IMPAACT-HPTN
Annual Meetings

Joint Plenary Session:
DAIDS and Grants Management Panel

7 April 2008
<table>
<thead>
<tr>
<th>Panel Members</th>
<th>Topics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Judi Miller</td>
<td>DAIDS: Big Picture</td>
</tr>
<tr>
<td>Ed Handelsman</td>
<td>TRP Overview</td>
</tr>
<tr>
<td>David Burns</td>
<td>PSP Overview</td>
</tr>
<tr>
<td>Donna Germuga</td>
<td>OCSO Overview and Roles</td>
</tr>
<tr>
<td>Lesia Norwood</td>
<td>DEA/Grants Management</td>
</tr>
</tbody>
</table>
OPCRO Mission

Supports the DAIDS clinical research and helps ensure compliance with applicable regulations, standards and good clinical practice guidelines; study participant safety and welfare; and study quality and integrity.
OPCRO Key Functions

- **PAB**: Oversees all pharmacy related activities
- **RAB**: All regulatory oversight: IND management, Amendments/LOAs
- **SPT**: Safety issues: SAE/EAE
- **HSP**: Human subject issues: Compliance with regulations, Review consent forms
- **PRT**: Oversees all aspects of the protocol registration process

**Regulatory Compliance Center (RCC)**
Contractor which assists OPCRO with workflow tracking and management
Panel Members

- Judi Miller  DAIDS: Big Picture
- Ed Handelsman TRP Overview
- David Burns  PSP Overview
- Donna Germuga OCSO Overview and Roles
- Lesia Norwood DEA/Grants Management
iMAP

- iMAP stands for the International Maternal Adolescent Pediatric branch
- iMAP is still sometimes referred to as PMB
- International includes the US and other countries – was not meant to exclude the US
- We thought of calling it “domestic and international…,” but diMAP sounded like car insurance or something
- iMAP sits within the Therapeutics Research Program (TRP)
- TRP also houses the HIV research branch, the Complications and Coinfections research branch, and the Drug Development and Clinical Sciences branch
- iMAP is unique in that it encompasses both treatment and prevention research
iMAP Roles (in alphabetical order)

- Branch Chief (me)
- Health Specialist (Renee Browning*)
- Medical Officers (Patrick Jean-Phillipe*, Paul Sato, Betsy Smith)
- Program Officer (Judi Miller)

* HJF Contractor
Branch Chef Role

- To cook all the food for the branch and the associated programs
Branch Chief Role

But seriously,

- Help lead the scientific agenda for the branch, thus advancing the agenda for women, children and adolescents within the program and division
- To represent the branch and DAIDS in other national and international bodies
- To oversee the day-to-day functioning of the branch
Health Specialist

- Coordinate the scientific activities of the branch
- Act as the safety specialist for the branch
- Make sure that all of the research activities sponsored by the branch meet DAIDS standards and the highest possible standards
Role of DAIDS Medical Officers

- Participate in scientific committees, ensuring that their priorities harmonize with DAIDS priorities
- Follow protocols from start to finish, giving scientific input, and shepherding through CSRC (note – an independent voice, not simply an advocate)
- Coordinate the protocol with other groups within DAIDS – regulatory, pharmacy, etc
Role of DAIDS Medical Officer

- Review every protocol, amendment, LOA, clarification memo – twice – once as a team member, once with a fine-toothed comb as a regulatory sign-off
- Review every EAE/SAE report, exchange with RCC to get details for report, make separate attribution, determine and review submission for FDA
Role of Program Officer

- Oversee administrative and fiscal support and interaction with the network
- Coordinate DAIDS and network activities, primary point of contact for ops center
- Work to coordinate scientific agenda with resources and support
- Liaison for the branch with the Office of Clinical Site Oversight
Other groups within DAIDS who interact with IMPAACT

- Pharmacy, Regulatory and Laboratory groups
- Human Subjects Protection, Biostatistics, Ethics, DSMB, Pharmacovigilance groups
- Contractors such as PPD (site monitoring) and RCC (Safety and Regulatory)
- Other programs – Prevention, Vaccine, Basic Science/Epi.
Other DAIDS Individuals who have assisted IMPAACT

