Feasibility Study of Optimal Approaches for Evaluating the Implementation of NIAID DAIDS-wide Standardized Clinical Policies and Procedures

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Contract Number: 263-FF-611594

October 15, 2007

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Executive Summary

The Division of Acquired Immunodeficiency Syndrome (DAIDS) of the National Institute of Allergy and Infectious Diseases (NIAID) is in the process of implementing a set of standard clinical research policies and procedures (P&Ps) for DAIDS-funded or -sponsored research. The overarching goal of DAIDS' P&Ps is to facilitate clinical research, i.e., to promote increased efficiency and flexibility, as well as greater integration and collaboration among DAIDS- funded or -sponsored clinical research programs, by implementing these standardized P&Ps. The focus of this feasibility study was to identify the most appropriate evaluation methodologies, techniques, and tools to measure the impact of these standardized P&Ps on the functioning of DAIDS programs and on DAIDS sponsored clinical research. Four major areas were identified as essential to assess the implementation and impact of the P&Ps: (1) Awareness and accessibility of newly developed P&Ps; (2) Understanding of the P&Ps; (3) Applicability of the P&Ps; and (4) Harmonization. While the overall emphasis of the feasibility study was on the impact of the P&Ps, i.e., outcomes, process information on the implementation was also suggested orcollected to provide context for the interpretation of outcomes. NOVA Research Company's (NOVA) evaluation team conducted this feasibility study and had the opportunity to collect actual pilot data, which assisted us in arriving at the recommendations contained in this report.

One of the first steps of the feasibility study was to conduct a review of the literature to determine if other studies or reports existed with regard to the impact of the implementation of standardized clinical research policies and procedures. While there were a number of reports that described the development and/or suggested implementation of standardized P&Ps within specific organizations (e.g., academic research institutions), including evaluation studies and reports of related training on specific topics (e.g., human subjects protection; good clinical practice), NOVA could not locate a single study or report that provided an actual evaluation or systematic assessment of the impact that the P&Ps had on organizational functioning or the process and outcomes of clinical research. Thus, NIAID/DAID's proposed evaluation of newly implemented P&Ps can make a significant contribution to existing knowledge in this area.

The DAIDS P&P Logic Model was developed in conjunction with the DAIDS P&P evaluation team. The logic model describes the P&P implementation process (activities and outputs) and the major expected outcomes — short-, intermediate-, and long-term —of the P&Ps. Based on the Logic Model, proposed evaluation questions, and surveys and focus group information obtained after the initial training on a subset of the standardized P&Ps delivered to POs, NOVA makes the following recommendations for a full-scale evaluation of the implementation and impact of standardized P&Ps:

Recommendation: Assess POs' (and other DAIDS staff with clinical site oversight responsibilities) and DAIDS-funded researchers' awareness of and perceived accessibility to DAIDS standardized P&Ps.

Justification: It is expected that, over time, POs and researchers will demonstrate increased awareness of the P&Ps and feedback to OPCRO will improve accessibility of the P&Ps.

Recommendation: Assess POs' (and other DAIDS staff with clinical site oversight responsibilities) and DAIDS-funded researchers' understanding of the P&Ps.

Justification: It is expected that POs and researchers perceive the P&Ps to be understandable, and demonstrate knowledge of the P&Ps.

Recommendation: Assess POs' (and other DAIDS staff with clinical site oversight responsibilities) and DAIDS-funded researchers' ability to apply the P&Ps across program areas, networks, and types of research.

Justification: It is expected that POs and researchers perceive the P&Ps are applicable to their job functions and the kinds of research they conduct, and are able to apply the P&Ps to multiple research problems and settings.

Recommendation: Assess the number of protocol and regulatory violations and the number of collaborations among sites across program areas and networks.

Justification: It is expected that a robust set of clinical research policies and procedures will foster protocol and regulatory compliance and increase the likelihood of research collaborations among sites.

In addition to the above recommendations, based on our experience with the initial in-person training on a subset of the P&Ps, NOVA believes it is possible to evaluate the training process and obtain feedback from the trainees in order to improve the training and/or presentation of the P&Ps.

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EXHIBIT 1. MATRIX OF FINAL REPORT COMPLIANCE WITH TECHNICAL REQUIREMENTS OF THE DIVISION OF AIDS-WIDE CLINICAL RESEARCH POLICY AND PROCEDURE IMPLEMENTATION FEASIBILITY STUDY

Detailed Technical Requirement	Description	Report Section Where Addressed
Identify relevant stakeholders Clarify issues and objectives Develop a logic model	Document those who have an interest in evaluation findings and the extent of their involvement in evaluation planning. Identify key stakeholders, P&Ps goals, objectives, and related issues of relevance to the evaluation. Develop a logic model of the P&Ps implementation to facilitate shared understanding of the program's structure, resources, planned activities, and outcomes.	Step 1 and Step 2, pages 4 to 6; Appendix A: P&Ps Logic Model.
Conduct a literature review Develop study questions for the evaluation Identify key variables	Review relevant literature, related studies on development, implementation, and impact of standardized P&Ps on conduct of clinical research. Identify evaluation questions on process and outcomes of interest to stakeholders which are clear, specific, and answerable. Discuss specific information needed to answer evaluation questions.	Step 2 and Step 3, pages 5 to 9; Answering Evaluation Questions, pages 13 to 15; Appendix B: Evaluation Matrix; Appendix F: Results of Literature Review.
Review existing data Plan for data collection and analysis	Review existing data sources to identify key variables for the evaluation. Determine types of data that will be used to answer study questions. Identify feasible performance and comparison groups. Develop data collection instruments. Develop data analysis plan Determine strategies to ensure data integrity and to address ethical considerations.	Answering Evaluation Questions, pages 13 to 14; Appendix D: Pilot Data.
Recommend evaluation design	Submit a design for an outcome evaluation. Recommend for or against proceeding with process and outcome evaluation and provide justification.	Evaluation Design Options, pages 14 to 20; Appendix E: Summary of Recommendations.

DAIDS-Wide Clinical Research Policy and Procedures Implementation

Evaluation Feasibility Study Report

Introduction

The National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS), is implementing a set of policies and procedures (P&Ps) to be used by extramural researchers conducting DAIDS-funded research. DAIDS staff, notably Program Officers (POs) with clinical oversight responsibilities, use these policies to advise sites of protocol requirements in order to comply with NIAID/DAIDS policies as well as policies set by other agencies, e.g., NIH, FDA. Staff from the Office of Policy in Clinical Research Operations (OPCRO) developed these newly standardized policies. Development of these policies was at least partially in response to findings of the Sullivan Working Group which noted, among other issues, a lack of consistency in interpreting regulatory requirements and clinical trial processes due to the lack of a common approach across the various program areas within DAIDS. The lack of a common approach is likely to lead to inefficiency in the activities of DAIDS staff responsible for clinical trial monitoring. Thus, one potential impact of standardized P&Ps is increased efficiency of DAIDS staff as a result of decreased time required to assess, evaluate, and respond to questions and inquiries from sites conducting DAIDS-funded research.

Implementation of new P&Ps will affect staff responsible for advising sites regarding the implementation of these policies and their subsequent monitoring activities. While theoretically a set of standardized P&Ps should be welcomed by DAIDS staff, people become comfortable with their roles and responsibilities, however complex or seemingly inefficient they might be. Introducing change could lead to increased job dissatisfaction, thus negatively affecting DAIDS' overall clinical site monitoring responsibilities. Consequently, implementation of these newly developed P&Ps (e.g., staff preparedness, introduction to and training on the P&Ps, support from management) is important for the initial acceptance of this change. Part of the comprehensive evaluation plan is documenting the context in which implementation occurs.

The implementation of a set of standardized P&Ps is also consistent with the NIH Clinical Research Policy Analysis and Coordination Program (CRpac) which states that *efficiency and effectiveness in the system of clinical research is hampered by variability in regulations and policies that pertain to the conduct and oversight of clinical research*. Implementing a set of standardized P&Ps aligns NIAID more closely with the CRpac goals of harmonizing policies and procedures for more efficient and effective conduct of clinical trials. Exhibit 2 describes DAIDS-Wide Standardized P&Ps goals.

EXHIBIT 2. DAIDS-WIDE STANDARDIZED P&PS GOALS

The overarching goal of NIAID's P&Ps is:

To improve clinical research, i.e., increased collaboration, efficiency, flexibility, and greater integration among DAIDS-funded clinical research programs, through implementation of standardized P&Ps

Specific goals include ensuring that P&Ps are:

a. Easily available and accessible
b. Clear and easy to understand
c. Applicable to clinical trial research
d. A conduit to facilitate harmonization of policies to conduct clinical trial research

The underlying assumption of the standardized P&Ps is that their implementation will make the conduct of clinical research simpler by harmonizing policies and procedures, thus facilitating regulatory compliance (e.g., development of a Manual of Operational Procedures). For example, sites that host multiple clinical trials, regardless of the program area in which the trial originates (e.g., Vaccine Research Program versus Therapeutics Research Program), will have the same policies and procedures for conducting that clinical trial. This should lead to increased efficiency and greater regulatory compliance, as there would be fewer misunderstandings, misinterpretations, or misguidance from DAIDS staff when interpreting a set of common policies and procedures.

Evaluation Plan Development

Purpose of Evaluation Feasibility Study

NIAID DAIDS Office for Policy in Clinical Research Operations (OPCRO), in partnership with NIAID Strategic Planning Evaluation Branch (SPEB), was interested in conducting an evaluation feasibility study of the implementation of DAIDS-Wide Clinical Research Policies and Procedures (P&Ps) to assess its effects on the efficient conduct of clinical research and increased collaborations among DAIDS-funded sites. OPCRO expects to use evaluation findings to justify the added value of the program, including ongoing training and presentation to extramural researchers. If evaluation findings demonstrate effectiveness of standardized P&Ps, similar programs may be adopted by other NIAID Divisions and NIH Institutes, as well as domestic and international extramural research communities.

The purpose of this DAIDS P&Ps evaluation feasibility study is to determine whether conducting a full-scale evaluation of the implementation of DAIDS P&Ps is appropriate, and to identify best possible evaluation designs, methodologies, and data collection strategies to assess its implementation and effects. The NOVA evaluation team conducted a systematic assessment of optimal plans to evaluate the implementation and impact of the P&Ps by proposing questions to be answered by the evaluation, developing data collection instruments, collecting and analyzing data from literature and document reviews, collecting pilot data from DAIDS staff (i.e., POs with clinical site oversight responsibilities who attended the initial training session of seven of the newly developed policies; see summary of findings in **Appendix D**), and identifying

appropriate evaluation designs (see **Appendix E)**]. This report provides guidelines and specific recommendations for designing a full-scale process and outcome evaluation of the DAIDS-Wide P&Ps.

Overview of Evaluation Approach

Implementation of the DAIDS standardized P&Ps represents a step towards harmonization to enhance consistency and clarity in conduct of DAIDS-funded/sponsored clinical research studies. Expected users of P&Ps include Program Officers, clinical investigators, study coordinators, clinical monitors, and others — pharmacists, nurses, case managers, laboratory staff, social workers, and administrative staff.

