Closeout Tasklist - Section 6. Human Subjects/IRB

Section Overview

At the time when the clinical research study is complete, the Closeout Tasklist must be completed in accordance with GAP 200.180, Closeout of Sponsored Projects. The Clinical Research Closeout Policy should be referenced throughout the closeout process.

About Section 6. Human Subjects/IRB

- A clinical research study involves research using human volunteers (also called participants) and is intended to add to medical knowledge.
- Human subjects research includes activities such as:
  - consenting patients to research studies
  - gathering a specimen for inclusion in a repository
  - analyzing research data
  - processing research patient charges
  - studying records or repositories to determine which option has the best outcome
  - interpreting institutional policies governing human subjects research

Determine the required subsection

- Determining the IRB category for your project ensures the appropriate Closeout Tasklist subsection (and associated questions related to human subjects research) is generated.
- You can determine the appropriate IRB subsection by reviewing the programmatic attribute, IRB review type, WBSE, and BFR for the project.

<table>
<thead>
<tr>
<th>Programmatic Attribute (ZF600)</th>
<th>IRB Review Board and Review Type (SPS)</th>
<th>BFR</th>
<th>Sponsor Type</th>
<th>WBSE</th>
<th>Required Tasklist Subsection</th>
</tr>
</thead>
<tbody>
<tr>
<td>SCE - Sponsored Clinical Research w/ Exempt IRB</td>
<td>MEDICAL CENTER IRB Exempt&lt;br&gt;6840XXXXXXX&lt;br&gt;6860XXXXXX</td>
<td>Non-Industry Industry</td>
<td>20x-29x&lt;br&gt;30x-39x</td>
<td>6.A. Exempt</td>
<td></td>
</tr>
<tr>
<td>SRF - Sponsored Research Federal&lt;br&gt;SRN - Sponsored Research Non-Government</td>
<td>CAMPUS IRB Full Board Review Expedited Review Exempt&lt;br&gt;60XXXXXX</td>
<td>Non-Industry Industry</td>
<td>20x-29x&lt;br&gt;30x-39x</td>
<td>6.B. Campus IRB</td>
<td></td>
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<tr>
<td>SCI - Sponsored Clinical Research w/ IRB</td>
<td>MEDICAL CENTER IRB Full Board Review Expedited Review&lt;br&gt;60XX0XXXXXX&lt;br&gt;6840XXXXXXX&lt;br&gt;6860XXXXXX</td>
<td>Industry</td>
<td>28x-29x&lt;br&gt;38x-393</td>
<td>6.C. Non-Industry Sponsored Clinical Research</td>
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<tr>
<td>SCI - Sponsored Clinical Research w/ IRB</td>
<td>MEDICAL CENTER IRB Full Board Review Expedited Review&lt;br&gt;6840XXXXXXX&lt;br&gt;6860XXXXXX</td>
<td>Industry</td>
<td>20x-28x&lt;br&gt;30x-38x</td>
<td>6.D. Industry Sponsored Clinical Research</td>
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</tr>
<tr>
<td>SCI - Sponsored Clinical Research w/ IRB&lt;br&gt;SDC - Coordinating Center Clinical Research</td>
<td>MEDICAL CENTER IRB Full Board Review Expedited Review&lt;br&gt;686050XXXX&lt;br&gt;6860450XXX</td>
<td>Non-Industry Industry</td>
<td>20x-29x&lt;br&gt;30x-39x</td>
<td>6.E. DCRI / DTMI</td>
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<tr>
<td>SNC - Sponsored Non Clinical Research&lt;br&gt;SRF - Sponsored Research Federal&lt;br&gt;SRN - Sponsored Research Non-Government</td>
<td>None</td>
<td>All</td>
<td>Non-Industry Industry</td>
<td>20x-29x&lt;br&gt;30x-39x</td>
<td>N/A</td>
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</tbody>
</table>

Programmatic Attribute: programmatic attribute designates the mission of a WBSE (Education, Clinical Service, Sponsored Research, Department Research, Administration, Other).