- Leadership (Carl Dieffenbach, Jeff Nadler)
- Pharmacy (Ana Martinez, Lynette Purdue)
- Regulatory (MaryAnne Luzar)
- Laboratory (Mike Ussery, Joe Fitzgibbon)
Thank You for your work, effort and caring
Panel Members

Judi Miller  DAIDS: Big Picture
Ed Handelsman  TRP Overview
David Burns  PSP Overview
Donna Germuga  OCSO Overview and Roles
Lesia Norwood  DEA/Grants Management
PSP Mission

The Prevention Sciences Program (PSP):

- plans, develops, implements, and evaluates a comprehensive extramural program in support of HIV prevention research

- collaborates with other Programs, Divisions, and Centers within DAIDS, NIAID, and across NIH, and with other government and non-government organizations

- provides oversight to the HPTN and MTN

- collaborates with the Therapeutics Research Program on selected studies performed by IMPAACT
HPTN Leadership Group
Program Officers

- Operations Center Leadership Group
  David Burns
- Statistical and Data Management Center
  Grace Chow
- Network Laboratory
  Usha Sharma
Panel Members

Judi Miller  DAIDS: Big Picture
Ed Handelsman  TRP Overview
David Burns  PSP Overview
Donna Germuga  OCSO Overview and Roles
Lesia Norwood  DEA/Grants Management
Objectives of Presentation

- Define the mission of OCSO
- Describe OCSO organizational structure
- Explain DAIDS OCSO Program Officer roles
- Define OCSO Network Liaison role
The mission of the DAIDS Office of Clinical Site Oversight (OCSO) is to facilitate the clinical research of the scientific programs of the Division of AIDS through oversight of clinical site capabilities and overall performance. This is accomplished in the context of the scientific and programmatic priorities of the DAIDS programs and Network Leadership Groups.
OCSO’s New Director

March 3, 2008
Manizhe Payton
OCSO Program Officer Role

- **Assignment by CTU**
  - International and Domestic Sites
  - Pleuripotent-one stop shopping
- **Liaison between the site and DAIDS**
  - Guidance and Problem Solving
- **Site Establishment/Site Approval**
  - Essential Contacts
  - Clinical Assessment Modules
  - Pharmacy Plan
  - Laboratory Sign-off
- **Budget (in conjunction with Grants Management)**
  - Review of annual Progress Report
  - Review and approval of carry-over requests, supplements, release of restricted funds
OCSO Program Officer Role Cont’d

- **Administrative changes (in conjunction with Grants Management)**
  - Review and approval of change in key-personnel
  - Change in physical location of CTU and/or CRS

- **Site Oversight**
  - Monitoring studies
  - Site performance
  - Coordination of on-site DAIDS or PPD site visit for special training needs

- **Point of contact for special requests**
  - Additional network affiliation
  - Addition of new site/s or satellite/s
OCSO Network Liaison Role

- Serve as the primary point of contact within OCSO for Network-wide issues related to sites.
- Review Network’s site performance and evaluation report for accuracy and completeness.
- OCSO representative in discussions about Network resource allocations involving sites and inform OCSO Program Officers about decisions and action items from these discussions.
- Represent OCSO at Network meetings and calls. If requested, make presentations about site-related issues at these meetings.
OCSO Network Liaisons

- IMPAACT - Donna Germuga
- HPTN - Eileen Pouliot
Take home messages

- Some of our roles overlap with grants management and program management.
- We work in concert with the other Offices and Programs within DAIDS.
- We may not always have the answer or the authority to honor your request, however, .......

