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

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| Study Identification\* | **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:** | Click here to enter text. | | |

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| Study Detail | **NCT#:** | Click here to enter text. | **Phase (I-IV):** | Enter phase if a non-device study, otherwise, enter N/A. |
| **Type of Billing Plan** (to be associated with this study) | Draft (Proposals Only)  Complete (Finalized Billing Plan) | **IND and/or IDE category and #:** | Enter IND and/or IDE category and IDE # if a device study, otherwise enter N/A. |

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| **Section A: 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 | |

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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. Was at least one question in Section A, above, answered with “Yes”? | Yes  No |
| 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 4 of the above questions answered with “***Yes***”?  **YES –** The study qualifies for CMS coverageof research-specific routine care costs. **Proceed to Section C to evaluate criteria for coverage by private insurers.**  **No** – The study does not qualify for CMS coverage of research-specific routine care costs associated with the clinical trial. **Proceed to Section C to evaluate criteria for coverage by private insurers.** | |

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\*The “Study Identification” table is standard for all VCU Coverage Analysis Forms to facilitate copy/paste. The “Study Detail” table is unique to each form.

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| **Section C: Criteria for Private Insurers via 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 to document “Yes” under US Affordable Care Act/Virginia Law.**  **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 to document “NO” under US Affordable Care Act/Virginia Law.** |

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| **Section D: Billing Plan notes as needed** |
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| **Section E: Determination and Certification** |
| **CMS / Medicare:** Based upon the above and the billing plan, does this study meet the standards qualifying the study for coverage of study-specific routine care by Medicare?  **Yes –** ‘Routine Care’ has been determined to be billable to insurance (or self-pay as applicable), to be reflected in the OnCore Study Calendar.  **No** – The Study Calendar in OnCore to specify that the study/sponsor pay all study specific items.  **Private Insurers:** Based upon the above and Calendar, does this study meet the standards qualifying the study for coverage of study-specific routine care under the U.S. Affordable Care Act and Virginia Law?  **Yes –** ‘Routine Care’ has been determined to be billable to private insurance (or self-pay as applicable), to be reflected in the OnCore Study Calendar. Pre-authorization still may be required.  **No:**  Request Pre-Authorization from insurance company for each participant.  ***OR***  The Study Calendar in OnCore to specify that the study/sponsor pay all study specific items.  **Sponsor as Sole Payer:** Has the sponsor opted to agree to pay for all procedures required in support of the protocol for ALL research participants regardless of their insurance or ability to pay?  **Yes**  **No**  **Not Applicable**  Signed approval below certifies that the PI agrees to verify the billing plan determinations documented in OnCore and is responsible for making billing decisions that are compliant with the applicable rules and regulations.  **Signature of PI (and date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **School or Center Approval: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |