

National Public Health Laboratory

Privacy regulation of the National Public Health Laboratory

Article 1. Scope of the regulation.

This regulation applies to the recording of patient data of the National Public Health Laboratory in [place]. It concerns patient data which have been presented to the National Public Health Laboratory for laboratory diagnosis.

Article 2. Holder of the personal data registration.

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Article 3. Administrator and adaptor of the personal data registration.

1. National Public Health Laboratory acts as administrator of the recording.
2. In dealing with the recording National Public Health Laboratory can be assisted by calculation centres and other institutions.
3. With adaptors, as meant in the previous paragraph, binding appointments are made with respect to the security of the recording, as well as with respect to secrecy.

Article 4. Objectives of the recording.

1. To supply to (para)medical personnel of results concerning research of their patients. This research is done at their request.
2. To make part of the registered data, incorporated for research and statistics, available. In this respect it can also be understood that data are made available to third parties for research.

Article 5. Registered data.

1. The data, which are incorporated in the recording, are mentioned in appendix A of this regulation.
2. The data pertaining to the material mentioned in Article 4, paragraph 2, which are made available for this purpose, are also mentioned in appendix A of this regulation.
3. The data in paragraph 1 are obtained from written or oral information sent in by the applicant of the diagnostic research, with additional written or oral information from the person in question added if necessary.

Article 6. Access to data.

1. Access to the data have only they, who need this access within the framework of their tasks as adaptor.
2. Persons, as meant in the previous paragraph and employee at National Public Health Laboratory, are bound to confidentiality. In the collective labour agreement it has been regulated that the individual employee is bound to confidentiality with respect to everything that reaches him as a result of his employment. By signing the employment contract an employee agrees that the collective labour agreement applies.
3. Persons, as meant in paragraph 1 of this Article and who have no work relation to National Public Health Laboratory, such as trainees, are bound to confidentiality. They have signed a declaration (appendix B) to that extent.
4. Others have, subject to their legally imposed tasks, no access to the recording.

Article 7. Supply of data from the recording by the holder.

1. The holder only supplies data from the recording to persons, who need these data to execute their task. Persons, as meant in the previous paragraph, are bound to confidentiality. They have signed a declaration as to that, as regulated in Article 6, paragraph 2 and 3.
2. The holder supplies data from the recording to persons and institutions legally charged with the related tasks.
3. To others no data from the recording are supplied, unless with the explicit written authorisation of those

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registered.

4. Supply of data remains, subject to supply in pursuance of a legal regulation, in default if the correctness of the data is not certain.

Article 8. Security.

1. The holder ensures adequate technical and organisational security of the recording.
2. Article 3, third paragraph, is of corresponding application.
3. Within the organisation of the holder a person is appointed, who guarantees the compliance with the security measures.
4. The holder ensures that within its organisation sufficient measures are taken against unauthorized use or abuse and against loss or theft of data.

Article 9. Storage periods of data residing with the holder.

Given the epidemiologic value of the data, which must be therefore be traceable down to an individual person, those data are kept for a minimum of 100 years after the last contact between the instructor/patient and National Public Health Laboratory.

Article 10. Rights of inspection by registered person(s).

1. To an explicit and written request by registered person(s) permission is granted to see the related data.
2. The inspection will take place at the offices of the holder of the recording after the identity of the applicant has been verified.
3. The inspection, as meant in the first paragraph, will take place within 15 working days after receipt of the request.

Article 11. Rights to copies for the registered person(s).

1. Registered persons can be issued with a complete duplicate of data concerning him/her, if required, after his/her identity had been verified.
2. The duplicate, as meant in the previous paragraph, is supplied within 15 working days after receipt of the request.

Article 12. Rights to correct by the registered person(s).

1. Registered persons can send a written request for a correction of incorrect facts.
2. The request for correction is addressed to the holder of the recording and mentions the modifications to be applied.
3. The holder commissions the adaptor to actually correct the data.
4. The correction, as meant in the first paragraph, takes place, within 15 working days after receipt of the request.

Article 13. Rights to add information by the registered person(s).

1. Registered persons can send a written request for incomplete data in the recording to be completed.
2. The request to add to the recording is addressed to the holder of the recording and mentions the addition to be introduced.
3. The holder commissions the adaptor to incorporate the addition in the recording
4. The addition, as meant in the first paragraph, takes place within 15 working days after the receipt of the request.

Article 14. Rights to remove information from registration recording.

1. Registered persons can send a written request to remove relevant data from the recording and destroy these.

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2. The request for removal and destruction is addressed to the holder of the recording and mentions the data to be removed.
3. The holder commissions the adaptor to ensure the removal and destruction of the data in question.
4. The removal and destruction, as meant in the first paragraph, takes place within 15 working days after receipt of the request.

Article 15. Protocol duty.

1. Of the data supplied as meant in Article 7, third paragraph, the holder keeps note.
2. The notes meant in the previous paragraph contain the date of access or supply, the purpose for which these took place, the name of the person or institution which had access or received data and the data to which access was granted or about which information was supplied.
3. The data, as meant in the previous paragraph, are kept for at least one year after the date of annotation in protocol.
4. Protocol information as meant in the previous paragraph, also applies to the right of inspection as meant in Article 10, as well as the right to copies as meant in Article 11.

Article 16. Refusal by the holder to requests.

1. A refusal by the holder to the right to examination, copy, correction, addition or removal is sustained with reasons.
2. A refusal, as meant in the previous paragraph, is communicated in writing to the registered person(s) within 15 working days after receipt of the request
3. If the holder refuses to comply with a request of a registered person, a procedure is open to the registered person(s) as meant in the Law on Personal registration.

Article 17. Liability.

The holder is accountable for possible damage as a result of not observing this regulation.

Article 18. Final provisions.

1. If a modification appears in the objectives of the recording, or in the registered data, as meant in appendix A and B or in the use of the data, this regulation must be adapted.
2. Adaptation of the regulation can only be initiated by the holder of the recording.
3. Appendices to this regulation are considered an integral part of the regulation.
4. The provisions in this regulation leave the rights of those registered and the duties of the holder on the basis of the Law Protection of Personal Data unimpeded.
5. In cases in which this regulation does not foresee, the holder of the recording decides.
6. This regulation is held for perusal by the holder.
7. This regulation becomes effective on 1 July 2013.
8. This regulation can be quoted as: "Privacy Regulation National Public Health Laboratory"

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Appendix A: To the Privacy Regulation of National Public Health Laboratory

Data of the patient, which can be used in the LIMS-registration are:

Surname and initials, address, postal code and place of residence;

Gender and birth date;

Requesting clinician;

Date of sample taking;

Requested tests with results that belong to this patient/test.

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Appendix B: To the Privacy Regulation of National Public Health Laboratory

Confidentiality agreement

Undersigned,

Working at National Public Health Laboratory in [*place*] oblige themselves, having regard to:

- Article 6 paragraph 3 of the privacy regulation,

To confidentiality of what he/she sees on account of his/her function, in so far that that obligation follows from the nature of the matter or has been imposed explicitly on him/her. This obligation also applies after termination of the activities at National Public Health Laboratory.

This obligation does not exist in relation to those, who share in the responsibility for a good addition to the activities of the undersigned nor also in relation with those, whose collaboration is considered necessary for that achievement, if and in so far as these persons themselves are obliged or oblige themselves to confidentiality.

Name:

Date:

Signature: