Closeout Tasklist - Section 6. Human Subjects/IRB
Section Overview & Subsection B. Campus IRB

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 6840XXXXXX 6860XXXXXX</td>
<td>Non-Industry</td>
<td>Industry</td>
<td>20x-29x 30x-39x</td>
<td>6.A. Exempt</td>
</tr>
<tr>
<td>SRN - Sponsored Research Non-Government</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SCI - Sponsored Clinical Research w/ IRB</td>
<td>MEDICAL CENTER IRB Full Board Review Expedited Review</td>
<td>60XXXXXX</td>
<td>Non-Industry</td>
<td>20x-28x 30x-38x</td>
<td>6.C. Non-Industry Sponsored Clinical Research</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></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<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.
**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.

   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
Closeout Tasklist – Section 6. Human Subjects
Subsection B. Campus IRB

B. Campus IRB

- Subsection B should be used for all Duke Campus non-exempt IRB sponsored projects managed through the Campus IRB Office.
  - The Campus Human Subjects Protections Program works with investigators to protect the rights and welfare of research participants. Program staff will pre-review submissions to the Institutional Review Board for Non-Medical Research, providing feedback, consultation, and interpretation of applicable regulations.

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**Duke Office of Research Support • GAP 200.180, Closeout of Sponsored Project**

<table>
<thead>
<tr>
<th>B. Campus IRB</th>
<th>0/2 Complete or N/A</th>
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<tbody>
<tr>
<td></td>
<td>Yes</td>
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<tr>
<td>□</td>
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</table>

6.B.1

If the IRB Protocol will remain active after the closing of this WBSE, the Campus IRB has been notified of the funding source change.

1

The IRB Protocol will remain active and the Campus IRB Office has been notified through a Request to Amend an Approved Protocol (regardless of type of review) and emailed to ors-info@duke.edu. An example of this form is shown below.

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**Request to Amend an Approved Protocol**

This form was last updated June 9, 2009

Use this form to amend any approved protocol, regardless of type of review (exempt, expedited, or full) conducted at the time of approval.

This document should be submitted by the investigator as an e-mail attachment to the IRB staff at ors-info@duke.edu. A signed cover sheet is not required. If there are attachments, submit them as another single Word file.

Amendments are our highest priority so we anticipate acting on these requests within no more than three business days.

Project Title: Test to evaluate funding source change
IRB Protocol Number: Pro00000001
Investigator(s): Harry D. Potter, PhD
Date: 07/01/2015

Please check all categories in which changes are proposed:

- [ ] Research Team Personnel
- [ ] Research Design and/or Method
- [ ] Measures/Instruments
- [ ] Subject Population
- [ ] Confidentiality
- [X] Other: Funding Source Change
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.

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.’