Work Instruction - Research Billing Risk

Velos eResearch
Version 9.2
Revision History

<table>
<thead>
<tr>
<th>Version/Amendment #:</th>
<th>Version Date:</th>
<th>Description:</th>
<th>Completed By:</th>
</tr>
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<tr>
<td>0.1</td>
<td>9/22/14</td>
<td>Initial Draft Document</td>
<td>Pamela Sabrsula</td>
</tr>
<tr>
<td>0.2</td>
<td>10/21/14</td>
<td>Peer Review</td>
<td>Lissa Persson</td>
</tr>
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<td>1.0</td>
<td>10/27/14</td>
<td>Final Document</td>
<td>Pamela Sabrsula</td>
</tr>
<tr>
<td>1.1</td>
<td>03/09/15</td>
<td>Review by Cancer Center</td>
<td>Kim Markosfeld/Kayla Jackson</td>
</tr>
<tr>
<td>1.2</td>
<td>03/10/15</td>
<td>Peer Review</td>
<td>Pamela Sabrsula/Lissa Persson</td>
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<td>2.0</td>
<td>04/03/15</td>
<td>Final Document</td>
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Documentation of Change History:

Version 1.0, 10/27/2014: Finalized version

Version 1.1, 03/09/2015: Review by Cancer Center with slight modifications; addition of BRQ screenshots

Version 1.2, 03/10/2015: Peer review changes in preparation for final version

Version 2.0, 04/03/2015: Finalize document
PURPOSE

The purpose of this work instruction is to describe the instructions for completing the Billing Risk Questionnaire (BRQ) in Velos eResearch for studies that are entered into the system. The BRQ is required as part of the review to assess billing risk potential in human subject research per the Standard Operating Procedure for Research Billing Risk (SOP-004_ResearchBillingRisk.docx).

RESPONSIBILITY

Clinical Trials Office Staff – Designated CTO staff are responsible for reviewing human subject research to determine if a patient billing risk exists and assess the need for additional measures to mitigate such risk. This review is documented by completing the Billing Risk Questionnaire form. The following responsibilities also apply:

- CTRC CTO – provide billing risk review for all cancer-related studies. Submit the completed BRQ to VPR CTO along with a coverage analysis, if required.
- VPR CTO – provide billing risk review for all studies that are not cancer-related. Submit the completed BRQ along with a coverage analysis, if required, for cancer and non-cancer studies to the Office of Clinical Research (OCR) as part of the Institutional Review.

Research Team (RT) – Provide relevant documents and study information as requested by CTO staff.

ENTRY/PREREQUISITE CRITERIA

The VPR CTO is notified by the Office of Clinical Research (OCR) when a study is ready for billing risk review as part of the Institutional Review process. The VPR CTO staff either:

- Proceeds to performing the billing risk review for all non-cancer studies, OR
- Refers the cancer-related studies to CTRC CTO Finance staff for review

RELEVANT DOCUMENTS

The latest versions of the following documentation is referenced while completing the Billing Risk Review within eResearch.

- Research Protocol
- Informed Consent Form
- Clinical Trial Agreement (CTA), Notice of Grant Award (NOGA) or other Funding Agreement
- Budget
- Documentation of the drug or device status with the FDA [e.g. Investigational New Drug (IND) number, Investigational Device Exemption (IDE) number, 510k approval], if available
### WORK INSTRUCTIONS

<table>
<thead>
<tr>
<th>Role/Function</th>
<th>Description of Action</th>
</tr>
</thead>
</table>
| Coverage Analyst       | 1. Log-in to eResearch  
                          2. CLICK the MANAGE button from the toolbar and select SEARCH under the STUDIES option  
                          3. From the list of studies that appear, locate the desired study and CLICK the Clipboard icon 📋 for quick access to the Study >> Summary Page  
                          NOTE: Enter the study number in the “Search a Study” text field, then click SEARCH to quickly locate the desired study. |
| Coverage Analyst       | 1. From the Study Summary tab, CLICK the Forms tab  
                          2. In the Jump to Forms field, SELECT “Billing Risk Questionnaire” and CLICK GO button  
                          3. Click NEW button to open a new form for completion.  
                          NOTE: The Form may be saved at any time by entering your e-Signature and CLICKING the SUBMIT button. This allows you to return to the form after obtaining the required information to finish the form, if needed.  
                          NOTE: LEAVE the Form Status as “Work in Progress.” |
| Coverage Analyst       | 1. Data Entry Date* - This is a system generated date.  
                          2. CLICK on the Select Study Information link to search the current study list. SELECT the appropriate study and CLICK the SUBMIT button. This will automatically populate the following Study Specific Information fields:  
                          a. CTMS Study No  
                          b. IRB No.  
                          c. PI  
                          d. Protocol Short Title  
                          e. NCT# |

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**Version 2.0, 04/03/2015**

**University of Texas Health Science Center at San Antonio**

**Clinical Trials Office**
NOTE: If any information is not populated in the fields, it must be entered on the Study Summary tab or under More Study Details. Once entered, navigate to form again and repeat steps 1-2 above to repopulate the fields.

