*(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**: |
|  |

|  |  |
| --- | --- |
| **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  No  If 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:**