**Study Title:
IRB #: Principal Investigator:
Sponsor: Study Site:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Study team member** | **Title** | **Signature** | **Initials** | **Start date** | **Stop date** | **Activities****(refer to code list below)** | **(\*)PI Initials & date** |
|  |  |  |  |  |  |  | PI:\_\_\_\_\_\_\_\_\_\_\_Date:  |
|  |  |  |  |  |  |  | PI:\_\_\_\_\_\_\_\_\_\_\_Date:  |
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|  |  |  |  |  |  |  | PI:\_\_\_\_\_\_\_\_\_\_\_Date:  |

Activity codes (please amend activities as appropriate for your study):

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| A | Informed consent process | B | Eligibility assessment | C | EDC completion | D | Obtain medical history |
| E | Regulatory documentation | F | Concomitant medication review | G | Perform physical exam | H | Review lab and procedure results  |
| I | Investigational product accountability | J | Investigational product storage | K | AE assessment | L | Interview participants |
| M | AE reporting to sponsor and/or IRB | N | IRB submissions | O | Shipping and handling of samples | P | Other |

**(\*) I have delegated the identified duties and will directly supervise the named personnel in the performance of protocol requirements.**

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**PI Signature PI Initials**