### Closeout Tasklist - Section 6. Human Subjects/IRB

**Section Overview & Subsection D. Industry Sponsored IRB**

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 (2F600)</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>
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<tbody>
<tr>
<td>SCE - Sponsored Clinical Research w/ Exempt IRB</td>
<td>MEDICAL CENTER IRB Exempt</td>
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<td>Non-Industry</td>
<td>20x-29x 30x-39x</td>
<td>6.A. Exempt</td>
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<tr>
<td>SRF - Sponsored Research Federal</td>
<td>CAMPUS IRB Full Board Review</td>
<td>600000000X</td>
<td>Non-Industry</td>
<td>20x-29x 30x-39x</td>
<td>6.B. Campus IRB</td>
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<tr>
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<td>Non-Industry</td>
<td>20x-28x 30x-38x</td>
<td>6.C. Non-Industry Sponsored Clinical Research</td>
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<td>SCI - Sponsored Clinical Research w/ IRB</td>
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<td>Non-Industry</td>
<td>20x-29x 30x-39x</td>
<td>6.E. DCRI / DTMI</td>
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<tr>
<td>SNC - Sponsored Non Clinical Research</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>SRF - Sponsored Research Federal</td>
<td>None</td>
<td></td>
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<tr>
<td>SRN - Sponsored Research Non-Government</td>
<td>All</td>
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</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.
Closeout Tasklist - Section 6. Human Subjects/IRB Guidance on choosing appropriate subsection

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>A</th>
<th>ORA</th>
<th>08/29/2016</th>
<th>07/30/2016</th>
<th>YG</th>
<th>SCI</th>
</tr>
</thead>
</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 with IRB
- SCE: Sponsored Clinical Research with 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
Closeout Tasklist – Section 6. Human Subjects
Subsection D. Industry Sponsored IRB

D. Industry Sponsored IRB

- Subsection D should be used for all industry sponsored clinical research projects.
- The Clinical Research Closeout Policy outlines the process and requirements for closing out an industry sponsored study and the approvals required to completion of the financial closeout.
  - Close-out cannot happen until all queries are addressed, data is analyzed, publications are submitted, documentation is stored, and the study is closed with the IRB.
  - In this phase, tasks are generally dependent on previous tasks and tend to fall into a time order.
- Once CRU approval is obtained on the Closeout Tasklist, the tasklist should be submitted to the Duke Office of Clinical Research (DOCR) using the docr-ctgov@dm.duke.edu email address.
  - DOCR will review, approve, and sign the form and then forward to School of Medicine Finance (SOMF) for review and approval.
  - SOMF will return a signed copy of the form to the CRU copying DOCR.

<table>
<thead>
<tr>
<th>D. Industry Sponsored Clinical Research</th>
<th>Yes</th>
<th>In-Progress</th>
<th>N/A</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Human Subjects/IRB included in study/award</td>
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</tbody>
</table>

6.D.1 If the IRB Protocol will remain active after the closing of this WBSE, the WBSE has been changed in Maestro via a Service Now ticket.

If the IRB will remain open either for active enrollment or data analysis, but the WBSE is expiring, a new fund code must be listed in Maestro for any anticipated/unanticipated expenses related to study activity. These may include charge corrections, insurance refunds, project charges, ongoing study activity. This change is accomplished by submitting a fund code change to Maestro through a Service Now ticket. Listing the Sponsor type (e.g., Industry) and indicating a WBSE change helps PRMO prioritize the request for quick turn around.

1. Log in to Duke Service Now and select the 'Service Request Catalog' link in the Self-Service menu.
2. Select the ‘Create a New Incident’ link.

6.D.2 If the IRB Protocol will remain active after the closing of this WBSE, the funding source amendment has been submitted in eIRB.

If the IRB will remain open either for active enrollment or data analysis, but the WBSE is ending, an eIRB expeditable amendment should be filed to reflect a funding source change. This may also include a consent form update. This is found in Section 04 in the eIRB and is typically turned around within 24-48 hours after PI approval.

For additional assistance, contact the Research Practice Manager (RPM) within your SoM/SoN Clinical Research Units (CRUs) for guidance.
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Subsection D. Industry Sponsored IRB

6.D.3 If the IRB Protocol will be closing, the WBSE has been closed in Maestro via a Service Now ticket.

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>Log in to Duke Service Now and select the ‘Service Request Catalog’ link in the Self-Service menu.</td>
</tr>
<tr>
<td>2</td>
<td>Select the ‘Create a New Incident’ link.</td>
</tr>
</tbody>
</table>

6.D.4 If the IRB Protocol will be closing, the “Final Progress Report for Closure of an IRB-Approved Study” form has been submitted to and approved by the IRB.

