INSTRUCTION

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ON

Processing of Personal Data in the Context of Clinical Trials of Drugs

Pursuant to letter c) and ç), Point 1 of Article 30 of Law No. 9887, dated 10.03. 2008 "On protection of personal data" the Commissioner for the Protection of Personal Data gives the following

INSTRUCTIONS

Chapter I
General Provisions

Article 1
Object

This Instruction regulates some rights and obligations related to personal data protection and processing in the context of clinical trials of drugs in human beings.

Article 2
Definitions

For the purposes of this Instruction, the following terms take these meanings:

1. "Clinical trial" is a systematic study on human beings undertaken to assess and verify the therapeutic and/or side effects of medical products, and to study their pharmacokinetics.
2. "Controller" is any health institution authorized to conduct clinical trial under the Law No.9323, date 25.11. 2004, "On Drugs and Pharmaceutical services".
3. "Test subject" is the individual (natural person) taking part in the clinical trial in the position of the test person.

[1] The translation was commissioned by the EU funded Project "Strengthening of the Data Protection Commissioner office in Albania, for alignment with EU standards"

4. “Personal data” is any information relating to an identified or identifiable test subject in the context of clinical trial.
5. “Informed consent” is the clearly stated manifestation of the will of the test subject**,** expressing his/her assent to personal data processing, which meets the following criteria:

a) it is given in writing,
b) dated and signed,
c) freely given after having obtained detailed information about the nature, significance, effects and risks of clinical testing,
ç) adequately documented.

Chapter II
Processing of Personal Data

Article 3
General Principles

1. Personal data in the context of clinical trials may be processed only by the person in charge, unless otherwise provided under a provision of any other special act. The provision of this paragraph shall in no way prejudice the rights provided under paragraph 5, of Article 3 of this Instruction.
2. Personal data related to the test subject are processed in observance of the Law No.9887, dated 10.03.2008, “On protection of personal data”, as amended (hereinafter referred as “Law on protection of personal data”).
3. The provisions of this Instruction shall not prejudice the obligations of the person in charge pursuant to other relevant legislation.
4. The person in charge is in the position of a data controller in the case of the processing of personal data.
5. The person in charge, pursuant to Article 20 of the Law on protection of personal data may contract a processor, most often the person carrying out the tests, to process personal data.
6. The test subject is in the position of personal data subject in case of the processing of his/her personal data.
7. The Commissioner for the Protection of Personal Data shall supervise the observance of the obligations provided by this Instruction.

Article 4
Data Processing

1. In processing of personal data, the person in charge shall ensure that the rights of the test subject are not infringed upon, in particular, the right to the preservation of human dignity**,** and shall also ensure that the privacy and personal data of the tested subject is protected against unauthorized interference.

2. Personal data may be processed only if the test subject has given the informed consent.
3. The person in charge may process personal data only if the processing is necessary:
   a) for granting the registration permission;
   b) to prove the clinical effect and safety of a drug during scientific research process;
   c) to reassess the efficiency and safety of a drug after its release in the market.

4. Personal data may be processed for other purposes only within limits of the provisions of Law or if the test subject has granted his/her informed consent in advance.

5. Personal data shall be erased or shall be made anonymous as soon as they are no longer necessary for the purposes provided under paragraph 3 of Article 4. The necessity to keep storing any personal data shall be reassessed every 6 months.

6. The person in charge shall not communicate, especially by sharing or making the personal data available to any third party if the purpose is not related to the purposes provided under paragraph 3, Article 4 of this Instruction.

Chapter III
Provision of Consent

Article 5
Informed consent

1. Informed consent is given by the data subject having legal capacity to act. If the data subject lacks legal capacity, the consent is given by his legal guardian. If the data subject cannot write, oral consent given in the presence of at least one trusted witness can be accepted. The provision of oral consent is recorded in writing. This consent shall be considered as it was granted in written form.

2. Informed consent explicitly states the purpose of processing and the recipient of personal data, what personal data are processed and what is the period of time for which the consent is given.

3. The person in charge shall inform the test subject about his/her rights provided for in the Law on protection of personal data.

4. The text of the informed consent is formulated in a form that it is clear and understandable for the test subject.

5. The person in charge shall prove the test subject consent for the processing of personal data during the whole period of processing.

Chapter IV
Final Provisions

1. Non-fulfillment of requirements of this Instruction constitutes a violation of the Law on protection of personal data and it is sanctioned under article 39 thereof.

2. All entities provided for in point 2, Article 2 of this Instruction are in charge for applying this Instruction.

This instruction enters into force immediately and it is published in the Official Gazette.

COMMISSIONER

FLORA ÇABEJ (POGAÇE)

ANNEX 1

Provision of the test subject consent for processing of personal data in the context of clinical trial of drugs

(Sample)

I _____ after having obtained detailed information about the nature, significance, effects and risks of clinical testing, and after having obtained detailed information about my rights provided for in Law No. 9887, date 10.03 2008 "On protection of personal data", amended, give herein my free consent to _____ (the authorised subject), to process my personal data related to my name, surname, date of birth and clinical effect of the drug _____ .

The purpose of such processing shall be exclusively for verification of the clinical effect of the drug_____. (The authorized subject) _____, as controller can disclose or make available my personal data to these recipients: _____, provided that such disclosure is absolutely necessary for verification of clinical effect of the drug_____, or if the controller is carries out a processing which is essential to comply with legal obligation.

The controller has the right to retain my personal data only for a period of __ months.

The controller is obliged to destroy or to make anonymous my personal data upon expiry of such period, unless otherwise provided under a provision of any other special act.

Date__/__/___ Signature_____