

EXECUTIVE SUMMARY

Successfully meeting the NIH's goals in global health requires a continual re-assessment of NIH's current and future international activities and the ability to track the results of these investments. However, NIH currently lacks the ability to accurately and comprehensively identify its investment in research being conducted in foreign countries. Improving the ability of NIH to report on its international activities—collaborators, collaborating organizations, and funding—is one of the highest priorities of the NIH Global Health Research Working Group (GHRWG), who formed an International Activity Data (IAD) Subcommittee to increase both the extent and quality of information on NIH Institutes and Centers' (IC's) global health research.

As a first step, the IAD Subcommittee undertook a survey of current NIH enterprise and IC-maintained information resources, as well as the IC business processes used to gather and maintain these data. In addition, the Subcommittee considered the impact of two recent government-wide efforts in research reporting that have the potential to enhance NIH's ability to report on its foreign investments in the future: the Federal Funding Accountability and Transparency Act (FFATA), which requires recipients of most new NIH grants to report on first-tier subawards¹ they make to other organizations, including foreign entities;

and a uniform Research Performance Progress Report (RPPR)² required for use by federal agencies that support research activities.

Findings

Presently, several NIH systems are used to capture data on projects with foreign components. These include the John E. Fogarty International Center (FIC) Foreign component Tracking system (FTS) (1820 Form), several IC project coding and reporting systems, and the OER electronic Research Administration (eRA)³ IMPACII system. For one IC, relatively complete FY 2009 foreign investment information was obtained through a staff review of the grant portfolio using an internal IC system. Of the 332 projects identified by staff, only 46% were present in all three of the data sources.

The newly-implemented FFATA reporting requirement should provide some data on NIH investments in foreign countries. FFATA reporting is required on first-tier subawards exceeding \$25,000 in value for most new awards. In FY 2009, about 30% of the subawards reported in FTS were under this reporting threshold. While this is a significant percentage of the number of projects in FTS, funding for these subawards represents a small percentage (about 3%) of the total costs of all foreign subawards in the system.

¹ The OMB issued guidance identifying the requirement to report first-tier sub-awards on April 6, 2010 and that guidance may be found at the OMB Open Government site at <http://www.whitehouse.gov/omb/open>. That guidance defines a sub-award as generally referring to a monetary award made as a result of a Federal award to a grant recipient or contractor to a sub-recipient or sub-contractor respectively.

² <http://www.ffata.org/ffata/ffataact.html>

³ The electronic Research Administration (eRA) is the NIH infrastructure that provides for the secure receipt, review and administration of electronic grants.

Short-Term Recommendations

1. Standardize definitions: Entry into FTS and IC coding of grants for foreign involvement are not consistent across ICs. NIH should more explicitly define what constitutes foreign involvement and develop more explicit criteria for entry into the FTS.

2. Make better use of current FTS data: FTS data would be more accessible, more widely used, and quality better maintained if it were integrated with other grant information in IMPAC II and accessible to staff through eRA Query/View Reporting (QVR) and NIH Research Portfolio Online Reporting Tools: Expenditures and Results (NIH RePORTER) ⁴query tools.

3. Modify the Program and Grants Management checklists: Along with making existing FTS data more accessible to program and grants management staff, include a checkbox on the Program and Grants Management staff checklists (both competing and type 5s) to indicate whether there is a “contribution” being made by a foreign partner. Provide more information to staff through enterprise systems to help them more consistently identify such contributions in competing and noncompeting applications.

4. Enforce existing policies for FTS data capture on all grants, contracts (and intramural projects): Whether or not the extent of foreign involvement is considered significant enough to trigger Department of State clearance, the presence of any type of

contribution by a foreign organization should be captured in FTS (and ultimately, IMPAC II). Review/update of this information should be required when processing noncompeting awards.

5. Explore use of existing tools for capture of unstructured data: Significant amounts of information on international collaborations and global health research appear in unstructured portions of grant applications and progress reports. Providing automated tools to help staff search this information could provide an aid to current manual coding processes and reduce barriers to more complete data collection. In addition, NIH international grants and contracts should be centrally and continuously geo-coded to facilitate the use of Geographical Information Systems (GIS) representations of international research activities.

Long-Term Recommendations

6. Incorporate FTS or FTS-like capabilities into NIH enterprise systems: Ease-of-use and lack of integration with other OER eRA modules was cited by staff as an impediment to accurate and timely reporting of foreign investments. Tracking of foreign involvement should be incorporated into existing program and grants management workflows, and enhancements made to QVR and RePORTER to access and present this information.

