Closeout Tasklist - Section 6. Human Subjects/IRB
Section Overview & Subsection C. Non-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:
  - consent 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>
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</thead>
<tbody>
<tr>
<td>SCE - Sponsored Clinical Research w/ Exempt IRB</td>
<td>MEDICAL CENTER IRB Exempt</td>
<td>6840XXXXXXX</td>
<td>Non-Industry</td>
<td>20x-29x</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>60XXXXXXXXX</td>
<td>Non-Industry</td>
<td>20x-29x</td>
<td>6.B. Campus IRB</td>
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<tr>
<td>SRN - Sponsored Research Non-Government</td>
<td>Expedited Review Exempt</td>
<td></td>
<td></td>
<td>30x-39x</td>
<td></td>
</tr>
<tr>
<td>SCI - Sponsored Clinical Research w/ IRB</td>
<td>MEDICAL CENTER IRB Full Board Review</td>
<td>60XXXXXXXXX</td>
<td>Non-Industry</td>
<td>20x-28x</td>
<td>6.C. Non-Industry Sponsored Clinical Research</td>
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<tr>
<td>SCI - Sponsored Clinical Research w/ IRB</td>
<td>Full Board Review</td>
<td>6860XXXXXX</td>
<td>Industry</td>
<td>20x-29x</td>
<td>6.E. DCRI / DTMI</td>
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<tr>
<td>SCI - Sponsored Clinical Research w/ IRB</td>
<td>Expedited Review</td>
<td>6860XXXXXX</td>
<td>Industry</td>
<td>30x-39</td>
<td></td>
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<tr>
<td>SNC - Sponsored Non Clinical Research</td>
<td>None</td>
<td>All</td>
<td>Non-Industry</td>
<td>20x-29x</td>
<td>N/A</td>
</tr>
<tr>
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<td></td>
<td>Non-Industry</td>
<td>30x-39</td>
<td></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.
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

**Determinate IRB Review**

1. **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.**

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
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Subsection C. Non-Industry Sponsored IRB

C. Non-Industry Sponsored IRB

- Subsection C should be used for all federal, foundation, and non-industry sponsored clinical research projects.
- The Clinical Research Closeout Policy outlines the process and requirements for closing out a non-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 departmental approval is obtained on the Closeout Tasklist, the tasklist along with the PI Attestation and ZF114 Report should be submitted to closeoutdocs@duke.edu with the Duke Office of Clinical Research (DOCR) copied using docr-crgov@dm.duke.edu email address.

<table>
<thead>
<tr>
<th>C. Non-Industry Sponsored Clinical Research</th>
<th>0/10 Complete or N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ No Human Subjects/IRB included in study/award</td>
<td></td>
</tr>
</tbody>
</table>

6.C.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., NIH) and indicating a WBSE change helps PRMO prioritize the request for quick turn around.

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

6.C.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.

Amendment Request Form

- Proposed Change Affects:
- Check all that apply
- Amendment Change
- Sponsor/Funding Source
- Protocol or Research Summary
- Subject Population / Exclusions (i.e. size of population, selection criteria)
- Drugs/Devices (i.e. investigator’s brochure, supplier: IND, IDE)

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

If the IRB has not been officially closed at the date of processing the closeout documents, a new fund code must be updated within Maestro until notification from DOCR to PRMO that the eIRB has been closed. Once PRMO receives notification of eIRB closure, PRMO completes necessary steps to ensure study is blocked to SAP uploads.

- Until the eIRB is officially closed, this change is accomplished by submitting a funding source 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.C.4 If the IRB Protocol will be closed, 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.C.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.

Research Enrollment Log (AMB559) Tip Sheet

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6.C.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.C.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.C.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/financial practice manager) 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.’
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6.C.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.C.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.