NOVA worked collaboratively with representatives from DAIDS/OPCRO and SPEB to develop the best overall approach and most appropriate measures to evaluate the implementation of the P&Ps. The statement of work for the feasibility study outlined the overall approach for the evaluation:

> *"In light of the fact that these policies and procedures will be adopted as the standard of practice for DAIDS extramural research, an evaluation of the accessibility, quality, and feasibility of their implementation is of great importance to DAIDS' harmonization plan."*

NOVA's first objective was to develop the best overall evaluation methodology to assess DAIDS P&Ps by gaining a clear understanding of DAIDS' expectations for a full-scale evaluation. The following questions were addressed to inform the evaluation feasibility study:

- What is the purpose and scope of the P&Ps evaluation?
- What evaluation questions are important to DAIDS?
- What process and outcome evaluation methodologies and techniques are most appropriate for assessing implementation of standardized P&Ps?
- Are internal DAIDS metrics and methods available to assess if users are aware of the new P&Ps?
- Are metrics and methods available to assess users' perceptions regarding ease of accessibility of the new P&Ps?
- Are metrics and methods available or can these be developed to measure users' perceptions of the applicability of the new P&Ps to their research?
- Are metrics and methods available or can these be developed to measure increases in collaborations across research programs?
- Are metrics and methods available or can these be developed to measure increases in research integration among DAIDS-funded clinical research programs?
- What existing data sources can be used to evaluate this program? What new data need to be collected? What are the most efficient strategies and methods for the data collection?
- What comparison groups are available and appropriate?
- What is the cost of collecting various types of data in dollars, time commitment, and burden on staff and evaluation participants?

- Is there adequate justification to conduct a full programmatic process and outcome evaluation at this time? If so, what are the most appropriate approaches to use in evaluating the effects of the standardized Policies and Procedures?

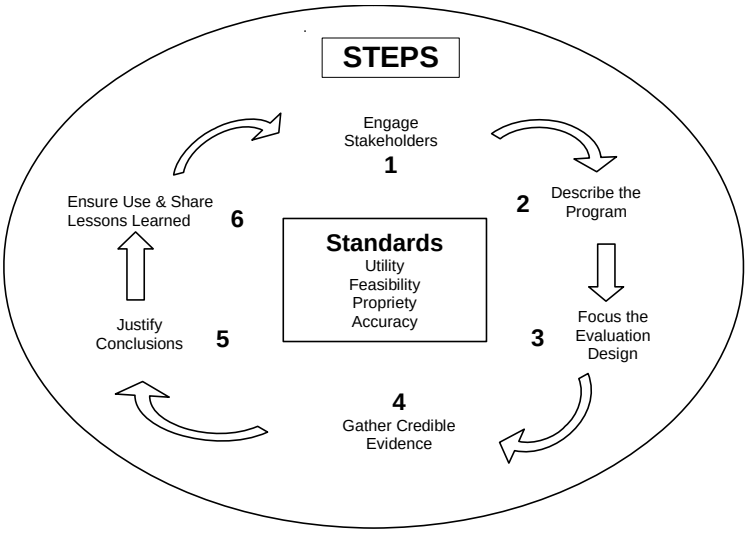
Answers to these questions provided useful information that was used during the study to conduct an evaluation of DAIDS' P&Ps, This gave evidence to support the evaluation design strategies and methodologies recommended in this report.

The development of an evaluation plan incorporates evaluation objectives within a conceptual framework that depicts program activities and outcomes, as viewed by key stakeholders. The NOVA team initiated the evaluation planning process with a face-to-face meeting with NIAID program Officers and SPEB staff. This team set goals of the evaluation planning process, discussed questions about NIAID's concept of how the P&Ps implementation would function, and identified documents that needed to be reviewed. The plan described in this report is comprehensive, relies on existing data sources where possible, is feasible, and provides an approach to the evaluation of DAIDS P&Ps implementation and effects based on credible evidence.

Theoretical Evaluation Framework

The NOVA team used a framework for program evaluation developed by the Centers for Disease Control and Prevention (CDC). Exhibit 3 shows this "Framework for Program Evaluation in Public Health" (CDC, 1999). NOVA used this framework, which includes a series of steps and tools, to inform the design of a comprehensive evaluation plan of the implementation of DAIDS P&Ps. This step-by-step approach is described to illustrate how it can result in a comprehensive evaluation of standardized P&Ps which meets the needs of NIAID DAIDS.

EXHIBIT 3. FRAMEWORK FOR PROGRAM EVALUATION



Source: CDC. 1999. Framework for program evaluation in public health. *Morbidity and Mortality Weekly Report* 48 (RR-11):1-40.

Evaluation Plan

Step 1. Engage Stakeholders

Key stakeholders are defined as individuals or organizations that have an investment ("stake") in what will be learned from an evaluation and what will be done with this information (CDC, 1999; Patton, 1997). Stakeholders often are experts in a program itself and understand how it can or should affect target audiences and/or national programs.

DAIDS P&Ps stakeholders include DAIDS leadership and executives, staff within NIAID SPEB, and DAIDS-funded extramural researchers and staff. Other stakeholders include DAIDS POs responsible for clinical site oversight and contractors and extramural science administrators. NOVA and DAIDS staff identified three main groups of stakeholders: (1) OPCRO Leadership and Branches , (2) those involved in P&Ps dissemination/implementation operations (e.g., NIAID, OPCRO program staff, PPD staff), and (3) those served or affected by the implementation of DAIDS P&Ps (e.g., DAIDS POs, medical officers, site monitoring contractors and DAIDS-funded or-sponsored researchers).

As this evaluation moves forward, other key stakeholders may become involved. The amount of involvement from stakeholders may range from minimal (such as providing feedback on materials) to extensive (such as completing tasks that have a direct impact on what the DAIDS P&Ps implementation does and accomplishes).

Recommendation:

- **DAIDS OPCRO P&Ps Task Leader will ensure that main stakeholders are involved in evaluation planning and implementation**. Key stakeholders of the evaluation include DAIDS leadership and staff within OPCRO and SPEB. Additional stakeholders may include individuals from the research community involved in DAIDS-funded or -sponsored clinical research.

Step 2. Describe the Program

The description of a program includes its purpose and information regarding the way it was intended to function and the way that it was actually implemented. A clear and accurate description of the program allows for a balanced assessment of its strengths and weaknesses. In addition, it helps stakeholders understand how the program components fit together and relate to the overall goal. Program description includes delineation of the program theory (i.e., logic model) so that a common understanding of the program's goals, structure, connections, and expected outcomes exists. The logic model also assists in focusing the evaluation design on the most critical program elements. The evaluation design is then applied to this model.

The NOVA team discussed goals and objectives of the P&Ps implementation and other issues relevant to the evaluation in early meetings with the DAIDS P&Ps Task Leader and Contract Project Officer; SPEB Acting Chief and Project Manager; and other DAIDS staff. These meetings provided a mutual understanding of the purpose of DAIDS P&Ps implementation, anticipated activities, resources, stage of development, expected effects, and context. In addition, the NOVA team conducted a literature review of relevant studies on implementation of standardized P&Ps and, specifically, on evaluation of the implementation and impact of standardized P&Ps on conduct of human subjects research (see **Appendix F** for summary of findings from the literature review). From our literature search and review we were unable to

locate any study or report that described an actual evaluation of the implementation and impact of a set of standardized clinical policies and procedures. There were a number of reports documenting the implementation of standardized clinical policies and procedures within, for example, medical research facilities. In all cases, those responsible made the assumption that having standardized policies would have a positive impact on their clinical research. This has intuitive appeal but provides no empirical evidence of the presumed positive impact on the clinical research endeavor. These activities did help determine the feasibility of (and need for) an evaluation, identify appropriate models or theories to guide the evaluation (e.g., logic model), and informed the evaluation design (e.g., relevant outcomes, measures, methodologies, data sources, and analyses). However, DAIDS now has the unique opportunity to evaluate and substantiate the benefits of standardized clinical policies and procedures to the clinical research process and output.

As part of DAIDS P&Ps dissemination and implementation activities, an in-person DAIDS Policy Training was conducted on selected policies (e.g., requirements for Human Subjects Protection-HSP and Good Clinical Practice-GCP training for clinical research site personnel; source documentation in DAIDS-funded or -sponsored clinical trials; manual of operational procedures-MOP; on-site monitoring of DAIDS-funded or -sponsored clinical trials; clinical quality management plans at DAIDS-funded or -supported clinical research sites). The training was mandatory for DAIDS staff responsible for oversight of clinical trials or clinical sites (i.e., all POs for clinical trials sites and networks, Medical Officers, and Project Officers for contracts supporting conduct of trials). It is possible that additional training will be offered to prepare DAIDS staff and DAIDS-funded researchers on the new P&Ps. Suggested evaluation methodologies and recommendations in this report will also address the assessment of this training as a main dissemination/implementation activity.

2.1. Evaluation Program Theory (Logic Model)

Based on input from involved parties and activities discussed above, a logic model was developed to provide a synopsis of the implementation of DAIDS P&Ps. The model shows relationships among major aspects of the implementation, activities and outputs envisioned by the P&Ps implementation, and desired outcomes associated with activities. It provides a logical sequence of how the resources invested by DAIDS, OPCRO will lead to refinements and desired results in implementing P&Ps. A logic model generally has the following elements: inputs, activities, outputs, short-term outcomes (1-2 years), intermediate-term outcomes (2-4 years) and long-term outcomes (4-6 years). **Appendix A** shows the Logic Model developed for the evaluation of DAIDS P&Ps implementation.

Recommendation:

- **Review DAIDS Logic Model for P&Ps Implementation annually.** DAIDS logic model for P&Ps implementation needs to be reviewed annually so that it accurately reflects changes. An effective logic model is refined and changed many times throughout the evaluation process as staff and stakeholders learn more about the implementation, how it operates, and why it works. This process aids in adjusting approaches and changing course as the implementation of standardized P&Ps evolves over time.

2.2. Outcomes of Interest to the DAIDS P&Ps Program

The evaluation plan focuses on two different but related aspects of the program specified in the logic model: formative aspects that reflect implementation of planned program activities (also referred to as *progress* or *process*) and summative outcomes that reflect expected short- and long-term program effects (also referred to as *outcomes*).

Common formative indicators or *outputs* describe program operations and elements of change that are precursors to system changes and contribute to evaluation of summative outcomes (end-of-program). The evaluation of formative aspects assesses the extent to which P&Ps are being implemented as planned (e.g., dissemination plan) and is measured on a regular basis (e.g., quarterly, annually). In addition, the evaluation seeks to measure summative changes brought about by the standardized P&Ps in outcomes of interest (e.g., consistent application of P&Ps by POs).

Step 3. Focus the Evaluation Plan

A focused plan increases chances that the evaluation will succeed in providing direction and determining what steps are practical, politically viable, and cost-effective. Among the items to consider when focusing an evaluation are purpose, users, uses, advisory committee, evaluation questions, benchmarks or indicators, and methods.

3.1. Purpose

The purpose of the evaluation of DAIDS P&Ps implementation is to consistently measure relevance, effectiveness, and impact of the implementation prospectively over the years and to produce meaningful reports to interested stakeholders both within and outside NIAID/DAIDS. The ultimate goal of the evaluation is to assess the impact of standardized P&Ps on conduct of DAIDS-funded or -sponsored research.

3.2. Users

Key stakeholders should be asked to review and prioritize evaluation questions, methods, and intended uses of the evaluation to prevent it from becoming misguided or irrelevant. To focus the evaluation, DAIDS staff and the evaluation contractor need to work with other key stakeholders to prioritize areas to address in the Evaluation Plan. Based on these priorities, feasible evaluation strategies can be refined and integrated into the P&Ps implementation Evaluation Plan.

3.3. Uses

The results of this evaluation will be used for multiple purposes, including making appropriate refinements (including training content and format) as information on implementation operations is gathered regularly; making decisions regarding continuation of implementation activities and funding; and providing lessons learned that can be applied to other instances of standardized P&Ps implementations and related effects.

3.4. Evaluation Advisory Committee

An Evaluation Advisory Committee should be used for the P&Ps implementation evaluation. This committee will serve both technical and practical functions. It will provide expertise and recommendations to focus the scope of the evaluation, methodologies, and data collection instruments, and to identify contextual circumstances to consider.

Recommendations:

- **Evaluation Advisory Committee needs to consist of members with relevant experience**. At a minimum, it should have members with experience in evaluation (i.e., evaluation of clinical policies and procedures or general regulatory requirements pertaining to the conduct of clinical trial research), as well as Subject Matter Experts (SMEs) on clinical policies and procedures, clinical trial monitoring, and adult learning.
- **Clarify purposes and responsibilities of Committee.** Evaluation Advisory Committee members should be clear about the committee's purpose, their roles and responsibilities, and estimated number of meetings per year.