7. Require use of optional RPPR data elements for reporting collaborations: Post-award, collect information on foreign involvement in the prior year using the

⁴ <http://projectreporter.nih.gov>

RPPR. The IAD Subcommittee should identify and recommend data elements to be included in the RPPR. If data elements recommended are not in RPPR format, NIH will need to provide justification for applicability and inclusion in the RPPR clearance request to OMB.

by NIH to pursue these recommendations should be accompanied by a commitment of these resources by NIH governance.

8. Enhance research personnel reporting:

Limitations in current competing and noncompeting grant applications affect NIH reporting capabilities. Both competing grant applications and noncompeting progress reports should require structured information on all collaborators (currently there is a limit on the number of collaborators required to be submitted) and their institutional affiliations.

9. Enhance tools: Based on the types of information contained in previous reports of NIH international activities, it appears that implementation of FFATA and any new RPPR reporting requirements are likely to leave a significant number of relevant activities unaccounted for. Enhanced or new tools that allow staff to systematically search their portfolios, identify relevant projects, and create reports may be needed to fulfill the need for reasonably comprehensive and accurate information on international collaborations and global health research.

Resources Required

Implementing some of these recommendations, particularly those related to enhancements in NIH enterprise systems, will require a significant amount of staff and financial resources. Any decision

SECTION 1: Background and Statement of the Problem

As the world's largest public sector health research agency, the National Institutes of Health (NIH) plays a major role in international research collaboration and capacity building. NIH programs with foreign components provide funding to support and facilitate global health research conducted by the United States (U.S.) and international investigators, build partnerships between health research institutions in the U.S. and abroad, and train the next generation of scientists to address global health needs. These goals comprise one of five major themes highlighted in the FY 2011 President's budget request for NIH.

In an article Dr. Collins wrote for the January 1, 2010 issue of *Science* (pp. 36-37), Dr. Collins articulated NIH's major goals in emphasizing global health research:

- To "go beyond the focus on the "big three" diseases to neglected tropical diseases of low-income countries that contribute to staggering levels of morbidity and mortality."
- Play "a major role in ramping up the discovery of novel targets in both pathogen and host and work to facilitate advances in prevention, diagnostics, and therapeutics.
- Help "build capacity and training opportunities in the developing world."

- "[R]espond to the growing challenge of chronic noncommunicable diseases and injuries."

Successfully meeting the NIH's goals in global health requires a continual re-assessment of NIH's current and future international activities and the ability to track the results of these investments. However, NIH currently lacks the ability to accurately and comprehensively identify its investment in research being conducted in foreign countries. NIH enterprise systems maintain information on only direct award recipients, not recipients of subawards made by domestic institutions to foreign components. While this deficiency in data collection is long-standing, awareness of it, and interest in its improvement, has been heightened by NIH's current emphasis on global health research. Improving the ability of NIH to report on its international activities is one of the highest priorities of the NIH Global Health Research Working Group (GHRWG), co-chaired by Dr. Roger Glass and Dr. Susan Shurin, who formed an International Activity Data (IAD) Subcommittee to increase both the extent and quality of information on Institute/Center's (IC's) global health research.



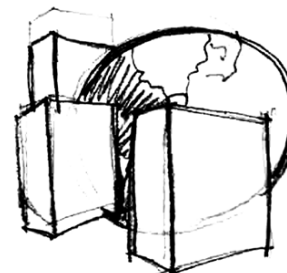
SECTION 2: Information Resources Survey



As a first step, the IAD Subcommittee undertook a survey of current NIH enterprise and IC-maintained information resources, as well as the IC business processes used to gather and maintain these data. A survey of IC representatives for international research and site visits to selected ICs were performed to gain a better understanding of:

1. The existing databases and systems containing information on each IC's research being conducted in foreign countries;
2. The procedures and practices that ensure accurate and comprehensive reporting on each IC's foreign investments, and how these data and or processes could be used by other IC's/NIH;
3. The issues and factors that are preventing each IC from collecting comprehensive data on investments in global health;
4. Existing reporting and analysis capacities and associated costs; and
5. Potential sources of information not currently being captured that might enhance an IC's ability to monitor and report on foreign investments.