The study must meet the following criteria in order for the IRB Protocol to be closed:
- The research is permanently closed to enrollment
- All participants have completed all research-related interventions
- Collection of identifiable private information is completed
- Analysis of identifiable private information is completed

Closing the IRB Protocol is completed through the eIRB and is typically handled by the clinical research staff or study PI associated with the project. For additional assistance, contact the Research Practice Manager (RPM) within your SoM/SoN Clinical Research Units (CRUs) for guidance.

6.D.5 Maestro Report AMB559, “All Patients Enrolled in a Clinical Trial”, has been processed.

The clinical research staff associated with the study are responsible for ensuring the review and accuracy of the list of enrolled study participants on the study protocol. This is managed through the AMB559 report within Maestro. Upon study completion, the clinical research staff should review the AMB559 report, verifying that all study participants that signed a consent form have been appropriately associated with the study and their current enrollment status has been updated to reflect the final study participation status (i.e., Completed, Terminated, Excluded). For additional assistance, contact the Research Practice Manager (RPM) within your SoM/SoN Clinical Research Units (CRUs) for guidance.
Closeout Tasklist – Section 6. Human Subjects
Subsection D. Industry Sponsored IRB

6.D.6 │ Maestro Report RSH010A, “Research FPM Payment Reconciliation”, has been processed.

The purpose of the Research FPM Payment Reconciliation Report (RSH010A) is to determine if the service activities for the patient, which posted to the fund code within SAP/R3, are accurate and have been reviewed by the PRMO and/or the clinical research study staff, to allow for proper reconciliation of the payments and/or payment reversals recorded in SAP/R3. For additional assistance, contact the Financial Practice Manager (FPM) within your SoM/SoN Clinical Research Units (CRUs) for guidance.

Maestro RSH010 Financial Recon Guidance

6.D.7 │ Maestro Report RSH005, “Patients Needing Coordinator Review”, has been processed.

This report enables a CRC to review patient charges and services to ensure that the charge is directed correctly to insurance, an insurance-research related fund code, or a research fund code. Remember that the charges will not display on this report until a biller has reviewed the charge. The CRC marks each service as reviewed. For additional assistance, contact the Research Practice Manager (RPM) within your SoM/SoN Clinical Research Units (CRUs) for assistance, verification, and guidance.

Maestro RSH005 Review Tip Sheet

6.D.8 │ Within the Duke ClinCard system, all study participant payments have been reconciled, and the study has been marked “COMPLETE”.

Duke University implemented a new system called “ClinCard” that uses a debit card system to compensate study participants for their involvement in clinical studies. This card system replaces the need for issuing checks or providing gift cards to study subjects, as well as enhancing the security around the Social Security Numbers needed to process a check. Research administrators (grant manager/FPM) are able to easily confirm if the new system is being used for their specific project by reviewing the ZFR1E report in SAP and search for the following specific cost elements that are attributable directly to the ClinCard system:

622510 Experimental Subject payments - ClinCard program / 622520 Experimental Subject Load Fees / 622530 Experimental Subject Card Fees

For additional assistance, contact the Financial Practice Manager (FPM) within your SoM/SoN Clinical Research Units (CRUs) for guidance.

1 Users (must have Administrator access): Log into the ClinCard System and select the ‘Edit Study’ button.

2 Select the appropriate study using the ‘Program’ and ‘Study’ drop-downs. Then select the ‘Submit’ button.

3 Update the ‘Study Status’ field to ‘Completed.’

Program:
Duke University ClinCard

School of Medicine Test Study

Study ID (optional):

Description (optional):

SSN Requirement Options:
Optional

Inhials:

Study Logo Image:
Choose File: No file chosen

Study Status:
Completed

Sponsor:

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6.D.9  All sponsor study requirements have been met (i.e., site closeout visit, sponsor queries, return/destruction of investigational products, etc).

Study close-out procedures are procedures undertaken to fulfill administrative, regulatory, and human subjects requirements after all aspects of the study has been completed. Despite the fact that all data has been collected, close-out cannot happen until all queries are addressed and the data is analyzed. If there is a chance of revisiting a study, the study should remain open.

Sponsored study closeout activities are performed to confirm that the site investigator’s study obligations have been met. Closeout activities verify that study procedures have been completed, data collected, and if relevant, study intervention is returned to the responsible party or prepared for destruction.

Per DUHS policy, all research records must be retained for at least six years beyond completion of all data collection, analysis, and submission of the IRB closing progress report. Research records involving minor subjects must be retained until the youngest child on the study is 21 years old or six years following completion of the study, whichever is longer. Review your contracts to make sure you are retaining records for the amount of time agreed upon in the contract. The retention obligation in the contract may extend beyond the six year period required by DUHS policy.