We are the conduit for forwarding information or questions on to the appropriate people within DAIDS on any site related subject.
<table>
<thead>
<tr>
<th>Panel Members</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Judi Miller</td>
<td>DAIDS: Big Picture</td>
</tr>
<tr>
<td>Ed Handelsman</td>
<td>TRP Overview</td>
</tr>
<tr>
<td>David Burns</td>
<td>PSP Overview</td>
</tr>
<tr>
<td>Donna Germuga</td>
<td>OCSO Overview and Roles</td>
</tr>
<tr>
<td>Lesia Norwood</td>
<td>DEA/Grants Management</td>
</tr>
</tbody>
</table>
Division of Extramural Activities

Department of Health and Human Services

Other Agencies

National Institutes of Health

National Institute of Allergy and Infectious Diseases

Division of Extramural Activities

Division of Acquired Immunodeficiency Syndrome
NIAID
Grants Management Program

Lesia A. Norwood
Branch Chief & DAIDS GM Liaison
Grants Management Program
Division of Extramural Activities, NIAID
Discuss

- Grants Management Specialist/Officer
- Organizational Structure
- Grants Management Program Contacts
- GMP IMPAACT & HPTN Contacts
- When and How to contact Grants Management staff?
- Solicited Questions
Grants Management Specialist/Officer

- **Grants Management Specialist**
  - Is an agent of the Grants Management Officer
  - Reviews, negotiates, awards, and administers an assigned grant portfolio
  - Interprets grants policies and provisions
  - Works closely with Program Official

- **Grants Management Officer**
  - Ensures NIH and grantee staff fulfill requirements of laws, regulations, & administrative policies
  - Responsible for business administration of the grants
<table>
<thead>
<tr>
<th>Name</th>
<th>Direct Line</th>
<th>Room #</th>
<th>E-Mail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ann Devine</td>
<td>402-5601</td>
<td>2114</td>
<td><a href="mailto:ADevine@niaid.nih.gov">ADevine@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Artisha Wright</td>
<td>451-4580</td>
<td>2246</td>
<td><a href="mailto:ARWright@niaid.nih.gov">ARWright@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Chanee’ Williams</td>
<td>435-2068</td>
<td>2248</td>
<td><a href="mailto:WilliaCC@mail.nih.gov">WilliaCC@mail.nih.gov</a></td>
</tr>
<tr>
<td>Christy Leake</td>
<td>402-5937</td>
<td>2242</td>
<td><a href="mailto:CLeake@niaid.nih.gov">CLeake@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Cindy McDermott</td>
<td>594-7456</td>
<td>2119</td>
<td><a href="mailto:McDermoC@niaid.nih.gov">McDermoC@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Dawn Mitchum</td>
<td>451-2667</td>
<td>2113</td>
<td><a href="mailto:DMitchum@niaid.nih.gov">DMitchum@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Deanna Ingersoll</td>
<td>451-2686</td>
<td>2262</td>
<td><a href="mailto:IngersollD@niaid.nih.gov">IngersollD@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Devon Bunbray-Quarles</td>
<td>402-6213</td>
<td>2253</td>
<td><a href="mailto:DBumbray@niaid.nih.gov">DBumbray@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Dhana Khurana</td>
<td>451-9894</td>
<td>2249</td>
<td><a href="mailto:KhuranaV@niaid.nih.gov">KhuranaV@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Donna Sullivan</td>
<td>594-6361</td>
<td>2112</td>
<td><a href="mailto:DSullivan@niaid.nih.gov">DSullivan@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Greg Smith</td>
<td>402-5540</td>
<td>2109</td>
<td><a href="mailto:GSmiht@niaid.nih.gov">GSmiht@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Helen Jarecki</td>
<td>402-6245</td>
<td>2111</td>
<td><a href="mailto:HJarecki@niaid.nih.gov">HJarecki@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Howard England</td>
<td>594-9875</td>
<td>2229</td>
<td><a href="mailto:EnglandH@niaid.nih.gov">EnglandH@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Jacki Johnson</td>
<td>402-5936</td>
<td>2127</td>
<td><a href="mailto:JJohnson@niaid.nih.gov">JJohnson@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Janice Carretero</td>
<td>594-7460</td>
<td>2261</td>
<td><a href="mailto:MedinaJa@niaid.nih.gov">MedinaJa@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Jen Twilley</td>
<td>451-2649</td>
<td>2252F</td>
<td><a href="mailto:TwilleyJ@niaid.nih.gov">TwilleyJ@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Julia Torres</td>
<td>451-2690</td>
<td>2247</td>
<td><a href="mailto:TorresJu@niaid.nih.gov">TorresJu@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Julie Waugh</td>
<td>451-7381</td>
<td>2239</td>
<td><a href="mailto:WaughJ@niaid.nih.gov">WaughJ@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Katie Ellis</td>
<td>451-2687</td>
<td>2240</td>
<td><a href="mailto:KEllis@niaid.nih.gov">KEllis@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Kim Belk</td>
<td>451-7380</td>
<td>2251</td>
<td><a href="mailto:BelkK@niaid.nih.gov">BelkK@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Kim Chatman</td>
<td>402-6580</td>
<td>2241</td>
<td><a href="mailto:ChatmanK@niaid.nih.gov">ChatmanK@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Kim Coats</td>
<td>451-4576</td>
<td>2243</td>
<td><a href="mailto:KCoats@niaid.nih.gov">KCoats@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Laura Eisenman</td>
<td>402-5541</td>
<td>2120</td>
<td><a href="mailto:LEisenman@niaid.nih.gov">LEisenman@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Lesia Norwood</td>
<td>402-7146</td>
<td>2116</td>
<td><a href="mailto:LNorwood@niaid.nih.gov">LNorwood@niaid.nih.gov</a></td>
</tr>
</tbody>
</table>
## GMP Contact Information