3.5. Evaluation Questions

Evaluation questions establish boundaries by stating what aspects of the program will be assessed. The process of identifying potential information needs often results in more questions than can be addressed in a single evaluation effort. A comprehensive look at potential evaluation questions make these possibilities clear to the DAIDS P&Ps implementation staff, allowing for informed choices when selecting questions.

The NOVA team developed both formative (process) and summative (outcome) evaluation questions. Answers to formative evaluation questions will provide information that can be shared quickly to improve the DAIDS P&Ps implementation, as these questions focus on implementation activities, challenges, and outputs for the purpose of monitoring progress and making midcourse corrections, when needed. Answers to summative (outcome) evaluation questions will provide information on the P&Ps' short- and intermediate-term implementation effects and long-term impact.

Generated information will be used to determine the overall value and worth of the DAIDS P&Ps, help identify changes necessary to improve accomplishment of overall goals, determine the extent to which the P&Ps have been implemented as planned, and determine whether they have succeeded as expected.

Evaluation questions were built on the logic model and reflect the processes and outcomes of the implementation of the new DAIDS P&Ps that are most useful to learn about. The evaluation questions focus on the short- and intermediate-term outcomes among target audiences (e.g., POs and DAIDS-funded researchers); and document processes related to dissemination and implementation and the training of target audiences.

Awareness of and Accessibility to DAIDS P&Ps

- Are target audiences aware of the availability of and how to access DAIDS P&Ps?
- What is the extent of use of the NIAID P&Ps Web site?
  - ✧ How easy is it to access the new P&Ps posted on the NIAID Web site (e.g., too many clicks) for target audiences?

Understanding of DAIDS P&Ps

- Are the new P&Ps easy for target audiences to understand ?

- Is there additional support to facilitate understanding of the new P&Ps (e.g., renewed training, contact information for questions)?

Applicability of DAIDS P&Ps

- Do P&Ps facilitate POs' clinical site oversight responsibilities?
- Do P&Ps facilitate working relationships among DAIDS staff?
- Are POs consistent in their responses to sites' inquiries regarding DAIDS P&Ps?
- How useful and applicable are the new P&Ps for Researchers to conduct clinical trial studies?
- What are common barriers and facilitators to the implementation of standardized P&Ps among target audiences?

Harmonization

- Do target audiences perceive that the new P&Ps apply to network and non-network studies?
- Is there an increase in collaborations among sites (both in- and out-of-network) after implementation of P&Ps?
- Is there an improvement in research efficiency over time after implementation of P&Ps?
    - ✧ To what extent do the P&Ps make it easier for sites hosting multiple clinical trials to meet regulatory requirements of?

Training on DAIDS P&Ps

- What is the level of participation of target audiences in the training (e.g., all, most, few)?
    - ✧ What are barriers to participation in training (e.g., location, times, not enough training offered)?
- What is the reaction of trainees to the P&Ps training (e.g., satisfaction, helpful to understand P&Ps and facilitate application of P&Ps)?
- Are trained target audiences more likely to access, understand, and apply DAIDS P&Ps than non-trained audiences?

3.6. Benchmarks and Performance Indicators

Quality evaluations include assessments that describe the criteria for success. Benchmarks or indicators of performance are necessary to establish the extent to which the implementation is accomplishing what it set out to do in terms of process (e.g., outputs) and outcomes (e.g., increased collaborations). Benchmarks and corresponding performance indicators will help answer questions such as: "Do P&Ps facilitate harmonization of policies across DAIDS-funded clinical trials studies? Do POs who received training on P&Ps demonstrate adequate knowledge? Do POs provide consistent information to their sites? Performance indicators are also useful for monitoring ongoing implementation status against a set of targets (objectives or goals). Based on set benchmarks, an alert system for unexpected developments or lack of progress can be built into the evaluation plan. This can help key stakeholders (e.g., DAIDS/OPCRO management) review how the P&Ps are being implemented, whether progress is as expected, and where there are issues or problems that need to be addressed.

3.7 Timeline

Several factors are considered when determining the nature and scope of an evaluation. Program characteristics (e.g., intended targets, outcomes of interest, locations), evaluation questions, and other practical considerations (e.g., resources, maturity of initiative) shape the scale (size, time period) of the evaluation.

Implementation of DAIDS new P&Ps is expected to have a wide reach and impact (e.g., DAIDS POs and other DAIDS staff with clinical site oversight responsibilities, and domestic and international extramural researchers). The planned evaluation is comprehensive because of the complexity of the implementation and the assessment of various aspects of the implementation including process and outcomes, short-, intermediate-, and long-term goals, multiple audiences, and locations. The evaluation needs to be sensitive to allow enough time for DAIDS P&Ps to be disseminated so that outcomes are measured at the right time. A comprehensive, reliable evaluation is dynamic, expanding or switching its focus and activities as DAIDS P&Ps are implemented over time to ensure a fair assessment of DAIDS P&Ps effects. A proposed Timeline/Schedule of evaluation activities is provided in **Appendix C.**

Recommendations:

- Implementation of DAIDS P&Ps needs to be evaluated over an extended period of time to accurately measure its effects on perceptions and use of the new P&Ps. A 5-year plan is recommended to conduct a comprehensive evaluation of DAIDS P&Ps implementation and effects.
- Evaluation can initially focus on DAIDS staff with clinical site oversight responsibilities (e.g., POs, contractors) during the first year and continuing throughout the evaluation period, then move on to extramural researchers the second year; examine domestic clinical research/clinical trials during the second and third year, and then international clinical studies in the fourth and fifth year (e.g., identify a country or type of international studies to evaluate).
- Significant changes (e.g., improvement) in clinical research which might result from or occur after DAIDS P&Ps (i.e., increased collaboration, efficiency) are likely to take some time as the P&Ps are a new, standard set of regulations. Repeated measurements over the years will yield data on any changes or trends in the use of P&Ps (e.g., in the expected direction, for certain types of studies, or for domestic vs. international researchers) .

3.8. Evaluation Planning Matrix

An Evaluation Planning Matrix is a useful organizational tool that flows from the DAIDS P&Ps Logic Model. It typically includes evaluation questions, types of data needed to answer evaluation questions, methods to be used, data sources, data analysis, limitations of findings, and knowledge gained from the evaluation. In collaboration with NIAID and DAIDS staff, the NOVA team created a matrix that describes how DAIDS P&Ps evaluation questions will be answered (see **Appendix B**).

3.9. Methods

A mixed-method approach using quantitative and qualitative evaluation measures strengthens the overall research design by allowing for more precise statistical measurement in the quantitative

components and in-depth insight in the qualitative components. Quantitative data produces estimates of the prevalence of knowledge, attitudes, opinions, behaviors, and other characteristics of P&Ps' target audiences. Surveys are commonly used to collect quantitative data and they are administered in a variety of ways (e.g., in-person, telephone, Internet). Qualitative data helps provide a better understanding of the program and its intended effects. Techniques for gathering qualitative information vary greatly; they can be in-depth individual interviews, focus groups, observational studies, and participant observation, among others.. Both quantitative and qualitative data will be collected to answer P&Ps implementation evaluation questions.

Recommendations:

- Employ qualitative and quantitative techniques in the evaluation to obtain a more comprehensive picture of the effects of DAIDS P&Ps implementation.
- The traditional measure to determine program effects based on quantitative data analyses is statistical significance. Statistical significance is compromised by small samples. The use of power analysis (for effect size) that specifies sample size to determine statistically significant changes (e.g., increased efficiency in responding to site inquiries) is recommended where appropriate. For example, due to the small number of all DAIDS POs (about 30), determining an effect size for significant changes is not feasible. However, changes based on effect size and related sample size can be appropriate when evaluating researchers because there is a larger number of them(See Section on "Answering Evaluation Questions", Goal 3, *Recommendations,* page 18).
- Evaluation methodologies should minimize respondent burden and ensure confidentiality or anonymity of sensitive personal information. Data from surveys, focus groups, and personal interviews can be obtained unobtrusively through system devices that ensure data integrity and meet DHHS/NIH requirements for data security.

Step 4. Gather Credible Evidence

Collecting data from various key sources using qualitative and quantitative methods, addressing formative and summative outcomes, helps ensure that the evidence will be trustworthy. Different types of data obtained from various sources and by different methods will convey a full picture of the implementation of DAIDS P&Ps; these data will be used by the evaluation's primary users to draw conclusions and make informed decisions. Although all types of data have limitations, multiple methods (e.g., qualitative, quantitative, surveys, interviews) for gathering, analyzing, and interpreting data enhance the quality of the data (CDC, 1999). The collected information will present a clear and reliable picture of the implementation of DAIDS P&Ps and its effects.

4.1. Data Sources

A variety of sources can provide the necessary information for the evaluation. Implementation records (e.g., "hits" on the P&Ps Web site), DAIDS program staff (e.g., OPCRO, OCSO staff), extramural clinical researchers, and key informants are some sources of data that will be used for a comprehensive evaluation of DAIDS P&Ps. Next is a description of the data that will be collected. The way(s) in which these data will be used to answer evaluation questions is outlined in the Evaluation Matrix (See **Appendix B**). Final versions of data collection instruments will be

developed and implemented with input from the Advisory Committee and relevant DAIDS and SPEB staff (e.g., DAIDS/OPCRO P&Ps staff, training staff).

4.1.1 Pilot Data

As part of the Feasibility Study, the NOVA team collected pilot data related to the implementation of, and training on the P&Ps. As mentioned earlier, an in-person training ("DAIDS Policy Training") was conducted which was mandatory for DAIDS staff responsible for clinical trial or clinical site oversight. The training targeted seven of the newly developed P&Ps. NOVA developed survey instruments to obtain information from training attendees regarding the actual training experience; NIAID/DAIDS staff perceptions of the awareness/accessibility, understandability and applicability of the P&Ps; and staff beliefs of P&Ps' impact related to harmonization. These survey instruments, with results, are presented in **Appendix D**. A comparison of POs' responses versus non-POs' responses is also included[1]. Note that, because DAIDS P&Ps were only put into effect fairly recently, staff responses to items pertaining to applicability and harmonization of P&Ps only reflect perceptions of how P&Ps will influence their job functions in the future. Over time, as the P&Ps have been in effect longer, responses will inform about actual experiences with the P&Ps. As a follow-up to the Survey data, NOVA conducted a focus group of POs who attended the training. The focus group questions, along with a summary of the focus group discussion, is shown in Appendix D.

NOVA conducted an analysis of POs' responses to the survey data and information provided in the focus group. Several points are worth noting:

- POs, generally, felt the training was "excellent," and felt the opportunity to hear questions from other DAIDS staff was helpful. However, they felt that the training might not be appropriate ("too dense") for persons with little experience with clinical policies and procedures.
- POs were well aware of the P&Ps but felt there was uncertainty as to the effective date of the new policies. POs recommended that an effective date be clearly communicated to the sites.
- While the survey data indicated that POs had some uncertainty as to how the newly implemented P&Ps would affect their job, those who attended the focus group welcomed the standardized P&Ps and believed these would facilitate their oversight responsibilities and reinforce their authority.

It should be noted that only four POs attended the focus group. Had this been a full-scale evaluation, NOVA would have conducted at least one other focus group with POs in order to get a broader sample of thoughts and opinions regarding the implementation and impact of the P&Ps.

The collection of pilot data demonstrated the feasibility of collecting data on the implementation and outcomes of DAIDS P&Ps. There are several implications from the pilot data regarding the ability to collect evaluation data and the usefulness of the information collected:

[1] Note of Caution: The sample size of POs (n=11) is too small to make any definitive statements.

