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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
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|  | 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
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| 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:       |