**Instructions:** Please submit the completed application along with revised protocol and summary of changes to [prmc@jefferson.edu](mailto:prmc@jefferson.edu).

# Study Information

|  |  |
| --- | --- |
| JeffTrial # |  |
| Principal Investigator |  |
| Protocol Title |  |

# Protocol Version

Please attach the clean, revised protocol and indicate the revised protocol version/amendment number and version date below.

|  |  |
| --- | --- |
| Protocol version/amendment No. |  |
| Protocol version date |  |

# Significant Changes in Study Amendment

Indicate if any of the following aspects of the protocol were affected by the amendment. Please also submit a detailed summary of changes with the application.

|  |  |
| --- | --- |
|  | Eligibility criteria |
|  | Objectives or endpoints |
|  | Response criteria |
|  | Sample size |
|  | Statistical plan |
|  | Stopping rules |
|  | Study rationale |
|  | Treatment |
|  | Study design |
|  | Accrual goal (IIS/IIT only) |
|  | Accrual duration (IIS/IIT only) |

If none of the above areas are affected and you still think it meets criteria for PRMC amendment review, please describe the changes below:

|  |
| --- |
|  |