Welcome to this video tutorial on Agent Transfers in the PMB Investigational Drug Accountability series. This video will review when and how to perform an agent transfer of PMB-supplied agents for DCTD-sponsored trials.
You can find the agent transfer form and other forms on the CTEP website.
PMB-supplied agents may be transferred from a DCTD-sponsored protocol to another DCTD-sponsored protocol for the same investigator or between eligible investigators within the same institution, also called an intra-institutional transfer. Transferring agents is not the same as transporting, which is moving agents back and forth between the control dispensing area and the satellite dispensing area, which does not require a formal transfer request. A transfer request between DCTD-sponsored protocols can only be considered if the protocols utilize the same agent, strength and formulation supplied by PMB. Except in situations of urgent medical need when PMB is not available, agent transfers require prior approval from PMB before the actual transfer occurs.
The form contains writable sections that may be typed out prior to printing for handwritten signature. Let’s discuss the three major portions of the form and what is required to successfully complete it from top to bottom.
Agent Transfer Form: Top Section Containing Transfer From Investigator and Transfer Reason

**Transfer Investigational Agent Form**

This form is to be used for an intra-institutional transfer, one transfer only.

<table>
<thead>
<tr>
<th>TRANSFER FROM:</th>
<th>CTEP Investigator ID:</th>
<th>Date of transfer:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator transferring agent:</td>
<td>Dr.</td>
<td></td>
</tr>
<tr>
<td>Name of institution:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Street Address:</td>
<td>City:</td>
<td>State:</td>
</tr>
</tbody>
</table>

Reason for transfer request: [ ] Protocol close to complete [ ] Unused agent obtained for Special Exception [ ] Agent has short duration [ ] Other**

(**Requires verbal clarification with PMB before approval)**

The top portion lists information about the investigator who is transferring the agent. The “Transfer From” investigator must be the investigator who either 1) originally ordered the agent or 2) was the “Transfer To” investigator on a previously PMB-approved transfer.
PMB-supplied agents may be transferred for various reasons. The more commonly accepted reasons are that:

1. The protocol is closed or completed and excess quantity of unused agent can be dispensed for another DCTD-sponsored protocol. This includes special exception protocols.
2. An agent with short dating can be used prior to the expiration date for another protocol.

Reasons that fall into the “other” category should be clarified with PMB before transfer request and may include the following:

1. A patient needs to be treated now and there is insufficient protocol supply to dispense or prepare a dose.
2. The control pharmacy or dispensing area relocates.
3. The responsible investigator at the site changes.
Agent Transfer Form: Middle Section Containing Transfer To Investigator and Agent Information

<table>
<thead>
<tr>
<th>TRANSFER TO:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator receiving agent:</td>
</tr>
<tr>
<td>Dr.</td>
</tr>
</tbody>
</table>

The following CTEP-supplied agent for NCI-approved protocol is being transferred to NCI-approved protocol:

<table>
<thead>
<tr>
<th>Received on NCI Protocol Number</th>
<th>Transferred to NCI Protocol Number</th>
<th>NSC Number</th>
<th>Agent Name</th>
<th>Strength and Formulation</th>
<th>Quantity</th>
<th>Manufacturer and Lot Number</th>
</tr>
</thead>
</table>

The middle portion lists information about the investigator to whom agent is being transferred. The remaining portion contains information about the protocols involved in the transfer and the agent that is being transferred. The agent being transferred must not be expired at the time of transfer. Only intact or whole units may be transferred. Check the shipment receipt for the specific unit or package multiplier information.
Agent Transfer Form: Bottom Section Containing Signature and Instructions for Submission to PMB

Authorized Signature (Investigator or Designee)

Printed Name

Telephone Number          Fax Number

Email Address

Return form to:
Pharmaceutical Management Branch, CTEP, DCTD
NCI Shady Grove
Room SW228, MSC 9725
9600 Medical Center Drive
Bethesda, MD 20892-9725

PMBAfterhours@mail.nih.gov

FAX: 240-276-7893


All requested information MUST be supplied for form to be valid.