- It is feasible and useful to collect quantitative and qualitative data for the evaluation. For example, the kinds of information obtained in a focus group could not be collected in a survey, and contributed to a better understanding of the implementation process
- Evaluation questions can be further refined to obtain critical information on the P&Ps implementation
- Required evaluation instruments (e.g., surveys) to collect relevant information can be identified or developed
- POs can be targeted as participants in the evaluation
- Data gathered provided useful information to DAIDS P&Ps staff on an important implementation activity — training — to disseminate knowledge about the P&Ps.
- Data gathered provided key information for additional content and format of implementation activities. For example, in the focus groups, all participants had years of experience as POs implementing clinical trial policies. While they praised the training and saw it as informative, they opined that similar training may be too "advanced" for new POs with little or no related experience. This implies that new POs may benefit from more or more detailed training on the new DAIDS P&Ps. Likewise, specific adaptations may be necessary for other kinds of trainees (e.g., extramural Study Coordinators).

  Recommendations:

  - Review evaluation questions and develop evaluation instruments and procedures to reflect findings from the pilot data (e.g., necessary changes, modifications)

4.1.2 Training Database.

Basic information on participants' characteristics was obtained during DAIDS-sponsored training. It is expected that future training on standardized P&Ps will collect similar information.

Recommendations: The following data elements and related procedures need to be incorporated into future DAIDS P&Ps training:

- Descriptive metrics on P&Ps training participation: number of people attending the training (e.g., accessing a Web/computer-based training); descriptive information on participants (e.g., job function, years of experience).
- Collect data on responses, by job function and years of experience, for items assessing satisfaction with the training. These responses can inform training content and format which may need to be different for different audiences.

4.1.3. NIAID Web site.

DAIDS P&Ps are laid out on the NIAID Web site to facilitate access. It is expected that target audiences will know where the P&Ps are available (NIAID Web site) to be accessed.

Recommendations:

- Obtain P&Ps Web site access data (number of users who access/open P&Ps Web site, number of users who access each of the specific policies including related Appendices, policies most frequently accessed), to assess awareness and access to DAIDS P&Ps.

- A prompt can be included in the link to DAIDS P&Ps that inquire about the user's background (e.g., PO, researcher, study coordinator). This will help assess the extent to which target audiences are likely to visit the Web site where P&Ps are located.

4.1.4. P&P-related Questions to OPCRO staff and/or POs

DAIDS staff will maintain a log of questions from site personnel regarding implementation of the newly developed policies and procedures. These logs will provide information about common questions and misperceptions and level of understanding of P&Ps. This information can be used to improve future training. In addition, these questions will be used to develop case scenarios, based on real questions and issues, which can then be used to assess POs' consistency of responses to similar questions (both within and across POs) and differences among target audiences in understanding P&Ps

* Note: Ethical concerns and issues with confidentiality and anonymity of data from specific individuals will be discussed with NIAID/DAIDS staff. No personally identifying information will be collected; general group characteristics will be collected to allow for meaningful interpretation of the data.

4.1.5. Surveys on P&Ps effects among DAIDS Project Oversight Staff

At regular intervals during the evaluation period, surveys will be administered to DAIDS POs, other persons responsible for advising sites on clinical policies and procedures, and other target audiences, to assess the effects of DAIDS P&Ps on relevant job functions. For POs, survey items will asses perceived the effects of P&Ps related to their clinical site oversight responsibility (see Appendix D). These surveys can be used to assess changes over time on adherence to P&Ps.

4.1.6. Surveys on P&Ps effects among Clinical Trial Research Staff

Surveys will be administered to appropriate clinical trial staff (e.g., extramural site personnel, Principal Investigators, Study Coordinators) conducting DAIDS-funded or -sponsored research on their perceptions regarding DAIDS P&Ps (e.g., availability, ease of understanding and access). Additional questions will assess PIs' and Study Coordinators' perceptions of the accuracy, timeliness, and consistency of responses to their inquiries that they receive from DAIDS POs.

4.1.7. Focus groups with project oversight staff of NIAID-funded or-sponsored clinical research

Focus group discussions allow for in-depth probing of pertinent topics. The purpose of conducting focus groups is to gain a more thorough understanding of: (a) critical issues regarding P&Ps based on results from the surveys (b) key factors that are frequent barriers to the implementation of standardized P&Ps and compliance in the conduct of clinical trial research.

It may be important to conduct focus groups with different NIAID oversight staff (e.g., POs, medical officers, Site Monitors) separately to obtain various perspectives based on their roles and responsibilities—and therefore experience with clinical P&Ps. Some of the findings from the surveys will also be addressed in focus groups for further clarification. Data from focus groups and surveys will help identify facilitators and obstacles to the implementation of DAIDS P&Ps, courses of action that can be taken, and recommendations based on lessons learned.

4.1.8. Interviews with Site PIs and Site Study Coordinators

In-depth interviews with Site PIs and Study Coordinators about the applicability of DAIDS P&Ps to all or most research studies, and their perceived impact on clinical research, and particularly the development of regulatory documents, will provide information on perceptions of the effect of the implementation of the standardized P&Ps on the efficiency of the associated research . Information obtained from the surveys can also be explored and clarified during these interviews. These interviews can be conducted during program Year 2, Year 3, and at Year 5. The focus of the interviews during Year 2 will be on clinical site staff's perceptions regarding POs' timely and accurate responses to their inquiries about clinical policies and procedures. The interviews conducted during Years 3 and 5 will focus on site staff's perception of the impact of the P&Ps on their ability to efficiently develop regulatory documents (e.g., MOPs and SOPs) and move from study planning to initiation in a shorter time frame.

4.2. Data Analysis

4.2.1. Quantitative Methods

Analysis of quantitative measures will begin with descriptive statistics (e.g., frequencies, means, cross-tabs) to characterize the data and answer evaluation questions related to the implementation of P&Ps. Other quantitative analysis will focus on improvement in aspects related to POs' consistency in responses to site staff inquiries (use of case scenarios; feedback from site staff). These data should be examined quarterly to monitor progress and detect any problems that require intervention such as messages to POs clarifying how a given policy should be applied. More complex analyses and causal modeling, such as analyses of variance and regression analysis, may be performed, depending on the quality and quantity of data. If the data support these more complex analyses, they would be performed as part of the summative evaluation (short- and intermediate-term outcomes). Data analysis on POs' demonstrated ability to apply the P&Ps, through the use of case scenarios, should be performed annually or every 2 years, based on decisions by DAIDS, and would be primarily descriptive in nature (e.g., recognition that a policy can apply to different kinds of research being conducted in different program areas). Descriptive data from other sources, such as POs' site monitoring documents and regulatory compliance documentation, should be used to complement understanding and measurement of program impact.

4.2.2. Qualitative Methods

Qualitative data from interviews and focus groups should be transcribed verbatim. These data should be analyzed and interpreted using content analysis in which main ideas, comments, and words are grouped based on variables of interest (Patton, 2001). To maximize reliability, coding (i.e., categorizing) of data and thematic analysis of text should be conducted by a minimum of two experienced evaluators. Qualitative software, such as ATLAS.ti, should be used for these analyses.

Step 5. Justifying Conclusions

Findings from the evaluation should be judged against desired outcomes (benchmarks) identified by key stakeholders. Conclusions on the basis of evidence include comparing objectives (predetermined measures of success) with analysis and synthesis of information, interpretation of evidence, and recommendations for consideration (CDC, 1999; Patton 1997). When appropriate, conclusions will be strengthened by: (1) summarizing plausible mechanisms of change (e.g.,

participation in P&Ps training led to knowledge of newly developed P&Ps and their applicability to DAIDS-funded or -sponsored research); (2) delineating temporal sequences between activities (e.g., training) and effects (e.g., timely, consistent responses to site staff inquiries); and (3) showing that effects can be repeated (e.g., standardized P&Ps) (CDC, 1999; Patton 1997). The DAIDS Director and key stakeholders should work together with the evaluation contractor to determine interpretations and conclusions supported by the evidence gathered.

Step 6. Ensuring Use and Sharing of Lessons Learned

The evaluation process ensures that stakeholders are aware of the evaluation's overall design (e.g., goals, procedures, methods), implementation, and findings in order to facilitate use of findings when implementing decisions or actions that affect the program (evaluation findings provide rationale for decisions). Evaluation process activities include designing the evaluation to answer evaluation questions; providing feedback to stakeholders regarding interim findings; and disseminating to stakeholders the procedures used and lessons learned from the evaluation (Patton, 1997).

Annual and summative evaluation reports would be submitted to DAIDS and SPEB. Feedback from stakeholders and other users of this evaluation is necessary to ensure the application of the findings. As directed by the NIAID OPCRO Task Leader, dissemination of lessons learned may include support for writing manuscripts, preparing presentations (e.g., content, slides, handouts), or developing other tailored communication strategies to meet needs of stakeholders.

Answering Evaluation Questions

In order to answer P&Ps implementation evaluation questions, specific information on key variables is needed. Data on key variables will be used to develop and interpret findings, and prepare recommendations and lessons learned specific to DAIDS P&Ps.

Key Variables

The following key variables related to resources, population characteristics, project activities, project goals, and external factors should be collected to answer evaluation questions.

1.1. Resources

This information includes the amount of funding, human capital, infrastructure, and other resources allocated to the implementation of P&Ps. Resources include DAIDS P&Ps funding, DAIDS staff, OPCRO staff, and DAIDS contractors. Information on these variables will need to be provided by DAIDS staff to the evaluation contractor.

1.2. Population characteristics

These variables describe the characteristics (e.g., demographics) of DAIDS P&Ps implementation target audiences. Population variables include type of target audience (i.e., POs, extramural researchers, DAIDS POs, site monitors, division regulatory staff), level of audience (e.g., Principal Investigator, study coordinator, research nurse, pharmacist), location of study (i.e., international or US), and experience with clinical site oversight responsibilities (e.g., years of experience). These data will be available as part of the collected surveys and include the trainee profile data that was collected as part of the Pilot Study (see **Appendix D**). As the Pilot

Study included only DAIDS program staff, the profile data will be expanded to include other important characteristics of target audiences .

1.3. Implementation activities

These variables depict implementation operations, processes, or other critical activities. Related variables are P&Ps dissemination and promotion plans and modifications. These are primarily process data that can be collected through forms that gather data on planned activities, whether objectives were met (e.g., specified number and type of activities were conducted), barriers found when implementing, decisions to address barriers, modifications, and lessons learned in the process. These data will need to be provided by DAIDS/OPCRO program staff to the evaluation contractor on a regular basis (e.g., quarterly).

1.4. External factors

External factors are conditions or circumstances that may influence the success of the implementation of DAIDS P&Ps. These variables provide context for interpreting the data gathered throughout the evaluation. Variables include problems encountered during implementation activities (e.g., with the training), decisions made to address them, lessons learned (e.g., DAIDS' consideration of mandatory P&Ps training), and unexpected positive and negative events occurring during implementation. Forms used to monitor implementation activities will also collect these data and will need to be provided by DAIDS/OPCRO program staff to the evaluation contractor on a regular basis (e.g., quarterly). Other tools that will be used to collect this kind of information include surveys and focus groups or in-depth interviews that will be the responsibility of the evaluation contractor to develop and implement.

1.5. Program goals, performance measures, and comparison measures

These variables are interrelated and focus on the program's outputs (from implementation activities—e.g., dissemination messages, training) and outcomes (effects on target audiences—e.g., aware of P&Ps, understand P&Ps). To the extent possible, each implementation goal is associated with performance and comparison measures. The DAIDS P&Ps implementation goals and objectives reflect short- and long-term goals (See **Appendix A —** Program Logic Model). Discussion of how goals can be evaluated will be divided into short- and intermediate-term goals and long-term goals. A goal for related training is also included as part of the evaluation, as it is possible that additional training on DAIDS P&Ps may be offered.