3. ENTER the following information
   a. **Reviewer** – Enter the name of the person completing the review
   b. **Review Type** – Select from drop down as appropriate:
      i. Initial – for reviews completed prior to study activation
      ii. Follow-up – for reviews completed after study activation (ex. protocol amendment or revised contract/CTA)
      iii. Retrospective* – for reviews completed on Legacy studies
   c. **Date Review Completed** – enter review completion date (may be same as Data Entry Date)

<table>
<thead>
<tr>
<th>Select Study Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTMS Study No:</td>
</tr>
<tr>
<td>IRB No:</td>
</tr>
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<tr>
<td>Protocol Short Title:</td>
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<td>NCT #:</td>
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<tr>
<td>Reviewer:</td>
</tr>
<tr>
<td>Review Type:</td>
</tr>
<tr>
<td>Date Review Completed:</td>
</tr>
</tbody>
</table>

**Coverage Analyst**

**Determine whether a billing risk is present**

1. REFERENCE the Standard Operating Procedures for Research Billing Risk (SOP-004_ResearchBillingRisk.docx) for guidance in determining whether a billing risk is present.
2. CLICK the NO or YES radial buttons to indicate the answer to Q1 and Q2
   a. If Q1 AND Q2 are both No, SKIP to the Form Completion section of this work instruction.
   b. If Q1 = Yes AND Q2 = No, SKIP to the Form Completion section of this work instruction and COMPLETE the Coverage Analysis.
      i. REFERENCE Velos Work Instruction – Coverage Analysis for guidance in completing the Coverage Analysis.
   c. If Q1 AND Q2 are both YES, CONTINUE to next section of this work instruction.

NOTE: If Q1=No AND Q2=Yes, then one of the answers is INCORRECT. Review the documentation again to correct.
**Coverage Analyst**

**Determine the applicable documents**

1. REVIEW the Funding Agreement to determine the level of funding being provided by the funding sponsor and SELECT the appropriate response.
   a. If “ALL” was selected, SKIP to the Form Completion section of this work instruction and COMPLETE the Coverage Analysis.
      i. REFERENCE Velos Work Instruction – Coverage Analysis for guidance in completing the Coverage Analysis.
   b. If “Some”, “None or N/A”, was selected, CONTINUE to next section of this work instruction.

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**Coverage Analyst**

**Determine the appropriate type of Medicare Coverage Analysis**

1. DETERMINE the appropriate type of Medicare Coverage Analysis
   a. SELECT “Yes” if the study involves a device, then SKIP to the Qualifying Criteria for Device Trials section of this work instruction.
   b. IF “No”. CONTINUE to next section of this work instruction.

**MEDICARE COVERAGE ANALYSIS**

**Determine appropriate Medicare Coverage Analysis**

Is this a device trial? (If No, continue to Section 4. If Yes, continue to Section 7)

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare Coverage Analysis (continue to Section 3)</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
### Coverage Analyst

#### Requirements for Medicare Coverage of Routine Costs


2. **CLICK** the NO or YES radial button to indicate the answers to the form questions.
   a. If “YES” was answered for all questions, **CONTINUE** to the next section of this work instruction.
   b. If ANY of these answers are “NO”, **SKIP** to the **Form Completion** section of this work instruction and **COMPLETE** the Coverage Analysis.
      i. **REFERENCE** Velos Work Instruction – Coverage Analysis for guidance in completing the Coverage Analysis.

### Coverage Analyst

#### Automatically Qualifying “Deemed” Trials

1. **REFERENCE** the Standard Operating Procedures for Research Billing Risk (SOP-004_ReSearchBillingRisk.docx) for guidance in determining whether a billing risk is present.

2. **CLICK** the NO or YES radial buttons to indicate the answers to the form questions.
   a. If any ONE of the answers is “YES”, **SKIP** to **Form Completion** section of this work instruction and **COMPLETE** the **Coverage Analysis**.
      i. **REFERENCE** Velos Work Instruction – Coverage Analysis for guidance in completing the Coverage Analysis.
   b. If all four are “NO”, **CONTINUE** to next section, if needed, OR **SKIP** to **Form Completion** section of this work instruction AND **COMPLETE** the Coverage Analysis
      i. **REFERENCE** Velos Work Instruction – Coverage Analysis and follow the steps a Non-Qualified Clinical Trial.
Coverage Analyst

Desirable Characteristics

1. COMPLETE this section ONLY IF the questions are verified by the Principal Investigator (PI) to self-certify that the study meets the seven (7) desirable characteristics in order to make the study a Qualifying Clinical Trial.
2. CLICK the NO or YES radial button to indicate the answers to the form questions.
   a. If PI answers all questions as “YES”, SKIP to the Form Completion section of this work instruction and COMPLETE the Coverage Analysis.
      i. REFERENCE Velos Work Instruction – Coverage Analysis for guidance in completing the Coverage Analysis for a Qualified Clinical Trial.
   b. If any answers are “NO” or are not provided by PI, SKIP to Form Completion section of this work instruction and COMPLETE the Coverage Analysis.
      i. REFERENCE Velos Work Instruction – Coverage Analysis for guidance in completing the Coverage Analysis for a Non-Qualified Clinical Trial.

