USAID Scientific Research Policy

A Mandatory Reference for ADS Chapter 200

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List of Acronyms

ADS:	Automated Directives System
AERA:	American Educational Research Association
AO:	Agreement Officer
A/COR:	Agreement or Contract Officer's Representative
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
IDA:	International Disaster Assistance
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
OFDA:	Office of Foreign Disaster Assistance
OHRP:	Office of Human Research Protections
OMB:	Office of Management and Budget
OSTP:	Office of Science and Technology Policy
PI:	Principal Investigator
PIO:	Public International Organization
PSC:	Personal Services Contractor
REO:	Regional Environmental Officer
RFA:	Request for Applications
RFP:	Request for Proposals
TA:	Technical Advisor
TAG:	Technical Advisory Group
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

1. Introduction

This document is written for the United States Agency for International Development (USAID) staff and implementing partners. The purpose of this document is to consolidate, in one convenient reference, operational policies of particular relevance to the design and management of research activities. Many of these policies exist in the Automated Directives System (ADS). While avoiding restating these policies, this document references them and, where necessary, provides further guidance on matters that frequently arise in the conduct of research. This document also fills important operational policy gaps that are not covered in the ADS, especially on subjects such as scientific peer review, quality standards for research plans and reports, open data, and scientific publication.

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 do as follows:

- 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 various 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; 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 - OMB) 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 Scientific Research Policy, is not absolute, as a general guideline, research includes:

- Experiments
- Observational studies
- Implementation research including pilot studies
- Qualitative studies
- Population-based surveys that provide data for global results monitoring, small area variation analyses and cross-national comparisons and analyses for example
- Product development activities including market research and acceptability studies

Research generally does **not** include:

- Routine product safety and/or quality monitoring and testing and other types of quality assurance and improvement activities
- Performance evaluations
- Routine program/project monitoring
- Descriptive geographic mapping and earth observations
- Assessments done for the purpose of program/project design or that contribute to strategy development
- Training activities for scientific and technical personnel

Using research methods such as surveys, assessments, focus groups, polls, and other quantitative and qualitative analytical techniques does not imply that the activity is research. In many instances, the activity may still be called a "study" and subject to the policies outlined herein including review by an institutional review board (IRB) for human subjects' protection as required by regulation.

Significant 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. While most impact evaluations are research, some impact evaluations, particularly those conducted to inform internal program/project design choices, may not be classified as research. In either case, both impact and performance evaluations continue to be subject to the standards and requirements of the USAID Evaluation Policy.

Impact Evaluations and Research

Impact evaluations and research can form a virtuous cycle: Research priorities help formulate and refine impact evaluation questions so that these can advance the state of knowledge around a particular subject. In turn, impact evaluations ground-truth research findings: they test innovative strategies and approaches in a real-world setting before they are scaled up with USAID funding, and in doing so, reveal new areas of research to be explored.

For more information on impact evaluations at USAID, refer to **ADS Chapter 203** and the **Technical Note on Impact Evaluations**.

The following key principles guide all aspects of USAID supported research:

Quality – USAID supports 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 and Missions) and externally (among implementing agencies, other agencies of the United States Government (USG), and among other donors) to ensure efficiency, avoid duplication, and maximize the impact of resources.

Ethics – Research meets ethical standards of accountability and social responsibility. Research must be conducted according to the highest scientific and professional standards of integrity. Research involving human subjects or laboratory animals must 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 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.

Relevance – Research priorities within a given topic or sector will reflect USAID's strategic goals.

Support – Long-term support may be required to ensure that research results and knowledge are used to improve programs and achieve impact at scale. Not all research activities can be completed within a five-year time horizon allowed by most cooperative agreements and contracts[1]. Strategic efforts that require a longer time horizon will be protected where appropriate[2].

2. Designing research activities

Planning

Good planning is essential for a successful research activity. In the design phase of an activity that will focus on or include research, all aspects of the conduct and management of the research should be considered – not just the topic of the research or the study questions to be addressed. For example, the kind of substantial involvement language included in an award document, the level of peer review required, the types of publications that may result, how the project will tackle local capacity development and gender issues, and how the research contributes to the overall development objectives can be included when applicable.

Setting research priorities

Research is an integral component of USAID's sustainable development programming. USAID's resources are limited compared to the magnitude and scope of research needs in international

[1] Another option that USAID offices have is to set up agreements that ensure continuity of personnel from one contract to the next – for instance prohibiting non-compete clauses for principal investigators (PIs) so that they can work for whatever firm wins the follow-up contract –and establishing clear guidance for how data is to be transferred. This is especially important in cases where it is more desirable to re-compete a contract than to extend it (for instance if a firm's performance is not ideal).

