



**USAID**  
FROM THE AMERICAN PEOPLE

# Research and Development in Global Health: A Handbook for USAID Staff and Implementing Partners



## TABLE OF CONTENTS

|  |    |
|--|----|
| <b>Abbreviations</b> .....   | 3  |
| <b>Purpose</b> .....   | 4  |
| <b>Definitions, Framework and Principles</b> .....                               | 4  |
| Definitions.....   | 4  |
| R&D for Sustainable Development.....   | 4  |
| Criteria for Establishing R&D Priorities.....                                    | 5  |
| Guiding Principles.....  | 5  |
| <b>Roles and Responsibilities of BGH Staff</b> .....                             | 6  |
| Scientific and Technical Responsibilities .....                                  | 6  |
| Writing and Publishing.....  | 6  |
| Project Management Responsibilities .....  | 8  |
| <b>Operational Guidelines for Research Administration</b> .....                  | 10 |
| Types of Award Instruments.....  | 10 |
| Solicitation and Award Procedures .....  | 10 |
| Work Plans.....  | 11 |
| Proposal Guidelines.....   | 11 |
| Peer Review Procedures.....  | 12 |
| Review Criteria.....   | 13 |
| Protection of Human Subjects.....  | 14 |
| Care of Laboratory Animals.....  | 15 |
| Reporting Requirements, Monitoring and Evaluation.....                           | 16 |
| Publications and Media Releases Under Cooperative Agreements and Contracts ..... | 16 |
| Copyright.....   | 17 |
| Patent Rights and Royalties.....   | 17 |
| Metric System of Measurement.....  | 17 |
| Research Misconduct .....  | 17 |
| <b>Annexes</b>   |    |
| A – Members of the BGH Research Managers Group.....                              | 18 |
| B – Protection of Human Subjects in Research.....                                | 19 |
| C – Patent Rights and Royalties .....  | 31 |
| D – Links to Regulatory and Policy Guidance.....                                 | 35 |

## ABBREVIATIONS

|                |  |
|----------------|--|
| <b>ADS</b>     | Automated Directives System                        |
| <b>APS</b>     | Annual Program Statement                           |
| <b>AIDAR</b>   | USAID Acquisition Regulation                       |
| <b>AO</b>      | Agreement Officer                                  |
| <b>AOTR</b>    | Agreement Officer's Technical Representative       |
| <b>APHIS</b>   | Animal and Plant Inspection Service                |
| <b>BGH</b>     | Bureau for Global Health                           |
| <b>CFR</b>     | Code of Federal Regulations                        |
| <b>CHSO</b>    | Cognizant Human Subjects Officer                   |
| <b>CO</b>      | Contract's Officer                                 |
| <b>COTR</b>    | Contract's Officer Technical Representative        |
| <b>ERC</b>     | Ethical Review Committee                           |
| <b>FAR</b>     | Federal Acquisition Regulations                    |
| <b>FWA</b>     | Federal-Wide Assurance                             |
| <b>HHS</b>     | Health and Human Services                          |
| <b>HIDN</b>    | Office of Health, Infectious Disease and Nutrition |
| <b>HRIT</b>    | Health Research Information Tracking               |
| <b>IRB</b>     | Institutional Review Board                         |
| <b>IPR</b>     | Intellectual Property Rights                       |
| <b>IQC</b>     | Indefinite Quantity Contract                       |
| <b>LPA</b>     | Legislative and Public Affairs                     |
| <b>LWA</b>     | Leader with Associates                             |
| <b>MPA</b>     | Multiple Project Assistance                        |
| <b>NAS</b>     | National Academy of Sciences                       |
| <b>NGO</b>     | Nongovernmental Organization                       |
| <b>NIH</b>     | National Institutes of Health                      |
| <b>NRC</b>     | National Research Council                          |
| <b>OHA</b>     | Office of HIV/AIDS                                 |
| <b>OMB</b>     | Office of Management and Budget                    |
| <b>PRH</b>     | Office of Population and Reproductive Health       |
| <b>R&amp;D</b> | Research and Development                           |
| <b>RFA</b>     | Request for Applications                           |
| <b>RFP</b>     | Request for Proposals                              |
| <b>TA</b>      | Technical Advisor                                  |
| <b>TAG</b>     | Technical Advisory Group                           |
| <b>TEC</b>     | Technical Evaluation Committee                     |
| <b>TO</b>      | Task Order   |
| <b>SOW</b>     | Scope of Work                                      |
| <b>USAID</b>   | United States Agency for International Development |
| <b>USAID/W</b> | USAID/Washington                                   |
| <b>USDA</b>    | United States Department of Agriculture            |
| <b>USG</b>     | United States Government                           |
| <b>UN</b>      | United Nations                                     |

## PURPOSE OF THIS HANDBOOK

This handbook provides an easy reference of policies and recommended best practices specifically related to research and development (R&D) grants, cooperative agreements, contracts and other types of awards. Policies are drawn from the Automated Directive System (ADS), the USAID Acquisition Regulation (AIDAR), the Code of Federal Regulations (CFR) and the Federal Acquisition Regulations (FAR). For issues where no official government policy exists, the members of the Bureau for Global Health (BGH) Research Managers Group (Annex A) developed recommendations on best practices. This handbook is also intended to provide more open and transparent information to our implementing partners and other stakeholders on how BGH designs, awards and manages R&D activities.

## DEFINITIONS, FRAMEWORK AND PRINCIPLES

### Definitions

Research and development activities comprise creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications. Basic research is defined as systematic study directed toward fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications towards processes or products in mind. Applied research is defined as the systematic study to gain knowledge or understanding necessary to determine the means by which a recognized and specific need may be met. Development is defined as systematic application of knowledge or understanding directed toward the production of useful materials, devices and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements. USAID engages in applied research and development but not basic research.

See: <http://www.nsf.gov/statistics/randdef/fedgov.cfm#ombc>

*Source: Office of Management and Budget (OMB) standard definitions of research.*

### R&D for Sustainable Development

The role of BGH-supported R&D derives directly from the USAID's mission to support the United States' national interests by promoting sustainable development. R&D allows USAID to develop, test, refine and evaluate new and improved products, tools, approaches and interventions that focus on the key health concerns of developing countries. R&D results help inform public health policy and practice and guide health systems reform. Overall, R&D-related activities funded by BGH have four specific aims:

- To enable scientific and technological discoveries that improve the health and well-being of people by offering sustainable solutions to key development challenges in health and nutrition, population, the environment, and humanitarian assistance;
- To develop innovative strategies to encourage the use of research results and best practices to strengthen programs and prevent morbidity and mortality;
- To foster host-country capacity to conduct research; and
- To promote open access to research results through knowledge management.

