*(Department/Division name)*

Clinical Research Unit (CRU) Reviewer Form

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| --- | --- |
| **eProtocol Number** |  |
| **Principal Investigator** |  |
| **Protocol Title** |  |
| **Reviewer’s Name** |  |
| **CRU Meeting Date** |  |

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| **Background/Rationale/Scientific Merit**: |
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| --- | --- |
| **Study Design:** (clinical trial, observational, etc.) |  |
| **Study funding** | [ ]  Institutional [ ]  Industry [ ]  NIH [ ]  other |
| **Multi-site** | [ ]  Yes [ ]  No |
| **Target Accrual** | Overall:Stanford:Duration of Accrual: |
| **Reasonable Time Period for Recruitment** |   [ ]  Yes [ ]  No |

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| [ ]  | **Very High Risk** | Studies involving recombinant DNA molecules (gene transfer), and/or the first use of the drug/device in humans, in which case the investigator may have the only relevant knowledge regarding the use of such new product. |
| [ ]  | **High Risk** | Any investigator-initiated trials using investigational agents or significant risk devices not yet approved by the FDA, investigator-initiated multi-center trials, all investigator-initiated IND/IDE trials. |
| [ ]  | **Moderate Risk** | Most investigator-initiated trials using FDA-approved, commercially available compounds/devices according to current labeling. |
| [ ]  | **Low Risk** | Most non-therapeutic trials. |

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| **Existence of Data and Safety Monitoring Plan**  | [ ]  Yes [ ]  No  |
| **Competing Studies**  | [ ]  Yes [ ]  NoIf yes, please explain: |
| **Overall Feasibility** | [ ]  Assessment for competing trials that limits enrollment[ ]  Adequate funding[ ]  Study team infrastructure availability[ ]  Research space[ ]  Pharmacy requirements (dispensing, cost, staffing)[ ]  Radiology/Diagnostic testing/Procedures accessible |
| **Overall Assessment** |  |
| **Comments/Questions** |  |

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| **Outcome** |
| [ ]  | **Approved** |
| [ ]  | **Approved with minor revisions** |
| [ ]  | **Response required** (make requested changes and resubmit to CRU |

**Reviewer Signature: Date:**