Attachment 3: Summary Tables for Data Collection and Analysis Plans Research Questions 1-9

Table 1. Data Collection and Analysis Plan for Research Question 1: How effectively does OPCRO make the target populations aware of policies?

Sub-Question	Performance Measures	Metrics	Data Sources	Analytic Techniques
1.1 What are the methods by which target populations know about policies?	Type of policy dissemination activity used	▪ Percentage of ERs who receive policies through OPCRO alerts, email communications, conference calls, HANC web site, NIAID web site, through other mechanisms including other web sites ▪ Identification of methods of accessing policies for ERs	▪ Survey ▪ Focus Groups	▪ Descriptive Analysis ▪ Thematic Analysis
1.2 Does DPIP disseminate policy information in a timely manner?	Time when policy is received	▪ Percentage of ERs who perceived to learn about policies in a timely fashion ▪ Time when ERs received policy	▪ Survey ▪ P&P Website Log	▪ Descriptive Analysis

Table 2. Data Collection and Analysis Plan for Research Question 2: Are policies readily accessible?

Sub-Question	Performance Measures	Metrics	Data Sources	Analytic Techniques
2.1 Are target populations satisfied with access to policies?	Access to policies	▪ Percentage of ERs who are satisfied with accessibility to policies ▪ Number of "clicks" on website required to access the policies ▪ Policies are consistently accessible to ERs	▪ Survey ▪ Website Database Output ▪ Focus Groups	▪ Descriptive Analysis ▪ Thematic Analysis
2.2 Are target populations satisfied with access to policies	Provision of sufficient information on accessing new policies and procedures	▪ Percentage of ERs who are satisfied with the provision of information on how to access policies and procedures	▪ Survey	▪ Descriptive Analysis

Table 3. Data Collection and Analysis Plan for Research Question 3: Are the policies written so that the content is clear?

Sub-Question	Performance Measures	Metrics	Data Sources	Analytic Techniques
3.1 Do target populations understand the policies?	Policies are easy to understand	▪ Percent of ERs who are satisfied that content of policies are easy to understand	▪ Survey	▪ Descriptive Analysis

Table 4. Data Collection and Analysis Plan for Research Question 4: Is there additional support to facilitate understanding of the new policies?

Sub-Question	Performance Measures	Metrics	Data Sources	Analytic Techniques
4.1 Do target populations find training useful to understand the policies?	Effectiveness of policy-training used	▪ Percentage of ERs who received training that found it effective ▪ Percentage of ERs trained in person, online, via teleconference or other mechanisms	▪ Survey	▪ Descriptive Analysis
4.2 Do target populations benefit from repeat training?	Renewed training helps support the understanding of new policies	▪ Percentage of ERs who have received renewed (updated, refresher) training ▪ Percentage of ERs satisfied with renewed (updated, refresher) training ▪	▪ Survey ▪	▪ Descriptive Analysis
4.3 Does DPIP provide adequate clarification on policy questions?	Effectiveness of resources available to facilitate the understanding of new policies	▪ Responses to questions received from OPCRO were perceived to be helpful ▪ Response to question addressed by OPCRO was perceived to be done in a timely fashion	▪ Survey	▪ Statistical analysis of number and funded value of multidisciplinary projects received by Institution

Table 5. Data Collection and Analysis Plan for Research Question 5: Does the target population understand which policies apply to the research projects in their portfolios?

Sub-Question	Performance Measures	Metrics	Data Sources	Analytic Techniques
5.1 Target populations utilize different methods to determine how policies apply to their studies	Training effectiveness on the applicability of policies	▪ Percent of ERs who indicated satisfaction on the training received of how to apply policies to research studies	▪ Survey	▪ Descriptive Analysis
5.2 Target populations utilize different methods to determine how policies apply to their studies and find DPIP activities and non-DPIP activities useful	Communication mechanism effectiveness on the applicability of policies	▪ Percent of ERs who indicated sources on how policies apply to their research studies from OPCRO Alerts, email communications, conference calls, HANC web site, NIAID web site, or other web sites ▪ Percent of ERs who are satisfied with their ability to apply the policies to their research studies based on policy information gained through either OPCRO Alerts, email communications, conference calls, HANC web site, NIAID web site, or other web sites	▪ Survey	▪ Descriptive Analysis
5.3 Target populations find DPIP activities and non-DPIP activities useful	Ability to apply policies to research projects in their portfolios.	▪ Percent of ERs who indicate the ability to apply policies to design or carry out clinical research activities ▪ Application of policies to design studies and conduct clinical research	▪ Survey ▪ Focus Groups	▪ Descriptive Analysis ▪ Thematic Analysis

Table 6. Data Collection and Analysis Plan for Research Question 6: Do policies effectively communicate staffs' roles and responsibilities in projects?

Sub-Question	Performance Measures	Metrics	Data Sources	Analytic Techniques
6.1 Target populations understand whose study roles are affected by the applied policies	Ability of policies to inform distinct research roles and responsibilities	▪ Percent of ERs who indicate that policies effectively inform clinical research responsibilities ▪ Identification on how policies communicate effectively about research staff roles and responsibilities	▪ Survey ▪ Focus Groups	▪ Descriptive Analysis ▪ Thematic Analysis

Table 7. Data Collection and Analysis Plan for Research Question 7: Do policies simplify the implementation of DAIDS funded/sponsored research for Extramural Researchers?

Sub-Question	Performance Measures	Metrics	Data Sources	Analytic Techniques
7.1 Target populations found that the policies provided a basis for carrying out clinical research	▪ Policies provide a framework to implement DAIDS funded/sponsored research	▪ Percent of ERs who are satisfied that policies create a framework to implement DAIDS funded/sponsored research ▪ Identification of how the framework can be used to implement DAIDS funded/sponsored research	▪ Survey ▪ Focus Groups	▪ Descriptive Analysis ▪ Thematic Analysis
7.2 Target populations can identify barriers and facilitators to policy implementation	Facilitators and barriers to the implementation of policies	▪ Thematic analysis of identified facilitators (aggregated and grouped by type) identified by ERs ▪ Thematic analysis of identified barriers (aggregated and grouped by type) identified by ERs	▪ Focus Groups	▪ Thematic Analysis

Table 8. Data Collection and Analysis Plan for Research Question 8: Do policies apply broadly within networks and non-networks?

Sub-Question	Performance Measures	Metrics	Data Sources	Analytic Techniques
8.1 Target populations can implement policies regardless of study location or type	Policies provide standards to consistently implement research	▪ Percent of ERs who are able to implement research consistently across sites. ▪ Percent of ERs who are able to implement research consistently across more than one research protocol ▪ Thematic analysis of key comments from ERs (aggregated and grouped by type) that policies provide guidance to consistently implement research	▪ Survey ▪ Focus Groups	▪ Descriptive Analysis ▪ Thematic Analysis

Table 9. Data Collection and Analysis Plan for Research Question 9: Do standardized policies facilitate greater integration among DAIDS funded clinical research programs?

Sub-Question	Performance Measures	Metrics	Data Sources	Analytic Techniques
9.1 Target populations found that policies helped facilitate collaboration between sites	Policies promote collaboration among sites (both in- and non-network, cross sites, sites hosting multiple trials, etc.)	▪ Percent of ERs satisfied with policies enhancing their ability to collaborate with other research sites ▪ Identification of collaboration opportunities with sites when policies were implemented ▪ Identification of SOPs being developed to enhance collaboration	▪ Survey ▪ Focus Groups	▪ Descriptive Analysis ▪ Thematic Analysis