### 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 6840000000 6860000000</td>
<td>Non-Industry</td>
<td>20x-29x 30x-39x</td>
<td>6.A. Exempt</td>
<td></td>
</tr>
<tr>
<td>SRF - Sponsored Research Federal</td>
<td>CAMPUS IRB Full Board Review Expedited Review Exempt 6000000000</td>
<td>Non-Industry</td>
<td>20x-29x 30x-39x</td>
<td>6.B. Campus IRB</td>
<td></td>
</tr>
<tr>
<td>SNC - Sponsored Non Clinical Research</td>
<td>None</td>
<td>All</td>
<td>Non-Industry</td>
<td>20x-29x 30x-39x</td>
<td>N/A</td>
</tr>
<tr>
<td>SRF - Sponsored Research Federal</td>
<td>MEDICAL CENTER IRB Full Board Review Expedited Review 6860505000 6860450000</td>
<td>None</td>
<td>All</td>
<td>Non-Industry</td>
<td>20x-29x 30x-39x</td>
</tr>
</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

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).

- 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.

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>
</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 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.

- 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