**VCU Clinical Research Coverage Analysis**

***Process Information and Forms***

The VCU Coverage Analysis process is designed to (1) determine if a clinical study qualifies for coverage of study-specific items that meet the criteria for ‘routine care’ costs and (2) ensure costs for clinical services or items are categorized by cost type and appropriate responsible payer.

VCU’s Coverage Analysis process, outlined within Compliance Notice [15-003 Clinical Research Coverage Analysis](https://wiki.vcu.edu/display/ResearchCompliance/Final+Compliance+Notices), reflects a harmonization of requirements found within:

1. The Patient Protection and Affordable Care Act ([42 United States Code 300GG-8 – Coverage for Individuals Participating in Approved Clinical Trials](http://www.gpo.gov/fdsys/granule/USCODE-2010-title42/USCODE-2010-title42-chap6A-subchapXXV-partA-subpart1-sec300gg-8));
2. The U.S. CMS National Coverage Determination for Routine Costs in Clinical Trials [§310.1](http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&fromdb=true); and
3. The Code of Virginia [§38.2-3418.8](http://law.lis.virginia.gov/vacode/38.2-3418.8/) – Coverage for Clinical Trials for Treatment Studies on Cancer and [§38.2-3453](http://law.lis.virginia.gov/vacode/38.2-3453%20/) – Clinical Trials.

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| **Step** | **Forms[[1]](#footnote-1)** | **Required for** | **Submission Information** |
| 1. Determine if a Coverage Analysis is required | [Coverage Analysis Screening Form](#Form1) | ALL clinical research studies | Submit according to your school/center procedures:   1. As part of your study documents, serving as the record that a Coverage Analysis is not needed OR 2. As the cover page to your Coverage Analysis Package |
| 1. Determine if the protocol qualifies for third-party coverage of ‘routine care’ costs | [**2A** – Qualification Form for Non-Devices](#Form1a)*and/or*  [**2B** – Qualification Form for Devices](#Form2B) | All clinical research studies found to require a coverage analysis in Step 1 | Submit according to your school/center procedures as part of the Coverage Analysis Package. |
| 1. Designate the responsible payer for clinical care services and items | [Billing Plan](#Form3)(for Study-Specific Requirements) | All clinical studies involving billable clinical care services or items | Submit according to your school/center procedures as the official billing plan for all study-specific clinical services and items.  *Note:* The Billing Plan document is relied upon for reviewing the account status pertaining to clinical care services and items. |
| 1. Report enrollment and visits to clinical service providers | [Enrollment Reporting Form](#Form4) | All studies involving clinical services provided by VCUHS (or other service providers) | DIRECTLY to the appointed staff within the VCUHS Billing Office at [clinicaltrialsbilling@mcvh-vcu.edu](mailto:clinicaltrialsbilling@mcvh-vcu.edu)\*  *Note:*  All participants should be entered on this log and submitted each day a participant visit has occurred. Any records maintained with private health information must meet protocol, HIPAA, and [VCU Information Security Standards](https://www.ts.vcu.edu/media/technology-services/content-assets/documents/VCU_DataClassificationStandard_Final.pdf) (see notes section for additional information). |
| 1. Revise Coverage Analysis Documents | [Amendments](#Form5) | All studies with amendments. | Submit according to your school/center procedures in order to assess/document Coverage Analysis revision requirements. |
| 1. Prepare Billing Set-Up | [VCUHS Billing Set-Up Form](#Form6) | All studies involving VCUHS | Prepare Billing Set-Up Form to establish accounting procedures with VCUHS (all documents must be final). |

*COVERAGE ANALYSIS GUIDANCE*

**Key Definitions:**

**Study specific:** Required tests, activities, procedures, or resources performed or necessary in order to conduct a study in accordance with a protocol/research plan. Activities may be designated as a ‘Routine Care’ (RC) or ‘Study Billable’ (SB).

**Responsible payer:**  The party responsible for coverage of costs related to the clinical research study. Examples include study sponsor, third party payer, including Medicare/Medicaid, or study participant.

**Notes:**

* **Study Management Relies Upon the Coverage Analysis** – The Qualification Form and Billing Plan (together, Coverage Analysis) serves as the official record for clinical cost management. Within the Billing Plan, all study specific clinical requirements are identified by payer, classifying each study specific requirement as either (i) ‘routine care’ (RC) – billable to insurer/participant or (ii) study billable (SB) – billable to the sponsor/funding source.

