Population Tracking Users Group

Date: Thurs., January 29, 2004
Time: 9:00–11:00 a.m.
Location: Rockledge 2, Room 9100
Chair: Carlos Caban

Next Meeting: February 19, Thurs., 9–11 a.m., Rockledge 2, Room 9100

Action Items

1. (Melissa Hirsch) Make the Enrollment and Target comments show on reports.
2. (Carlos Caban) Send a draft of the new 398 instructions to the members of ePTUG.
3. (Carlos Caban) Investigate the roles related to population-tracking data entry and quality control in relation to the MEO.
4. (Mark Siegert) Check to be sure that enrollment numbers have to be equal to or larger than the numbers of the previous year (they cannot be less than) in the Pop Tracking Module.

Welcome and Introductions

Carlos welcomed the group to the new year. With the last meeting held in September 2003, he wants to reenergize the group. The purpose of the group is to discuss the Population Tracking Module, provide feedback as to its use, and make recommendations for improvements and enhancements. Carlos noted that he has been involved in population tracking since 1990, taking a sabbatical from it while Della Hann took the helm. He is now back and interested in moving ahead with the User Group and the module.

After introductions around the table, it was clear that there is a wealth of experience with human subjects among the group, which should provide an excellent advocate group for the continued success and use of the module.

eRA Update

Mark Siegert announced that he represented Maria Koshy, who has been appointed the business analyst for Population Tracking. There also will be a requirements analyst assigned to the project in the near future.

The eRA System is in a transition period with very little activity because of a change in the project contract and business processes. For new work, the requirements have to be written and from them task orders prepared. Approved contract companies then bid on the specific task order.

Dr. John (JJ) McGowan stepped down as eRA Project Manager in December and an acting manager has been appointed but not announced. The analyst for Pop Tracking, Dan Hall, left the project (to work for the Redskins).

Consequently, many of the changes for the Pop Tracking module have not been implemented. With this first meeting of 2004, Carlos hopes to resurrect the change list, reevaluate it, get it into the system and start to move forward.

Discussion

System problems—The current system for recording and fixing bugs is as follows:

Find bug → Send to Helpdesk → Logged in → Sent to Melissa Hirsch and Carlos Caban

Document changes—Program Officials are not able to make changes to the data and documents submitted by Principal Investigators (PIs) through eSNAP. There are many examples for the necessity of overriding PI input, e.g., incorrect counts, updated data from PI, etc. There is an override role, but this role should be usually be limited to one person per IC. It will be useful to have a list of the IC persons with the Overide Role.

Old and new forms—Some ICs are requiring everyone to use the new forms even when the old forms should be used because they don't want to support two forms.

Documenting "unknown"—It is not correct to mark "unknown" without putting in an comment of explanation. One IC prepared a list of standard comments that can be used instead of "unknown."

Action: (Melissa Hirsch) Make the Enrollment and Target comments show on reports.

In the past, the comments field was used for other comments. Now, it should be used only for "unknown" comments. Comments are not printed on the Snapshot Report.

Target Data—The group agreed that they shouldn't have to approve target data unless it changes.

398 instructions—When Carlos Caban wrote new instructions for the 398, he used January 20, 2001, as the break date for determining when to use the new form.

Action: (Carlos Caban) Send a draft of the new 398 instructions to the members of ePTUG.

Target Table—The Target Table required and is to go in the Human Subjects section. However, sometimes the table is placed at the end of the application, before or part of the Appendices. When the table is not in a standard place in the application, it is easily missed. Mary Lou Prince mentioned that NIMH requests the Target Table in the Just-In-Time document from the PI/Institution and gets a high percentage of responses.

MEO—There was some discussion of the roles that are part of MEO, with the group agreeing that there is a difference between what to put in for population tracking data and actually putting it in. If the MEO structure only defines a role for entering the data, there may have to be a structure implemented where the PO has to verify and sign off on the data. Right now, many ICs use the data-entry person as the quality-control person. Removing the quality control responsibility from the data-entry role could prove a problem.