**Investigational Drug Services**: Unless you notify IDS that he project will no longer be using the study drug and request that IDS contact the sponsor for drug return, IDS monthly maintenance fees will continue to accrue until the drug is removed.

For additional assistance, contact the Research Practice Manager (RPM) within your SoM/SoN Clinical Research Units (CRUs) for guidance.

6.D.10  Clinicaltrials.gov listing has been updated.

The Food and Drug Administration Amendments Act of 2007 requires reporting of results and adverse events for applicable clinical trials within one year of the study’s primary outcome completion date.

ClinicalTrials.gov is a national web registry of federally and privately supported research studies conducted in the US and around the world. DOCR acts as the system administrator for ClinicalTrials.gov at Duke.

Failure to post study results is considered out of compliance with FDA regulations and significant monetary or other penalties could be imposed. In addition, approval of new studies in the IRB may be held until the PI submits the required results in ClinicalTrials.gov.

For additional assistance, contact the CT.gov team in DOCR at docr-ctgov@dm.duke.edu.

6.D.11  All earned revenue has been received and reconciled.

The research administrator (grant manager/financial practice manager) assigned to monitor the day to day financial activities related to the industry sponsored clinical research project is responsible for:

- validating the amount of earned revenue
- coordinating with the study team regarding invoiceable activities
- analyzing the sponsor payments
- contacting the study sponsor to understand any variances
- all check depositing is validated and correct in SAP
- monitoring accounts receivable

For additional assistance, contact the Financial Practice Manager (FPM) within your SoM/SoN Clinical Research Units (CRUs) for guidance.
6. D.12

All expenses are accurate and accounted for (including effort and Maestro as appropriate).

The research administrator (grant manager/financial practice manager) assigned to monitor the day to day financial activities related to the industry sponsored clinical research project is responsible for the post award management activities related to transaction analysis, revenue and expense monitoring, working with study teams to track subject activity & milestones, matching contract payment terms and determining earned revenue for individual studies, determining monthly accrual amounts, ensuring appropriate effort assignment, and compliance with institutional standards. According to GAP 200.012 - Reconciliation of Financial Transactions, financial transactions must be verified (reconciled) on a monthly basis.

Once the study team attests that the study is complete, the research administrator should work with the Financial Practice Manager and Research Practice Manager of their SoM/SoN Clinical Research Units (CRUs) to finalize fund code closeout, including completing the final financial reconciliation and obtaining necessary approval signatures.

1. Final Financial Reconciliation

<table>
<thead>
<tr>
<th>A. Total Rev. Rcvd</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>$</td>
<td></td>
</tr>
<tr>
<td>B. Total Residual</td>
<td></td>
</tr>
<tr>
<td>$</td>
<td>to Cost Object: $</td>
</tr>
<tr>
<td>C. Disposition of Residual / Coverage of Overdraft</td>
<td>$</td>
</tr>
<tr>
<td>D. SOM Assessment from Residual Transfer to Discretionary Code</td>
<td>$</td>
</tr>
</tbody>
</table>

A. **Total Rev. Rcvd**: Indicate total revenue received and posted to the general ledger. This is verified within SAP/R3

B. **Total Residual**: Indicate the remaining funds after all study related expenses have posted to the general ledger, including F&A costs

C. **Disposition of Residual / Coverage of Overdraft**: Per Clinical Research Unit/departmental policy, indicate the amount and WBSE/cost object for the disposition of residual funds or coverage of study overdraft

D. **SOM Assessment**: The School of Medicine Finance Office will determine the assessment amount based on the current Clinical Research Closeout Policy and complete the entries via Journal Voucher within SAP/R3

2. Industry Sponsored Clinical Research Approvals

<table>
<thead>
<tr>
<th>Industry Sponsored Clinical Research Approvals</th>
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<tbody>
<tr>
<td><img src="CRU" alt="CRU Finance Practice Manager (or Primary Grant Manager)" /></td>
</tr>
<tr>
<td><img src="CRU" alt="CRU Research Practice Manager (or Asst Research Practice Manager or CRC III Lead)" /></td>
</tr>
<tr>
<td><img src="DOCR" alt="DOCR Office" /></td>
</tr>
<tr>
<td><img src="SOM" alt="SOM Finance Office" /></td>
</tr>
</tbody>
</table>

- PI Attestation and signatures (eConfirmation encouraged) of the Research Practice Manager and Financial Practice Manager are required.
- Established processes within the Department/Center/Institute should also be followed.
- For additional assistance, contact the Financial Practice Manager (FPM) within your SoM/SoN Clinical Research Units (CRUs) for guidance.
- The Closeout Tasklist should be submitted to DOCR at docr-ctgov@dm.duke.edu
- Additional information may be found in the Clinical Research Closeout Policy