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| **Overview:**  Studies requiring HRPP Facilitated Scientific Review per the Investigator Manual must complete this form to gather additional information used to determine whether the study is scientifically valid.  **Instructions:**  Upload completed form along with the principal investigator’s CV to the Other Attachments in the Local Site Documents section in ETHOS. | | |
| 1. Summary of Experience   Provide information regarding the PIs relevant experience for this project. | | |
|  | | Years of PI’s clinical trial research experience:  Has the PI previously done a clinical trial using the proposed trial design? (Y/N):  Provide the name of a research advisor/mentor if needed:  The principal investigator’s CV must be uploaded to the Other Attachments in the Local Site Documents section in ETHOS. Check box to confirm. |
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| 1. Documentation of Departmental Support | | |
|  | What departmental resources will you rely upon to complete this project?  Has the PI confirmed the availability of the departmental resources listed above? (Y/N)? | |
| 1. Rational for the number of potential participants | | |
| Explain the rational for the number of potential participants requested/required:  Is this study industry sponsored? (Y/N):  If the study is not industry sponsored, please provide the following information regarding the biostatistician who assisted with the development of this project:  Name:  Degree:  Years for clinical trial design experience:  Address:  Email:  Phone: | | |