Population Tracking Users Group

Date: Thurs., April 15, 2004
Time: 9:00–11:00 a.m.
Location: Rockledge 2, Room 3087
Chair: Carlos Caban

Next Meeting: May 20, Thurs., 9–11 a.m., Rockledge 2, Room 9100

Action

1. (Carlos Caban) Make arrangements for the Pop Tracking capability in QVR be demonstrated at a future Pop Track User Group meeting.

New Summary Table

Carlos Caban presented a new Summary Table that was developed by Dr. Carl Roth and that will be used by ORWH in its annual reports. He reviewed the data in the table and showed how to read the data correctly. The table, entitled, Table *1A: Percent Analysis for All Extramural Research Protocols Funded in FY2002 Reported in FY2003*, shows the total of all subjects reported using the 1977 OMB standards from the old form. There is a corresponding table for the new form. Some key data on the table includes:

- Percentage of total number of participants in research protocols (old or new form)
- Percentage of total number of participants sorted by sex/gender (row total)
- Percentage of total number of participants sorted by race/ethnicity (column total)

ORWH would like to move this table to the Pop Tracking module as a standard report.

It was noted that there are now many requests for data regarding the distribution of "Hispanic or Latino" by race. Carlos wants to find a way to retrieve that data and make it a standard report also.

Reports and QVR

Karen Bashir had asked that some standard reports for Pop Tracking be added to the QVR reporting tool. The QVR analysts developed one and demonstrated it at the last QVR meeting, which Karen and Carlos attended; they suggested some changes to the report, and asked that this QVR capability be demonstrated at a future Pop Track User Group meeting.

Action: (Carlos Caban) Make arrangements for the Pop Tracking capability in QVR be demonstrated at a future Pop Track User Group meeting.

Carlos asked the group to suggest types of reports they would like to see in QVR. There is a Pop Tracking snapshot for Program Officers and some other standard reports already available apart from QVR. Carlos noted that several reports are available using eRA's Cool Tools at http://impacii.nih.gov/tools/pop/pop_index.cfm. Some suggested reports were:

- eSNAPs that are in progress. Carlos noted that in the Program Module, the Program Official can see the status of their eSNAPs.
- Sort grants by Health Scientist Administrator (HSA). It was noted that the information is in the Snapshot but it can't be sorted. (Grants assigned to an HAS are available through the Program Module.)
- Which grants that require tracking have data entered in them.
- Make the Grant Folder available via the Pop Tracking Module.
- Show which applications are missing target data by Council date.

Some issues were raised:

- PIs continue to paste their own tables as part of the Progress Report, instead of using the one provided.
- The approval of a Type 5 automatically sets up the shell for the next year. If the data hasn't been entered and approved in Pop Tracking, the wrong shell will be generated. Therefore, it is important that the Type 5 and Pop Tracking approvals be linked. The issue was raised concerning target data that is entered after the Notice of Grant Award (NGA) is published.
- We need to notify the PI at the time of award when their mechanism is not being tracked, telling them that they don't have to provide target data. This message should be in eSNAP. However, the message should also say to please continue to follow the inclusion policy even though their mechanism will not be tracked. There are several technical issues to work out before this is implemented.

OER Intranet for Human Subjects

Carlos distributed a prototype of a new Human Subjects intranet http://grants.nih.gov/grants/policy/hs/index.htm that has been developed in OER. The left column includes the major subjects found at the site:

- OER Human Subjects Home
- PHS 398 Instructions Human Subjects Section
- Staff Roles
- Vulnerable Populations
- International Research
- NIH Policies and Procedures
- Regulations, Policy & Guidance
- Training Resources
- FAQs
- Glossary

The "FAQs from Staff" section of the site provides information pertaining to the following questions:

- What is the NIH system for assigning human subjects protections codes?
- Why does this application have a HS code "20" after review?
- What documentation do I need to send to OER when requesting an HS code change?
- How should I address a package to OER containing a request for an HS code change?
- What is the NIH system for assigning human subjects inclusion codes?
- What is the process for changing Unacceptable inclusion codes?