Short- and Intermediate-term goals		Long-term goals	
Goal 1:	Target audiences are aware of and access DAIDS P&Ps	Goal 5:	Increased efficiency in the conduct of clinical trial research
Goal 2:	DAIDS P&Ps are easy to understand	Goal 6:	Decrease in number of protocol and regulatory violations
Goal 3:	DAIDS P&Ps are applicable to clinical trial research	Goal 7:	Increased collaborations among researchers
Goal 4:	DAIDS P&Ps facilitate harmonization of policies in conduct of clinical trial research		
Training goal			
Goal 8:	Trainees have favorable reactions to the training		

Short-term Goals of DAIDS P&Ps

Goal 1: Target audiences are aware of and access DAIDS P&Ps

Accomplishment of this goal can be evaluated by examining:

- The P&Ps comprehensive dissemination plan to inform target audiences of the availability of the P&Ps, including any associated training (e.g., type of dissemination activities, message content).
- Whether there is increased use of the DAIDS Clinical Policies and Procedures Web pages over time.

Performance Measures (outputs)*:* Tracking sheet on dissemination activities from DAIDS/OPCRO program staff (e.g., number and type of activities, targets of disseminations activities), periodic (e.g., annual) cross-sectional surveys (e.g., awareness of available P&Ps training), P&Ps training use log (e.g., number of users over time, users' characteristics), and information from Web site visitors (e.g. number of hits).

Comparison Measures (outputs)*:* Changes over time as compared to original plan in tracking sheet on dissemination activities (e.g., number and type of activities, targets of disseminations activities), periodic (e.g., annual) cross-sectional surveys (e.g., awareness of available P&Ps training), P&Ps Web-based training use log (e.g., number of users over time, users' characteristics), and information from Web site visitors (e.g., number of hits).

Recommendation:

- Dissemination plan should be specific, describing number of expected activities, to whom, by whom, and by when, and identifying benchmarks for activities (e.g., minimum amount of training for a given audience). The evaluation will assess the extent to which the dissemination plan was implemented as planned, barriers, corrective courses of action, and lessons learned in the process.
- Include a prompt in the link to DAIDS P&Ps Web site that ask for user's posotion (e.g., PO, researcher, study coordinator).

Goal 2: DAIDS P&Ps are easy to understand

The accomplishment of this goal can be evaluated by examining:

- Target audiences understand P&Ps and their related roles and responsibilities (i.e., POs understand protocol approval, oversight process)
- Target audiences understand which policies apply to network vs. out-of-network clinical trials or to all human subjects research vs. clinical trials

Performance Measures: For DAIDS project oversight staff: answers from oversight staff to questions posed by researchers recorded on log of P&P-related questions to OPCRO staff or Pos; focus groups about clarity of P&Ps; responses to items from Survey on P&Ps' effects among Clinical Trial Research Staff on accuracy and consistency of responses to their inquiries by POs.

For clinical trial research staff, information from log on P&P-related questions to OPCRO staff or POs and responses to Survey on P&Ps' effects among Clinical Trial Research Staff.

Comparison Measures: Changes over time in logs, responses to Survey on P&Ps' effects among Clinical Trial Research Staff, and focus groups with project oversight staff.

Recommendation:

- Surveys and focus groups will be conducted semi-annually for the first 2 years of the evaluation and annually thereafter.

Goal 3: DAIDS P&Ps are applicable to clinical trial research

The accomplishment of this goal can be evaluated by examining whether:

- Target audiences perceive that P&Ps are applicable to their clinical trial research activities (i.e., POs perceive that P&Ps are applicable to clinical trial oversight; Researchers perceive that P&Ps are applicable to their clinical trial studies)
- POs provide consistent responses to researchers' questions regarding DAIDS P&Ps (i.e., Researchers believe they receive accurate and consistent guidance from POs)

Performance Measures: For DAIDS project oversight staff: responses to Survey on P&Ps effects among DAIDS Project Oversight Staff; to questions on P&Ps applicability to job functions; focus groups with Project Oversight staff. For clinical trial research staff, responses to Survey on P&Ps effects among Clinical Trial Research Staff.

Comparison Measures: Changes over time—for DAIDS project oversight staff: responses to Survey on P&Ps' effects among DAIDS Project Oversight Staff to questions on P&Ps' applicability to job functions. Focus groups with Project Oversight staff. For clinical trial research staff, responses to Survey on P&Ps effects among Clinical Trial Research Staff.

Recommendation:

- Surveys of, and focus groups with, DAIDS POs will be conducted semi-annually for the first 2 years of the evaluation and then annually thereafter.
- Surveys of, and focus groups with, Researchers will be conducted annually.

Goal 4: DAIDS P&Ps facilitate harmonization of policies in conduct of clinical trial research

The accomplishment of this goal can be evaluated by examining whether:

- Target audiences perceive that P&Ps are applicable to network and non-network clinical trial studies and studies across program areas

Performance Measures: Summary of previous years of Survey on P&Ps effects among DAIDS Project Oversight Staff to questions on P&Ps applicability to job functions, focus groups, and Survey on P&Ps' effects among Clinical Trial Research Staff. Interviews with site PIs and Study Coordinators.

Comparison Measures: Changes over time in summary of previous years of Survey on P&Ps' effects among DAIDS Project Oversight Staff to questions on P&Ps' applicability to job functions, focus groups, and Survey on P&Ps effects among Clinical Trial Research Staff. Interviews with site PIs and Study Coordinators.

Recommendation:

- Annual interim analyses will be conducted on the collected data and related to target audience responsibilities.

Long-term Goals of DAIDS P&Ps

Long-term goals reflect the application of standardized P&Ps over time which would lead to increased efficiency, decreases in protocol and regulatory violations, and increased collaborations among researchers both in- and out-of-network. The rationale behind these desired outcomes is that having standardized P&Ps that can be applied across program areas and across sites, whether domestic or international, in- or out-of network, will facilitate start-up and completion of the project and make it easier for clinical researchers to comply with all regulatory requirements. The proposed evaluation will collect data regarding these long-term outcomes; however, it will be difficult to attribute positive changes in the variables described above to the implementation of a set of standardized P&Ps.

1. The focus of the P&Ps training is knowledge acquisition. POs are required to implement the policies and advise sites on how sites can meet these requirements. Thus, the impact on behavioral measures such as increased efficiency and decreases in protocol/regulatory requirements are only indirectly tied to the implementation of the P&Ps.
2. There are a number of site-specific factors that could influence (either positively or negatively) the behavioral outcomes described above. Some of these include:
    - Changes in regulatory requirements independent of DAIDS P&Ps (e.g., FDA requirements).
    - Increases in sites located in resource-poor countries.
    - Increased international movement towards harmonization.
    - Organizational changes within DAIDS.
    - Increased requirements for training related to Good Clinical Practice.

3. P&Ps long-term outcome data will be collected at the research site/study level only; not at an individual level (e.g., each PI, Study Coordinator). Individuals' measures of knowledge of P&Ps and their applicability cannot be directly linked to the outcome data.

Recommendation:

- Collect information on other factors that may influence the long-term outcomes of interest. For example, NIH has established the R-34 Clinical Trial Planning Grants, which are designed for PIs to complete the up-front work (e.g., development of SOPs and MOPs; establish pharmacy), so that research dollars are used for research and not for the time required to obtain all the necessary regulatory documents and establish SOPs and MOPs. These kinds of factors need to be taken into account when trying to attribute outcomes to the putative cause.
- Collect data semi-annually as opposed to annually. Having a shorter time-frame between data collection points will help in establishing temporal relationships.

Goal 5: Increased efficiency in the conduct of clinical trial research

Accomplishment of this program goal can be evaluated by examining if:

- POs/Site monitors perceive increased application of P&Ps over time.
- PIs/Study Coordinators perceive that standardized P&Ps facilitate the conduct of clinical research
- Existing documentation demonstrates trends toward increased efficiency over time.

Performance Measures: Surveys of DAIDS Project Oversight Staff and PIs/Study Coordinators related to sites' increased use and application of new P&Ps. Surveys and focus groups or in-depth interviews will be used to collect this information.

Goal 6: Decrease in number of protocol and regulatory violations

The accomplishment of this program goal can be evaluated by examining whether:

- Existing documentation shows a trend towards decreased numbers of protocol and regulatory violations over time.

Performance Measures: Data from site monitoring tools and records on protocol and regulatory violations, obtained at successive points in time beginning with pre-implementation of P&Ps through 3 to 4 years post-implementation.

Goal 7: Increased collaborations among researchers

The accomplishment of this program goal can be evaluated by examining whether:

- The numbers of collaborations increases over time in a consistent fashion from before to after implementation of P&Ps

Performance Measures: Data on the number of newly implemented collaborations should exhibit an orderly and increasing trend beginning with pre-implementation through 3 to 4 years post-implementation.

Individual data versus aggregate data

Data can be collected at an individual or aggregate level. At an individual level, each participant's data is linked to a non-identifying unique ID to protect the person's anonymity and the confidentiality of that person's answers. There is no need for a non-identifying ID linked to a participant's responses if data is collected and reported only in an aggregated state.

Recommendation:

- Collect data at an individual level. Matching a person's job function (e.g., PO) to his or her knowledge and ability to consistently apply this knowledge is critical to making any statements regarding the value of having standardized P&Ps. It is also important to link these data over time, as it is expected that measures of consistency and applicability will be obtained from POs and other designated staff at multiple times throughout the evaluation period.

DAIDS P&Ps Training Goal

Goal 8: Trainees have favorable reactions to the training

The accomplishment of this program goal can be evaluated by examining whether:

- P&P trainees are satisfied with the training
- P&P trainees perceive that the training is relevant to their job tasks.

Performance Measures: Average ratings from trainee surveys of trainee interest, satisfaction, and perception of relevance and transferability of P&Ps administered at the end of the training. This will be an optional survey (although it may be worth discussing the value of making this survey mandatory.(see **Appendix D**).

Comparison Measures: Set criteria for acceptable ratings of P&P training regarding scope, relevance, and applicability of P&P training.

Recommendation:

- Set benchmarks for expected ratings on overall satisfaction with P&P training. Set criteria should specify (a) minimum rating score that would demonstrate P&P training satisfaction and (b) proportion of users expected to score at least the minimum satisfaction score.

Implications of evaluation design

- Because this is an optional survey, there is uncertainty about the proportion of trainees who will complete the post-training survey(s). Based on the pilot data, however, we know that 47 trainees completed the survey out of the approximately 100 persons who attended. Thus, the results will be biased based on characteristics of those who respond.
- Survey findings may indicate the need to make significant changes in the training, ranging from content to system design.

Recommendations:

- Survey items should collect information which will be of use to DAIDS program staff and stakeholders (e.g., to make program modifications, if necessary).
- The pilot study of the post-training evaluation indicated that useful data can be collected, through surveys and focus groups, and these data can inform both the content and format of the training for trainees with specific characteristics. Regular monitoring can lead to more effective and tailored training.

Summary

A summary of Recommendations for a Comprehensive Evaluation of the P&Ps Program is provided in **Appendix E** of this document.

The results of the proposed evaluation will provide DAIDS with empirical evidence on the value of implementing a robust set of standardized clinical policies and procedures. Information from the evaluation will permit DAIDS to assess the understandability of these P&Ps and provide information about the need for revisions as appropriate. More importantly, knowledge gained from the evaluation will assist DAIDS in assessing the applicability of these policies across a wide range of human subjects research, including epidemiological research and clinical trials research. Moreover, these P&Ps should be applicable to research conducted within different program areas of DAIDSsponsored or -funded research; this information will be collected as part of the evaluation study.

DAIDS Program Officers and other staff having clinical site oversight responsibility should benefit from the implementation of the P&Ps as a way to ensure the consistent application of policies in multiple settings. Thus, POs should perceive that P&Ps facilitate their oversight responsibility through the application of a policy across program areas and networks; the "no need to reinvent the wheel" analogy applies here. Both quantitative and qualitative information collected as part of the evaluation will provide evidence for this benefit and should reduce the strain on DAIDS staff as a result of the uniform application of clinical and regulatory requirements (*see* The Sullivan Report).