The three technical offices of BGH – Health, Infectious Diseases and Nutrition (HIDN), Population and Reproductive Health (PRH) and HIV/AIDS (OHA) -- fund R&D activities across a spectrum of issues including vaccine development, contraceptive technology, micronutrients and food supplements, development of products to prevent the spread of HIV/AIDS, operations research to improve programs, and behavioral/social science research to improve service utilization and health seeking behavior. BGH also supports systematic reviews of scientific evidence to support programming, consensus development conferences, and other related scientific activities in support of development objectives. Detailed

information on the objectives, accomplishments and breadth of BGH research may be found in the research reports to Congress on Health-Related Research and Development Activities at USAID:

[http://pdf.usaid.gov/pdf\\_docs/PDACN515.pdf](http://pdf.usaid.gov/pdf_docs/PDACN515.pdf) (2009)

[http://pdf.usaid.gov/pdf\\_docs/PDACL916.pdf](http://pdf.usaid.gov/pdf_docs/PDACL916.pdf) (2008)

[http://pdf.usaid.gov/pdf\\_docs/PDACHI11.pdf](http://pdf.usaid.gov/pdf_docs/PDACHI11.pdf) (2006)

[http://pdf.dec.org/pdf\\_docs/PDACF051.pdf](http://pdf.dec.org/pdf_docs/PDACF051.pdf) (2005)

*Source: USAID Research: Policy Framework, Principles and Operational Guidance (1995)*

### **Criteria for Establishing R&D Priorities**

During the planning phase of a new research activity, USAID scientific and technical staff consult with experts from within the Agency, Missions, host-country governments, other donors and United Nations (UN) agencies, universities, other United States Government (USG) agencies, and nongovernmental organizations (NGOs) to identify major gaps in knowledge and critical research priorities. Research priorities are then identified that reflect the strategic goals set by each technical office of BGH and contribute to the strategic priorities outlined in State/USAID policy documents. The following criteria are used by the technical offices and their divisions in selecting topics for investigation and allocating resources to research:

- Relevance - Research contributes to achieving development assistance activities.
- Alignment - Research reflects BGH/USAID strategic priorities.
- Importance - Magnitude or severity of the problem that the research is designed to mitigate is of major public health significance and opportunities for impact exist.
- Feasibility - Research will likely produce useful knowledge, product or technology.

*Source: USAID Research: Policy Framework, Principles and Operational Guidance (1995)*

### **Guiding Principles**

The following principles guide all aspects of BGH-funded R&D activities:

- Quality – BGH supports high quality R&D that not only meets USG standards for research implementation but also assures review of the R&D activities at all appropriate stages, from proposal to outcome.
- Responsible management – BGH maintains a highly-skilled scientific and technical staff to assure responsible management and oversight of R&D activities.
- Research utilization – BGH research findings will be fully incorporated and integrated into development assistance activities.
- Coordination – R&D activities will be coordinated internally (within BGH, 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 – BGH-supported R&D 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 (see section III). Research will also conform to all applicable US and host-country regulations related to environmental risks and/or safety.
- Participation – Where appropriate, local, informed participation (e.g. through community advisory boards) will help guide all aspects of R&D from identifying the problem, to conducting the research and analysis, to incorporating the findings into strategies, policies and programs.
- Support for short- and long-term R&D – Not all R&D activities can be completed within the 5-year time horizon of most cooperative agreements and contracts. Strategic efforts that require a longer time horizon will be protected where appropriate.

*Source: USAID Research: Policy Framework, Principles and Operational Guidance (1995)*

## ROLES AND RESPONSIBILITIES OF BGH STAFF

### Scientific and Technical Responsibilities

BGH R&D managers and technical advisors are scientific and technical experts who, together with colleagues in their respective offices and the larger development community, are responsible for strategic planning, identifying research priorities and defining the technical of research within the context of development. BGH staff are responsible for program design and technical evaluation leading to award of cooperative agreements, grants and contracts. BGH staff help guide:

- Knowledge management and synthesis of findings;
- Research to practice/research to policy activities and engagement with policy makers, program implementers, missions and the scientific community both globally and at country-level;
- Capacity development of host country partners and institutions to conduct research.

BGH staff also provide technical support to USAID field missions and to USAID/Washington colleagues and implementing partners who occasionally need to conduct research to guide programs in the field. BGH staff provide a range of services including: support in the design and implementation of R&D activities; advice on human subjects issues; proposal review; and other related matters. BGH staff also provide support in communicating significant R&D results and encouraging the incorporation of results into programs and policy development activities. Missions, USAID/Washington staff and implementing partners are encouraged to seek support from BGH R&D staff in the design and conduct of research.

*Source: BGH Research Administrators Core Group*

### Writing and Publishing

BGH staff may be afforded opportunities during regular business hours to write and publish in scientific books and journals, conduct secondary data analyses on open access data sets, attend scientific conferences and study sections, present papers, attend journal discussion groups and keep up to date with the scientific literature. According to Gloria Steele, Deputy Assistance Administrator of the Global Health Bureau:

“A critical function of technical staff in the Bureau for Global Health is to provide technical leadership. It is essential that our staff demonstrate such leadership and continually develop their technical expertise. One way to show and develop technical leadership is by publishing, especially in peer-reviewed journals. Other ways which I strongly support include providing input into book chapters and websites, writing technical briefs, and making technical presentations at national and international fora.”

### Approval Process for Written Materials

BGH staff may write and publish in both traditional media as well as in new media forms but must follow the procedures outlined in ADS 558.5.3. Note that this guidance applies only to outside publication (e.g. in scientific journals and books) of manuscripts or technical documents of official USAID concern.

- All written materials relating to the work of USAID which have been written by USAID personnel for publication in the United States shall be submitted for approval by the office director to which the material most closely pertains, and by Legislative and Public Affairs (LPA) before submission to literary agents or publishers. Before submitting written materials to the office director it is advisable to seek concurrence from one's division chief as well. Only on a case by case basis or when one's office director believes it prudent, seek Assistant Administrator or Deputy Assistant Administrator approval.

- When publishing materials which are not of official concern, but which might be thought to be USAID related, USAID employees shall include a specific statement to the effect that the opinions and views expressed are those of the author and not necessarily those of USAID. If there is doubt as to the propriety of the publication, the employee shall seek guidance or advice from LPA.
- USAID employees shall not make commitments to publishers until material has been approved for publication by LPA.
- Upon written request, LPA shall forward approved materials to publishers or agents as designated by the author.
- USAID personnel shall not accept compensation or fees for material written as a matter of official business, as prohibited by statute.

Check with the GH Communications Team prior to submitting the manuscript to LPA as the appropriate point person in LPA changes from time to time. The LPA shall conduct its review and either approve or disapprove material to be published which is submitted for approval within 30 calendar days after receipt thereof, except in extraordinary circumstances.

- If extraordinary circumstances, as determined by LPA, prevent a review and approval or disapproval of the material within 30 days, LPA shall notify the submitter of the material in writing to that effect. Such notice shall set forth the reasons why the material was not acted upon within 30 days and shall establish an estimated time, not to exceed 15 calendar days, by which the material will be acted upon.
- If the review cannot be completed within this period, LPA shall again notify the submitter of the material of the delay and the reasons for it. This procedure of written notices shall continue at a maximum interval of 15 days until LPA approves or disapproves the material for publication.
- In the case of short manuscripts concerning matters of particular timeliness, where the submitter requests an expedited review within a reasonable time period of less than 30 days and gives specific reasons warranting such an expedited review, LPA shall either approve or disapprove the material for publication within the time requested or as soon thereafter as possible.