SECTION 3: Other Relevant Efforts

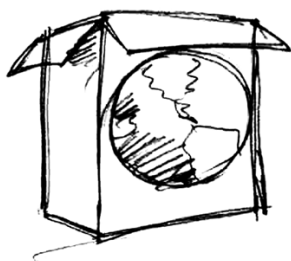


Two recent government-wide efforts in research reporting have the potential to enhance NIH's ability to report on its foreign investments in the future:

- The Federal Funding Accountability and Transparency Act (FFATA) requires recipients of NIH grants to report on first-tier subawards of \$25,000 or more they make to other organizations, including foreign entities. A federal government-wide system is being implemented by the Office of Management and Budget (OMB) to collect subaward information on most new grants awarded by the NIH on or after October 1, 2010. This remains a work-in-progress.
- In April 2010, the OMB and the Office of Science and Technology Policy issued a policy establishing a uniform Research Performance Progress Report (RPPR) for use by federal agencies that support research activities. The RPPR, which is to be used for reporting performance progress on grants and cooperative agreements, consists of both mandatory data elements that all agencies must collect and optional elements that agencies can decide to require.

Included among the optional elements is information on (foreign) collaborators participating in the research project. The NIH Office of Extramural Research (OER) is currently reviewing the optional elements and developing policies for NIH grant awards.

SECTION 4: Findings



Databases/Systems/Information Resources

Presently, several NIH systems are used to capture data on projects with foreign components. These include the John E. Fogarty International Center (FIC) Foreign component Tracking system (FTS) (1820 Form), several IC project coding and reporting systems, and the eRA IMPACII system.

FIC FTS: The FTS, managed by FIC, is used by all extramural NIH staff to obtain State Department clearance for awards involving a significant foreign component. There is anecdotal evidence that not all foreign components on awards represent the level of “significant involvement” that would trigger State Department clearance, and that standards vary across ICs.

In the FTS, project clearances are only required to be submitted for the first year involving global investment; subsequent years are requested to be voluntarily verified. Therefore, the FTS listing by fiscal year will display the project for the first year in which clearance is sought, but it may not display the subsequent years of the approved projects or the information about subsequent years may not be “actual” but the estimates submitted at the inception of the project. Thus, the FY listing for any given year does not include all funded projects involving global investment. The FTS is not integrated with IMPAC II, making it difficult to search and report using data elements not captured in FTS.

IC Coding and Reporting Systems: The systems reviewed included:

- National Center for Complementary and Alternative Medicine (NCAAM), Computer Analysis and Management Reporting Application (CAMERA)
- National Institute for Child Health and Human Development (NICHD), Child Health Information Retrieval Program (CHIRP)
- FIC, International Reporting and Scientific Tracking System (FIRST)
- National Institute of Allergy and Infectious Diseases (NIAID) Global Research Affairs Database System (GRADS) and their scientific coding system SCORS/MACS). The GRADS is designed to integrate NIAID award information and scientific coding

databases with additional division-level data.

- National Institute of Nursing Research (NINR), NOVA
- National Institute of Mental Health (NIMH), Program Analysis Research Information System (PARIS)
- National Institute of Dental and Craniofacial Research (NIDCR), Scientific Coding and Reporting System (SCORES) (also used by NEI)

These grant coding and reporting systems generally do the following:

- Allow staff to code projects for foreign involvement using standard codes and criteria defined by the IC
- Capture the extent of foreign involvement in a project, as a percentage of a project's cost
- The prorated amount of foreign involvement, based on these percentages
- Capture the names of the participating countries

The estimated funding to each country is generally derived by dividing the total prorated foreign amount by the number of countries funded within the project.

The following is an example of a coding procedure used by some ICs to prorate the grant costs. This is often based upon in-depth staff review of the budget, abstract, specific aims, methods, performance site, and human subjects sections of the grant application:

- An award to a scientist or organization outside the U. S.: Coded as 100% foreign, but could be further prorated if there are additional foreign subcontracts.
- An award to a domestic organization engaged primarily in international research: Proration is 100% or a percentage of the total grant when information about the international subcontract cost is not available.
- Project title includes the word "international," or the name of a foreign country or region: Proration is generally 100%.
- Project description indicates significant research will take place outside the US: Proration is based on actual foreign subcontract dollars, or ICs make their best estimate.
- Project description identifies significant international scientific exchange, particularly international consultants: IC estimates a prorated portion if the extent of foreign involvement exceeds some threshold (e.g. 20%).
- Project description identifies significant training of U.S. citizens outside of the country or foreign students in the U.S.: IC estimates a prorated portion if the extent of foreign involvement exceeds some threshold (e.g. 20%).

