**BHS-CRA support for a BHS study**

**Request to the BHS board**

(Version 1, July 7, 2012)

|  |  |
| --- | --- |
| Name of BHS committee |  |
| Chair of BHS committee |  |
| Title of clinical trial |  |
| EUDRACT |  |
| Funding sources |  |
| Amount (€) scheduled for BHS-CRA |  |
| If no such funding, justify : |  |

**List of requested tasks for the BHS-CRA**

|  |  |  |
| --- | --- | --- |
| **Task** | **Requested by BHS committee** | **Approved by BHS board** |
| Writing of protocol | 🞏 Yes 🞏 No | 🞏 Yes 🞏 No |
| Writing of ICF | 🞏 Yes 🞏 No | 🞏 Yes 🞏 No |
| Writing of other documents | 🞏 Yes 🞏 No | 🞏 Yes 🞏 No |
| Certificate of insurance  | 🞏 Yes 🞏 No | 🞏 Yes 🞏 No |
| Submission to EC | 🞏 Yes 🞏 No | 🞏 Yes 🞏 No |
| Submission to FAGG/AFMPS | 🞏 Yes 🞏 No | 🞏 Yes 🞏 No |
| Distribution of protocol documents | 🞏 Yes 🞏 No | 🞏 Yes 🞏 No |
| Initiation visits | 🞏 Yes 🞏 No | 🞏 Yes 🞏 No |
| Patient inclusion | 🞏 Yes 🞏 No | 🞏 Yes 🞏 No |
| Patient randomization | 🞏 Yes 🞏 No | 🞏 Yes 🞏 No |
| CRF collection | 🞏 Yes 🞏 No | 🞏 Yes 🞏 No |
| Data verification | 🞏 Yes 🞏 No | 🞏 Yes 🞏 No |
| Monitoring visits | 🞏 Yes 🞏 No | 🞏 Yes 🞏 No |
| Pharmacovigilance | 🞏 Yes 🞏 No | 🞏 Yes 🞏 No |
| Management of AE | 🞏 Yes 🞏 No | 🞏 Yes 🞏 No |
| Preparation of database for statistical analysis | 🞏 Yes 🞏 No | 🞏 Yes 🞏 No |
| Other : ………………………. | 🞏 Yes 🞏 No | 🞏 Yes 🞏 No |
| Other : ………………………. | 🞏 Yes 🞏 No | 🞏 Yes 🞏 No |
|  |  |  |
| Name of committee chair |  |  |
| Date |  |  |
| Signature |  |  |
| Name of BHS President |  |  |
| Date |  |  |
| Signature |  |  |