* + *For Studies Found to be Qualified:*

1. Study specific ‘routine care’ costs must be identified with the responsible payer,
2. The responsible payer must be identified consistently for all research participants, and
3. All study specific costs not deemed ‘routine care’ must be borne by the study sponsor.

* *For Studies Found NOT Qualified:*  ALL study specific costs, including ‘routine care,’ must be accounted for within the study budget (e.g., no third-party/participant billing) and should be borne by the study sponsor.

The study management team (research team, financial administrators, and persons responsible for clinical billing) shall utilize the Billing Plan in a collaborative effort to support billing compliance. The clinical costs outlined within the Billing Plan shall mirror the clinical procedures/costs outlined within IRB-approved study documents, sponsor contracts, or other official study documentation.

* **Changes to the Protocol, Qualification, or Billing Plan:**  When ANY change is made to a clinical research study (e.g., protocol/research plan, budget, and contract), the PI must evaluate the change to determine what official records/approvals must be updated or amended, including Coverage Analysis and Billing Plans. All revised documents must be submitted for school/center approval with supporting documentation. Subsequently, all applicable documents must be submitted to [clinicaltrialsbilling@mcvh-vcu.edu](mailto:clinicaltrialsbilling@mcvh-vcu.edu)\* and maintained in compliance with applicable program requirements (e.g. human research protections, OnCore, etc.).
* **Form Alternatives** – OnCore-prepared versions of this form shall be accepted if all information is included.
* **Proposals** - In order to facilitate proposal submissions, draft documents may be accepted by the school/center.
* **Confidentiality** - For studies that may require additional confidentiality protections, special procedures for transmission of information contained within the enrollment form may be set up on an as needed basis upon review of the study.
* **Internally Sponsored Research** - All Coverage Analysis documents should be forwarded to [clinicaltrialsbilling@mcvh-vcu.edu](mailto:clinicaltrialsbilling@mcvh-vcu.edu) and maintained in compliance with applicable program requirements (e.g. human research protections, OnCore, etc.).
* **Responsibilities** - Responsibilities outlined above may be borne by the school/center as school/center processes dictate.

\*Monitored by VCUHS Special Accounts Authorized Personnel (Margaret Johnson and Alice Fowler)

**Coverage Analysis Screening**

**\*Required For All Clinical Research Studies** **Form 1**

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| **Prepared by:** | Click here to enter text. | **Study Coordinator:** | Click here to enter text. |
| **Principal Investigator:** | Click here to enter text. | **Department:** | Click here to enter text. |
| **Sponsor:** | Click here to enter text. | **Protocol #:**  **Version /date** | Click here to enter text. |
| **Study Title:** |  | | |

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| **Coverage Analysis Decision Tree** |
| Yes |
| **CERTIFICATION** | |
| ***Based upon the review of my clinical research plans, a Coverage Analysis is:***  NOT REQUIRED (complete and sign only this one-page form, route with your research compliance documents).  REQUIRED  **Signature of PI (and date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **School/Center Approval (if required): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  If help is needed with this form, please consult your research administration office within your school, center, or institute. | |

**Qualification Form for *Non-Devices***  **Form 2A**

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| **Prepared by:** | Click here to enter text. | **Study Coordinator:** | Click here to enter text. |
| **Principal Investigator:** | Click here to enter text. | **Department:** | Click here to enter text. |
| **Sponsor:** | Click here to enter text. | **NCT#:** | Click here to enter text. |
| **Protocol #:**  **Version /date** | Click here to enter text. | **Phase (I-IV):** | Enter phase if a non-device study, otherwise, enter N/A. |
| **Type of Billing Plan** | Initial  Revision Enter Date    Draft (Proposals Only) | **IND and/or IDE category and #:** | Enter IND and/or IDE category and IDE # if a device study, otherwise enter N/A. |
| **Study Title:** | Click here to enter text. | | |

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| **Section A: ‘Deemed’ Criteria for Automatic Qualification by CMS**  *Ref:* [*CMS National Coverage Determination for Routine Costs in Clinical Trials §310.1*](http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&fromdb=true) | |
| 1. Funded by NIH, CDC, AHRQ, CMS, DOD or VA? | Yes  No |
| 1. Funded by centers or cooperative groups supported by the above agencies? | Yes  No |
| 1. Conducted under an Investigational New Drug application (IND) reviewed by the FDA? | Yes  No |
| 1. Exempt from having an IND under 21 CFR 312.2(b)(1)? | Yes  No |
| Click to enter optional comments | |
| Is the study ‘deemed’ automatically qualified (a yes to ***any*** one or more of the above 4 questions)?  **Yes** – **Proceed to Section B.**  **No** – **Proceed to Section B.** | |