IRB Review Board and Review Type: all human subjects research review is done either through Medical Center or Campus IRB and is required to complete IRB review prior to project start.

WBSE (Fund Code): hierarchical model of a project that can be split into manageable units and have attributes that help to further categorize based on Project Type, Responsible Person, Funding Type, etc.

BFR (Budget & Financial Reporting Code): the BFR code is a series of ten digit codes within the general ledger that provides a five level organizational hierarchy structure. Every cost object at Duke is linked to a BFR code within the hierarchy.

Sponsor Type: all externally funded sponsored human subjects research will be funded by either Non-Industry or Industry Sponsors.

Required Tasklist Subsection: human subjects research closeout tasks are determined by the IRB type associated with the project.
Determining Programmatic Attribute

- SAP transaction ZF600 and the Protocol Tab in SPS Web will give the research administrator some key data needed to assist with determining the IRB category for the project closeout.
  - ZF600 identifies the programmatic attribute assigned to each specific WBSE
  - SPS Web Protocol Tab identifies the type of IRB review assigned to the project

1. In the SAP GUI, launch transaction ZF600. Enter applicable WBSE(s) into the ‘Project Selection’ field and the current fiscal period into the ‘Fiscal Period’ field and execute the transaction (F8).

2. A row displays for each WBSE entered. Scroll to the right until the last column, ‘PRGM ATTR’ is visible.

<table>
<thead>
<tr>
<th>DEPT</th>
<th>ORA</th>
<th>PreAwdOtc</th>
<th>Spon DueDt</th>
<th>OSP Due Date</th>
<th>LOC ATT</th>
<th>PRGM ATTR</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEPT</td>
<td>A</td>
<td>ORA</td>
<td>08/29/2016</td>
<td>07/30/2016</td>
<td>YG</td>
<td>SCI</td>
</tr>
</tbody>
</table>

**A. Programmatic Attribute:** Programmatic Attribute designates the mission of a WBSE (Education, Clinical Service, Sponsored Research, Department Research, Administration, Other).
- SCI: Sponsored Clinical Research w/ IRB
- SCE: Sponsored Clinical Research w/ Exempt IRB
- SDC: Coordinating Center Clinical Research
- SNC: Sponsored Non Clinical
- SRF: Sponsored Research Federal
- SRN: Sponsored Research Non-Government

Determining IRB Review

- At time of pre-award preparation, SPS is used to identify whether human subjects will be part of the proposed project. Upon award, the IRB protocol number and review type should be updated in SPS.

1. In the SPS Web Proposal Module, enter the WBSE into the ‘WBS Element’ field and select the ‘Search’ button.

2. A row displays below the search criteria for each proposal matching the WBSE.

   Find the appropriate proposal and select the ‘Go to…’ drop-down menu on the left of the row. Then select ‘Protocols’ in the list of options in the drop-down.

3. IRB information is displayed for the proposal. ‘Review Type’ is displayed toward the right side of the window.

**A. Review Board – Medical Center or Campus IRB Review**
**B. Review Type**
- Full IRB: Full Board Review-Research that does not qualify for expedited or exempt review and/or presents more than minimal risks to subjects
- Expedited Review: Research that can be approved as ‘expedited’ if it is no more than ‘minimal risk’ and fits in one of 9 federally designed expedited review categories
- Exempt: Research that can be approved as ‘exempt’ if it is no more than ‘minimal’ risk and fits into one of 6 federally designated exempt review categories
The expectation of clean close is that all allowable expenses are posted to the ledger when closeout documentation is submitted to closeoutdocs@duke.edu. The workflow status reports support clean close, providing users visibility into transactions in workflow that have not yet posted in order to determine appropriate action to facilitate approvals/resolve issues in a timely fashion.

**About the Workflow Status Reports**

- This guide covers 4 reports: Workflow Status Report, Workflow Status Report by Cost Object, iForms Workflow Status Report, & iForms Workflow Status by Cost Object
- Reports provide important status related information including the transaction type, current person(s) able to approve the transaction, how long it has been in the current workflow step, when it was initially created, and other transaction details.
- Report data is updated every 30 minutes and should not be used to manage deadlines.
- Reports can be filtered to display specific transaction types.
- Reports can be run by multiple cost objects/org. units (appropriate access required).
- Cost Object-based reports include only those transactions which were initiated or have moved in workflow as of 10/14/15. Run the BFR-based reports to view transactions initiated prior to 10/14/15 without workflow activity after 10/13/15.

### Transaction Type & Availability
(Transaction becomes visible on designated report at point indicated below)

<table>
<thead>
<tr>
<th>Transaction Type</th>
<th>Workflow Status Report</th>
<th>Workflow Status Report by Cost Object</th>
<th>iForms Workflow Status Report</th>
<th>iForms Workflow Status by Cost Object</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accounts Payable Check Requests (APCR)</td>
<td>Submitted</td>
<td>Submitted</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accounts Receivable (AR)</td>
<td>Completed*</td>
<td>Completed*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Online Expense Reports (Travel)</td>
<td>Submitted</td>
<td>Submitted</td>
<td></td>
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</tr>
<tr>
<td>Electronic Research Administration (ERA)</td>
<td>Saved as Draft/Submitted</td>
<td>Saved as Draft/Submitted</td>
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<td></td>
</tr>
<tr>
<td>Journal Entries/Vouchers (JV)</td>
<td>Completed*</td>
<td>Completed*</td>
<td></td>
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<td>Accounts Payable Vendor Invoices (APInv)</td>
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<tr>
<td>Buy@Duke (B@D)</td>
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<td>Saved as Draft/Submitted</td>
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<td></td>
</tr>
<tr>
<td>Security Administration Requests (Security)</td>
<td>Submitted</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Faculty System (dFAC)</td>
<td></td>
<td></td>
<td>Saved as Draft/Submitted</td>
<td>Saved as Draft/Submitted</td>
</tr>
<tr>
<td>iForms</td>
<td></td>
<td>Saved as Draft/Submitted</td>
<td>Saved as Draft/Submitted</td>
<td></td>
</tr>
</tbody>
</table>

### Report Location
(Access to tabs on Duke@Work is restricted by security role)

<table>
<thead>
<tr>
<th>Report Location</th>
<th>Workflow Status Report</th>
<th>Workflow Status Report by Cost Object</th>
<th>iForms Workflow Status Report</th>
<th>iForms Workflow Status by Cost Object</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duke@ Work - iForms Tab - Reporting</td>
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<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Duke@ Work - Grants Mgmt. Tab – Effort and Payroll Tools &amp; Reports</td>
<td></td>
<td></td>
<td></td>
<td>✔️</td>
</tr>
<tr>
<td>Duke@ Work - Grants Mgmt. Tab – Sponsored Research Reporting</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duke@ Work - Finance Tab – Financial Reports</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*‘Completed’ does not indicate final approval of the transaction. ‘Completed’ indicates that the transaction has entered workflow.*
Workflow Status Reports

Workflow Status Report

The Workflow Status Report displays transactions currently in workflow based on the BFR/Org Unit of the transaction.

1. Navigate to the Workflow Status Report on Duke@Work via the “Grants Management” tab or the “Finance” tab. The report may take time to load. Multiple pop-ups may display during loading.

   **Via Grants Management Tab**
   Select the “Grants Management” tab, followed by the “Sponsored Research Reporting” link. On the resulting page, select the “Workflow Status Report” link to launch the report.

   **Via Finance Tab**
   Select the “Finance” tab, followed by the “Financial Reports” link. On the resulting page, select the “Workflow Status Report” link and then “Workflow Status Report” again to launch the report.

2. When the “Prompts” window displays, (A) select the “Refresh Values” button to display the Organizational Hierarchy or (B) use the search to display a list of matching BFR’s. If using the search, place the wildcard asterisk * at the end of the BFR entered or no results will display (i.e. 6860201*).

