



HDP Guidelines CRITERIA: MINIMUM STANDARD

Version 1, November 2008

Referring to:

Homeopathic Drug Proving Guidelines, ECH Subcommittee Provings 2004, version 1.

I. COMPULSORY

- A. Proved Substance (HDP Protocol 6.2; Appendix 1)**
- 1. Exact name of the substance, Source, Composition, Toxicology**
 - 2. Original Manufacturer and Manufacturing technical requisites (HDP Protocol 6.1)**
 - 3. Potency of the proving substance and technology of the preparation**
 - 4. Accessibility of the substance for confirming provings or its therapeutic use**
 - 5. Preparation of Blanks (placebo, inert control substance) if used**
 - 6. Safety (HDP Protocol 6.8; 6.2.3)**
- B. Investigator: (Sponsor, Monitor)**
- Name, qualifications and address of the responsible Principal Investigator(s)**
(HDP Protocol 6.1.5; Appendix 2)
- C. The volunteer/ prover:**
- **Group demographics (HDP Protocol 6.2.6), including the number of provers and their sex and age distribution.**
 - **Case Report Form (CRF) of each individual prover, including**
 - **Medical history**
 - **Inclusion and exclusion criteria**
 - **Withdrawal criteria (HDP Protocol 6.5)**
 - **Informed consent (including storage of electronic data)**
 - **Prover information sheet**
- D. A description of the type/design of the Homeopathic Drug Proving (HDP Protocol 6.4) Existence of a written protocol**
- E. Outcome: number of volunteers involved/dropouts**
- F. Adverse Event Report Form - Diagnostic and therapeutic measures taken. (CRF last page)**
- G. Place of storage and duration of availability of the proving data (CRF) (HDP Protocol 6.10; 6.13; 6.15)**

II. LEGALLY COMPULSARY

(Depending on legal requirements of the country of the proving)

- A. Approval of an ethical committee or legal equivalent**
(HDP Protocol 6.12, 6.8)
- B. Insurance protection for investigators and volunteers** (HDP Protocol 6.14)

III. RECOMMENDED / HOMEOPATHIC QUALITY

- A. Former provings of the proved substance – bibliographic sources.**
(HDP Protocol 6.2)
- B. Curriculum vitae of Principal Investigator and Observers**
(Appendix 2)
- C. Lifestyle of volunteers during proving period** (HDP Protocol)
- D. Qualifications of symptoms** (CRF)
 - **Intensity of proving symptoms** (rating: vague, light, clear, strong, bothersome)
 - **Spontaneous symptoms or symptoms by interrogation**
 - **Hetero-anamnesis (family, friends, people familiar with the prover)**
 - **Modalisation of symptoms**
 - **Environmental influences**
- E. Symptoms classification:** (CRF)
 - ES = existing symptom at the start of the substance intake
 - NS = new symptom that has not been experienced before
 - OS = old symptom. Give the dates of occurrence and disappearance
 - AS = altered symptom, existing but modified
 - CS = cured symptom. It existed up to the taking of the experimented substance
 - FS = family symptom that has not been experienced by the concerned person but that has been manifested in some member of his family. Give the reference of the member of the family
- F. Proving's objectives and purposes** (HDP Protocol 6.3)
- G. Translation of the volunteer's wording in repertorial symptoms**
- H. Statistics (compilation of symptoms in different categories)**
(HDP Protocol 6.9)
- I. Accessibility of the proving's data, documents and volunteer's symptoms in their original language/wording** (HDP Protocol 6.10; 6.13; 6.15)

This document is an ongoing paper and will be updated when necessary. We kindly invite your suggestions. You can send them to jjjansen@antenna.nl.

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