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APPENDIX A: DAIDS P&P Logic Model

Overall goal: The goal of the DAIDS P&P Program is to increase efficiency and collaborations both within NIAID/DAIDS administrative structure and among extramural researchers funded by DAIDS. Standardized P&Ps will provide the infrastructure for harmonization of practices for planning and implementing clinical research across sites within network and across networks.

CONTEXT	IMPLEMENTATION		OUTCOMES		
Resources/Inputs	**Activities**	**Outputs**	**Short-Term**	**Intermediate-Term**	**Long-Term***
NIAID • DAIDS staff • OPCRO staff • SPEB staff • PPD staff NIAID funding Sullivan report	Dissemination of P&Ps • Design and implement dissemination plan to inform and prepare POs of P&Ps • Design and implement dissemination plan to inform and prepare extramural researchers of P&Ps Training of P&Ps • Design and implement training plan of P&Ps in which POs will participate • Design and implement training plan for extramural researchers • Develop remote-access version of training • Develop refresher trainings	Dissemination of P&Ps • Number of dissemination activities by type (e.g., staff meetings, NIAID Web and email announcements) to inform POs and extramural researchers • Number of POs and extramural researchers reached by type of dissemination activity Training of POs and Extramural Researchers • Number of live trainings conducted on the P&Ps • Number of POs and extramural researchers attending the live trainings • Number of POs and extramural researchers who used the remote-access trainings • Number of POs and extramural researchers who used the refresher trainings	Efficient Project Oversight by POs *Awareness/Accessibility* • POs are aware of the P&Ps and their effective date • P&Ps posted in the NIAID website are easy to access *Understanding* • POs understand P&Ps relative to their roles and responsibilities • POs understand which policies apply to network vs. non-network clinical trials • POs understand which policies apply to all human subjects research vs. clinical trials *Applicability* • P&Ps are applicable to Pos' clinical research oversight • P&Ps facilitate Pos' oversight activities • POs provide consistent responses to extramural researchers' questions *Harmonization* • P&Ps are applicable to network and non-network clinical trials research • P&Ps apply to most human subjects research	Facilitates Clinical Research *Awareness/Accessibility* • Researchers are aware of the P&Ps and their effective date • P&Ps posted in the NIAID website are easy to access *Understanding* • Researchers understand the P&Ps • Researchers perceive P&Ps as applicable to their clinical research • Researchers know which policies apply to network vs. non-network research • Researchers know which policies apply to all human subjects research vs. clinical trials. *Applicability* • Researchers perceive P&Ps are applicable to clinical trials and other human subjects research • Researchers believe they receive accurate guidance from POs • Researchers perceive they receive consistent guidance from POs *Harmonization* • P&Ps are applicable to researchers' clinical trial studies across program areas and across networks	• Decrease in number of regulatory violations when conducting clinical research • Decrease in number of protocol violations • Increased collaborations: between network and non-network researchers; across program areas • Increase in research efficiency and quality such as data quality • New clinical research sites set up more rapidly

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Growth of clinical trials (domestic vs international	NIAID – DAIDS – OPCRO
Type of clinical trial research	Support of P&Ps from awardees' institutions
Location of clinical research studies (domestic vs international)	

* Long-Term Outcomes are placeholders and have not been fully developed.

APPENDIX B: DAIDS P&P Evaluation Matrix

Overall goal: The goal of the DAIDS P&P Program is to increase efficiency and collaborations both within NIAID/DAIDS administrative structure and among extramural researchers funded by DAIDS. Standardized P&Ps will provide the infrastructure for harmonization of practices for planning and implementing clinical research across sites within networks and across networks.

Evaluation Questions Addressed	Information Required	Information Source(s)	Data Collection Methods	Data Analysis Methods	Limitations	What the Analysis Will Allow to Say
P&P Awareness and Accessibility						
Are target audiences aware of availability of and how to access the P&Ps?	# and type of P&P availability dissemination activities (including to whom disseminated) % of known target audience aware of P&Ps # of target audience who access P&P website # of target audience who believe P&P website is easy to access	DAIDS P&P Team OPCRO Alerts Target audience Website data	Tracking sheet on dissemination activities from DAIDS P&P Team Periodic (e.g., annual) cross-sectional surveys User Profile data P&P Web site use log Focus groups	Descriptive analysis	Total N for extramural research target audience is unknown (except for POs)	Impact of dissemination activities Appropriateness of plan (e.g., type of activities, messages, intensity) to affect awareness/ access to P&Ps
What is the rate of participation in P&P trainings?	# of POs who attend/access training, by training type # of extramural researchers who attend or access training, by training type	DAIDS P&Ps Team PPD data P&Ps Web site data	P&Ps training sign-in logs P&Ps Web-based trainings logs	Descriptive analysis		Participation in the P&Ps trainings among targeted audiences

Evaluation Questions	Information Required	Information	Data Collection	Data Analysis	Limitations	What the Analysis
Understanding of P&Ps						
Do POs understand the P&Ps relative to their roles and responsibilities?	Understanding of roles and responsibilities Understanding of P&Ps	Target audience	Post-training and/or periodic surveys Focus groups	Quantitative and qualitative descriptive analysis	Self-reported data Survey completion and focus group attendance are optional	P&Ps help clarify roles and responsibilities of POs
Do POs and researchers understand which policies apply to network vs. non-network and clinical trials vs. all human subjects research?	Knowledge or check list of which policies apply to which types of research Questions addressed to OPCRO and/or POs	Target audiences	Post-training and/or periodic surveys	Quantitative and qualitative descriptive analysis	Optional measures	POs and Researchers possess fundamental knowledge in order to apply P&Ps appropriately

Evaluation Questions Addressed	Information Required	Information Source(s)	Data Collection Methods	Data Analysis Methods	Limitations	What the Analysis Will Allow to Say
Applicability of P&Ps						
Are P&Ps applicable to Pos' oversight responsibilities?	Pos' perceptions of P&Ps relevance to their job functions	POs	Post-training and/or periodic surveys Focus groups	Quantitative and qualitative descriptive analysis	Self-reported data	POs believe the P&Ps are applicable to their oversight responsibilities
Do P&Ps facilitate Pos' oversight activities?	Pos' perceptions of how P&Ps make their jobs easier compared to pre-P&Ps	POs	Post-training and/or periodic surveys Focus groups	Quantitative and qualitative descriptive analysis	Self-reported data	POs believe the P&Ps help simplify their oversight responsibilities
Do POs provide accurate and consistent responses to extramural researchers' questions?	Researchers' perceptions of Pos' responses to their queries Pos' Responses to real-life case scenarios	Researchers POs	Periodic surveys Focus groups Case scenarios	Quantitative and qualitative descriptive analysis	Self-reported data	Researchers believe the POs provide them with accurate and consistent information. POs are able to apply the P&Ps accurately and consistently
Do Researchers believe the P&Ps are applicable to their research and do they implement the P&Ps correctly?	Researchers' perception of the applicability of the P&Ps Researchers' ability to implement the P&Ps	Researchers Regulatory documents POs	Periodic surveys Case scenarios Pos' checklists of researchers' regulatory documents	Quantitative descriptive analysis	Self-reported data	Researchers are able to apply the P&Ps to their research

Evaluation Questions	Information Required	Information	Data Collection	Data Analysis	Limitations	What the Analysis
Harmonization						
Are P&Ps applicable to network/non-network research? All human subjects research?	POs' perceptions of wide-scale applicability of P&Ps. Researchers' perceptions of wide-scale applicability of P&Ps.	POs Researchers	Periodic surveys Focus groups	Quantitative descriptive analysis Qualitative analysis	Self-reported data	POs are able to apply the P&Ps across a wide range of research Researchers are able to apply the P&Ps across a wide range of research
Do P&Ps result in a decrease in the number of regulatory and protocol violations?	Number of regulatory and/or protocol violations, by protocol	POs	Site/protocol monitoring tool	Quantitative analysis—repeated measures	Confounding events	P&Ps decrease the likelihood that regulatory and/or protocol violations will occur
Do P&Ps facilitate collaborations across program areas? Between network and non-network sites?	Perceptions of DAIDS-funded/sponsored researchers Perceptions of POs	Researchers POs	Focus groups • Researchers • POs Program records	Quantitative/ qualitative descriptive analysis	Data quality and reliability Self-reported data Confounding events	P&Ps increase Researchers' perceptions that collaborations are simpler; number of collaborations increases over time after implementation of P&Ps

APPENDIX C: Proposed Evaluation Timeline

The following is the timeline for the evaluation work plan –that specifies key evaluation activities and the timeframe to complete them.

YEAR 1

***Focus of evaluation*:** Program Officers and Other Staff with Site Monitoring responsibilities

- Form and convene Evaluation Advisory Committee (EAC)
    - Review measures developed during Feasibility or Pilot Study
    - Review survey data obtained during Feasibility or Pilot Study
    - Review focus group data obtained during Feasibility/Pilot Study
- Update Program Logic Model
- Finalize evaluation study questions
- Update evaluation planning matrix
- Finalize measures on P&P implementation and impact
- Conduct regular meetings with DAIDS P&P Team
- Administer surveys to POs or Clinical site oversight staff
- Conduct focus groups with POs or Clinical site oversight staff
- Conduct annual meeting with EAC
- Prepare Annual Report on P&P implementation and impact

YEAR 2

***Focus of evaluation*:** Program Officers or Clinical site oversight staff, Domestic Extramural Researchers

- Analyze and report to DAIDS P&P Team and EAC on results of surveys and focus group
- Conduct regular meetings with DAIDS P&P Team
- Administer surveys to POs or Clinical site oversight staff and Domestic Extramural Researchers
- Conduct focus groups and/or in-depth interviews with POs or Clinical site oversight staff and Domestic Extramural Researchers
- Conduct annual meeting with EAC
- Prepare Annual Report on P&P implementation and impact

YEAR 3

Focus of evaluation: Program Officers or Clinical site oversight staff, Domestic Extramural Researchers

- Analyze and report to DAIDS P&P Team and EAC on results of surveys and focus groups
- Conduct regular meetings with DAIDS P&P Team
- Administer surveys to PO or Clinical site oversight staff, Domestic extramural researchers
- Conduct focus groups with POs or Clinical site oversight staff
- Conduct in-depth interviews with domestic extramural researchers (teleconference)
- Conduct annual meeting with EAC
- Prepare Annual Report on P&P implementation and impact

YEAR 4

Focus of evaluation: Program Officers or Clinical site oversight staff, Domestic Extramural Researchers, International Extramural Researchers

- Analyze and report to DAIDS P&P Team and EAC on results of surveys and focus groups; trend data from Pos or Clinical site oversight staff
- Conduct regular meetings with DAIDS P&P Team
- Administer surveys to Pos or Clinical site oversight staff, Domestic extramural researchers, International extramural researchers
- Conduct focus groups with POs or Clinical site oversight staff
- Conduct in-depth interviews with Domestic and International extramural researchers (teleconference)
- Conduct annual meeting with EAC
- Prepare Annual Report on P&P implementation and impact

YEAR 5

Focus of evaluation: Program Officers or Clinical site oversight staff, Domestic Extramural Researchers, International Extramural Researchers

- Analyze and report to DAIDS P&P Team and EAC on results of surveys and focus groups; trend data from POs or Clinical site oversight staff; quantitative data on regulatory/protocol violations and numbers of collaborations
- Conduct regular meetings with DAIDS P&P Team
- Administer surveys to POs or Clinical site oversight staff, Domestic extramural researchers, International extramural researchers
- Conduct focus groups with Pos or Clinical site oversight staff
- Conduct in-depth interviews with Domestic and International extramural researchers (teleconference)
- Conduct annual meeting with EAC
- Prepare Final Report on P&P implementation and impact

APPENDIX D

Table 1
DAIDS Clinical Research Policies and Standard Procedures:
Evaluation of Implementation and Impact
(Total Survey Respondents, n=47)