[2] 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 accordance with a mutually agreed upon budget. For reference see USAID ADS 303.3.14, ADS 303.6.5, and 22 CFR 226.25.

development issues. 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 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 redundant or duplicate other donor supported research or 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 include the following:

- Magnitude and significance of the problem. Significant factors include, but are not limited to numbers of people affected, geographic area affected, and economic impact
- Relevance of the research to USAID's strategic priorities and mission statement, Missions' identified needs and country-defined priorities
- 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
- 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
- Research design is informed by a strong contextual understanding

Engaging new partners
It is critical to ensure that requests for applications (RFA), requests for proposals (RFP), and annual program statements (APS) 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 in addition to encouraging new partners to apply.

Guidance includes 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 prospective implementer
- 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, and host country governments, patents registered, etc.)

Intellectual property considerations
Research awards may include more complex intellectual property (IP) issues than other USAID awards. Research awards may, for example, involve IP that is used in the award, which may belong to the implementing partner or to a third party, or 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 and provisions can be included in the award. Where the IP issues are complex, Operating Units should consult with The Office of the General Counsel and consider an IP Management Plan.

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 pre-existing 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
- 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 226.36 provides the standard IP provision for US organizations under assistance, and the Standard Provisions for Non-US Non-Government Organizations entitled "Patent Rights" provides the standard IP provision for non-US organizations under assistance (see ADS 303). For contracts, AIDAR 52.227-14 provides the standard IP clause. USAID policy on Intellectual Property may be found in 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 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.

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. Capacity development also extends to the enabling environment for research, which includes a

country's policy for supporting and funding science, how it prioritizes areas for research, and how it uses evidence in decision making.

The process of change occurs at the individual level to improve individual competencies, and at the organizational level to improve the functions, policies, 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. Individuals and their organizations take ownership to build skills and organizational systems that ultimately enable participation in research that is both intellectually and managerially on par with counterpart investigators and research organizations globally. 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 principles outlined in USAID Forward. Therefore USAID's research activities, to the maximum extent possible, should adhere to the following:

- 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, relationships with, and awards to developing country researchers and research organizations to conduct all aspects of research studies
- Support the capacity development of women scientists
- Ensure that developing country researchers receive credit for contributions they make on research studies concerning standards for protecting confidentiality of original data, retrieval mechanisms, copyright and embargo periods, etc.
- Involve from the beginning and throughout the research process country stakeholders best placed to benefit from, and act upon, the research findings. Establishing technical advisory groups that consist 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 and publications

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 funded 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 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 order applies to data generated as a result of research activities. See USAID's Public Access Plan and Open Data Policies for additional information concerning standards for protecting confidentiality of original data, retrieval mechanisms, copyright and embargo periods, etc.

3. Quality Standards in Research

Sound development programming relies on robust 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. The National Research Council (NRC)[3] describes quality research as having the following characteristics:

- 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 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;
- Considers alternative explanations for findings;
- Assesses the possible impact of systematic bias;
- Submits research to the peer review process; and
- 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
All research requires a detailed research plan prior to approval of the use of USAID funds. A well-written research plan (sometimes referred to as a protocol) facilitates quality research results. Regardless of discipline, the main elements of a research plan are similar. Research plans usually include:

- Abstract;

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

- 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;
- Methodology section that includes study design, population, sample size and statistical power, subject selection, data collection, measurement methods, and possible limitations;
- Statistical analyses planned;
- Strategies for data management and dissemination to the public;
- Project management, personnel roles and responsibilities, data handling;
- Ethical considerations (protections of human subjects and/or animals);
- Budget and timeline;
- Persons responsible for the research and their roles; and
- Partners (local and international).

Given the nature of USAID's work, the research plan should also discuss community and/or stakeholder involvement in the research planning and dissemination and utilization of the research results.

USAID employs different models of funding research that 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 part of 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, and activities to increase the capacity of the house country partners to conduct research, and activities to address knowledge management challenges). For such projects, it is not practical to expect research plans 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. Each research plan, therefore, must be approved by the agreement or contract officer's representative (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 provide implementing partners clear guidelines on the preparation of research plans for submission to USAID. 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 USG agencies that fund and that scientific and technical merits of research plans submitted to USAID and influential scientific, financial, and statistical information disseminated by the Federal Government[4].

[4] Peer review guidelines are not required for studies and assessments done through grants to public international organizations (PIOs) or supported by the Office of Foreign Disaster Assistance using International Disaster Assistance (IDA) funds.