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| **Section B: Specific Criteria for Qualification by CMS**  *Ref:* [*CMS National Coverage Determination for Routine Costs in Clinical Trials §310.1*](http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&fromdb=true) | |
| 1. Is the purpose of the study to evaluate an item or service that falls within a Medicare benefit category and is not statutorily excluded from coverage? | Yes  No |
| 1. Does the trial have therapeutic intent and is not designed exclusively to test toxicity or disease pathophysiology? | Yes  No |
| 1. Does the trial enroll patients with a diagnosed disease/condition rather than only healthy volunteers? | Yes  No |
| Click to enter optional comments | |
| Were all 3 of the above questions answered with “***Yes***”?  **Yes** – The study does qualify for CMS coverage of research-specific routine care costs. **Proceed to Section C.**  **No** – The study does not qualify for CMS coverage of research-specific routine care costs associated with the clinical trial. **Proceed to Section C.** | |

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| **Section C: U.S. Affordable Care Act and Virginia Law**  *Ref: The Patient Protection and Affordable Care Act* [*42/300GG-8 – Coverage for Individuals Participating in Approved Clinical Trials*](http://www.gpo.gov/fdsys/granule/USCODE-2010-title42/USCODE-2010-title42-chap6A-subchapXXV-partA-subpart1-sec300gg-8)*; The Code of Virginia* [*§38.2-3418.8*](http://law.lis.virginia.gov/vacode/38.2-3418.8/) *– Coverage for Clinical Trials for Treatment Studies on Cancer and* [*§38.2-3453*](http://law.lis.virginia.gov/vacode/38.2-3453%20/) *– Clinical Trials.* |
| Is this a phase I-IV clinical study conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition?  **Yes** – By law, ‘non-exempt’ private insurance plans must cover ‘routine care’ costs associated with said clinical research participation. Participants are responsible for any co-pays associated with insurance plan coverage of ‘routine care’ costs. **Proceed to Section D.**  **No** – By law, private insurers are not required to cover routine costs of study participation when a study is outside of the scope defined above. The budget must be developed accordingly. **Proceed to Section D.** |

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| **Section D: Determination and Certification** |
| Based upon the above, does this study meet the standards for qualification for study-specific routine care costs to be billed to Medicare?  **Yes –** ‘Routine Care’ has been determined to be billable to insurance (or self-pay as applicable), as is reflected on the attached Billing Plan.  **No** – The attached Billing Plan specifies that the study/sponsor pay all study specific items.  Based upon the above, does this study meet the standards for qualification under the Affordable Care Act and Virginia Law?  **Yes –** ‘Routine Care’ has been determined to be billable to insurance (or self-pay as applicable), as reflected on the attached Billing Plan.  **No** – The attached Billing Plan specifies that the study/sponsor pay all study specific items.    **Signature of PI (and date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **School, Center, Institute Approval:**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

**Qualification Form for *Devices*** **Form 2B**



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| **Prepared by:** | Click here to enter text. | **Study Coordinator:** | Click here to enter text. |
| **Principal Investigator:** | Click here to enter text. | **Department:** | Click here to enter text. |
| **Sponsor:** | Click here to enter text. | **NCT#:** | Click here to enter text. |
| **Protocol #:**  **Version /date** | Click here to enter text. | **IND and/or IDE category and #:** | Enter IND and/or IDE category and IDE # if a device study, otherwise enter N/A. |
| **Type of Billing Plan** | Initial  Revision Enter Date    Draft (Proposals Only) |
| **Study Title:** | Click here to enter text. | | |