Action: (Carlos Caban) Investigate the roles related to population-tracking data entry and quality control in relation to the MEO.

Today, there is only the Update role. It would not be difficult to break out an Approval role in addition. It was suggested that a third role, Read-Only, be added.

Management Controls Self-Assessment—The OER, in conjunction with OMA, has developed an extramural research Management Controls Self-Assessment Tool questionnaire to help ICs identify potential areas for improved compliance with both NIH and their own established policies and procedures. The focus of the questionnaire is grants and cooperative agreements. This initial version of the questionnaire will provide a baseline of current operations. Future versions will include additional performance metrics. The instrument will be updated and re-administered by OER every two years. The IC"s EPMC representative is responsible for coordinating the responses within the IC and submitting the IC"s response to OER by February 6, 2004. For more information on the questionnaire and a complete listing of questions in each area (Peer Review, Program and Grants Management) you may download the Management Controls Self-Assessment Tool. One of the topics is IC handling of inclusion of women and minority policies, which is of interest to this group, who may be contacted to assist the EPMC member.

Grants funded before targets—It was suggested that there be a code or flag in place to remove grants that were funded before the target population data is put in place from discrepancy reports. However, it was noted that the committee has to approve any new codes and it is very hard to process reports if exceptions are added. All comments show on the discrepancy report, which should provide information regarding the data.

Old table vs. new table—Most of the issues are with controlled data. It was suggested that there be more specific rules or instructions in the PHS forms 2590 and 398 so that statistics are more reliable. Standards should be set for required information and when this information has to be entered.

Saving data—It is important to click Save after entering data before clicking Approve.

Aggregate reports—Melissa Hirsch said that she would be sending out aggregate reports soon.

Zero Enrollment data—Melissa explained that zero enrollment data is automatically put in Table C, implying that the study has not started. The award can't be approved if the data hasn't been entered. Bring in the previous enrollment data and add a comment. If you don't approve, it doesn't show in Table C.

Foreign data—It was pointed out that the foreign country should be entered and there is a table of foreign countries to choose from. All foreign data can be presented in one table, or an IC can choose to enter a separate table for each country. It was suggested to add F/D on the hard copy of the enrollment data table. The prior forms also had grant number and PI name on the top and this should be added to the new forms.

Enrollment data—In eSNAP, enrollment numbers have to be equal to or larger than the numbers of the previous year; they cannot be less than. This is for totals only, not by cell.

Action: **(Mark Siegert) Check to be sure that enrollment numbers have to be equal to or larger than the numbers of the previous year (they cannot be less than) in the Pop Tracking Module.**

Phase III Checklist data status—In response to an inquiry to ORWH, OER has looked at the Phase III checklist information in database. If a protocol is Phase III, it should be checked as Phase III and the checklist should be filled out. Our preliminary analysis shows that some of the checklist questions are not answered Yes or No, but should be. Also, if there is one or more Phase III protocol in a grant, the overall grant should be coded as Phase III. If the grant has a single

Phase III protocol, then both the grant and the protocol should be coded a Phase III. We will continue to analyze this and send out a report identifying the discrepancies that need to be corrected.

Attendance

Barnes, Martha (NIEHS)
Caban, Carlos (OER)
Douglas, Clarissa (NCI)
Fobbs, Tinera (NIBIB
Gulya, Julie (NIDCD)
Hirsch, Melissa (OD)
Lee, Delores (NCRR)
Manischewitz, Jack (NIDA)
McClure, Shelia (NCRR)
Mowery, Richard (NIDCR)
Parker, Marie (NIAID)
Prince, Mary Lou (NIMH)
Schafer, Susan (NIAID)
Seppala, Sandy (PCOB), recorder
Siegert, Mark (OD)
Witherspoon, Kim (NCI/CTEP)
Yerg, Diane, (NIAID)