*Source: ADS 558.5.3*

### **Guidelines for Authorship**

In addition to this ADS requirement, BGH encourages its staff to adhere to the Uniform requirements for manuscripts submitted to biomedical journals [<http://www.icmje.org/>]. BGH staff may coauthor scientific publications of their own or that result from research conducted under USAID funded grants, cooperative agreements and contracts. However, authorship credit should be based on the following conditions, all of which should be met:

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

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

In addition to meeting the criteria for authorship, first authors have these additional responsibilities:

- Provide leadership for the authorship team in determining author order, establishing writing assignments and deadlines for written contributions and coauthor reviews, and ensure an open forum for coauthors to share their comments and suggestions.
- Compile drafts, distribute them for review, and provide specific direction for reviews and revisions.
- Ensure all ethical considerations (Institutional Review Board review, disclosure of conflicts of interest) have been addressed.

The order of authorship should be a joint decision of the coauthors. 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 be listed, with their permission, elsewhere.

*Source: BGH Research Administrators Core Group*

### **Scientific Conferences, Study Sections, Editorial Activities**

BGH staff are also encouraged to attend scientific conferences to keep current in their fields of expertise and training and to present papers and poster sessions. Likewise, BGH staff may participate in scientific panels, study sections, and serve as reviewers for scientific journals.

*Source: BGH Research Administrators Core Group*

### **Project Management Responsibilities**

USAID scientific and technical officers often have project management responsibilities and are designated as Contract Officer Technical Representatives (COTR) or Agreement Officer Technical Representatives (AOTR) depending on whether the project they manage is a contract or grant/cooperative agreement. COTRs and AOTRs must be USG direct hires and are responsible for the functions discussed below. However, with the exception of approval of documents that authorize spending USG funds (e.g. work plans, proposals and sub-awards) and hiring of key staff, many of these duties may be delegated to non-direct hire technical experts designated as technical advisors (TAs)

The following summarizes the main project management responsibilities of AOTRs and COTRs (and TAs where permissible):

- Carry out all responsibilities as delegated by the Contracts Officer (CO) for contracts or as noted by the Agreement Officer (AO) in the case of cooperative agreements;
- Provide technical guidance and input;
- Maintain contact with project staff, including conduct of site visits;
- Review and analyze reports and verify timely performance, including monitoring reporting requirements;
- Ensure compliance with the terms and conditions specified in the award document;
- Monitor financial reports and in the case of contracts, approve requests for payment;
- Notify the CO/AO promptly of any developments that could have a significant impact on performance;
- Prepare internal documents to support amendments to the award document;
- Assist the CO/AO in the review of proposed Branding Strategy and Marking Plans and monitor the execution of approved Marking Plans;
- Ensure all environmental measures and conditions in the award are implemented throughout the life of the award and that timely amendments are undertaken as needed and the relevant Bureau Environmental Officer approves them in writing;
- Monitor compliance with all security specifications and notify the CO/AO and the Office of Security of any problems or suspected non-compliance with requirements;
- Evaluate the effectiveness of the project and submit a final report to the CO/AO; and

- Perform other duties, as requested or delegated by the CO/AO, to ensure prudent management of funds. In the case of contracts these would include, for example, receipt and inspection of completed services or supplies upon delivery and monitoring of Government-furnished property.

*Source: FAR, and ADS 300*

Cooperative agreements are most commonly used for R&D projects. Substantial involvement for R&D projects includes but is not limited to the following elements:

- Approval of annual work plans and all modifications which describe the specific activities to be carried out under the contract or grant/cooperative agreement. Note: A work plan may include brief descriptions of numerous studies to be initiated in a given year. Proposals for specific research studies are considered *modifications to work plans and require separate approval*.
- Designation of key positions and approval of key positions and any changes.
- Approval of monitoring and evaluation plans. The COTR/AOTR will be involved in monitoring progress toward achievement of the objective and expected results during the course of the contract/agreement and in monitoring financial expenditures.
- Review and approval of all sub-awards, grants under contracts, and associate awards (in the case of for leader with associate cooperative agreements).
- Other monitoring as appropriate as described in 22 CFR 226.

*Source: ADS 300; BGH Research Administrators Core Group*

## OPERATIONAL GUIDELINES FOR R&D ADMINISTRATION

### Types of Award Instruments

BGH supports R&D through a variety of available federal funding mechanisms -- each with their own distinct policies, forms, procedures and associated documents. The major types used to conduct R&D are categorized as follows:

- *Contracts* purchase services, equipment or commodities according to a specified scope of work (SOW). The SOW spells out the exact nature of the purchase, when and where it is to be delivered, and other particulars as needed.
- *Indefinite Quantity Contracts (IQC)* are a type of contract that may be used when the purpose is to provide an unfixed amount of supplies and services within stated limits overall stated period. As needs become defined, USAID prepares task orders (TO) defining the contract details and specifications.
- *Cooperative agreements* are used when the principal purpose of the relationship is the transfer of money, property, services or anything of value to the recipient in order to accomplish a public purpose. Typically USAID is substantially involved in carrying out the program at a level specified in the agreement.
- *Leader with associates (LWA) awards* are a specific type of cooperative agreement used frequently by USAID/Washington. It involves the issuance of an award that covers a specified worldwide activity (the Leader Award). The Leader Award includes language that allows a Mission or other office to award a separate grant to the Leader Award recipient without additional competition and which supports a distinct local or regional activity that fits within the terms and scope of the Leader Award. This is called an Associate Award.
- *Grants* are similar to cooperative agreements but allow the recipient more latitude to pursue its stated program without substantial involvement by USAID.
- USAID may also use other types of formal arrangements to conduct research including:
  - Transfers to other federal agencies
  - Contributions to international organizations such as the United Nations
  - University partnerships
  - Annual program statements (APS)
  - Unsolicited proposals and through
  - Global Development Alliances which are public-private partnerships for improving social and economic conditions in developing countries.

As mentioned previously, BGH typically supports research through cooperative agreements that are usually established for a period of five years although occasionally the IQC or APS may be used. Multiple research studies may be conducted under a single award.

Source: USAID Primer. See: [www.usaid.gov/about\\_usaid/primer.html](http://www.usaid.gov/about_usaid/primer.html)

### Solicitation and Award Procedures

Notices of contract opportunities and corresponding Requests for Proposals (RFP) are publicized at FedBizOpps [www.fbo.gov](http://www.fbo.gov). Direct contracts are subject FAR [www.gsa.gov/far/current/html/toc.html](http://www.gsa.gov/far/current/html/toc.html), the USAID supplement to the FAR (AIDAR) [www.usaid.gov/policy/ads/300/aidar.doc](http://www.usaid.gov/policy/ads/300/aidar.doc), and applicable portions of the ADS series 300 [www.usaid.gov/policy/ads](http://www.usaid.gov/policy/ads).