- International conference attendance, proration is always 100%

OER electronic Research Administration (eRA)/IMPACII (Information for Management, Planning, Analysis, and Coordination): IMPAC II captures information on direct grant awards to foreign institutions. When awards are processed, it also provides the capability for grants management staff to indicate whether the grant has a foreign component for which State Department clearance is required. There is anecdotal evidence that not all foreign components on grants represent the level of “significant involvement” that would trigger State Department clearance. Moreover, the funding information in IMPAC II is not prorated for the foreign country.

QVR and NIH RePORTER: Although not data collection systems, QVR and RePORTER are widely-used by NIH staff and the public, respectively, for reporting and searching of foreign awards in IMPACII. The NIH RePORT program also is piloting Geographical Information System interfaces for international activities with several ICs.

System Comparison

For one IC, relatively complete FY 2009 foreign investment information was obtained through a staff review of the grant portfolio using an internal IC system. Staff identified a total of 332 grants. This list of grants was compared to a QVR search of foreign awards in IMPAC II (both direct awards and domestic awards with foreign performance sites) and FTS records. The matrix below shows the percentage of overlap in the project lists derived from these 3 sources:

NAME	PERCENT OF PORTFOLIO CAPTURED
IC Foreign Grant Portfolio (n=332)	100%
in IMPAC II	53%
in FTS	75%
in both IMPAC II and FTS	46%
in either IMPAC II or FTS	82%
in neither IMPAC II nor FTS	18%

(Few grants in IMPAC II or FTS were missing from the manually-created portfolio, perhaps due to the use of IMPAC II and FTS to conduct the review.)

Of the 332 projects, only 46% were present in all three of the data sources. Furthermore, the matching among these datasets was based on only the presence of records having the same grant number. No attempt was made to assess the extent of agreement among the databases in the project details contained in the matched records.

Anticipated Impact of FFATA Subaward Reporting

The newly-implemented FFATA reporting requirement should provide some data on NIH investments in foreign countries. FFATA reporting is required on first-tier subawards exceeding \$25,000 in value for most new awards. In FY 2009, about 30% of the subawards reported in FTS were under this reporting threshold. While this is a significant percentage of the number of projects in FTS, funding for these subawards represents a small percentage (about 3%) of the total costs of all foreign subawards in the system. Countries will vary in the

extent to which support flowing to them will be captured by the FFATA reporting.

SECTION 5: RECOMMENDATIONS



Recommendations have been divided into both short-term and long-term changes in NIH systems and business practices to improve data collection on foreign activities. The short-term recommendations are those that could be implemented relatively quickly and require few resources. The long-term recommendations are those that will take several years and a substantial amount of IT resources.

Short-Term Recommendations

1. Standardize definitions: The need for entry into FTS and IC coding of grants for foreign involvement are not consistent across ICs. NIH should more explicitly define what constitutes foreign involvement and develop more explicit criteria for entry into the FTS. In addition to information on subawards to foreign organizations, the definitions of “partner contributions” appearing in the RPPR might be useful in more consistently categorizing NIH grants:

- Financial support to the project (from the foreign organization)
- In-kind support (e.g., foreign partner makes software, computers, equipment, etc., available to project staff)
- Facilities (e.g., project staff use the foreign partner's facilities for project activities)
- Collaborative research (e.g., foreign partner's staff work with other project staff)
- Personnel exchanges (e.g., project staff and/or foreign partner's staff use each other's facilities or work at each other's site)

2. Make better use of current FTS data:

FTS data would be more accessible, more widely used, and quality better maintained if it were integrated with other grant information in IMPAC II and accessible to staff through eRA Query/View Reporting (QVR) and NIH Research Portfolio Online Reporting Tools: Expenditures and Results (NIH RePORTER) query tools.

3. Modify the Program and Grants

Management checklists: Along with making existing FTS data more accessible to program and grants management staff, include a checkbox on the Program and Grants Management staff checklists (both competing and type 5s) to indicate whether there is a "contribution" being made by a foreign partner. The checkbox would serve as a flag to Grants Management or other responsible IC staff to enter/review/update information in the FTS for every year of the grant. Provide more information to staff

through enterprise systems to help them more consistently identify such contributions in competing and noncompeting applications.