***Awareness/Availability/Accessibility*:**

Question	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
I was given sufficient advance notice by DAIDS that new clinical policies and procedures were forthcoming.	62%	38%	0%	0%	0%
General information regarding the rationale behind the standardized policies and procedures was well communicated by DAIDS.	43%	43%	9%	6%	0%
DAIDS provided sufficient information on how to access the new policies and procedures.	49%	40%	6%	4%	0%
It was easy to get to the Web site containing the new policies.	38%	40%	17%	2%	2%
The Web site screen layout describing the new policies facilitated understanding of the policies (e.g., font size, amount of information displayed on screen, arrangement of information).	32%	38%	28%	0%	2%
I know whom to ask if I have a question about the new policies.	43%	38%	13%	2%	4%

Table 1 (cont'd)

DAIDS Clinical Research Policies and Standard Procedures:
Evaluation of Implementation and Impact
(n=47)

***Understandability*:**

Question	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
In general, the new policies and procedures are clearly written.	30%	51%	17%	2%	0%
There is little or no ambiguity as to the meaning of each of the policies.	19%	49%	26%	6%	0%
I feel comfortable responding to questions from other POs regarding the new policies.	21%	36%	40%	2%	0%
The new policies will foster communication among DAIDS staff, including regulatory staff.	26%	34%	34%	2%	4%
I am confident that I will be able to provide sufficient guidance to the sites regarding how to implement the newly developed policies.	23%	38%	32%	4%	2%

Table 1 (cont'd)
DAIDS Clinical Research Policies and Standard Procedures:
Evaluation of Implementation and Impact
(n=47)

***Applicability*:**

Question	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
The new policies will facilitate my site oversight responsibilities.	21%	23%	53%	0%	2%
It is clear which policies apply to which kinds of research (e.g., epidemiology versus clinical trials).	23%	40%	19%	15%	2%
I am able to easily determine whether a policy applies to in-network versus out-of-network sites.	17%	36%	28%	17%	2%
It will be difficult to apply the policies to international sites, particularly in resource-poor countries.*	6%	23%	32%	32%	6%
The standardized policies will facilitate development of SOPs.	30%	45%	19%	4%	2%
I feel like I will be better able to provide guidance to the sites.	21%	43%	32%	0%	4%

*Needs to be "reverse-coded".

Table 1 (cont'd)
DAIDS Clinical Research Policies and Standard Procedures:
Evaluation of Implementation and Impact
(n=47)

***Harmonization*:**

Question	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
I will be able to respond to sites' questions in a timelier manner.	19%	34%	43%	0%	4%
I feel more confident in my ability to advise new sites in development of a Manual of Operational Procedures (MOP).	13%	26%	55%	2%	4%
I am prepared to respond to sites' questions whether they pertain to a vaccine trial or a prevention trial.	17%	26%	51%	2%	4%
I am more likely to encourage cross-site collaborations.	19%	23%	49%	2%	6%
Cross-program collaborations will be facilitated with the standardized policies.	26%	43%	28%	2%	2%
My clinical site oversight responsibilities will be easier because all sites will be following uniform policies and procedures.	21%	28%	47%	0%	4%
Sites hosting multiple trials funded through different programs within DAIDS will find it easier to develop SOPs.	28%	36%	28%	6%	2%

Table 2
Comparison of Responses of POs (n=11) and Non-POs (n=36) to Post-Training Evaluation Survey

	Strongly Agree Agree		***Uncertain***		***Strongly Disagree Disagree***	
Aware/Available/Accessible:	**POs**	**Non-POs**	**POs**	**Non-POs**	**POs**	**Non-POs**
Sufficient Notice	100%	100%	0%	0%	0%	0%
Rationale	82%	86%	9%	8%	9%	6%
*How to access	100%	86%	0%	8%	0%	6%
Easy access via Web	81%	78%	9%	19%	9%	3%
*Good Web layout	81%	67%	18%	31%	0%	3%
Know whom to ask	81%	80%	9%	14%	9%	6%
Understandability:						
*Clearly written	90%	78%	0%	22%	9%	0%
Meaning is clear	73%	66%	18%	28%	9%	6%
*Comfortable fielding Qs from POs	45%	61%	55%	36%	0%	6%
Foster communication	54%	61%	36%	33%	9%	6%
Guidance to site re: implementation	63%	61%	18%	36%	18%	3%
Applicability:						
*Facilitate oversight responsibilities	54%	41%	45%	56%	0%	3%
*Application to types of research	54%	66%	18%	19%	27%	14%
Apply to in- vs. out-of-network	54%	53%	18%	31%	27%	17%
*Difficult to apply to Int'l sites	45%	15%	18%	36%	36%	39%
Facilitate development of SOPs	72%	75%	27%	17%	0%	9%
Able to guide sites	63%	64%	27%	33%	9%	3%
Harmonization:						
Respond to sites timelier	54%	53%	36%	44%	9%	3%
*Confident to advise sites on MOPs	27%	41%	55%	56%	18%	3%
Respond to site Qs for all types of trials	45%	42%	45%	53%	9%	6%
*Encourage cross-site collaborations	54%	41%	27%	53%	18%	6%
*Facilitate cross-program collaborations	81%	63%	18%	31%	0%	6%
Oversight responsibilities easier	45%	50%	45%	47%	9%	3%
*Easier to develop SOPs at multi-trial sites	45%	70%	36%	25%	18%	6%

Table 3
Summary of Focus Group
May 9, 2007

Implementation/Impact of Standardized Policies and Procedures

Attendees: n = 4.
Request made not to tape-record the session

Awareness/Availability/Accessibility

- Everyone was well aware of the new policies – numerous emails/reminders
- Not easy to get to (access) the policies
    - Provide some obvious link from NIAID homepage
    - Concerned that extramural researchers may have difficulty locating the policies
    - One person reported confusing NIAID policies with DAIDS policies
- General Web presentation
    - "Sufficient"
    - List the policies in some logical order, e.g., alphabetical
- Effective Date
    - Indicated sites are upset about the "effective date"; they take this to mean that new policies and procedures need to be implemented as of February 5th
    - Recommend that DAIDS/OPCRO management send out a clarifying memo as to when sites must be in compliance with the new P&Ps
        - Make it VERY clear

Training

- General agreement that training was "excellent"
    - Liked the face-to-face
    - Liked hearing others' questions
    - Good pace of presentation (but probably too fast for someone not already somewhat familiar with policies)
    - Allowed for discussion
    - Reinforced points already known
    - Clarified points of uncertainty
- Minor negatives
    - Did not provide information on implementation, but they felt they did not need that
    - The teleconference link-in was distracting
- Recommend:
    - Similar format for presentation of other policies using logical groupings of policies
    - Provide Web-based refresher trainings
    - Provide Web-based introductory, i.e., overview training of policies for new POs and site personnel (felt that the training as conducted would be too overwhelming for a new PO)

Communication among DAIDS staff as it relates to the new P&Ps

- POs would prefer that sites send questions directly to them, as opposed to OPCRO
    - Feel out of the loop regarding sites' questions
    - Minimally, would like OPCRO to cc the PO when providing an e-mail response to a site's question
- The standardized P&Ps will not improve working relationships with RAB staff
    - Will likely decrease the number of interactions, which is a good thing

Table 3 (cont'd)

    - Will not need to go to RAB – and commented that RAB gave inconsistent responses to questions
- Some confusion as to whom to go to if a PO has a question – Judy Brooks/Jane Reynolds/RAB?

Empowerment/Barriers

- These POs feel empowered to implement the policies now
- Are already advising sites regarding the new P&Ps
- Easier to enforce compliance but would like consequences for sites if they fail to comply with the new policies – give some "teeth" to their monitoring/oversight responsibilities
- Believe that the new P&Ps will make their jobs easier by making it more efficient as a result of a standard set of policies
- Did not perceive any barriers to implementing the policies

APPENDIX E: Summary of Recommendations for a Comprehensive Evaluation of the DAIDS P&P Implementation

Step 1- Engage Stakeholders

- Involve appropriate stakeholders in the evaluation. Key stakeholders include DAIDS leadership and staff within OPCRO, and SPEB, members of Evaluation Advisory Committee, DAIDS POs, and DAIDS funded- or -sponsored researchers.

Step 2- Describe the Program

- Review the program logic model annually to accurately reflect program changes.

Step 3 – Focus the Evaluation

Evaluation Advisory Committee:

- At a minimum, Committee should have members with experience in evaluation (i.e., evaluation of clinical policies and procedures, or general regulatory requirements related to clinical research, SMEs on clinical policies and procedures).

Evaluation questions:

- Select main evaluation questions on process and outcomes of interest.

Benchmarks and performance indicators:

- Establish realistic benchmarks for process and outcome indicators.

Timeline:

- Allow enough time to assess implementation and impact of standardized P&Ps. A 5-year plan is an appropriate time period to conduct a comprehensive evaluation.
- Plan for incremental steps in the evaluation (e.g., initial focus is on DAIDS POs and other staff having clinical site oversight responsibility,; then include domestic extramural researchers in years 2-5, and international extramural researchers in years 3-5; and collect longitudinal data over a reasonable period to examine long-term goals).

Methods:

- Use a mixed-method evaluation design of qualitative and quantitative techniques to obtain a complete picture of P&P effects.
- Collect data over successive years to examine change and orderliness of data.
- Minimize respondents' burden and ensure confidentiality or anonymity of sensitive personal information.

Step 4 – Gather Credible Evidence

Data Sources:

- Data collection instruments should be identified/developed with the input of the Evaluation Advisory Committee and relevant DAIDS staff (SPEB, OPCRO)

The following data elements and data gathering procedures are part of the P&P evaluation database::

- Descriptive metrics on trainees (e.g., job function; years in job)
- Item level survey responses, linked to descriptive metrics, from POs or Site oversight staff and Researchers
- P&P related questions (from the field) to OPCRO staff or POs
- Focus groups with POs and Site oversight staff.
- Interviews with Site PIs and Site Study Coordinators.

Answering Evaluation Questions on Program goals, performance and comparison measures

Goal 1: Targeted audiences are aware of and access DAIDS P&Ps

- P&P dissemination plan should be very specific, describing number of expected activities, to whom, by whom, and by when, and identifying benchmarks for activities (e.g., minimum number of activities by type planned).
- Number and/or percent of target audience who have accessed the DAIDS P&P Web site.

Goal 2: DAIDS P&Ps are easy to understand

- Responses to survey items regarding understandability of P&Ps.
- Focus groups/interviews about clarity of P&Ps.
- Log of questions from Researchers and answers from POs to those questions.
- Interviews with Research Staff on accuracy and consistency of POs' responses to their inquiries.

Goal 3: DAIDS P&Ps are applicable to clinical research

- Targeted audiences perceive that P&Ps are applicable to their clinical research (either as oversight responsibility or conduct).
- Develop case scenarios based on questions posed by Researchers and evaluate target audience responses to those case scenarios.
- Serial surveys of target audiences regarding applicability to job function (POs) and kinds of research conducted (Researchers).
- Serial focus groups/in-depth interviews regarding P&Ps impact on job function (POs) and research activities (Researchers).

Goal 4: DAIDS P&Ps facilitate harmonization of policies in conduct of clinical trial research

- Target audiences perceive P&Ps are applicable to different types of clinical research across (or out of) networks, and across program areas.
- Summary of previous years' surveys for changes over time.
- Focus groups or in-depth interviews with POs or Researchers.

Goal 5: Increased efficiency in the conduct of clinical research

- POs perceive greater facility over time in oversight responsibilities.
- PIs/Study Coordinators believe that development of regulatory documents is simplified.

Goal 6: Decrease in number of protocol and regulatory violations

Goal 7: Increased collaborations among Researchers

Goal 8: Trainees have favorable reactions to the training

- Surveys of trainees' ratings of training sessions/modules

APPENDIX F: DAIDS P&P Review of Literature Summary

Purpose

To assess published literature on implementation of standardized clinical research policies and procedures. The search included evaluating literature on implementation of P&Ps and the evaluation of the implementation process and outcomes.