Notices of assistance opportunities (grants and cooperative agreements) and corresponding Requests for Applications (RFA) are publicized at FedGrants [www.grants.gov](http://www.grants.gov). This site will also publish annual program statements. Grants, cooperative agreements and annual program statements are subject to

Office of Management and Budget (OMB) Circulars A-21 (University Cost Principles), A-122 (Non-profit Cost Principles), A-133 (Audit Principles) [www.whitehouse.gov/omb/circulars](http://www.whitehouse.gov/omb/circulars), 22 CFR 226 (Administration of Assistance to US Nongovernmental Organizations) <http://ecfr.gpoaccess.gov>, and applicable portions of the ADS [www.usaid.gov/policy/ads](http://www.usaid.gov/policy/ads).

RFAs and RFPs invite interested parties to submit applications or proposals to USAID and explain timelines, application procedures and contact persons, what the application should contain, how it should be written, and the evaluation criteria to be used.

Once submitted, applications and proposals are evaluated by an internal USAID technical evaluation committee (TEC). A TEC has three or more technical and scientific experts the majority of whom must be direct hire employees of USAID. They evaluate the merits of each application or proposal against the evaluation criteria described in the RFA or RFP. Based on this evaluation the TEC scores each application or proposal and recommends one or more for award. The AO or CO takes this recommendation into account and makes the final determination of award based on best value to the government.

More information and details concerning doing business with USAID may be found at [www.usaid.gov/business/business\\_opportunities/](http://www.usaid.gov/business/business_opportunities/). Links to all policy and regulatory documents may be found at [www.usaid.gov/business/regulations/](http://www.usaid.gov/business/regulations/).

### **Work Plans**

After a proposal or application is selected and an award is made, the implementing partner must submit an annual work plan for review and approval by the AOTR/COTR. AOTRs/COTRs provide technical direction and input to the work plan and engage in a consultative process with Office Directors, other managers and technical experts within BGH to coordinate activities with other implementing partners and set priorities for funding.

However, an annual work plan contains only brief descriptions of planned studies to be implemented during the forthcoming fiscal year. Once an annual work plan is approved, the implementing partner must **prepare a full study proposal for each research activity under the work plan. These proposals are considered extensions of the work plan and must also receive AOTR/COTR approval before the work can begin.** They may be submitted at any time after work plan approval. Research proposals must receive rigorous technical and scientific review.

*Source: BGH Research Administrators Core Group*

### **Proposal Guidelines**

Implementing partners submitting research proposals to USAID should include, as appropriate, the following information:

- **Significance.** Provide a compelling rationale for the study. Explain how the study addresses an important problem in developing countries. Explain how the study ties to the agreed upon life-of-project results expected under the contract or agreement.
- **Approach.** Provide the following information to enable a technical and methodological evaluation of the proposal:
  - Brief review of the literature
  - Countries/settings where the research will take place
  - Hypothesis to be tested or study objectives
  - Investigators and collaborators
  - Case definition (if applicable)
  - Inclusion and exclusion criteria

- Design
- Intervention
- Description of randomization procedures or procedures for selection of controls
- Sample size calculation, power calculation
- Sampling frame and methodology
- Analysis plan and statistical software to be used
- Quality assurance procedures
- Enrollment and consent processes
- Study personnel training
- Community involvement and communications, especially in the case of clinical trials
- Protections of human subjects, animal welfare protections procedures and IRB review
- Analysis of gender considerations
- Description of variables and how measured
- Description of data collection and handling procedures
- Plan for building capacity of developing country researchers involved in carrying out the study
- Plan for dissemination and utilization of study results
- Plan for data sharing
- Data collection instruments
- Data safety and monitoring (if applicable)
- Detailed budget and timeline
- Partnerships and sub-agreements or sub-contracts.

*Source: BGH Research Administrators Core Group*

### **Peer Review Procedures**

Because our portfolio covers such a broad range of issues, COTRs and AOTRs have the flexibility to choose among several different “models” of peer review of R&D proposals as described below.

#### **Models of Peer Review**

*Model 1 Internal review only* – R&D proposals are reviewed by COTRs/AOTRs and TAs to the project for methodological rigor, programmatic relevance and importance, and costs. Technical expertise from other staff within BGH may be called upon as needed.

*Model 2 Combined internal/external review* – R&D proposals are reviewed by BGH staff as described above and at least one subject matter or methodological expert from outside the agency. COTRs/ AOTRs maintain a database of potential reviewers willing to provide timely technical review and manage the process of sharing proposals, collating comments of reviewers and communicating these comments with the implementing partner.

*Model 3 Technical advisory group* - The implementing partner or alternatively the USAID COTR/AOTR assembles a group of recognized technical experts from outside its own organization. Experts may be drawn from research and technical organizations such as non-governmental organizations, United Nations’ (UN) agencies, USG sister agencies, universities, industrial counterparts or respected think-tanks. The technical advisory group meets at least annually, and also as needed, to review research/project initiatives, monitor progress, decide research priorities, identify gaps, and review proposals.

*Model 4 External convener group* - USAID creates a contractual relationship with an outside scientific body (such as the National Academy of Sciences) which then serves as a convener of technical experts drawn from research and technical organizations such as non-governmental organizations, UN agencies, other USG agencies, universities, or industrial counterparts to review the state of the scientific evidence on a given topic, identify gaps in knowledge, develop consensus on research priorities, reviews proposals and/or monitors progress in research.

The type of R&D activity determines which model is appropriate (see Table). Model 1 is appropriate for studies that pose no risk to human subjects (such as secondary analysis of Demographic and Health Survey data, Cochrane reviews, meta-analyses) as well as field support-funded small, local studies to improve service delivery that pose low risk to human subjects and would be exempt from human subjects review (such as post-marketing surveillance of a new contraceptive). Model 2 applies to larger operations research and biomedical research studies that may involve human subjects review such as new service delivery intervention studies and Phase I and II clinical research studies. Models 3 and 4 typically apply to clinical trials of new contraceptive technologies, drugs, drug delivery systems or vaccines that require special attention and highly skilled technical review because of the potential risks to human subjects and the commitment of tax-payer resources to see these studies through to completion. However, preparatory or ancillary research leading up to or in conjunction with a clinical trial may be more appropriately considered under Model 2.

### Models of peer review and types of studies to which they typically apply.

| Type of research  | Model 1 | Model 2 | Model 3 | Model 4 |
|---|---------|---------|---------|---------|
| Secondary analysis of existing datasets, Cochrane reviews; small, field support-funded studies  | X       |         |         |         |
| Operations research; Health services research; Social science research (including surveys and research embedded within clinical trials); Population surveys | X       | X       | X       |         |
| Clinical trials   |         |         | X       | X       |

Source: BGH Research Administrators Core Group

### Review Criteria

Just as the conduct of a technical review will vary depending on the type of R&D proposed, so will the criteria for evaluating the merits of proposals. The aim of peer review is to provide constructive feedback to researchers to enable them to clarify any outstanding questions, strengthen the design of the study, and make sure it is in keeping with the overall goals of the grant, contract or cooperative agreement.

In general, scientific and technical experts within USAID and those external to the agency should determine whether:

- Investigators adequately describe the likely contribution the study will make to the overall goals of the contract or cooperative agreement and to the development goals of BGH.
- Investigators clearly describe the intervention and can the intervention can likely be replicated and brought to scale. The cost-effectiveness of an intervention is an important consideration since interventions that may be too costly to implement at scale in developing countries should not receive priority for research funding.
- The study methodology is sufficiently scientifically rigorous.