4. Enforce existing policies for FTS data capture on all grants, contracts (and intramural projects):

Whether or not the extent of foreign involvement is considered significant enough to trigger State Department clearance, the presence of any type of contribution by a foreign organization should be captured in FTS (and ultimately, IMPAC II). Review/update of this information should be required when processing noncompeting awards.

5. Explore use of existing tools for capture of unstructured data:

Significant amounts of information on international collaborations and global health research appear in unstructured portions of grant applications and progress reports. NIH should develop proofs-of-concept for automated tools to help staff search this information, providing an aid to current manual coding processes and reducing barriers to more complete data collection.

Long-Term Recommendations

6. Incorporate FTS or FTS-like capabilities into NIH enterprise systems:

Ease-of-use and lack of integration with other OER eRA modules was cited by staff as an impediment to accurate and timely reporting of foreign investments. Tracking of foreign involvement should be incorporated into existing program and grants management workflows.

7. Require use of optional RPPR data elements for reporting collaborations:

Post-award, collect information on foreign involvement in the prior year using the RPPR. This includes:

Name of foreign partner

Foreign principal investigators

Country

Type of contribution

- Financial Support (funds for project provided by the foreign partner)
- In-Kind support (e.g., partner makes software, computers, equipment, etc. available to project staff)
- Facilities (e.g., project staff use the partner's facilities for project activities)
- Collaborative research (e.g., partner's staff work with project staff on the project)
- Personnel exchanges (e.g., project staff and/or partner's staff use of each other's facilities or work at each other's site)

8. Enhance research personnel reporting:

Limitations in current competing and noncompeting grant applications affect NIH reporting capabilities. Both competing grant applications and noncompeting

progress reports should require structured information on all collaborators (currently there is a limit on the number of collaborators required to be submitted) and their institutional affiliations.

9. Enhance tools: Based on the types of information contained in previous reports of NIH international activities, it appears that implementation of FFATA and any new RPPR reporting requirements are likely to leave a significant number of relevant activities unaccounted for. Enhanced or new tools that allow staff to systematically search their portfolios, identify relevant projects, and create reports may be needed to fulfill the need for reasonably comprehensive and accurate information on international collaborations and global health research.

Resources Required

Implementing some of these recommendations, particularly those related to enhancements in NIH enterprise systems, will require a significant amount of staff and financial resources. Any decision by NIH to pursue these recommendations that require additional staff and financial resources should be accompanied by a commitment of these resources by NIH governance.



APPENDIX A: INITIAL SURVEY TEMPLATE

Dear IC Survey Contact for global health research information,

You have been designated by your IC Director as the point-of-contact to help us learn more about information ICs maintain on their investments in global health research. As a first step, we have a few short questions below. We would appreciate answers from your IC by next **Monday, April 26th 2010.**

Background: Dr. Collins has identified global health as one of five areas ripe for significant scientific advances and he's made investment in global health research a priority for NIH. To coordinate NIH efforts in this area, Dr. Collins formed the NIH Global Health Research Working Group (GHRWG), co-chaired by Drs. Susan Shurin and Roger Glass. Hampering the efforts of the GHRWG is the lack of good information on current NIH investments in research being conducted in foreign countries. As you know, while NIH does maintain information on grants and R&D contracts awarded directly to foreign institutions, it is much more difficult to identify NIH grants and contracts awarded to U.S. institutions and supporting research being conducted in a foreign countries, which may or may not involve subcontracts between domestic and foreign partners. The GHRWG has made the improvement of data on NIH investments in global research a high priority and formed an International Activity Data Subcommittee, co-chaired by Drs. Sally Rockey and James Herrington, to address the issue.

As a first step toward increasing extent and quality of information on IC's global health research, the Subcommittee is undertaking an effort to survey current NIH enterprise and IC-maintained information resources, identify IC business processes used to gather and maintain these data, and recommend both short- and long-term changes that are feasible and have the potential to increase the both the extent and quality of data NIH-wide.

The information needed from your IC:

For purposes of answering these questions, the term "foreign investments" is defined as:

- grants and R&D contracts awarded directly to foreign institutions and awards to domestic institutions that involve foreign components (e.g. subcontract, subproject, collaboration, etc.) and intramural projects with foreign collaborators.