<table>
<thead>
<tr>
<th>Name</th>
<th>Direct Line</th>
<th>Room #</th>
<th>E-Mail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leslie Boggs</td>
<td>402-6450</td>
<td>2110</td>
<td><a href="mailto:BoggsL@mail.nih.gov">BoggsL@mail.nih.gov</a></td>
</tr>
<tr>
<td>Lisa Scott-Morring</td>
<td>451-3697</td>
<td>2232</td>
<td><a href="mailto:ScottLi@niaid.nih.gov">ScottLi@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Maggie Wells</td>
<td>594-9847</td>
<td>2250</td>
<td><a href="mailto:WellsMaggie@niaid.nih.gov">WellsMaggie@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Mary Ann Garlic</td>
<td>451-3680</td>
<td>2126</td>
<td><a href="mailto:MGarlic@niaid.nih.gov">MGarlic@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Mary Ledford</td>
<td>402-6446</td>
<td>2107</td>
<td><a href="mailto:MLedford@niaid.nih.gov">MLedford@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Mary Kirker</td>
<td>402-6400</td>
<td>2115</td>
<td><a href="mailto:MKirker@niaid.nih.gov">MKirker@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Michael Frase</td>
<td>451-2677</td>
<td>2226</td>
<td><a href="mailto:MFrase@niaid.nih.gov">MFrase@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Michael Wright</td>
<td>451-2688</td>
<td>2118</td>
<td><a href="mailto:MAWright@niaid.nih.gov">MAWright@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Mike Fato</td>
<td>402-6581</td>
<td>2123</td>
<td><a href="mailto:MFato@niaid.nih.gov">MFato@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Mildred Qualls</td>
<td>402-6611</td>
<td>2125</td>
<td><a href="mailto:MMartinez@niaid.nih.gov">MMartinez@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Mollie Shea</td>
<td>402-6576</td>
<td>2234R</td>
<td><a href="mailto:MShea@niaid.nih.gov">MShea@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Quadira Huff</td>
<td>451-2696</td>
<td>2231</td>
<td><a href="mailto:HuffQ@niaid.nih.gov">HuffQ@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Roberta Wolcott</td>
<td>451-2685</td>
<td>2244</td>
<td><a href="mailto:WolcottR@niaid.nih.gov">WolcottR@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Shellie Wilburn</td>
<td>594-9676</td>
<td>2233</td>
<td><a href="mailto:SWilburn@niaid.nih.gov">SWilburn@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Susan Hickman</td>
<td>451-7379</td>
<td>2252R</td>
<td><a href="mailto:SHickman@niaid.nih.gov">SHickman@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Tamara Kees HPTN</td>
<td>496-7065</td>
<td>2227</td>
<td><a href="mailto:TKees@niaid.nih.gov">TKees@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Terri Jarosik</td>
<td>451-9892</td>
<td>2117</td>
<td><a href="mailto:TJarosik@niaid.nih.gov">TJarosik@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Theresa Mercogliano MTN</td>
<td>402-5512</td>
<td>2124</td>
<td><a href="mailto:TMercoglia@niaid.nih.gov">TMercoglia@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Tina Carlisle IMPAACT</td>
<td>402-6579</td>
<td>2121</td>
<td><a href="mailto:CarlislT@niaid.nih.gov">CarlislT@niaid.nih.gov</a></td>
</tr>
<tr>
<td>Victoria Connors</td>
<td>402-5065</td>
<td>2122</td>
<td><a href="mailto:ConnorsV@niaid.nih.gov">ConnorsV@niaid.nih.gov</a></td>
</tr>
</tbody>
</table>