Types of review: Scientific peer review involves the review of research plans by scientific experts who have in-depth expertise in the topic of the research and who do not have a conflict of interest (COI)[5].

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 the investigators of the research being proposed. "Internal" reviewers are scientific or program experts on the staff of USAID and are not directly involved in the financial sponsorship of the research.

Aims and scope: Regardless of whether a reviewer is considered "internal" or external," it is important to seek opinions from reviewers who can comment on the scientific methodology and on the relevance of the research to field programs and development priorities. 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 clearly describe:

- The likely contribution the study will make to the overall goals of the award;
- The intervention so that it could be replicated and brought to scale if it proves successful;
- The previous research reported in the literature and how the current research contributes to new knowledge;
- The costs of an intervention and the investment required to implement at scale in developing countries;
- The study methodology;
- The plans for data sharing, knowledge transfer, host-country investigator capacity development, and knowledge management;
- Appropriate steps for protection of human subjects and animal welfare; and
- Budget and timeline for the work proposed[6].

While research plans require scientific 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 variety 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 second scientific peer review.

In other words, one model of peer review is not appropriate for all situations. The research question, the complexity of the research methodology, the possible implications of the research, ethical considerations and the need to seek fairness and balance in the review should also determine the level and extensiveness of scientific peer review required. Some illustrative

[5] Conflict of Interest for a peer reviewer is determined by three primary criteria: (1) The affiliation of the reviewer with an applicant institution, (2) A relationship with an investigator, project director, or other person who has a personal interest in the proposal or other application, and (3) Other affiliations or relationships between the reviewer and the applicants.

[6] Because budgets are often considered sensitive information and thus implementing partners may not wish to share such information with other implementing partners, budget information may be redacted from the research plan shared with peer reviewers.

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, persons with disabilities);
- The 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;
- Anticipated challenges to equitable participation in or benefit from research (for example, gender equity);
- Whether the study results will likely lead to policy changes nationally or globally that would impact large numbers of people, animals, systems, or the environment;
- Whether there are likely to be political, economic, or social implications of the research that would result in challenges based on the study's methodology or conclusions.

Conduct of the review pre-award: 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** in conjunction with the technical evaluation committee (TEC) review. In such cases the application or proposal for funding must describe the research plan in sufficient detail to allow the TEC reviewers to assess its scientific and technical merit.

In keeping with USG procurement regulations, the majority of reviewers on a TEC must be USAID staff regardless of hiring mechanism. However, external scientific peer reviewers may participate on a TEC as long as they have no real or perceived conflict of interest (COI)[7]. TEC members are required to certify that they have no COI and must sign a non-disclosure agreement.

External scientific reviewers selected as peer reviewers must be recognized scientific or technical subject matter experts, and it is often beneficial for at least one reviewer to 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, or from non-governmental organizations, and the private sector. 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. Additionally, because of the nature of development-related research, a good peer review process should seek feedback from implementers and communities of practice who understand the realities of conducting research in developing country settings.

It is the responsibility of the chair of the TEC to summarize the findings of the review and the

[7] A COI 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.

consensus opinion of the reviewers regarding the scientific and technical merit of the research.

Conduct of the review post-award: In instances where research plans will be developed **post-award** e.g. for projects designed to conduct multiple studies over timestudies that respond to emerging needs or requests from the field or headquarters or for projects 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 throughout the course of the project 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 should review research plans as part of their normal duties, and the Agency standard is to also seek the scientific opinion of peer reviewers external to USAID and to the investigator's organization. The level and extensiveness of the review depends on the research to be undertaken as described previously. The selection of peer reviewers follows the same principles and guidance outlined above for pre- award reviews.

General Principles: Various methods may be used to conduct a technically sound, balanced and fair peer review in an efficient and time sensitive manner. For example, USAID has contracted with a number of different external organizations to facilitate and help organize panels of scientific peer reviewers, or A/CORs recruit external scientific peer reviewers themselves and handle all aspects of the review.

Regardless of the method chosen, it is critically important to conduct the review in a timely way. Typically, reviews should not extend beyond a few weeks.

In a typical review, investigators are "blind" to the identities of the peer reviewers selected and sometimes peer reviewers are blind to the identity of the investigator(s) in an effort to encourage unbiased assessment in the review process.

A/CORs and technical advisors (TA) who manage research should reach out to their own networks of scientific experts to identify appropriate peer reviewers. A/CORs and TAs who are not researchers by training are strongly encouraged to reach out to Chief Scientists or other colleagues with scientific expertise in Pillar Bureaus for help in selecting reviewers or in managing the review process.

