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

**Section Overview & Subsection A. Exempt 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 (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</td>
<td>6840000000 6860000000</td>
<td>Non-Industry Industry</td>
<td>20x-29x 30-39x</td>
<td>6.A. Exempt</td>
</tr>
<tr>
<td>SRN - Sponsored Research Non-Government</td>
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<tr>
<td>SNC - Sponsored Non Clinical Research</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>SRF - Sponsored Research Federal</td>
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<td></td>
</tr>
<tr>
<td>SRN - Sponsored Research Non-Government</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.
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Guidance on choosing appropriate subsection

Determining Programmatic Attribute

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.

- 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.

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

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.

- 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.

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 A. Exempt IRB

A. Exempt IRB

- Subsection A should be used for all Federal, Foundation, and Non-Industry Sponsored Exempt IRB Research Projects.
- SAP Master Data must indicate “SCE” and SPS Web must indicate “Exempt”.

The federal regulations for protecting research subjects [45 CFR 46.101(b)] list six categories of research activity that are exempt from the provisions of the regulations, such as the requirement for annual review.

Research that qualifies for exemption include:
- Research in educational settings.
- Surveys, interview procedures, observations of public behavior, educational tests.
- Research involving the use of educational tests if the human subjects are elected/appointed public officials or candidates for public office.
- Research involving the collection or study of existing data, documents, and records.
- Research and demonstration projects which are conducted by or subject to the approval of Federal Department or Agency heads.
- Taste and food quality evaluation and consumer acceptance studies.

Duke University restrictions:
- Exemptions cannot be secured for research using the following populations:
  - Pregnant women when they are the targeted subject population
  - Students participating in the Psychology Subject Pool
  - Students if the investigator is their instructor
  - Employees if the investigator is their supervisor
  - Most research with children
  - Prisoners

Exemptions cannot be secured for research that uses:
- Deception
- Experimental manipulations

<table>
<thead>
<tr>
<th>A. Exempt</th>
<th>0/2 Complete or N/A</th>
</tr>
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<tbody>
<tr>
<td>Human Subjects/IRB research is not eligible for an exemption from human subject regulations</td>
<td>Yes</td>
</tr>
</tbody>
</table>

6.A.1 Approved exemption documentation is on file

If the study was appropriately submitted for review by the eIRB, the current approval state will show Exempt Research. The Principal Investigator will be able to provide the Research Administrator with the following documentation from the eIRB website.
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 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

The following shows a step by step guide to marking the study COMPLETE within the ClinCard System.

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.’