**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) |
|  |       |