**Coverage Analysis Screening**

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

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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. | **Proposal/Protocol #:****Version /date** |  Click here to enter text. |
| **Study Title:** |  Click here to enter text. |

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| **Coverage Analysis Decision Tree** |
| Coverage analysis decision tree: 1. Does your clinical research study involve the provision of clinical care services/items such as those customarily identified as covered services by an insurance provider? No: Only screening form needs to be submitted Yes: Coverage analysis is required. If yes, does your study involve a device? No device: submit qualification form for non-devices Yes, a device: submit qualification form for device |
| **SCREENING CERTIFICATION:** |
| **Based upon the review of my clinical research plans, this study is a** (see [Research vs. Trial Decision Tree](https://grants.nih.gov/policy/clinical-trials/ct-decision-tree.pdf)):[ ]  Clinical Trial per NIH definition (NOT-OD-15-015).[ ]  Clinical Research (does not meet NIH definition of a Clinical Trial).**This study is** [ ]  **REQUIRED** or [ ]  **NOT REQUIRED** to be managed within OnCore (see Compliance Notice [16-001](https://research.vcu.edu/media/office-of-research-and-innovation/secure/complianceprogram/16-001.pdf)).**Based upon the above, a Coverage Analysis is (select one):** [ ]  NOT REQUIRED (complete and sign only this one-page form, route with applicable research compliance documents).  [ ]  REQUIRED: If this study is a proposal, check here: [ ]  NOTE: Final Coverage Analysis screening must be confirmed at time of award. **Signature of PI (and date): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****School or Center Approval (if required): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**\*For assistance with this form, consult your research administration office within your school, center, or institute.\*\*Standard study identification information for all VCU Coverage Analysis forms (Tip: Copy and paste, as needed). |