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| **Section A: Approval Process by FDA Submission Date** |
| What was the FDA Submission Date  ***On/After*** January 1, 2015 (New) or  ***Prior*** to January 1, 2015 (Grandfathered Process)  ***Note***: Effective January 1, 2015, the Centers for Medicare & Medicaid Services added criteria for coverage of investigational device exemption (IDE) studies that changed from local Medicare administrative contractor (MAC) review and approval to a centralized review and approval. CMS approval is required for investigational device trials conducted at VCU. *Ref:* [*Medicare Benefit Policy Manual – Ch. 14 Medical Devices 11-6-14*](http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c14.pdf)  **ESSENTIAL RESOURCES supporting the approval process:**   * VCU investigators acting as the sponsor must refer to the detailed CMS submission guidance at <http://www.cms.gov/Medicare/Coverage/IDE/>. This CMS website includes updated information on where and how to submit (e.g., via email to [clinicalstudynotification@cms.hhs.gov](mailto:clinicalstudynotification@cms.hhs.gov) -- requires specific file naming standards). * [Medicare Coverage IDE Study Criteria Checklist and Crosswalk [PDF, 83KB]](http://www.cms.gov/Medicare/Coverage/IDE/Downloads/IDE-Study-Criteria-Crosswalk-Sep-2014.pdf) * [MM8921 – Medicare Coverage of Items and Services in Category A and B Investigational Device Exemption (IDE) Studies [PDF, 69KB]](http://www.cms.gov/Medicare/Coverage/IDE/Downloads/MM8921.pdf) |

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| **Section B: Submission Identification** | |
| **Please indicate the appropriate classification of device and approval information.** | |
| *Note device type or classification:*  FDA-Approved Pre-Market Approval (PMA) device: Will device be used as approved (on label)?  ***Yes***   ***No***  FDA-Cleared 510(k) device  Category A IDE - *Devices where the ‘absolute risk’ of the device has not been established.*  Category B IDE - *Non-experimental investigational devices determined to be ‘reasonable and necessary’* | **CMS Approval Process (FDA submission *On/After*** January 1, 2015**):** Study sponsor must submit a request for CMS review and approval (or agree to pay all costs). If the VCU investigator is the study sponsor, the VCU investigator assumes this responsibility as outlined in [Medicare Benefit Policy Manual Ch. 14 - Medical Devices](http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c14.pdf)  **CMS Approval Process (FDA submission *Prior*** to January 1, 2015**):** PI must request CMS approval through the CMS contractor and shall develop the clinical budget in accordance with CMS approval. Refer to [Palmetto GBA](http://www.palmettogba.com/) (<http://www.palmettogba.com/>) |
| NSR Devices Approved By Local IRB | **CMS Approval Process:** Following local IRB-approval of the device as “non-significant risk”, the VCU investigator must request CMS approval through the CMS contractor. Refer to [Palmetto GBA](http://www.palmettogba.com/) (http://www.palmettogba.com/) |

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| **Section C: CMS Review Documentation** |
| The VCU investigator must attach documentation to support one of the following:  CMS Approval obtained by the external sponsor or obtained as the Sponsor-Investigator  ***or***  CMS Approval received by Palmetto GBA |
| Click to enter optional comments |

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| **Section D: Determination and Certification** |
| Based upon the above, does this study meet the standards for qualification under CMS/Medicare?  **Yes** – To Complete your Coverage Analysis Package, prepare a Billing Plan indicating coverage as approved by CMS and attach all documentation for submission.  **No** – To complete your Coverage Analysis Package, prepare a Billing Plan indicating that the sponsor/funding entity will pay ALL study specific clinical services/items and attach all documentation for submission.  The PI understands and accepts the responsibilities outlined by CMS for this study, as the:  Principal Investigator or  Sponsor-Investigator  **Signature of PI (and date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **School, Center, Institute Approval:**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

**Billing Plan for Study Specific Requirements** **Form 3**

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| **Prepared by:** | Click here to enter text. | **Study Coordinator:** | Click here to enter text. |
| **Principal Investigator:** | Click here to enter text. | **Department:** | Click here to enter text. |
| **Sponsor:** | Click here to enter text. | **NCT#:** | Click here to enter text. |
| **Protocol #:**  **Version /date** | Click here to enter text. | **Phase (I-IV):** | Enter phase if a non-device study, otherwise, enter N/A. |
| **Type of Billing Plan** | Initial  Revision Enter Date    Draft (Proposals Only) | **IND and/or IDE category and #:** | Enter IND and/or IDE category and IDE # if a device study, otherwise enter N/A. |
| **Study Title:** | Click here to enter text. | | |

***Notes*:**

List all study-specific items/services and associated CPT/HCPCS code ranges, as available. Per item/service, per visit, indicate "RC" for ‘Routine Care’ (billable to third party/participant), ‘SB ’for Study Billable. Any indication of ‘RC’ requires a comment to be entered.