The bottom portion of the form requires an authorized signature from either the investigator or designee of the investigator, either shipping or ordering designee. Transfer forms must be completely filled out to be considered for approval.
Agent Transfer Form: Bottom Section Containing Signature and Instructions for Submission to PMB

Completed forms must be submitted by fax or by email. Requests are usually responded to in the same business day. Mailing forms to PMB through the postal service is not recommended.
Here is a completed transfer form for Dr. John Smith. The request is made because NCI protocol 1234 closed and remaining pazopanib 200 mg tablets can be used on NCI protocol 2341.
The transfer request is approved because Dr. Smith is an active registered investigator at State University Hospital and both studies utilize PMB-supplied pazopanib 200 mg tablets. Here is the transfer approval letter from PMB that must be retained with the appropriate agent accountability records.
Approved transfers should be documented on the two DARFs that are involved in the transfer. The assigned transfer number can be recorded on the DARF for reference. Note the transfer must be made from the control record. Transfers cannot be documented on satellite records. For more about the responsibilities of control dispensing areas, refer to PMB’s “Policy and Guidelines for Investigational Agent Distribution.”

On the DARF for protocol 1234, line 16 shows documentation of an agent transfer made to NCI protocol 2341 for 10 bottles of pazopanib 200 mg tablets. Transfer number T14273-0001 was documented on the DARF and 10 bottles were subtracted from the balance for NCI protocol 1234.
On the DARF for protocol 2341, line 4 shows documentation of a transfer of 10 bottles pazopanib 200 mg tablets from protocol 1234. Notice that Dr. Smith was already the ordering investigator on study 2341 and a new DARF was not required. If Dr. Smith were not an ordering investigator for study 2341 previously, a new DARF would need to be created.
Circumstances may arise when a transfer is needed and PMB is not open for business. In these urgent cases, the transfer can be made without prior PMB approval. Transfer forms for urgent medical need should be submitted within 72 hours of the actual transfer. There is always a risk that the transfer will not be approved retroactively because it was not a valid transfer. Denied transfer requests should be documented on the DARF and kept with the appropriate agent accountability records.

Other special cases that are not urgent require prior PMB approval. Please call for transfer requests that include the following:

1. Transfer of agent between institutions (also known as inter-institutional transfer)
2. Relocation of control dispensing area
3. Patient-specific supplies
**Examples of Non-Valid Transfer Requests**

1. Agent being transferred is not the same strength or formulation between protocols
2. The “Transfer To” investigator does not have an active registration
3. The “Transfer To” investigator is not an eligible participant on the study
4. PMB-supplied agent is transferred to a non-DCTD-sponsored protocol
5. PMB-supplied agent is transferred for commercial use
6. Commercial agents are transferred to a DCTD-sponsored protocol
7. Borrowing from one protocol to supply another without an approved transfer
8. Transfer of partial containers
9. Transfer of patient-specific agents without prior PMB approval
10. Transfer requests to retrospectively correct errors in accountability

Examples of instances when agent transfer is NOT valid include:
1. Agent being transferred is not the same strength or formulation between protocols
2. The “Transfer To” investigator does not have an active registration
3. The “Transfer To” investigator is not an eligible participant on the study
4. PMB-supplied agent is transferred to a non-DCTD-sponsored protocol
5. PMB-supplied agent is transferred for commercial use
6. Commercial agents are transferred to a DCTD-sponsored protocol
7. Borrowing from one protocol to supply another without an approved transfer
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9. Transfer of patient-specific agents without prior PMB approval
10. Transfer requests to retrospectively correct errors in accountability
To learn more, please refer to the “Pharmaceutical Management Branch Policy and Guidelines for Investigational Agent Transfers” available here on the PMB website.
Thank you for watching this video tutorial. Additional PMB Investigational Drug Accountability videos are available through our YouTube Playlist. Please note that the video and any items displayed within the videos are subject to change. Check back periodically for updates. Questions can be directed to the Pharmaceutical Management Branch, CTEP, NCI by phone Monday through Friday from 8:30am to 4:30pm Eastern Time or by email any time.