# ◆ Population Tracking Users Group

**Date:** Thurs., May 20, 2004
**Time:** 9:00–11:00 a.m.
**Location:** Rockledge 2, Room 9100
**Chair:** Carlos Caban

**Next Meeting:** June17, Thurs., 9–11 a.m., Rockledge 2, Room 9100

## Action

1. (All) Review the Program Module, Pop Tracking Snapshot and the checklists. Send suggestions to Carlos for what could be done to make it easier for Program Officers to do their jobs pertaining to Pop Tracking.

2. (All) Read the revised PHS 398 form and instructions and send suggestions and comments for improving the instructions to Carlos.

3. (All) Review Scenario D in Section of the 398 instructions and send Carlos input and suggestions for changes and improvement.

## Inclusion Tracking Committee Recommendations

As follow-up from the last meeting, Carlos presented the policy issues for discussion and approval at the April meeting of the Inclusion Tracking Committee. The following recommendations (from the draft minutes) were agreed to by the Inclusion Tracking Committee:

1. Principal Investigators should be notified in the Notice of Grant Award whether submission of tracking data is required in annual progress reports.

2. Notification of exceptions for tracking should include language indicating that compliance with the NIH inclusion policy is expected although submission of an enrollment data table is not required. Target data are required at the time of application submission and grant renewal.

3. The language in the eSNAP process should be revised to inform PIs when a project is not tracked and to provide a list of reasons for "excepting" studies from tracking.

4. Principal Investigators are required to provide an explanation for ~~"0" or~~ "unknown" if it appears in the ~~target and~~ enrollment data.

5. An IMPAC II code should be added to allow conditional awards when inclusion issues have not been resolved and an IC wants to make an award

In the discussion about #4, it was agreed that there is no place for an "unknown" designation in the new target table, so this should be deleted from the original draft. Target data is not an issue, but enrollment is an issue. It was suggested that there be a flag or identifier for Program staff.

# Inclusion and Coding Update

Carlos presented several recommendations to the RPC and POPOF, which he presented to the group. The recommendations also will be presented to GMAC and EPMC in June. The recommendations included:

- Inclusion of Children Policy

- Inclusion of Women and Minorities Policy

There were several items that were discussed that were related items to these policies:

- The Population Tracking Snapshot is available in the Program Module (only) GRANT FOLDER and includes the protocol information, the target data, the enrollment data and the Phase II checklist if applicable

  **Discussion**: The group agreed that this needs to be available through QuickView, QVR and any other appropriate data-access and reporting tools.

- OER and eRA are investigating scanning all Type 5 progress reports beginning October 1 and making them available in the GRANT FOLDER of IMPAC II. Thus the enrollment tables also will be available electronically if not entered via eSNAP. The target enrollment tables already are available in the scanned competitive type 1 and 2 applications in the GRANT FOLDER.

- The eRA Population Tracking User Group has prepared a document "eSNAP Process for Internal Population Tracking Users" that is being finalized to include the Inclusion Tracking Committee recommendations before distribution.

- DEAS staff will perform data entry and verification of population tracking data. Program or other designated staff still will need to approve the data.

  **Discussion**: This is being addressed by dividing the current role and adding others so that the possible roles are: *Read Only, Update, Approval, or Override.*

There are issues with how people are using the inclusion coding and how it relates to Pop Tracking. The third-character codes are:

A   scientifically acceptable

U   scientifically unacceptable

C   conditional award (proposed)

R   resolved

$$U \rightarrow C \rightarrow R$$

$$U \rightarrow R$$

The current policy is that Grants Management (or designated staff) can make an award only if the coding is acceptable or resolved. Grants Management should not make the award if the inclusion code is "U" (scientifically unacceptable).

Incorrect coding also affects the data in the annual ORWH Summary Tables

## Population Tracking Home Page on IMPAC II Web site

Carlos pointed out that he recently posted the "NIH Policy and Procedures for Clinical Research Grants and Contracts" from the 2002 Notebook under Addition Documentation on the IMPAC II Pop Tracking page (http://impacii.nih.gov/applications/apps_pop.cfm) so that it is more accessible. Also in that section are the Population Tracking Exception Codes, NIH Grant/Contract Mechanisms Requiring Population Tracking, and Clinical Research—Case Examples.

New Release Notes will be available on this page in early July, which will include bug fixes and new roles.

The group suggested that there be two other items available on the page: FAQs and Q&As.

The group also discussed the need for a report similar to the one that Melissa Hirsch used to send—a report listing missing items only. They would like this report sent to them but also would like some "canned" reports available on the Web site. Another report they requested was one for "unknowns."

There are two data access tools that could be used to define queries and pull up reports: Web QT and QVR. QVR has developed a query for Pop Tracking but for it to be more useful, its analysts would need to know what this group would want of the capabilities of QVR. There will be a QVR demo at a future meeting.

## Grant Snapshot Report

Some items are being fixed on this report:

- Show fiscal year
- Expand text field
- Expand protocol title field

The issue of how to address subprojects was discussed. There are two subproject numbers: one for CRISP and one for the IC. There needs to be clarification of these two numbers as well as a definitive definition of a subproject.

It would also be useful to show whether program has approved the target and enrollment table data on the Snapshot.