1. At any time over the past 3 years, not including the information your IC submits to FIC for State Department clearance of foreign awards and available in the NIH Foreign Tracking System (FTS), has your IC gathered information on its foreign investments?

Mark one with an X

- Yes, at some point in the past 3 years, our IC has gathered information on foreign investments that is not available in the FTS (i.e., the information provided to FIC for State Department clearance).

- No, we have not gathered information beyond what's available in the FTS. [Go to 7.]
2. Does your IC gather this information routinely, or have these collections been ad-hoc?
Mark one with an X
- Routinely gathered.
 Ad-hoc (e.g., for a special report, Council briefing, etc.)
3. To gather this information, do/did you use a central IC-wide system for data collection?
Mark one with an X
- Yes, information was collected using a central IC-wide system.
 No, information not collected using a central IC-wide system.
4. Is/was the information gathered by your IC centrally stored in your IC?
Mark one with an X
- Yes, centrally stored in a single location.
 No, information not stored centrally (e.g., program officials collect and store information individually). [Go to question 5.]
5. For information stored centrally, is/was it stored in a structured format (e.g., database, Excel spreadsheet, table in Word document) or in an unstructured format (e.g., text document with no tables)?
Mark one with an X
- Stored in structured format.
 Stored in unstructured format only.
5. If someone other than yourself, please provide us the name(s) of the person(s) in your IC who can tell us more about your IC's foreign investment information
Collection: _____
Storage: _____
6. Please send us copies of any documents, reports, etc., that your IC has generated using foreign investment information.
7. Please use this space to ask questions, provide comments and suggestions, identify any specific needs of your IC for global health research information, etc.

APPENDIX B: INITIAL SURVEY RESULTS

	IC	Data Collected	Stored Centrally	Structured Data	Routinely Collected
Centralized Data	NIMH	Y	Y	Y	Y
Routine Collection	NIDCR	Y	Y	Y	Y
	NICHD	Y	Y	Y	Y
	NIAID	Y	Y	Y	Y
	NCCAM	Y	Y	Y	Y
	FIC	Y	Y	Y	Y
	NINR	Y	Y	Y	Y
Centralized Data	NCRR	Y	Y	Y	N
Ad hoc Collection	NEI	Y	Y	Y	N
	NHLBI	Y	Y	Y	N
	NIDDK	Y	Y	Y	N
	NIEHS	Y	Y	Y	N
Decentralized Data	NCI	Y	N	N/A	N
Ad hoc Collection	NIA	Y	N	N/A	N

APPENDIX C: SITE VISITS

IC	NAME OF SYSTEM	INTERVIEWEES	DATE	LOCATION
National Center for Complementary and Alternative Medicine (NCAAM)	Computer Analysis and Management Reporting Application (CAMERA)	Dr. Ilze Mohseni	September 29, 2010, 1:00- 2:00 p.m.	2 Democracy Blvd/ 401
National Institute for Child Health and Human Development (NICHD)	Child Health Information Retrieval Program (CHIRP)	Daniel Singer, Brenda Underwood, and Winnie Tam	October 1, 2010, 1:00 - 2:00 p.m.	6100 Executive Blvd/2A01
National Institute of Mental Health (NIMH)	Program Analysis Research Information System (PARIS)	Yancy Bodenstein	October 6, 2010, 1:00 - 2:00 p.m.	6001 Executive Blvd/ 8203
National Institute of Nursing Research (NINR)	Grant Coding System: NOVA	John Grason	October 6, 2010, 3:00 - 4:00 p.m.	1 Democracy Blvd/ 700C
National Institute of Dental and Craniofacial Research (NIDCR)	Scientific Coding and Reporting System (SCORE)	Amy Adams and Carolyn Tolbert	October 7, 2010, 2:00 - 3:00 p.m.	Building 31/ 5B55
John E. Fogarty International Center (FIC)	Foreign component Tracking system (FTS) and International Reporting and Scientific Tracking System (FIRST)	James Herrington, Julie Burke, Archana Mohale, Thomas Mampilly, Judy Levin, Kevin Bialy, Farah Bader, Flora Katz, and Rachel Sturke	October 13, 2010, 1:00 - 2:30 p.m.	Building 31/ B2C08
National Institute of Allergy and Infectious Diseases (NIAID)	Global Research Affairs Database System (GRADS)	Michael Tartakovsky	October 15, 2010, 1:00 – 2:00 p.m.	Fernwood/2NE04