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

This initial agreement should be **completed,** **signed, and dated before study start** (= prior to the first subject's first visit), thereafter **updated and re-signed** in case routines at site are changed during the trial (= should always reflect the current procedures at site).

The variable(s) in the left-hand column may be completed/typed, based on the protocol, prior to printing the agreement.

NB! Source Data **can only be in ONE place** (= one “X” only, per variable)!

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Variable(s) | Medical records | CRF | Other\*) | Comments |
|       | [ ]  | [ ]  | [ ]  |       |
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**\*)** *Specify in the comments field (only ONE location per line)*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |
| Principal Investigator’s Signature |  | Date |  | Sponsor Representative/Monitor’s Signature |  | Date |

**INFORMATION PÅ SVENSKA**

**Instruktion**

Ansvarig sponsorrepresentant (monitor) ska **tillsammans** med huvudansvarig prövare (PI) på varje prövningsställe som deltar i den kliniska prövningen, gå genom alla prövningsprotokollets/-planens relevanta variabler och ange var källdata finns noterat, för respektive variabel, enligt prövningsprotokoll/-plan.

Formuläret måste uppdateras och signeras om prövningsställets rutiner ändras under prövningen.

***Exempel***

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**Bakgrund**

Journaler måste föras för att verifiera försökspersoners omhändertagande i vården och skall innehålla uppgifter om tillstånd, behandling och resultat därav, samt uppgifter om information och samtycke från patienten.

Uppgifter som insamlas enbart för en klinisk prövning kan noteras på källdataformulär eller direkt i CRF. Eftersom detta kan variera från prövningsställe till prövningsställe bör ett separat dokument, som förklarar var källdata finns, upprättas på respektive prövningsställe.

Listningen av prövningsspecifika variabler sammanställs utifrån den specifika prövningens protokoll/plan och CRF, och kan förberedas av sponsor. Var källdata för de olika variablerna registreras definieras av prövningsstället och signeras av ansvarig prövare eller av denne delegerad person. Monitor granskar listan och säkerställer att den är tydlig och komplett.

**Svensk lagreferens**

**Patientdatalag, SFS 2008:355, 3 kap., §2**

**Referenser – klinisk läkemedelsprövning**

**ICH E6(R2) GCP 1.51, 1.52, 1.63, 4.9**

**European Medicines Agency website:** > Human regulatory > Research and development > Compliance > Good clinical practice > Q&A > Question 3

Klicka på länken [Hur och var ska källdata definieras?](https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-clinical-practice/qa-good-clinical-practice-gcp) för att komma till EMAs Q&A: Good clinical practice (GCP)

**Referenser – klinisk prövning av medicinteknisk produkt**

**ISO 14155:2020 GCP 3.47, 3.48, 7.5.3, 7.8.1, 7.8.2, Annex E, 1.2.3**

**INFORMATION IN ENGLISH**

**Instruction**

Responsible Sponsor representative (monitor) should **together with** the Principal Investigator (PI) at each site that participates in the clinical trial, review all relevant trial protocol/plan variables, and specify where source data is noted, for each variable.

The form must be updated and re-signed if the site changes their routine during the trial.

***Example***

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**Background/References**

The medical records are available to verify the patient’s medical care and shall contain information on the patient's condition, treatment and outcome thereof, as well as information on patient information and consent.

Data collected for clinical studies can only be noted on source data forms or directly in the CRF. As this may vary from center to center, a separate document should be established at the respective centers explaining where source data is available. (ICH GCP 6).

The study-specific variables listing, which is compiled from the specific study protocol and CRF, can be prepared by the sponsor. The location of source documentation for the different variables is defined by the study site and signed by the principal investigator (or its delegated person). The Monitor reviews the listing and ensures it is clear and complete.

**Swedish Legal Reference**

**Swedish Patient Data Act, SFS 2008:355, 3 chapter, §2**

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

**ICH E6(R2) GCP 1.51, 1.52, 1.63, 4.9**

**European Medicines Agency website:** > Human regulatory > Research and development > Compliance > Good clinical practice > Q&A > Question 3

Click the link [How and where should source data be defined?](https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-clinical-practice/qa-good-clinical-practice-gcp) to get to Q&A: Good clinical practice (GCP)

**References – clinical investigation of medical device**

**ISO 14155:2020 GCP 3.47, 3.48, 7.5.3, 7.8.1, 7.8.2, Annex E, 1.2.3**