The Inclusion Tracking Committee approved the recommendation to add a "conditional = C" code. The current inclusion codes are under the sections, *What is the NIH system for assigning human subjects inclusion codes, gender codes,* and minority codes. The intent would be to add C for Conditional as one of the options for the *third character*. *Conditional* would mean that data has not yet been received in an acceptable table or approved by NIH Program Officials.

MEO and Pop Tracking

Carlos distributed the Section 5.3.1.3 of the Performance Work Statement (PWS), *IMPAC II and Other Data Management,* which defines the requirements for the new Most Efficient Organization (MEO) that NIH has established and will be implementing this summer. The organization is named "*Division of Extramural Activities Support (DEAS).* One of the bullets under this section reads:

> Enter and verify required information on human subjects into IC and IMPAC II Population Tracking databases

Under the subsection, 5.3.1.3.0: Conditions of Performance, one section reads:

> For grants with protocols involving human subjects, information of race, gender and ethnicity of both targeted and enrolled study participants must be obtained from investigators or other designees, verified, and entered into IC specific databases and, after obtaining necessary approvals, into the Population Tracking module of IMPAC II. Data entry into population tracking data bases requires knowledge of NIH gender and minority inclusion policies and procedures.

Carlos explained that the terms "enter" and "verify" are data entry issues. The question that arises is "where is the data coming from to enter and verify?" Verification in the terms of data entry means to verify that the data given is the data entered, not whether or not the data given is correct.

The data comes from several sources:

- Electronic grant application (e.g., scanned applications).
- Automatic data entry by the PI through eSNAP.
- Scanned Type 5 applications, starting October 1, which will be put in the Grants Folder. The data will be available electronically and can be entered by MEO staff as "data entry."
- Entered by data-entry staff from a paper application.

Some of the issues discussed regarding MEO and Pop Tracking follow:

- If there is a problem with the actual data (e.g., the numbers don't add up), the data-entry people will have to send it back since they can't fix it. The roles and rules, e.g., defining exactly what data-entry staff can do versus IC staff, will be clarified.
- Currently, the scanners are not scanning the appendices. They stop scanning after the last checklist so they miss a lot, including population tables, which often are after the checklists. It's important that the population tables be in the scanned application. This may require better instructions in the PHS 298. If investigators do put tables outside the currently scanned document, then the appendices and rest of the application will need to be scanned.
- There will need to be some quality-control process set in place by MEO staff to verify entries by data-entry staff.
- Pop Tracking Quick Tips, which were written so that Program staff could enter population data step-by-step, could serve as a basis for training.
- It's important that Approval Roles be clearly defined. Carlos said that there will be levels of roles showing who has responsibility for approvals, data entry, and read-only.
- The advantage of the MEO model is that staff can give their population data to their cluster of data-entry staff throughout the year. Now, data entry is often put off by staff until late in the year. With the new model, data will be available earlier and data-entry delays will be eliminated.
- There is no on-line checklist for Type 1s. There was some question as to who has responsibility for verifying and signing off when all action on a Type 1 is complete. There also is some missing linkage between modules/business areas. This issue is under discussion as part of the new grant checklist that is being developed in eRA. Carlos noted that some of these issues will be resolved when there is a common sign-on and staff can easily move between modules.
- Tracking is done by protocol, not by grant. There may be a need to have a specialized person assigned to address complex issues.
- It was suggested that the process should be that the data-entry person enters the data and then the Program person looks at it and approves. The Program person should not review the data before it is entered.
- Add a button on the Checklist Screen to access the Snapshot.

Attendance

Burge, Lori (NIGMS)	Gulya, Julie (NIDCD)	Parker, Marie (NIAID)
Caban, Carlos (OER)	Jones, Tina (NEI	Parker, Michelle (NIMH)
Davis, Trenita (NIDCR)	Lee, Delores (NCRR)	Prince, Mary Lou (NIMH)
Doherty, Margaret (NIAMS)	Lingham, Angela (NIA)	Richardson, Carmen (NIAAA)
Douglas, Clarissa (NCI)	Martin, Michael (OD)	Robuck, Patricia (NIDDK)
Everett, Donald (NEI)	Michel, Mary Ellen (NINDS)	Seppala, Sandy (PCOB)
Fobbs, Tinera (NIBIB)	Palagi, Sharry (NHLBI)	Whalin, Michael (NICHD)

Witherspoon, Kim (NCI/CTEP)