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**SOP No. COE-119.00**

Attachment 1: Risk Assessment

Questions to assess risks and associated risk scores:

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| **Question** | **Risk points** |
| Type of study:  Industry-sponsored,  Cooperative,  Federally-funded Investigator-Initiated,  Investigator-Initiated | 0  0  0  1 |
| Is the trial greater than minimal risk? | 1 |
| Is there FDA approval for the investigational product? | 2 if No |
| If yes, is the approval for the same indication? | 2 if No |
| Is the study ‘first in human’? | 4 |
| Is the investigator responsible for the IND/IDE? | 2 |
| Is there indemnification for the trial and/or the investigational product? | 4 if No |
| For how many clinical trials has the Principal Investigator for this trial been the PI prior to this one? | ≤3 adds 1 |