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| ***Visits (Code each service per visit as RC/SB)*** | | | **Visit** | **Visit** | **Visit** | **Visit** | **Visit** | **Visit** | **Visit** | **Visit** | **Visit** | **Visit** | **Visit** | **ADD VISITS HERE** | **Comments** |
| **Clinical Service/Item Description** | **\*CPT HCPCS Code/Code Range (as available)** | **Unit Cost** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** |  |  |
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| ***School/Center/Institute***  ***Review and Approval*** |  |  |  |  |  |  |  |  | ***Date*** |  |  |  |  |  |  |
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**Enrollment Reporting Log** **Form 4**

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| **Prepared by:** | Click here to enter text. | **Study Coordinator:** | Click here to enter text. |
| **Principal Investigator:** | Click here to enter text. | **Department:** | Click here to enter text. |
| **Sponsor:** | Click here to enter text. | **NCT#:** | Click here to enter text. |
| **Protocol #:**  **Version /date** | Click here to enter text. | **Phase (I-IV):** | Enter phase if a non-device study, otherwise, enter N/A. |
| **Type of Billing Plan** | Initial  Revision Enter Date    Draft (Proposals Only) | **IND and/or IDE category and #:** | Enter IND and/or IDE category and IDE # if a device study, otherwise enter N/A. |
| **Study Title:** | Click here to enter text. | | |

***Note***: This form serves as a model for tracking enrollments and visits. Other formats are acceptable as long as all the information listed below is captured and conveyed to the health system, including enrollment reports generated through OnCore (as available). Any records maintained with private health information must meet protocol, HIPAA, and [VCU Information Security Standards](https://www.ts.vcu.edu/media/technology-services/content-assets/documents/VCU_DataClassificationStandard_Final.pdf). Certain studies may warrant additional confidentiality procedures. Consult with the IRB or your school/center.

***Instructions:*** Enter all participants on this log, update, and submit each day that a participant visit has occurred to [clinicaltrialsbilling@mcvh-vcu.edu](mailto:clinicaltrialsbilling@mcvh-vcu.edu)\*.

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| **WARNING PRIVATE INFORMATION -- ENSURE ADEQUATE PROTECTIONS** | | | | | |
| **#** | **MRN #** | **Name** | **Date Consent Signed:** | **STUDY-RELATED VISIT DATE RECORD:** | **Participation Ended On:** |
| X1 | 12345566 | Sample, Jane Doe | 1/12/2014 | 01/13/20XX; 02/13/20XX; 03/12/20XX; 07/03/20XX; | Enter date of last study visit for completion (including withdraw) |
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\*Monitored by VCUHS Special Accounts Authorized Personnel (Margaret Johnson and Alice Fowler).

**Coverage Analysis *Amendment Form*** **Form 5**

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| **Prepared by:** | Click here to enter text. | **Study Coordinator:** | Click here to enter text. |
| **Principal Investigator:** | Click here to enter text. | **Department:** | Click here to enter text. |
| **Sponsor:** | Click here to enter text. | **NCT#:** | Click here to enter text. |
| **Protocol #:**  **Version /date** | Click here to enter text. | **Phase (I-IV):** | Enter phase if a non-device study, otherwise, enter N/A. |
|  |  | **IND and/or IDE category and #:** | Enter IDE category and IDE # if a device study, otherwise enter N/A |
| **Study Title:** | Click here to enter text. | | |

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| **Section A: Summary of Amendment to Protocol, Consent Documents, Budget and/or Contract** |
| The following documents have been amended or will require modifications:  Yes  No **Coverage Analysis** Date Coverage Analysis Changed  Yes  No **Protocol**  Protocol Amendment Date  Yes  No **Consent Documents** Consent Documents Amendment Date  Yes  No  **Budget** Date Budget Amendment Received  Yes  No **Contract** Date Contract Amendment Received |

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| **Section B: Determination and Certification** |
| **CHANGES DO NOT NECESSITATE ANY CHANGES TO EXISTING COVERAGE ANALYSIS OR BILLING PLAN**  No further action is required. PI and School/Center/Institute Designee signatures required.  **CHANGES ARE REQUIRED TO THE APPLICABLE QUALIFICATION FORMS AND BILLING PLAN**  Revisions are required on all applicable forms. PI and School/Center/Institute Designee signatures required.  **Signature of PI (and date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **School, Center, Institute Approval:**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

***VCUHS* BILLING SET-UP FORM (Clinical Research/Trials)**  **Form 6**

The purpose of this form is to establish a clinical research billing procedure for your study with VCUHS (or amend an existing clinical research billing procedure).