- The plans for data sharing, research utilization, 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 as dictated by 22 CFR 225.
- Budget and timeline reasonable and aligned with the work proposed.

*Source: BGH Research Administrators Core Group*

### **Protection of Human Subjects**

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, and [http://www.access.gpo.gov/nara/cfr/waisidx\\_06/22cfr225\\_06.html](http://www.access.gpo.gov/nara/cfr/waisidx_06/22cfr225_06.html)). 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 a guidance document (an Agency reference, Annex B, part 2, and <http://www.usaid.gov/policy/ads/200/200mbe.pdf>) that aids project management by further explaining the underlying principles and their application in various situations. This guidance is intended to help AOTRs and COTRs, Technical Advisors (TAs,) Mission staff, and partners or recipients to understand and apply the USAID regulations when supporting or conducting research involving human subjects.

These USAID regulations and the guidance help address common questions such as 1) ‘When is an activity considered research?’, and 2) ‘When are human subjects involved?’ AOTRs/COTRs, 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.

AOTRs and COTRs 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 – GH/PRH/RTU, Lee Claypool), 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). 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 at the National Institutes of Health (NIH). Alternative assurance provisions can sometimes be acceptable for USAID but are rarely used. The FWA is the institution’s commitment to meet requirements, for example, regarding the frequency of IRB reviews, record keeping, and the composition of the IRB to ensure adequate technical and community representation, knowledge of local conditions, and no conflicts of interest. 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 subrecipient 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 Federal Agencies also maintain their own IRBs to supplement or duplicate the IRBs of 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 functions 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 profits beyond reasonable costs, may be questionable. 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.

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

*Source: Common Federal Policy for the Protection of Human Subjects, Part 225 of Title 22 of the Code of Federal Regulations*

### **Care of Laboratory Animals**

In some biomedical research of new drugs and other medical products animal testing may be required in order to obtain stringent regulatory authority approval of the product. AOTRs and COTRs must ensure that implementing partners comply with regulations regarding the care of laboratory animals. Before undertaking performance of any grant involving the use of laboratory animals, the recipient organization of a grant, cooperative agreement, contract or other award shall register with the Secretary of Agriculture of the United States in accordance with Section 6, Public Law 89-544, Laboratory Animal Welfare Act, August 24, 1966, as amended by Public Law 91-579, Animal Welfare Act of 1970, December 24, 1970. The recipient shall furnish evidence of such registration to the Agreement Officer. The recipient shall acquire animals used in research under this award only from dealers licensed by the Secretary of Agriculture, or from exempted sources in accordance with the Public Laws enumerated above.

In the care of any live animals used or intended for use in the performance of research, the recipient shall 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, and in the United States Department of Agriculture's (USDA) regulations and standards issued under the Public Laws enumerated above. In case of conflict between standards, the higher standard shall be used. The recipient's reports on portions of the award in which animals were used shall contain a certificate stating that the animals were cared for in accordance with the principles enunciated in the *Guide for Care and Use of Laboratory Animals* prepared by the Institute of Laboratory Animal Resources, NAS-NRC, and/or in the regulations and standards as promulgated by the Agricultural Research Service, USDA, pursuant to the Laboratory Animal Welfare Act of 24 August 1966, as amended (P.L. 89-544 and P.L. 91-579). NOTE: 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 and at <http://www.aphis.usda.gov/ac/>.

## **Reporting Requirements, Monitoring and Evaluation**

Implementing partners are required to submit routine progress reports to AOTRs/COTRs. Most AOTRs/COTRs require these reports quarterly along with reports of financial status. AOTRs/COTRs may also engage with implementing partners through periodic management reviews, technical meetings, and site visits. Implementing partners are generally required to submit a performance monitoring plan with indicators and benchmarks to enable reporting and monitoring progress. It is also common to conduct mid-term and end-of-project evaluations to assess the extent to which the project met its aims.

BGH also maintains two research tracking databases: the Health Research Information Tracking (HRIT) and the Microbicides database. Both are web-based applications designed to collect research data from the BGH's implementing partners. Data are used by BGH staff to answer critical internal and Congressional questions. Data entry is the responsibility of the implementing partners but AOTRs and COTRs must verify the accuracy of those entries.

*Source: BGH Research Administrators Core Group*

## **Publications and Media Releases under Cooperative Agreements and Contracts**

**APPLICABILITY:** This provision is applicable when publications are financed under the award.

The recipient of a grant, contract or cooperative agreement shall provide the USAID AOTR/COTR one copy of all published works developed under the award with lists of other written work produced under the award. In addition, the recipient shall submit final documents in electronic format unless no electronic version exists at the following address: <http://www.dec.org/submit.cfm>

Mailing address:

Document Acquisitions  
USAID Development Experience Clearinghouse (DEC)  
8403 Colesville Road Suite 210  
Silver Spring, MD 20910-6368  
Contract Information  
Telephone (301) 562-0641  
Fax (301) 588-7787  
E-mail: [docsubmit@dec.cdie.org](mailto:docsubmit@dec.cdie.org)

Electronic documents must consist of only one electronic file that comprises the complete and final equivalent of a hard copy. They may be submitted online (preferred); on 3.5" diskettes, a Zip disk, CD-R, or by e-mail. Electronic documents should be in PDF (Portable Document Format). Submission in other formats is acceptable but discouraged.

Each document submitted should contain essential bibliographic elements, such as 1) descriptive title; 2) author(s) name; 3) award number; 4) sponsoring USAID office; 5) strategic objective; and 6) date of publication.

In the event award funds are used to underwrite the cost of publishing, in lieu of the publisher assuming this cost as is the normal practice, any profits or royalties up to the amount of such cost shall be credited to the award unless the schedule of the award has identified the profits or royalties as program income.

*Source: ADS 303 Mandatory Standard Provisions*

Published work (research studies/reports/web sites) should comply with USAID branding and marking requirements and contain the following disclaimer:

*This study/report/Web site (specify) is made possible by the support of the American People through the United States Agency for International Development (USAID.) The contents of this (specify) are the sole responsibility of (name of organization) and do not necessarily reflect the views of USAID or the United States Government.*

*Source: ADS 320 Branding and Marking*

## **Copyright**

Except as otherwise provided in the terms and conditions of the award, the author or the recipient is free to copyright any books, publications, or other copyrightable materials developed in the course of or under this award, but USAID reserves a royalty-free nonexclusive and irrevocable right to reproduce, publish, or otherwise use, and to authorize others to use the work for Government purposes.

*Source: ADS 303 Mandatory Standard Provisions*

## **Patent Rights**

BGH serves as the cognizant USAID office for patent and other intellectual property rights (IPR) issues arising directly from USAID-funded research, technology development, and technology transfer for commercialization or other means of diffusion. Global Health is responsible for formulating current USAID practice, procedures and policies related to patent rights of the US Government as legislated in the Bayh-Dole Act including administering a system to report and track patent or other IPR on behalf of USAID. See Annex C for the full text of the ADS addressing patent rights and royalties.