3. Select an item from the hierarchy or search results list. Then select the right arrow “>” button to add the BFR to the report. It will display in the right box on the “Prompts” window. Repeat to add any additional BFR.

4. Select the “Run Query” button to generate the report.

**Additional Options**

- **Option 1**: Use the Input Controls button to access transaction type filters.
- **Option 2**: Use the Export button to save the report in Excel format.
- **Option 3**: Use the Refresh button to update the results or modify the report selections.
Workflow Status Reports

Workflow Status Report by Cost Object

The Workflow Status Report by Cost Object displays transactions currently in workflow based on the cost object associated with the transaction.

1. Navigate to the Workflow Status Report by Cost Object on Duke@Work via the “Grants Management” tab or the “Finance” tab.

- **Via Grants Management Tab**: Select the “Grants Management” tab, followed by the “Sponsored Research Reporting” link. On the resulting page, select the “Workflow Status Report by Cost Object” link.

- **Via Finance Tab**: Select the “Finance” tab, followed by the “Financial Reports” link. On the resulting page, select the “Workflow Status Report” link and then “Workflow Status Report by Cost Object” to launch the report.

2. Enter cost object(s) into the text box and select the “Go” button. If entering multiple cost objects (either by typing or pasting), ensure that each cost object appears on a new line in the text box (see “A” below).

Addition Options

1. Use the “Show/Hide History” button to view/access cost objects utilized in your previous report runs.

2. Use the Input Controls button to access the transaction type filters.

3. Use the Export button to save the report in Excel format.

4. Use the Refresh button to update the results or modify the report selections.

**Additional Options (Continued)**

- **A. Typing multiple entries**: Press the “Enter” or “Return” key after typing each cost object so that each cost object appears on a new line.

- **Option 2**: Use the Input Controls button to access the transaction type filters.

- **Option 3**: Use the Export button to save the report in Excel format.

- **Option 4**: Use the Refresh button to update the results or modify the report selections.

**Workflow Status by Cost Object**

**Enter or Paste Cost Objects:**

- 2031324
- 2036789
- 2038525
- 2039856

**Workflow Status by Cost Object**

**Enter or Paste Cost Objects:**

- 3834444
- 2035555

**Additional Options**

- **Show/Hide History**: Displays or hides cost object listing from prior report runs.
- **Clear All History**: Permanently removes history of all prior report runs.
- **Delete Row**: Delete corresponding row from history.
- **Select Row**: Populates cost object text box with cost objects listed in selected row.

**Cost Object Details**

<table>
<thead>
<tr>
<th>Cost Object</th>
<th>ID</th>
<th>Type</th>
<th>Org</th>
<th>BFR Cost Cent</th>
</tr>
</thead>
<tbody>
<tr>
<td>3834444</td>
<td>1100123456</td>
<td>Travel</td>
<td>50000803</td>
<td>6860101000</td>
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<td>2035555</td>
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<td>Travel</td>
<td>50000803</td>
<td>6860101000</td>
</tr>
</tbody>
</table>

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Workflow Status Reports

iForms Workflow Status Report

The iForms Workflow Status Report displays payroll related transactions currently in workflow based on the BFR/Org Unit of the transaction.

1. Navigate to the iForms Workflow Status Report on Duke@Work via the “iForms” tab, followed by the “Reporting” link. On the resulting page, select the “iForms Workflow Status Reporting” link and then “iForms Workflow Status by Cost Object.” The report may take time to load. Multiple pop-ups may display during loading.

2. When the “Prompts” window displays, (A) select the “Refresh Values” button to display the Organizational Hierarchy or (B) use the search to display a list of matching BFR’s. If using the search, place the wildcard asterisk * at the end of the BFR entered or no results will display (i.e. 6860201*).

3. Select an item from the hierarchy or search results list. Then select the right arrow “>” button to add the BFR to the report. It will display in the right box on the “Prompts” window. Repeat to add any additional BFR.

4. Select the “Run Query” button to generate the report.

Additional Options

1. Use the Input Controls button to access transaction type filters.
2. Use the Export button to save the report in Excel format.
3. Use the Refresh button to update the results or modify the report selections.

