**Specification of resources, additional costs etc. for clinical trial AND NON-INTERVENTIONAL STUDIES, remuneration to Principal**

### Administrative information and description of the Study

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **1** | Pharmaceutical company (address) | | | | | | |
|  | | | | | | |
|  | Contact (name, position) | | | | | Telephone No. | |
|  | | | | |  | |
| **2** | Hospital, or the equivalent (address) | | | | | | |
|  | | | | | | |
|  | Contact concerning agreement, economy etc (name,position) | | | | | Telephone No. | |
|  | | | | |  | |
|  | Department or clinic | | | | | | |
|  | | | | | | |
|  | Head of operations or head of department (or clinic) (name) | | | | | Telephone No. | |
|  | | | | |  | |
| **3** | Title of the Study | | | | | | |
|  | | | | | | |
|  | Time schedule of Study from – to | | | | | | |
| Time schedule, total | – | | | | | |
| Recruitment time | – | | | | | |
| Treatment period | (total)       (per patient) | | | | | |
| Number of patients |  | included | randomised | completed  not applicable | | |
|  | Brief description of the Study | | | | | | |
|  | | | | | | |
|  | Responsible investigator (name, position) | | | | | | Telephone No. |
|  | | | | | |  |

**Administrative information and description of the Study, continuation.**

|  |  |
| --- | --- |
| 4 | The Study is also being conducted at the following hospitals/clinics/health centres (multicentre study) in Sweden |
|  |
|  | Investigator with main responsibility/coordinator |
|  |

### Staff/Resources which the company supply

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 5.1 | Staff (the following employees of the Company are assisting in the Study at the clinic/equivalent e.g. study nurse) | | | | | |
| Name | | | | | |
|  | | | | | |
|  | Telephone No. and e-mail address | | | Position | | |
|  | | |  | | |
|  | Duties | | | | | |
|  | | | | | |
|  | Period | | | | | |
|  | | | | | |
|  | Staff (the following employees of the Company are assisting in the Study at the clinic/equivalent e.g. study nurse) | | | | | |
|  | Name | | | | | |
|  | | | | | |
|  | Telephone No. and e-mail address | | Position | | | |
|  | |  | | | |
|  | Duties | | | | | |
|  | | | | | |
|  | Period | | | | | |
|  | | | | | |
| **5.2** | Equipment – technical or other | | | | | |
| The Company will provide the following equipment etc during the Study | | | | | |
|  | | | | | |
|  | Remaining value |  | | | Swedish Crowns SEK |  |

### Estimation of costs

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 6.1 | Staff, including payroll overheads \* Plan and design, introduction, execution (or according to 6.3, 6.4) and evaluation.  State as total costs or specified. | | | | | |
|  | Staff category | Working time (total) | at price | | | Cost |
|  |  |  | | |  |
|  | TOTAL | | | | Swedish Crowns SEK |  |
| 6.2 | Laboratory investigations | | | | | |
|  | Type of investigation | | | Number | | Cost |
|  | | |  | |  |
|  | TOTAL | | | | Swedish Crowns SEK |  |
| 6.3 | Additional costs | | | | | |
|  |  | | | | | Cost |
|  | | | | |  |
|  | TOTAL | | | | Swedish Crowns SEK |  |
| 6.4 | Possible remuneration for registered medicines | | | | Swedish Crowns SEK |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | TOTAL for points 6 | Swedish Crowns SEK |  |

|  |  |
| --- | --- |
| 7 | Possible agreement for adjusting remuneration upwards during the execution of the Study |
|  |

*\* These cover statutory costs, costs according to the agreement, costs for stand-ins, locums or other staff substituting for the ordinary staff during holidays, costs for holiday supplements and special holiday pay supplements.*

### Other information about the Study

|  |  |
| --- | --- |
| 8 | Other information, (e.g consequences if a trial is interrupted or undergoes major changes, see further instructions in Specification of resources and additional costs etc) |
|  |  |