### General Information:
- **Main Number:** 301-496-7075
- **Fax Numbers:** 301-493-0597 or 301-480-2599
- **Address:** 6700 B Rockledge Drive, Bethesda, MD 20892 or 20817 (express delivery) MSC 7614
GMP Contact Information

**HPTN Coordinator**
Tamara Kees  
Grants Management Program  
6700 B Rockledge Drive  
Room 2227  
Bethesda, MD  20892  
TEL:  301-496-7065  
Email:  TKees@niaid.nih.gov  
FAX:  301-493-0597 or 301-480-2599

**IMPAACT Coordinator**
Tina Carlisle  
Grants Management Program  
6700 B Rockledge Drive  
Room 2121  
Bethesda, MD  20892  
TEL:  301-402-6579  
Email:  CarlisIT@niaid.nih.gov  
FAX:  301-493-0597 or 301-480-2599
Rule of Thumb...

Whenever Principal Investigators are contemplating post-award changes and are uncertain about the need for prior approval, consult **in advance** with:

- Grants Management Specialist listed on the Notice of Award (NoA)
- Written policies and regulations
  (e.g.: NIH Grants Policy Statement)
When to contact us?

PRIOR APPROVALS

- Change in Principal Investigator
- Change of Grantee Institution or Research Sites
- Pre-Award costs more than 90 days
- Carryover of restricted funds
- Rebudgeting over 25% of Total Cost Awarded
- Undertaking activities disapproved or restricted as a term of award
- Change in Scope or Research Objectives
- Actions needing additional funding
- No-Cost Extensions beyond the first extension
Requests for Prior Approvals

- Submitted in writing via letter or email – include complete grant number, PI name and contact information, grantee name.
- Signed or sent by the Authorizing Official.
- Submitted to the awarding Institute/Center (IC) Grants Management Specialist no later than 30 days before the proposed change.
- Only responses to prior approval requests signed by the Grants Management Officer are valid.
QUESTION: Will the use of unobligated balances be allowed for ongoing trials?

ANSWER:

- Cooperative Agreements (U mechanisms) do **not** have automatic carryover authority of unobligated balances. Upon receipt of the annual FSR, the GMO and DAIDS Program Officer will analyze the unobligated balance shown and the funds needed for the current budget period. A decision will then be made to either:
  - a) revise the current NoA to authorize the grantee to spend the excess funds for additional approved purpose, or
  - b) Offset the current award or a subsequent award by an amount representing some or all of the excess.
QUESTION: On the Notice of Award, how does a site know how much funding is awarded per protocol (especially for those sites that may be actively participating across multiple Networks and studies)?

Each CTU should know how much they are receiving from each Network.

- Program Officer should be contacted for protocol specific information and dollars
- Grants Management issues grants based on submitted application not protocols
- Specific terms for protocol would be restrictive and decrease budget flexibility
Thank You

Lesia A. Norwood
Branch Chief & DAIDS GM Liaison
Grants Management Program
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
National Institutes of Health, DHHS
6700B Rockledge Drive, Rm. 2116
Bethesda, MD 20892
Tel: 301-402-7146
Fax: 301-493-0597
Email: ln5t@nih.gov
Comments or Questions?