|  |  |
| --- | --- |
| Trial Name/Protocol/Plan number: | Site Name/number: |
| Principal Investigator (PI): | Sponsor: |

## Responsibility key:\*

|  |  |  |  |
| --- | --- | --- | --- |
| 1. | 2. | 3. | 4. |
| 5. | 6. | 7. | 8. |
| 9. | 10. | 11. | 12. |
| 13. | 14. | 15. | 16. |
| 17. | 18. | 19. | 20. |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Full Name (TEXTED) | Trial Role | Responsibilities per above key\* | Delegation **Start**  (dd-Mmm-yyyy) | PI initials | Signature | Initials | Delegation **Stop**  (dd-Mmm-yyyy) | PI initials |
|  | PI |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

To be signed & dated by PI at closure visit/end of trial: Date:

## **INFORMATION PÅ SVENSKA**

**OBS!**

**Delegeringar måste vara skriftliga, ha ett startdatum och vara signerad innan delegerad(e) person(er) får utföra specifika uppgifter inom ramen för den kliniska prövningen. Personen måste ha kompetens för uppgifterna som delegeras och ha fått den utbildning som krävs för att utföra uppgifterna.**

## **Instruktioner**

**Överst på sidan** Ange efterfrågade uppgifter: Prövning, Sponsor, Huvudprövare och Prövningsställe.

**Responsibility Key** Delegerade uppgifter i prövningen (ej rutinuppgifter). Kan med fördel ifyllas av Monitor.

***Exempel***

|  |  |  |  |
| --- | --- | --- | --- |
| *1. Provide Participant Information* | *2. Obtain Participant Consent* | *3. Perform physical examination* | *4. Confirm eligibility criteria* |
| *5. Assess AE/SAE causality* | *6. Record SAE* | *7. Prepare/dispense and/or administer IP/drug* | *8. Manage IP receipt, storage, accountability* |
| *9. Collect/process/ship biological samples* | *10. Enter CRF data, corrections and queries* | *11. Sign off on CRF data* | *12. Maintain essential records* |
| *13. Manage IXRS* | *14. Other (specify)* | *15.* | *16.* |
| *17.* | *18.* | *19.* | *20.* |

**Full Name** Förnamn och efternamn på den person som uppgift delegeras till

**Trial Role** Roll som personen har i prövningen. Med denna roll följer ett visst ansvar.

***Exempel: Sub-I*** *(Sub investigator),* ***SN*** *(Study Nurse), etc.*

Notera: Huvudansvarig prövare (PI) kan inte delegera uppgifter till sig själv, ska därför endast skriva namnteckning och signatur

**Responsibilities** Skriv nummer för varje delegerad uppgift, enligt ”Responsibility Key”

**Delegation Start** Datum när PI delegerade uppgift/-er. Ändringar kan ske under prövningens gång. Ska gällande delegation ändras, avslutas den och ny rad skrivs med rätt delegerade uppgifter (använd efterfrågat datumformat)

**PI initials** PI attesterar att delegationen träder i kraft

**Signature** Delegerad person signerar (namnteckning), för att bekräfta att delegeringen accepteras

**Initials** Delegerad persons signatur/initialer

**Delegation Stop** Datum när delegation upphör/ändras (använd efterfrågat datumformat)

**PI initials** PI attesterar av att delegation upphört

**To be signed and dated at end of trial:**

Huvudansvarig prövare undertecknar när prövningen är avslutad, för att bekräfta att delegerade personer/uppgifter är korrekta

**Nederst på sidan; Page no \_\_\_ of \_\_\_**

Ange sidnummer, samt totalt antal sidor efter att prövningen stängts (visar att alla sidor som använts finns med när prövningen avslutas)

## **Referenser – klinisk läkemedelsprövning**

**ICH E6(R3) 2.3.1, 2.3.3, Essential records table**

## **Referenser – klinisk prövning av medicinteknisk produkt**

**ISO 14155:2020, GCP 7.2, 9.2.1 f, Annex E.1.7**

## **INFORMATION IN ENGLISH**

**NB!**

**Delegations must be made in writing, with start date and be signed before delegated person(s) may perform trial related task(s). The person must be qualified for the delegated task(s) and must have received the training required for performing the task(s).**

## **Instructions**

**Page Header** Enter requested information about Trial, Sponsor, Principal Investigator, Site

**Responsibility Key** delegated trial tasks (No routine tasks). Can be pre-filled by the Monitor.

***Examples***

|  |  |  |  |
| --- | --- | --- | --- |
| *1. Provide Trial Participant Information* | *2. Obtain Trial Participant Consent* | *3. Perform physical examination* | *4 Confirm eligibility criteria* |
| *5. Assess AE/SAE causality* | *6. Record SAE* | *7. Prepare/dispense and/or administer IP/drug* | *8. Manage IP receipt, storage, accountability* |
| *9. Collect/process/ship biological samples* | *10. Enter CRF data, corrections and queries* | *11. Sign off on CRF data* | *12. Maintain essential records* |
| *13. Manage IXRS* | *14. Other (specify)* | *15.* | *16.* |
| *17.* | *18.* | *19.* | *20.* |

**Full Name** Firstand family name of person to whom task(s) have been delegated

**Trial Role** Role the person has in the trial. With this role, a certain responsibility follows;

***Examples: Sub-I*** *(Sub investigator),* ***SN*** *(Study Nurse), etc.*

Note: Principal Investigator cannot delegate tasks to her-/himself and should therefore only complete their name and sign

**Responsibilities** Enter a number for each delegated task, referencing the ”Responsibility Key”

**Delegation Start** Enter date when the PI delegated the task(s). Changes may occur during the course of the trial. When a current delegation is changed, it should be terminated, and a new row completed with the corrected delegation (please use requested date format)

**PI initials** PIsigns with their initials, to confirm the start of delegation

**Signature** Person, who has received delegated task(s) signs to confirm acceptance of delegation

**Initials** Person, who has received delegated task(s) signs their initials

**Delegation Stop** Date when delegation is terminated/changed (please use requested date format)

**PI initials** PI signs/initials, to confirm that delegation is terminated

**To be signed and dated at end of trial:**

PI signs when the trial is completed, to verify correct delegated persons/information

**Page Footer; Page no \_\_\_ of \_\_\_**

Enter page number and total number of pages after trial closure (shows that all completed pages are available when the trial ends)

## **References – clinical trial of pharmaceutical/drug**

**ICH E6(R3) 2.3.1, 2.3.3, Essential records table**

## **References – clinical investigation of medical device**

**ISO 14155:2020, GCP 7.2, 9.2.1 f, Annex E.1.7**