*Source: ADS 318 Patent Rights*

## **Metric System of Measurement**

Wherever measurements are required or authorized, they shall be made, computed, and recorded in metric system units of measurement, unless otherwise authorized by the CO/AO in writing when it has found that such usage is impractical or is likely to cause US firms to experience significant inefficiencies or the loss of markets. Where the metric system is not the predominant standard for a particular application, measurements may be expressed in both the metric and the traditional equivalent units, provided the metric units are listed first.

*Source: ADS 323.3.1 and 3.2*

## **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 or differences of opinion.

Agencies and research institutions are partners who share responsibility for the research process. Federal agencies have ultimate oversight authority for federally funded research, *but research institutions bear primary responsibility for prevention and detection of research misconduct, and misconduct and for the inquiry, investigation, and adjudication of research misconduct alleged to have occurred in association with their own institution.*

*Source: The White House. Office of Science and Technology Policy*

## **ANNEXES**

### **Annex A: Members of BGH Research Managers Group**

Patricia Stephenson (Coordinator - PRH)  
Jacob Adetunji (PRH)  
Neal Brandes (HIDN)  
Delivette Castor (OHA)  
Lee Claypool (PRH)  
Margaret D'Adamo (PRH)  
Carter Diggs (HIDN)  
La Hanh (OHA)  
Sarah Harbison (OHA)  
Mihira Karra (PRH)  
Benny Kotiri (OHA)  
Ya-Shin Lin (OHA)  
Rachel Lucas (PRH)  
Judy Manning (PRH)  
Margaret McCluskey (PRH)  
John Novak (OHA)  
Glenn Post (OHA)  
Sarah Sandison (OHA)  
Madeleine Short (PRH)  
Jeff Spieler (GH)  
David Standon (OHA)  
Nandita Thatte (PRH)

## **Annex B – Protection of Human Subjects in Research**

### **Code of Federal Regulations Annex A: Title 22 – Foreign Relations Chapter II – Agency for International Development**

#### **Part 225\_Protection of Human Subjects – Table of Contents**

Sec.

225.101 To what does this policy apply?

225.102 Definitions.

225.103 Assuring compliance with this policy--research conducted or supported by any Federal Department or Agency.

225.104-225.106 [Reserved]

225.107 IRB membership.

225.108 IRB functions and operations.

225.109 IRB review of research.

225.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

225.111 Criteria for IRB approval of research.

225.112 Review by institution.

225.113 Suspension or termination of IRB approval of research.

225.114 Cooperative research.

225.115 IRB records.

225.116 General requirements for informed consent.

225.117 Documentation of informed consent.

225.118 Applications and proposals lacking definite plans for involvement of human subjects.

225.119 Research undertaken without the intention of involving human subjects.

225.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

225.121 [Reserved]

225.122 Use of Federal funds.

225.123 Early termination of research support: Evaluation of applications and proposals.

225.124 Conditions.

Authority: 5 U.S.C. 301; 42 U.S.C. 300v-1(b), unless otherwise noted.

Source: 56 FR 28012, 28020, June 18, 1991, unless otherwise noted.

225.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in Sec. 225.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in Sec. 225.102(e) must be reviewed and approved, in compliance with

Sec. Sec. 225.101, 225.102, and Sec. Sec. 225.107 through 225.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

(i) research on regular and special education instructional strategies, or

(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) The human subjects are elected or appointed public officials or candidates for public office; or

(ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs;

(ii) Procedures for obtaining benefits or services under those programs;

(iii) Possible changes in or alternatives to those programs or procedures; or

(iv) Possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies,

(i) if wholesome foods without additives are consumed or

(ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the department or agency but not otherwise covered by this policy, comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the Federal Register or will be otherwise published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy. Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, and shall also publish them in the Federal Register or in such other manner as provided in department or agency procedures.

Institutions with HHS-approved assurances on file will abide by provisions of title 45 CFR part 46 subparts A-D. Some of the other Departments and Agencies have incorporated all provisions of title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at 45 CFR part 46.101(b) do not apply to research involving prisoners, subpart C. The exemption at 45 CFR part 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

[56 FR 28012, 28020, June 18, 1991; 56 FR 29756, June 28, 1991, as amended at 70 FR 36328, June 23, 2005]

#### Sec. 225.102 Definitions.

(a) Department or agency head means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(b) Institution means any public or private entity or agency (including federal, state, and other agencies).

(c) Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) Research subject to regulation, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains--

- (1) data through intervention or interaction with the individual, or
- (2) identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(g) IRB means an institutional review board established in accord with and for the purposes expressed in this policy.

(h) IRB approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(i) Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(j) Certification means the official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Sec. 225.103 Assuring compliance with this policy--research conducted or supported by any Federal Department or Agency.

(a) Each institution engaged in research which is covered by this policy and which is conducted or supported by a federal department or agency shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Human Research Protections, HHS, or any successor office, and approved for federal wide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Human Research Protections, HHS, or any successor office.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department- or agency-supported or regulated research and need not be applicable to any research exempted or waived under Sec. 225.101 (b) or (i).

(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant. Changes in IRB membership shall be reported to the department or agency head, unless in accord with Sec. 225.103(a) of this policy, the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Human Research Protections, HHS, or any successor office.

(4) Written procedures which the IRB will follow

(i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;

(ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and

(iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of

(i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB and

(ii) any suspension or termination of IRB approval.

(c) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes.

(d) The department or agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the department or agency and such experts or consultants engaged for this purpose as the department or agency head determines to be appropriate. The department or agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the department or agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The department or agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under Sec. 225.101 (b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by Sec. 225.103 of this Policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by Sec. 225.103 of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or

agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

(Approved by the Office of Management and Budget under control number 0990-0260)  
[56 FR 28012, 28020, June 18, 1991; 56 FR 29756, June 28, 1991, as amended at 70 FR 36328, June 23, 2005]

#### Sec. 225.107 IRB membership.

- (a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.
- (b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.
- (c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- (d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- (e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
- (f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

#### Sec. 225.108 IRB functions and operations.

In order to fulfill the requirements of this policy each IRB shall:

- (a) Follow written procedures in the same detail as described in Sec. 225.103(b)(4) and, to the extent required by, Sec. 225.103(b)(5).
- (b) Except when an expedited review procedure is used (see Sec. 225.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

#### Sec. 225.109 IRB Review of Research.

- (a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.

- (b) An IRB shall require that information given to subjects as part of informed consent is in accordance with Sec. 225.116. The IRB may require that information, in addition to that specifically mentioned in Sec. 225.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.
- (c) An IRB shall require documentation of informed consent or may waive documentation in accordance with Sec. 225.117.
- (d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
- (e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

(Approved by the Office of Management and Budget under control number 0990-0260)

[56 FR 28012, 28020, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

Sec. 225.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

- (a) The Secretary, HHS, has established, and published as a Notice in the Federal Register, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the Federal Register. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.
- (b) An IRB may use the expedited review procedure to review either or both of the following:
  - (1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,
  - (2) Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in Sec. 225.108(b).