Key Search Terms

In addition to key search terms, below, the search strategy included consideration of:

1. Possible appropriate ending of words based on a word root (see note on symbol "*")
2. Possible alternative words (included in the table below)

Key search terms:

- Evaluation + standard* policies + clinical research
- Evaluation + standard* procedures + clinical research
- Evaluation + policies + clinical research
- Implement* + standard* policies + clinical research
- Implement* + standard* + procedures clinical research
- Implement* + policies + clinical research
- Standardizing + policies + clinical research

* Symbol denotes when endings of the same word root are possible and that need to be searched (e.g., "standard" = standard, standardized).

Alternative words used in combinations with the key search terms during the literature search:

Replace this search term	***With this search term(s)***
Evaluation	Assessment
Implementation	Dissemination Carrying out Effecting
Standardized	Uniform
Policies Procedures	Regulations Guidelines Rules
Clinical	Medical Scientific
Research	Studies Investigations

Sources for Literature Review

- Pub Med
- Google search
- Department of Health and Human Services (DHHS) website
- National Academy of Science – including the Institute of Medicine (IOM)
- The National Science Foundation

DAIDS Clinical Policy and Procedure Evaluation:
Literature Review Findings

Citation	Purpose of Publication	Summary
American Society of Clinical Oncology. American Society of Clinical Oncology policy statement: Oversight of clinical research. J Clin Oncol. 2003 Jun15;21(12):2377-86. Epub 2003 Apr 29.	This is a report that provides recommendations in several areas which serve as principles to support improved system of oversight for clinical cancer research.	**Recommendations:** o Centralized IRB review – more cost-effective way to provide greater consistency across trial sites to enable review boards and investigators to implement more quickly and consistently protocol and informed consent amendments o Education and training – all participants in clinical research process should receive comprehensive education and training to ensure they are aware of elements and steps necessary to ensure safety of participants and integrity of research o Informed consent – nature of process needs to be changed to refocus on primary goal of educating potential participants about trial participation and fully informing them of risks and benefits, to allow them to make informed decision about enrolling; current process is overwhelming to patients because of complex, legalistic language of documents o Federal oversight – create uniformity of regulatory approaches by HHS Office for Human Research Protections and FDA to improve efficiency and consistency in human research protection system o Resources supporting clinical research infrastructure – institutions should dedicate sufficient support and resources to entire research oversight and clinical trials support system to ensure highest standards of ethical and scientific research conduct o Conflict of interest – adopt standards for identifying, managing, and eliminating conflict of interests (whether they are actual, potential, or

Citation	Purpose of	Summary
		apparent)
Barnes BE, Friedman CP, Rosenberg JL, Russell J, Beedle A, Levine AS. Creating an infrastructure for training in the responsible conduct of research: The University of Pittsburgh's experience. Acad Med. 2006 Feb;81(2):119-27.	This is a research study that assessed the University of Pittsburgh's experience in the design, implementation, and evaluation of a Web-based, institution-wide responsible conduct of research training program that uses a centralized, comprehensive approach.	• **Measures:** o Completion rate for each training module o Users' performance on module tests o Number of module certifications issued o User questionnaire responses assessing perceptions of quality, educational effectiveness, and appropriateness of content • **Results:** o During first 3 years of operation, program served 17,128 users and issued 38,234 training certificates o 90% of users found modules clearly written all or most of time o 70% found material interesting all or most of time o Less than 10% found navigation of Web site difficult o Over 80% felt test questions were clear all or most of time o 80% found amount of material in modules to be "about right" • **Conclusions:** o Training program has been affordable, scalable, and sustainable o Provides efficient mechanism for deploying content to large, diverse cohort of learners o Supports needs of research administrators by providing access to information about who has successfully completed training
Califf RM, Morse MA, Wittes J, Goodman SN, Nelson DK, DeMets DL, Iafrate RP, Sugarman J. Toward protecting the safety of participants in clinical trials. Control Clin Trials. 2003 Jun;24(3):256-71.	This is a report that identifies limitations of each oversight group's ability to ensure the safety of participants in clinical trials at major institutions and offers recommendations for improving the current system.	**Limitations identified, with recommended solutions indicated in parentheses:** o Research ethics review boards – unable to perform safety monitoring by review of individual adverse events (make certain monitoring plan exists, require human research participant protection program to provide safety monitoring for activities at local sites, data monitoring program for all multisite studies with letter sent to IRB with recommendations, data monitoring plan for all single-site studies); often burdened by duplicative reviews of large multicenter studies (use central review board) o Data monitoring committees – have no standards to ensure they can reliably identify safety issues (create national standards for DMC composition

Citation	Purpose of	Summary
		and function) o Sponsors – may be overreliant on data audits (focus on auditing adverse events); slow to disseminate safety data in coherent summary (require database of safety data) o Investigators/staff – may not fully appreciate nuances of GCP (basic educational requirement or other evidence of competence, funding mechanisms for additional training); may be inattentive to daily conduct of studies (conduct protocols in way that requires active investigator involvement) o Clinical site – lacks awareness of details of clinical trial (patient education: investigator to be notified of any drug changes or adverse events, site-specific standard procedures that can be referenced) o Regulators – have failed to completely harmonize their policies with each other or with international regulatory agencies (harmonize with international standards) o System as whole – lacks data about efficacy of interventions to ensure safety (apply academic rigor to study efficacy of various components of system)
Clinical Trials Working Group of the National Cancer Advisory Board. "Restructuring the National Cancer Clinical Trials Enterprise." June 2005.	This is a report from the Clinical Trials Working Group that details 22 initiatives (organized into 5 categories) resulting from a consensus-building process among its members to design a restructured national clinical trials enterprise that is more efficient, coordinated, and founded on the best science.	• **Proposed initiatives, organized by category:** o Coordination – directed at enhanced information sharing, incentives for collaborative team science, and coordination of regulatory processes o Prioritization/Scientific Quality – establish new processes for design and prioritization of clinical trials and for facilitating conduct of correlative science and other ancillary studies o Standardization – promote development of standardized tools and procedures to minimize duplication and reduce effort required to initiate and conduct clinical trials o Operational Efficiency – focus on improving patient accrual rates and reducing operational barriers to speed initiation and conduct of clinical trials o Enterprise-Wide – address restructuring management and oversight of NCI's clinical trials program from within NCI and in partnership with extramural community
Lind RA. Evaluating research misconduct	This is a research study that evaluated the accessibility and	• **Measures:** o Accessibility – number of clicks to get from university's home page to RM policies

Citation	Purpose of	Summary
policies at major research universities: A pilot study. Account Res. 2005 Jul-Sep;12(3):241-62. [**NOTE:** Unable to obtain copy of article – summary based only on abstract]	usefulness of research misconduct (RM) policies at top-25 universities, as ranked by NIH and NSF grant awards.	o Usefulness – policy information coded into categories comprising total of 20 topic areas and subsequently grouped into 5 content domains • **Results:** o On average, took 5 clicks to get from home page to RM policies o Only 9 policies accessed within 3 or fewer clicks o Policies revealed broad range of usefulness – some provided relevant details on almost every topic area, while others left most questions unanswered o 3 of 20 topic areas almost universally covered in policies analyzed o 5 topic areas averaged less than half of information that could have been included • **Conclusions:** o Message sent by policy that lacks clarity and precision should be revised to include appropriate level of detail
Morse MA, Califf RM, Sugarman J. Monitoring and ensuring safety during clinical research. JAMA. 2001 Mar 7;285(9):1201-5.	This is a report based on information discussed during a meeting among a group of professionals with expertise in various aspects of clinical trials that offers recommendations on adverse event (AE) reporting to enhance the safety of human subjects participating in large-scale multicenter trials.	• **Recommendations:** o Regulatory agencies – define nomenclature for AEs with more precision and harmonize requirements for reporting o IRBs – examine and improve plan for study-wide monitoring; certify that investigators understand regulations governing continued safety of patient-subjects on trial; review aggregate AE reports and DMC communications as part of thorough, continuing review of research; seek input from study sponsors in making assessments of safety in trials o Data monitoring committees – provide monitoring plan to IRB, provide summaries of study safety to IRB at agreed-on intervals o Sponsors – provide aggregate data regarding safety of experimental intervention to IRB when requested, report serious and unexpected AEs to IRB with detailed interpretation of likeliness of association with intervention o Investigators – supply interpretation of AEs within context of known data about intervention
Sather MR, Raisch DW, Haakenson CM, Buckelew JM, Feussner JR.	This is a research study that evaluated changes in good clinical practice	• **Measures** (each site review conducted by 1 trained reviewer; data compared between 2-year implementation period and continuing follow-up period):

Citation	Purpose of	Summary
Promoting good clinical practices in the conduct of clinical trials: experiences in the Department of Veterans Affairs Cooperative Studies Program. Control Clin Trials. 2003 Oct;24(5):570-84.	(GCP) adherence by the VA's Cooperative Studies Program, as measured by results of formal site visit reviews conducted over a 3-year period by a GCP Review Group.	○ Assessment tool – 62 ICH-derived GCP key elements related to 8 GCP focus areas (e.g., patient consent issues, safety monitoring, IRB); each question has 3 possible responses: pass, fail, or not applicable ○ Overall summary scale – compilation of assessment of 14 GCP-selected items identified as critical (e.g., consent obtained prior to study procedures, annual IRB review obtained without lapse) ○ Overall GCP performance – reviewers provided summary evaluation of overall GCP performance of each site; divided into 3 categories: high, average to good, below average • **Results:** ○ 335 site reviews conducted from FY 1999 through FY 2001 ○ High GCP adherence exhibited by 11.3% of sites in FY 1999/2000 versus 20.6% in FY 2001 ○ Average to good adherence exhibited by 84.3% versus 77.0% in these 2 periods ○ Below average adherence exhibited by 4.4% versus 1.5% in these 2 periods ○ Adherence to GCP improved significantly in 5 of 8 focus areas for assessment – areas that did not improve already at high levels of compliance in initial phase of implementation ○ Significant improvement in median scores for combined scores of all 62 GCP assessments and combined scores for 14 selected critical items • **Conclusions:** ○ Site-oriented activities developed by Site Monitoring and Review Team combined with centralized quality assurance activities of coordinating centers represent integrated, versatile program to promote and assure GCP adherence and data integrity in Cooperative Studies Program trials
Stair TO, Reed CR, Radeos MS, Koski G, Camargo CA, on behalf of the MARC Investigators. Variation in institutional review	This is a research study that assessed IRB responses to one standard protocol among U.S. investigators involved in MARC-4, a multicenter,	• **Measures:** ○ Survey mailed to investigators at sites with IRB review of the MARC-4 protocol that asked questions about the approval process, dates of submissions and replies, queries from the IRB, and revisions requested • **Results:** ○ Site investigators (n = 44) submitted standard

Citation	Purpose of Publication	Summary
board responses to a standard protocol for a multicenter clinical trial. Acad Emerg Med. 2001 Jun;8(6):636-41.	randomized, double-blind, placebo-controlled trial of outpatient therapy for acute asthma.	protocol to local IRBs median of 58 days after receiving it o Median time from submission to final IRB approval was 38 days o Overall, median of 102 days elapsed from date of protocol delivery to IRB approval o 59% of applications returned once for revision, 16% returned twice, 5% returned three times, 2% returned four times o 9% of applications approved without any modification; 9% approved with only minor consent form changes requested o IRBs requested average of 3.5 changes o Changes involved study logistics and supervision for 45%, research process for 43%, and consent form for 91% • **Conclusions:** o Variability across IRBs in initial response to single clinical trial protocol represents important burden to investigator-initiated multicenter trials, particularly those with limited budgets o National, multicenter IRB process might streamline ethical review