## Program Module

Carlos Caban demonstrated the Program Module so that the group could have an idea of the data and features in it. He told that group that they could try out the Program Module by contacting their IC IT person to be granted the "assistant" role. This would allow them to access the major capabilities of the Module. Key would be for each person to suggest better ways of linking the Program Module to Pop Tracking.

The purpose of the Program (PGM) module, according to the login homepage (http://apps.era.nih.gov/pgm/), is to provide one place where a Program Official (PO) can access his/her grant-related work. Some of its features are:

- Getting information quickly on a grant's status when a PI calls, using the SEARCH feature

- Quickly accessing your assigned grants and related documents, using MY PORTFOLIO

- Monitoring your portfolio workload at each stage of the grant cycle, including Pre-Submission, Pending SRG, Pre-Council, Post Council, Pending Type 5s, and Post Award

- Providing Program Approval for pre-award and Progress Reports requirements while in MY PORTFOLIO

- Accessing reports and exporting lists to Excel from each portfolio

- Linkage to other electronic Research Administration (eRA) modules, e.g., Commons, ECB, QVR, QuickView, etc.

The Program Module is a good template for Grants Management and Review, with modifications for data specific to each role.

*Checklists*—Most checklist items are standard for all ICs, but ICs can add their own items to the standard one.

*Notes*—Notes are accessible to people with approval authority to view. The access rights will change when the new organizational hierarchy is changed from *role* to *rights*.

*Links*—It was suggested that there be a button on each checklist that takes the user to Pop Tracking as well as one on the sign off/approval sheet.

*K awards*—K awards are not being tracking but they are still being brought into Pop Tracking.

*Extra data*—Is it possible to use the module to store extraneous data about a grant? It is possible as long as the data is marked with an exception code.

*Grant Folder*—The Pop Tracking Grant Snapshot is currently accessible in the Program Module grant folder by clicking on the grant number on the hitlist. The Snapshot should show up only if the grant is coded "00" and not HS codes 10 or 98; however, the Snapshot shows up for all grants, and this bug fix has been requested.

**Action:** **(All) Review the Program Module, Pop Tracking Snapshot and the checklists. Send suggestions to Carlos for what could be done to make it easier for Program Officers to do their jobs pertaining to Pop Tracking.**

## PHS 398

Carlos provided the group with a copy of the draft revised 398 section that addresses Pop Tracking: Targeted/Planned Enrollment Table, Inclusion Enrollment Report and the Inclusion Table. Accompanying these were the specific Pop Tracking instructions found in Part 1 and in Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan. He asked the group to read the sections for clarity and to pay special attention to the changes in the tables.

**Action:** **(All) Read the revised PHS 398 form and instructions and send suggestions and comments for improving the instructions to Carlos.**

The 398 will be in three parts on the Web, with interlocking URLs that provide navigation to each one.

The Research Plan instructions are on p. 28 with Human Subjects Research being number "e" of that section (p. 30). There are five questions that must be answered:

1. Does your proposed research involve human subjects?

2. Is your proposed research described by one or more of the exemptions in the Department of Health and Human Services (HHS) Regulations (45 CFR Part 46)?

3. Does your proposed research include Clinical Research?

4. Does your proposed research include a Clinical Trial?

5. Does your proposed research meet criteria for an NIH-Defined Phase III Clinical Trial?

Grantees can determine which category they are in by answering these questions.

Carlos asked the group also to look at Scenario D on page 26 of Section II and to send him their input.

**Action:** **(All) Review Scenario D in Section of the 398 instructions and send Carlos input and suggestions for changes and improvement.**

*Pop Tracking Homepage in IMPAC II and User Reports*—Carlos discussed a marked up handout of the IMPAC II Population Tracking homepage http://impacii.nih.gov/applications/apps_pop.cfm, which showed the recent additions under "Additional Documentation": Population Tracking Exception Codes, NIH Grant/Contract Mechanisms Requiring Population Tracking, and Clinical Research—Case Studies. He suggested that the URL be saved as a bookmark or favorite, or saved on the desktop (go to the URL, then File, Send, Shortcut to Desktop) for easy access.

*User Reports*—Carlos also discussed the "User Reports" section that linked to the Pop Tracking reports that are available, and that can be downloaded as spreadsheets by saving the hitlist as filename.xls, and then opening it in Excel. When in Excel, one can have gridlines and row and column headings printed out by going to File, Page Setup, Page (set at landscape, 65%) and then Sheet (Gridlines, Row & Column headings). Then save. It was suggested that a single report incorporating all five reports would be very useful.

## Attendance

Bashir, Karen (NIA)
Bates, Angela (ORWH)
Burge, Lori (NIGMS)
Caban, Carlos (OER)
Corbett, Dawn (NIMH)
Davis, Trenita (NIDCR)
Fobbs, Tinera (NIBIB)

Freeman, Julia (NIAMS)
Gulya, Julie (NIDCD)
Koshy, Maria (OER)
Lee, Delores (NCRR)
Lingham, Angela (NIA)
Meskill, Lauren (NIDDK)
Palagi, Sharry (NHLBI)

Parker, Michelle (NIMH)
Richardson, Carmen (NIAAA)
Schafer, Susan (NIAID)
Seppala, Sandy (PCOB)
Witherspoon, Kim (NCI/ CTEP)