- (c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure.
- (d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

[56 FR 28012, 28020, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

Sec. 225.111 Criteria for IRB approval of research.

- (a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:
  - (1) Risks to subjects are minimized:

(i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and

(ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by Sec. 225.116.

(5) Informed consent will be appropriately documented, in accordance with, and to the extent required by Sec. 225.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

#### Sec. 225.112 Review by institution.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

#### Sec. 225.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

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[56 FR 28012, 28020, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

#### Sec. 225.114 Cooperative research.

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for

safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

#### Sec. 225.115 IRB records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in Sec. 225.103(b)(3).

(6) Written procedures for the IRB in the same detail as described in Sec. 225.103(b)(4) and Sec. 225.103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by Sec. 225.116(b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

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[56 FR 28012, 28020, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

#### Sec. 225.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

- (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
  - (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
  - (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
  - (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
  - (8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- (b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:
- (1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
  - (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
  - (3) Any additional costs to the subject that may result from participation in the research;
  - (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
  - (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
  - (6) The approximate number of subjects involved in the study.
- (c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:
- (1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
    - (i) Public benefit of service programs;
    - (ii) Procedures for obtaining benefits or services under those programs;
    - (iii) Possible changes in or alternatives to those programs or procedures; or
    - (iv) Possible changes in methods or levels of payment for benefits or services under those programs; and
  - (2) The research could not practicably be carried out without the waiver or alteration.
- (d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
- (1) The research involves no more than minimal risk to the subjects;
  - (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
  - (3) The research could not practicably be carried out without the waiver or alteration; and
  - (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- (e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.
- (f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

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[56 FR 28012, 28020, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

Sec. 225.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by Sec. 225.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by Sec. 225.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked

whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

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[56 FR 28012, 28020, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

Sec. 225.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under Sec. 225.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

Sec. 225.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

Sec. 225.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

Sec. 225.122 Use of Federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

Sec. 225.123 Early termination of research support: Evaluation of applications and proposals.

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

Sec. 225.124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

## **Annex C – Patent Rights**

### **Functional Series 300: Acquisition and Assistance ADS Chapter - 318 Patent Rights**

#### **318.1 Authority**

1. The Bayh-Dole Act of 1980
2. **Title 35 of the U.S. Code**
3. Technology Transfer Act of 1986

#### **318.2 Objective**

The objective is to promote the use of inventions arising from U.S. Government (USG)-supported research or development, to ensure that the inventor's and USG's rights regarding inventions that are conceived or first actually reduced to practice under a funding agreement (contract, grant, or cooperative agreement) with USAID are protected, and that taxpayer's rights to the technology are protected.

#### **318.3 Responsibility**

1. The Bureau for Global Programs, Field Support and Research (Global) serves as the cognizant USAID office for patent and other Intellectual Property Rights (IPR) issues arising directly from USAID-funded research, technology development, and technology transfer for commercialization or other means of diffusion. Global is responsible for formulating current USAID practices, procedures, and policies related to patent rights of the U.S. Government, as legislated in the Bayh-Dole Act, including administering a system to report and track patent or other IPR on behalf of USAID.

Currently, the National Institutes of Health (NIH) under a "Memorandum of Understanding" (MOU) with USAID has provided the Agency with the right to use the NIH EDISON invention reporting and tracking database system.

Global's Office of Program Development and Strategic Planning (G/PDSP), under the terms and conditions established in the MOU as amended, is responsible for coordinating with NIH the receipt, acknowledgement, and tracking of invention reports under USAID-funded agreements. G/PDSP is the point of contact for the Agency with the NIH on the administration of the EDISON invention reporting system, including implementation of specific USAID policy related to patent title, licensing, and waivers. G/PDSP will also be responsible for coordinating with USAID's operating units to ensure that USAID-funded contractors and grantees report research inventions through the EDISON system, in accordance with the Bayh-Dole Act requirements. In addition, G/PDSP will be responsible for issuing annual summary reports, specific to each Cognizant Technical Office (CTO) of activities tracked in the database.

G/PDSP is the point of contact for USAID officers for patent and IPR issues. G/PDSP maintains a current list of activities that are involved in these issues, with most activities being funded through the Global Bureau. USAID officers associated with such activities that ought to be added to the list may contact G/PDSP. G/PDSP maintains contact with involved Cognizant Technical Officers (CTOs) annually and provides appropriate training for the proper reporting through NIH's EDISON invention reporting and tracking database system.

2. The Bureau for Management, Office of Procurement (M/OP) and Mission Contracting Officers are responsible for ensuring that the appropriate patent provisions and clauses from the Federal Acquisition Regulation are included in solicitation documents and contracts, that USAID Regulation 26 is incorporated in grants and cooperative agreements with U.S. non-governmental organizations, and that the patents provision is included in grants and cooperative agreements with non-U.S. organizations when applicable.

3. The Cognizant Technical Officer (CTO) is responsible for taking necessary actions under the provisions of FAR Subparts 27.2 and 27.3 and 37 CFR Part 401 with regard to USAID's rights to subject inventions. This includes being responsible for granting the funding recipient extensions in time for disclosure, election to retain title, and filing at the CTO's discretion and determining whether to shorten the time for election of title. (See [318.5.3](#) and [318.5.4](#))

4. The funding recipient is responsible for complying with the terms of the provisions of its contract, grant or cooperative agreement and any applicable regulations including requirements for disclosure and election of title. Such disclosure and elections must be provided to the CTO via the NIH EDISON system.

#### **318.4 Definitions (See [ADS Glossary](#))**

funding recipient

invention

subject invention

#### **318.5 POLICY**

The statements contained within the .5 section of this ADS chapter are the official Agency policies and corresponding essential procedures.

##### **318.5.1 APPLICABLE REGULATIONS**

USAID's contractors and recipients are subject to applicable regulations governing patents and inventions, including the government-wide regulations issued by the Department of Commerce at 37 CFR Part 401, "Rights to Inventions Made by Nonprofit and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements," Federal Acquisition Regulation (FAR) Subpart 27.2, "Patents," and Subpart 27.3, "Patent Rights Under Government Contracts," and any clauses or provisions on patents or inventions included in the specific contract, grant, or cooperative agreement with USAID. USAID's rights and responsibilities with regard to subject inventions are also set forth in 37 CFR Part 401 and FAR Subparts 27.2 and 27.3. (See **Mandatory References [37 CFR Part 401](#), [FAR Subpart 27.2](#) and [FAR Subpart 27.3](#)**)

##### **E318.5.1 Applicable Regulations - N/A**

##### **318.5.2 ALLOCATION OF PRINCIPAL RIGHTS**

The funding recipient may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions and exceptions of applicable regulations, this Chapter and 35 USC Sec. 203. (See **Mandatory Reference [35 USC Sec. 203](#)**) When the funding recipient retains the title to any subject invention, the Federal Government shall have a non-exclusive, non-transferable, irrevocable, paid-up license to practice or have practiced for, or on behalf of the U.S., the subject invention throughout the world.

