, number, title of patent, and evidence of government support clause.	At the time of issue.	Patent must include government support clause.	401.5(f)(2) 401.14(f)(4)	All issued patent information can be received using iEdison. Evidence of inclusion of government support clause may be provided electronically as a PDF or TIFF file through iEdison. Alternatively, a hard copy may be submitted via fax or U.S. mail.
Request for Extension of Time: An extension of up to two years may be requested for election of title, or one year for filing a patent application.	Prior to any statutory bar.	Extension of 2 years for title election and one year for patent application are preapproved for funded inventions. Additional extensions need written approval from the federal agency sponsor.	401.14(c)(4)	Can be requested electronically if using iEdison; otherwise request must be in writing.
Discontinuance of Patent Application, Payment of Maintenance Fees, or Defense in a Reexamination or Opposition proceeding on a Patent: Grantee/contractor must notify federal agency sponsor of changes in patent status.	At anytime in the process, but prior to established deadlines.	Relevant information and documents (e.g., patent application or patent) must be provided such that a determination to protect government interests can be made. The federal agency sponsor has the option to pursue the patent application or the patent if not being properly pursued or maintained. Any change in status must be reported at least 30 days prior to	401.14(f)(3) 401.6	Indication may be made via iEdison or through written correspondence.

		pending PTO office actions.		
Annual Utilization Report: For agencies that require utilization reporting the report is for all subject inventions that have had title elected or are licensed without a patent. Report includes stage of development, date of first commercial sale or use, number and type of licenses, gross income, licensing to small business, status of U.S. manufacturing and identification of any FDA-approved product names.	Annually for agencies that require utilization reports.	Not all agencies require invention utilization reports. When in doubt, organization should consult the lead agency on the invention in question. For NIH grantee/contractor establishes a 12 month reporting cycle beginning in the month of their choosing. Information requirements defined in iEdison.	401.14(h)	Can be submitted electronically using iEdison, otherwise submission of the same data may be made in writing.
Final Invention Statement and Certification: Report all subject inventions derived or reduced to practice during the performance of the grant or contract.	Due within 90 days after the project ends.	If no inventions occurred during the award period, a negative report must be submitted. The report is to be submitted to the awarding unit grants or contracts management office.	401.5(f)(1)	The completed form must be submitted in hard copy. No electronic submission is yet possible.

For general information contact:
Division of Extramural Inventions & Technology Resources
National Institutes of Health (NIH)
6705 Rockledge Drive, Suite 310, MSC 7980
Bethesda, MD 20892-7980
(301) 435-1986 FAX (301) 80-0272

Interagency-Edison Home Page:
http://www.iedison.gov
E-mail: Edison@nih.gov

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