Coverage Analyst

Qualifying Criteria for Device Trials

1. ENTER the name of device being studied
2. ENTER the Investigational Device Exemption number (IDE), if applicable.
3. SELECT the applicable CMS Category
4. INDICATE who is responsible for paying for the device in the text field provided.
5. INDICATE if the Medicare Administrative Contractor has provided coverage approval
6. ENTER the Date of the Approval Letter provided by the Medicare
Administrative Contractor.

7. COMPLETE the next section, Form Completion

**Qualifying Criteria for Device Trials**

- Device Name: 
- Device Number (if applicable): 
- Classify the type of device being used in the study (select one):
  - CMS Category A (investigational device)
  - CMS Category B (non-investigational device)
- Who will pay for the device?

Medicare and other third-party payers may provide coverage for certain research-related clinical services, items, or tests provided to device study participants if not provided free from the sponsor.

In addition, Medicare may cover the investigational device itself if not provided free of charge by the sponsor, however, Category A devices are not typically covered. In order for the study to qualify for coverage the device must apply to the local Medicare contractor for approval. For all other insurance, seek pre-authorization requirements.

- Has the Medicare Administrative Contractor approved coverage for the device and/or related costs of the study?
- Yes
- No

- Date of Approval: 
- If approved, complete billing and coverage analysis according to Medicare coverage approval.

- If the form is NOT yet COMPLETE, SET the Form Status to “Work in Progress”.
- If the Review and the Form are COMPLETE, SET the Form Status to “Completed”.

**Note**: There are other statuses available, but ONLY select “Completed” for this form.

3. ENTER your e-Signature, then CLICK the SUBMIT button to SAVE and FINALIZE the form.

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**Coverage Analyst**

**Form Completion**

1. ENTER any additional comments as needed in the Comment/Review Summary field.

2. SELECT a Form Status
   - a. If form is NOT yet COMPLETE, SET the Form Status to “Work in Progress”.
   - b. If the Review and the Form are COMPLETE, SET the Form Status to “Completed”.

**Note**: There are other statuses available, but ONLY select “Completed” for this form.

3. ENTER your e-Signature, then CLICK the SUBMIT button to SAVE and FINALIZE the form.

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**Coverage Analyst**

**CMS Qualifying Clinical Trial**

1. RETURN to Study Summary tab and CLICK on the More Study Details icon

2. SELECT the appropriate answer to the question “CMS Qualifying Clinical Trial?” based on the outcome of the BRQ.
3. ENTER your e-Signature and CLICK the SUBMIT to SAVE the data.

**VPR CTO**

Submit to OCR for Institutional Review

| 1. | RUN Ad Hoc Query for all Billing Risk Questionnaire Forms with a status of “Completed”. |
| 2. | VERIFY forms are completed. |
| 3. | SET the Form Status to “Lockdown” |
| 4. | CREATE a PDF export files of the following forms  
   a. Billing Risk Questionnaire Form  
   b. Coverage Analysis (Billing Grid) as needed |
| 5. | SUBMIT the forms to the OCR. |

**EXIT CRITERIA**

Upon completion of these work instructions, the Billing Risk Review portion of the Institutional Review process is complete.

**APPENDIX A ROLES & RESPONSIBILITIES**

<table>
<thead>
<tr>
<th>FINANCIAL MANAGEMENT</th>
<th>Clinical Trials Office</th>
<th>Research Team</th>
</tr>
</thead>
<tbody>
<tr>
<td>-Research Billing Risk</td>
<td>VPR CTO</td>
<td>Coverage Analyst</td>
</tr>
<tr>
<td>-Navigate to Study Summary</td>
<td>-</td>
<td>R</td>
</tr>
<tr>
<td>-Navigate to Billing Risk Questionnaire Form</td>
<td>-</td>
<td>R</td>
</tr>
<tr>
<td>-Enter Study Specific Information</td>
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<tr>
<td>-Determine whether a billing risk is present</td>
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<td>-Determine the applicable documents</td>
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</tr>
<tr>
<td>-Submit to OCR for Institutional Review</td>
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</tbody>
</table>

R = Responsible party  
A = Accountable party  
C = Consulting party  
I = Party to be kept informed

**APPENDIX B DEFINITIONS**

N/A
REFERENCES

CMS NCD 310.1 Clinical Trial Policy
Novitas Clinical Trials and Devices
HOP 7.7.1, Budgeting & Billing for Clinical Services Provided as Part of Research Involving Human Subjects
OCR Policy 1.3.2. Clinical Trial Billing

END OF DOCUMENT