Select an item from the hierarchy or search results list. Then select the right arrow “>” button to add the BFR to the report. It will display in the right box on the “Prompts” window. Repeat to add any additional BFR.
Workflow Status Reports

iForms Workflow Status by Cost Object

The iForms Workflow Status by Cost Object displays payroll related transactions currently in workflow based on the cost object associated with the transaction.

1. Navigate to the iForms Workflow Status by Cost Object Report on Duke@Work via the “Grants Management” tab or the “iForms” tab.

Via Grants Management Tab
Select the “Grants Management” tab, followed by the “Effort and Payroll Tools and Reports” link. On the resulting page, select the “Grants Manager iForms Workflow Status by Cost Object.”

Via iForms Tab
Select the “iForms” tab, followed by the “Reporting” link. On the resulting page, select the “iForms Workflow Status Reporting” link and then “iForms Workflow Status by Cost Object.”

2. Enter cost object(s) into the text box and select the “Go” button. If entering multiple cost objects (either by typing or pasting), ensure that each cost object appears on a new line in the text box (see “A” below).

Enter or Paste Cost Objects:

GM iForms Workflow Status by Cost Object

2031324
2036789
2038525
2039856

A. Typing multiple entries: Press the “Enter” or “Return” key after typing each cost object so that each cost object appears on a new line.

Additional Options

Additional Options (Continued)

Use the Input Controls button to access transaction type filters.

Use the Export button to save the report in Excel format.

Use the Refresh button to update the results or modify the report selections.
**Quick Reference**

**ZF114 – Transactions After End Date**

The ZFI14 is a tool that provides communication from departments to the Office of Sponsored Programs (OSP) in order to facilitate accurate and timely reporting and/or invoicing, and ultimately the closeout of sponsored projects.

**The ZF114 & Clean Close**

- Submission of the ZF114 by the department is confirmation that all transactions listed on the ZF114 contribute to the generation of the final invoice/report.
- Departments are responsible for initiating any required corrections prior to submitting the ZF114.
- Any corrections or anticipated transactions which have not yet posted must be entered manually by the department on the ZF114 to be included on the final invoice/report to the sponsor.
- Any debit posted to the WBSE after the end date, and not captured on the ZF114 will be assumed unallowable and not included on the final invoice/report. (resolution window available).
- Any credit posted to the WBSE after the end date, and not captured on the ZF114 will be considered allowable and included on the final invoice/report.

**About the ZF114**

The ZF114 must be submitted via email in Excel format (no signature required). PDF documents are not accepted.

**Corrections in Workflow/Anticipated Charges**

The ZF114 should not be submitted until corrections are at least initiated in order to be considered when the final report/invoice is prepared. Corrections currently in workflow or approved and waiting to post (i.e., personnel adjustments) are entered manually as new line items when completing the ZF114. Any other anticipated expenses must also be entered as new line items.

**Posted Corrections**

Since the goal of clean close is for all transactions to post to the ledger prior to closeout submission, administrators are encouraged to be proactive with adjustments. If no corrections are needed, or all required corrections post to the ZF114 prior to submission, no manual entries to the ZF114 are necessary.

**Executing in SAP & Saving**

The ZF114 file is generated using the ZF114 transaction in SAP and can be saved directly to your computer when the transaction is executed.

1. Enter the WBSE of the project which is closing in the “Project” field on the ZF114 transaction screen in SAP.

2. Enter the Fiscal Year and Fiscal Period following the project end date in the corresponding fields. For example, if your project ends 12/31/2015 (Fiscal Year 16, Fiscal Period 6) you would enter Fiscal Year 2016, Fiscal Period 7. It is important to ensure that the proper Fiscal Year and Fiscal Period are entered in order for the ZF114 file to generate correctly.

3. The ZF114 must be submitted in Excel format. The “Enable Download” checkbox should be checked by default. To save the file to your computer, ensure that the “Enable Download” checkbox is checked. Then choose a directory to export the file and ensure that the file name ends with the “.xls” file extension.