##### **E318.5.2 Allocation of Principal Rights - N/A**

##### **318.5.3 INVENTION DISCLOSURE, ELECTION OF TITLE, AND FILING OF PATENT APPLICATIONS BY FUNDING RECIPIENT**

a) The funding recipient must disclose each subject invention to USAID, through the NIH EDISON system and the Cognizant Technical Office, as prescribed in the applicable regulations. The funding recipient must also provide to NIH detailed invention disclosures for entry into the EDISON patent tracking system. In addition, after disclosure to USAID, the funding recipient must promptly notify USAID of the acceptance of any manuscript describing the invention for publication or of any on sale or

- public use planned by the funding recipient. A contract clause or assistance provision entitled, Patent Reporting Procedures, provides contractors/recipients information on using the EDISON tracking system.
- b) The funding recipient must elect in writing whether or not to retain title to any such invention by notifying, via EDISON, the USAID Cognizant Technical Office in accordance with the applicable regulations. In any case where publication, on sale, or public use has initiated the one-year statutory period wherein valid patent protection can still be obtained in the United States, the period of election of title may be shortened by the Cognizant Technical Office to a date that is no more than 60 days prior to the end of the one-year statutory period.
  - c) The funding recipient must file an initial patent application on a subject invention when it elects to retain title in accordance with the requirements, including timing, of the applicable regulations.
  - d) Requests for extension of the time for disclosure to USAID, election, and filing may, at the discretion of USAID, be granted by the Cognizant Technical Office.

### **E318.5.3 Invention Disclosure, Election of Title, and Filing of Patent Applications by Funding Recipient**

The Cognizant Technical Office must refer any reports of inventions to the Global Bureau's Office of Program Development and Strategic Planning (G/PDSP). G/PDSP must reconcile this information with the data entered into the EDISON reporting and tracking database system operated by the National Institutes of Health.

### **318.5.4 RIGHTS AND RESPONSIBILITIES**

The funding recipient has rights and responsibilities with regard to subject inventions. These are set forth in the applicable regulations. Where the regulations require or allow USAID to take action or authorize action by the funding recipient, unless the regulations, contract clause, or assistance agreement provide otherwise, the responsible office for taking such actions and granting approvals shall be the Cognizant Technical Office, in consultation with G/PDSP and the Office of General Counsel.

### **E318.5.4 Rights and Responsibilities - N/A**

### **318.5.5 APPLICABILITY OF GOVERNMENT'S RIGHTS TO CONTRACTORS AND RECIPIENTS**

Whatever rights the Federal Government has in any patent apply also to contractors and recipients under their agreements with USAID. When the Government is entitled to royalty free use, the right does not end by virtue of its being exercised under a USAID contract or assistance instrument.

### **E318.5.5 Applicability of Government's Rights to Contractors and Recipients - N/A**

### **318.5.6 ROYALTIES**

The Contracting/Agreement Officer must ensure that the appropriate patent and royalty clauses are included in contracts, grants, and cooperative agreements. Contracting Officers must request royalty information in accordance with the requirements of FAR Subpart 27.2. **(See Mandatory Reference FAR Subpart 27.2)**

### **E318.5.6 Royalties - N/A**

### **318.5.6a ADJUSTMENT OF ROYALTIES**

1) If at any time the Contracting/Agreement Officer has reason to believe that royalties paid, or to be paid, under an existing or prospective contract, grant, cooperative agreement, subcontract, or subaward are inconsistent with Government rights, excessive, or otherwise improper, the Contracting/Agreement Officer (or someone else with knowledge of the case) must promptly report the facts in writing to

USAID's Office of General Counsel (GC) with a copy to G/PDSP. GC must review the royalties thus reported and such royalties as may be reported in accordance with other regulatory requirements and recommend appropriate action to the Contracting/Agreement Officer.

2) In coordination with GC, the Contracting/ Agreement Officer must promptly act to protect the Government against payment of royalties on supplies or services:

- a) When the Government has a royalty-free license;
- b) At a rate in excess of the rate at which the Government is licensed; or
- c) When the royalties in whole or in part otherwise constitute an improper charge.

### **E318.5.6a Adjustment of Royalties - N/A**

### **318.6 Supplementary Reference - N/A**

### **318.7 Mandatory Reference**

37 CFR Part 401 "Rights to Inventions Made by Nonprofit and Small Business Firms under Government Grants, Contracts, and Corporate Agreements"

[\*\*FAR Subpart 27.2 "Patents"\*\*](#)

[\*\*FAR Subpart 27.3 "Patent Rights under Government Contracts"\*\*](#)

[\*\*35 USC Sec. 203 "Patent Rights in Inventions Made With Federal Assistance - March-in Rights"\*\*](#)

## **Annex D -Links to Regulatory and Policy Guidance**

The following links may be particularly useful to research administrators:

|   |  |
|---|--|
| Branding and marking:                         | <a href="http://www.usaid.gov/ghintranet.usaid.gov/GH/resources/branding/standard.html">http://www.usaid.gov/ghintranet.usaid.gov/GH/resources/branding/standard.html</a>  |
|   | <a href="http://www.usaid.gov/policy/ads/300/320.pdf">http://www.usaid.gov/policy/ads/300/320.pdf</a>  |
| Patent rights:                                | <a href="http://www.usaid.gov/policy/ads/300/320.pdf">http://www.usaid.gov/policy/ads/300/320.pdf</a><br><a href="http://www.usaid.gov/policy/ADS/300/AIDAR.pdf">http://www.usaid.gov/policy/ADS/300/AIDAR.pdf</a> |
| Royalties:                                    | <a href="http://www.usaid.gov/policy/300/318.5.6.pdf">http://www.usaid.gov/policy/300/318.5.6.pdf</a>  |
| Environmental procedures:                     | <a href="http://www.usaid.gov/policy/200/204.pdf">http://www.usaid.gov/policy/200/204.pdf</a>  |
| Tobacco policy:                               | <a href="http://www.usaid.gov/policy/200/210.pdf">http://www.usaid.gov/policy/200/210.pdf</a>  |
| Breastfeeding promotion:                      | <a href="http://www.usaid.gov/policy/200/212.pdf">http://www.usaid.gov/policy/200/212.pdf</a>  |
| Contracts:                                    | <a href="http://www.usaid.gov/policy/300/302.pdf">http://www.usaid.gov/policy/300/302.pdf</a>  |
| Grants & cooperative agreements:              | <a href="http://www.usaid.gov/policy/300/303.pdf">http://www.usaid.gov/policy/300/303.pdf</a>  |
| Interagency agreements:                       | <a href="http://www.usaid.gov/policy/300/306.pdf">http://www.usaid.gov/policy/300/306.pdf</a>  |
| Grants to public international Organizations: | <a href="http://www.usaid.gov/policy/300/308.pdf">http://www.usaid.gov/policy/300/308.pdf</a>  |
| Gender  | <a href="http://www.usaid.gov/policy/200/201.3.9.3.pdf">http://www.usaid.gov/policy/200/201.3.9.3.pdf</a>  |
| Research misconduct                           | <a href="http://www.ostp.gov/cs/federal_policy_on_research_misconduct">http://www.ostp.gov/cs/federal_policy_on_research_misconduct</a>  |

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