Ultimately the A/COR or TA for the project conducting the research assumes responsibility for a timely, fair and balanced review process. Regardless of the method chosen to conduct the review they must ensure that the reviewers selected are appropriate and have the necessary expertise. They must ensure that feedback from reviewers is consolidated and communicated to the implementing partner in a timely manner. A/CORs and TAs are also responsible for refereeing any divergent opinions among reviewers and working with the implementing partner on a plan to resolve any scientific and technical issues. Again, if A/CORs and TAs do not have a strong research background they should consult with scientific experts in Pillar Bureaus who do.

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
OMB has issued guidelines for ensuring the quality and objectivity of information disseminated by Federal agencies[8]. OMB requires federal agencies to submit all influential scientific information to peer review before the information is publicly 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 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" (as defined above) must be subjected to rigorous unbiased scientific peer review. The policy may be found in ADS Chapter 578.

For further information see:

- OMB Memo: Final Information Quality Bulletin for Peer Review Revised Information Quality Bulletin for Peer Review OMB Information Quality Guidelines

4. Ethical Standards in Research

Protection of human subjects
Along with many other agencies of the USG, USAID has adopted the Common Federal Policy

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

for Protection of Human Subjects in Research (the "Common Rule") see 22 CFR part 225[9]. 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: **ADS 200mbe**. 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;
- 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?
- When are human subjects involved?

A/CORs, TAs, and Mission staff has 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. Therefore A/CORs for USAID projects that include research involving human subjects should be knowledgeable about these regulations. It is the responsibility of a CO/AO to ensure the AIDAR clause 752.7012 (applicable to contracts) or a standard provision (for assistance instruments) is included in the award document. 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 the United States. Criteria for the proper constitution and function of an IRB are included in the Common Rule and USAID recipients subject to these

[9] When other USG agencies are involved in research additional provisions of the Common Rule may apply, for example 45 CFR part 46.

regulations must formally certify that they will comply with these criteria. Many research institutions (in the United States 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[10], 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 reinforce 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 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. In no case should such fees 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

Assistance awards that anticipate using animals in research must contain the ADS standard provision entitled "Care of Laboratory Animal." The provision notes that award recipients performing research in the United States 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.

[10] 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.

To ensure 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.

The AIDAR currently does not contain similar requirements for care of laboratory animals for contracts. Contractors should adhere to the guidelines developed by the National Academy of Sciences-National Research Council cited above.

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 or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism – is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research misconduct does not include honest error, differences of opinion, data cleaning, and or 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. For additional discussion, background, and guidance concerning scientific misconduct see 45 CFR part 689.

5. 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[11]. Research reports should be reviewed by the A/COR

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

before they are finalized and disseminated only to ensure high quality of scientific content.

All publications that result from work funded by USAID whether published during or upon completion of the award must acknowledge that the work was supported in whole or part by USAID and cite the award number with the following statement of acknowledgement: “This material is based upon work supported by the United States Agency for International Development under award number (awardee must enter USAID award number).” For additional information related to branding and marking strategies see ADS Chapters **302** and **303**.

Progress reports
Implementing partners are required to submit routine progress reports in accordance with 22 CFR 226.25, 51 and 91 and AIDAR 752.242-70. 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 an Activity Monitoring and Evaluation 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 published 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, Pillar Bureaus have databases to track investments in research that are designed to meet specific 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 patents and patents pending on USAID-supported products, inventions, pharmaceuticals and related processes; and
- Number of new researchers trained.

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, 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.

6. Supporting Scientific and Technical Excellence among USAID Staff

Publication

USAID staff is 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. It also 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 adhere 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 periodicals and books (including electronic publications), and abstract submissions to scientific conferences. 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 any of the following criteria are met:

- 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;
- 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 is directed to adhere to commonly accepted standards such as 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 they intend to publish. These requirements often include the disclosure of relevant financial interests, activities, relationships, and affiliations.

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[12].

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 manuscript 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
- 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

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

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 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, United States Direct Hires (USDHs) and Personal Services Contractors (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, grant or agreement. If staff are asked to sign publishing agreements in their professional capacity, they should consult 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.

Conference Attendance

Opportunities to engage in scientific exchange at scientific and technical conferences are important for USAID scientists and technical experts, particularly those in direct hire positions. New OMB directives to federal agencies further restricted travel budgets in general and conference attendance in particular.[13] In response to concerns about the new policy raised by the scientific community within and outside the federal government, OMB along with the Office of Science and Technology Policy (OSTP) issued a **Controller Alert** in May 2013 that encourages agencies to recognize the critical role that conferences play in scientific collaboration, dissemination of scientific information, and scientific exchange[14].

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 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.

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[13] OMB Memorandum M-12-12

[14] 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.