4. Execute the transaction to generate the ZF114 file. The file will be saved to the directory entered in Step 3.
ZF114 – Transactions After End Date

Prepping the Excel File
The first time the ZF114 file is opened, additional formatting is required for the content (credit signs) to display properly. The steps required to prep the file will vary based upon the method used to open the file.

Option A: Opening the file from within Excel
If you open the file from within Excel, the Text Import Wizard will display automatically the first time the file is opened, allowing you to properly format the file.

1. Launch Excel on your computer if it is not already open.
2. In Excel, select “File” then “Open” to find the ZF114 file in the directory where it was saved.
3. If a prompt appears, warning the file is in a different format than specified by the extension, select “Yes” to open the file.
4. The Text Import Wizard will display. Select the “Delimited” radio button.
5. Select the “Finish” button to complete the wizard.

Option B: Opening the file directly
If you open the file directly from the desktop, a local folder/directory, or network file path, you will need to manually launch the Convert Text to Columns Wizard to format the file.

1. Find the ZF114 file by searching or navigating to the location it was saved and select the file to open in Excel.
2. If a prompt appears, warning the file is in a different format than specified by the extension, select “Yes” to open the file.
3. Select all cells in the “Amount” column.
4. Select “Data” then “Text to Columns” in the Excel Ribbon/Menu to display the Convert Text to Columns Wizard.
5. The Text Import Wizard will display. Select the “Delimited” radio button.
6. Select the “Finish” button to complete the wizard.
ZN14 – Transactions After End Date

**Anatomy of a ZN14**

All transactions listed on the ZN14 will be included in the final report/invoice. Required adjustments which do not appear on the ZN14 when generated must be entered manually as new rows.

**Monthly Process Implications**

Transactions appearing on the ZN14 are impacted by the timing of monthly central office processes. It is important to consider whether all applicable central postings have been completed when the ZN14 is generated or whether manual entries to the ZN14 are required to reflect upcoming transactions (i.e. if payroll posts, is all applicable fringe and cost share on ZN14?).

**Entering Corrections in Workflow**

Correctations which have not yet posted when you are ready to submit closeout documentation and therefore do not appear when the ZN14 is generated may be entered manually by adding additional line items to the bottom of the ZN14 report. Transactions must be initiated prior to inclusion on the ZN14 report in order to obtain the required Document Number.

**Example: Payroll Correction**

A. **Transactions Requiring Correction**: Existing rows for payroll and associated fringe postings, generated automatically during ZN14 file creation.

B. **New Correction Lines (Manual Entry)**: New rows entered manually by user to provide information about corrections to payroll and associated fringe.

Fields Requiring Manual Entry: Doc Number, G/L Account, Charge Description (CORRECTION), Amount

C. **Document # of Correction (Manual Entry)**: In the rows for the original transaction requiring correction, enter the Document Number of the correction in the “Document # of Transaction in Workflow” column. This allows OSP to identify the related transaction on the ZN14.
ZF114 – Transactions After End Date

Entering Anticipated Expenses

A new row is entered for each anticipated expense. Unlike corrections, depending on the expense type, the Document Number may not be known when entering anticipated expenses. Since there is no original transaction being corrected, the document number does not need to be entered next to one of the existing rows generated on the ZF114.

Example 1: Cost Share Transfers
In the example below, the ZF114 is generated prior to Cost Share Transfer (GL 808000) posting. If the closeout documentation is due prior to the Payroll Cost Share Transfer posting, a new line is entered manually as an anticipated transaction. The Doc Number is not known because the transaction is not posted by the department.

Example 2: Tuition Remission & Tuition Remission Cost Share
In the example below, the ZF114 is generated prior to Tuition Remission (Average Rate Basis) posting and it has been determined that the tuition remission must be cost shared. If the closeout documentation is due prior to the Tuition Remission posting, new lines are entered manually as anticipated transactions for Tuition Remission and Tuition Remission Cost Share associated with the Ph.D. Graduate Student payroll.