***How to use this form:***

1. Complete this form when your Coverage Analysis documents are completed and finalized.
2. Submit this *Billing Set Up* form together with your *Cost Coverage Analysis and Billing Grid* by funding type:
   * External - include package with your Internal Approval Form (IAF) – to OSP
   * External /Just in Time – include with your JIT documents – to OSP
   * Internal Support – transmit this form via email to: [vfowler@mcvh-vcu.edu,](mailto:vfowler@mcvh-vcu.edu,%20) (Alice Fowler, Sp. Accts. Supervisor) and [mejohnson@mcvh-vcu.edu](mailto:mejohnson@mcvh-vcu.edu) (Margaret Johnson – Sp. Billing Supervisor)
3. Following receipt, the billing office(s) will respond with account number(s) for your study.
4. Update this form if study amendments result in additional ancillary contracts and transmit to billing offices (email noted above)

**Questions:**

*Physician Billing Contact: A*lice Fowler, Special Accts. Supervisor, MCV Physicians (358-6100 ext.1249)

*Hospital Billing Contact:* Margaret Johnson, Special Billing Supervisor (281-0620 ext. 1099)

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| 1. **Submission Type:** |
| New  Revision: Click here to indicate when change will become effective.  Does this revision affect all participants in the study after the effective date?  Yes  No: If no, please click here to explain. |

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| 1. **Account INFORMATION:** | |
| **Account Type** (check as applicable)**:**  *Government*  *Non-Government* | Grant/Study Clinical Trial Contract/Other |
| **Account Name (mnemonic):**  Click here to enter text. | **Account/Study Alias Name(s):**  Click here to enter text. |
| **Billing Department:**  Click here to enter text. | **Department Billing Address:**  Click here to enter text. |
| **Department Billing Contact:**  Click here to enter text. | **Phone:**  Click here to enter text. |
| **PT#:** Click here to enter text. | **Sponsor:** Click here to enter text. |

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| 1. **Study Information:** |

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| **PI Name:** Click here to enter text. | **Effective Date:** Click here to enter text. |
| **Study Coordinator Name:** Click here to enter text. | **Effective Date:** Click here to enter text. |
| **Grant Number:** Click here to enter text. | **Expiration Date:** Click here to enter text. |
| **Account Name (mnemonic):** Click here to enter text. | **Site Accrual Goal:** Click here to enter text. |

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| 1. **billing instructions:** |

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| Please choose **one** of the following billing methods:  PO #  Bill Grant/Study Only  Government Funded Grant/Study (Must be billed to Institutional Account for the same service) |

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| 1. **Requirements to complete the billing set up:** |

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| ***Cost Coverage Analysis*** is completed and attached  ***Billing Grid*** is completed and attached  ***Enrollment Log*** is prepared for transmittal of participant list with each enrollment change (+/-)  Prepare the Enrollment Log and transmit with each new enrollment (as directed on the log form)  ***Ancillary Service Agreements***are attached – Check all that apply:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Anesthesiology | Human Genetics | OB/GYN | Pediatrics | Surgery | | CRSU | Internal Medicine | Ophthalmology | Physical Med/Rehab | Other: Click here to enter text. | | Dermatology | Inv. Pharmacy | Orthopedics | Psychiatry | | Emergency Services | Neurology | Otolaryngology | Radiation Oncology | | Family Medicine | Neurosurgery | Pathology – Lab | Radiology | |

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| 1. **billing agreement:** |

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| Agreement is made between Click here to enter PI/Department and MCV Hospitals/Physicians regarding reimbursement for professional services rendered on behalf of the above-mentioned organization or Grant/Study. Payment in full to MCV Hospitals/Physicians is due upon receipt of our statement. Balances over 45 days old are considered past due. In the event that a grant should expire or funds are dissipated before all outstanding charges have been paid, the PI agrees that MCV Hospitals/Physicians will bill the covering account identified by the PI.  ***PI Signature* Date: Click here to enter text.**  ***Coordinator Signature* Date: Click here to enter text.** |

1. \*Monitored by VCUHS Special Accounts Authorized Personnel (Margaret Johnson and Alice Fowler) [↑](#footnote-ref-1)