

On approval of the Rules for conducting medical research and requirements for research centers

Invalidated Unofficial translation

Order of the Minister of Health of the Republic of Kazakhstan dated May 4, 2019 no. ҚР ДСМ-64. Registered with the Ministry of Justice of the Republic of Kazakhstan on May 8, 2019 no. 18630. Abolished by the Order of the Minister of Health of the Republic of Kazakhstan dated December 21, 2020 No. KR DSM-310/2020

Unofficial translation

Footnote. Abolished by the Order of the Minister of Health of the Republic of Kazakhstan dated December 21, 2020 No. KR DSM-310/2020 (effective after ten calendar days from the date of its first official publication).

In accordance with clause 9 of article 180 of the Code of the Republic of Kazakhstan dated September 18, 2009 "On public health and health care system" I HEREBY ORDER:

1. to approve the Rules for conducting medical research and requirements for research centers according to the annex to this order.

2. Department of Science and Human Resources of the Ministry of Health of the Republic of Kazakhstan in accordance with the procedure established by the laws of the Republic of Kazakhstan shall ensure:

1) state registration of this order with the Ministry of Justice of the Republic of Kazakhstan;

2) within ten calendar days from the date of state registration of this order, direction of its copy in paper and electronic form in Kazakh and Russian languages to the Republican State Enterprise on the right of economic management "Institute of Legislation and Legal Information of the Republic of Kazakhstan" of the Ministry of Justice of the Republic of Kazakhstan for official publication and placement in the Reference Control Bank of the Regulatory Legal Acts of the Republic of Kazakhstan;

3) posting this order on the Internet resource of the Ministry of Health of the Republic of Kazakhstan after its official publication;

4) within ten calendar days after the state registration of this order, submission to the Department of Legal Service of the Ministry of Health of the Republic of Kazakhstan of information about implementation of measures stipulated by sub-clauses of 1), 2), and 3) of this clause.

3. Control over execution of this order shall be entrusted to Vice-Minister of Health of the Republic of Kazakhstan Abishev O.A.

4. This order shall come into force upon expiry of ten calendar days from the date of its first official publication.

Annex to the order of the
Minister of Health
of the Republic of Kazakhstan
dated May 4, 2019
no. ҚР ДСМ-64

Rules for conducting medical research and requirements for research centers

Chapter 1. General provisions

1. The Rules for conducting medical research and requirements for research centers (hereinafter referred to as the Rules), have been developed in accordance with clause 9 of article 180 of the Code of the Republic of Kazakhstan dated September 18, 2009 года "On public health and health care system" (hereinafter referred to as the Code) and shall determine the procedure for conducting medical research as well as establish the requirements for research centers.

2. The following terms and definitions shall be used in these Rules:

1) informed consent is the procedure for voluntary confirmation by the subject of research or his legal representative of consent to participate in a particular research after receiving information about all aspects of the research that are significant for him to make a decision;

2) biobank is a specialized repository of biological materials for scientific and medical purposes;

3) biological material are samples of material, such as urine, blood, tissues, cells, DNA, RNA, proteins, etc. collected from humans;

4) bioethical examination is a preliminary review of medical research materials and the issuance of a sound conclusion of the Bioethics Commission from the perspective of ethical acceptability, safety for participants and the appropriateness of this research;

5) genomic information is the information about fragments or the complete nucleotide sequence of deoxyribonucleic acid, ribonucleic acid of a person and related organisms;

6) sponsor is an individual or legal entity initiating a clinical research and responsible for its organization and (or) financing.

7) authorized body in the field of health care (hereinafter referred to as the authorized body) is the central executive body that provides leadership and intersectoral coordination in the field of public health, medical and pharmaceutical science, medical and pharmaceutical education, sanitary and epidemiological welfare

of the population, circulation of medicines and medical devices, quality control of medical services;

8) research subject is a living person or animal participating in a medical research;

9) interventional research is a research in which the subjects of the research perform a prospective prescription of one or more medical interventions in the form of preventive intervention, prescribing drugs, performing surgical interventions, behavioral therapy and others in order to assess the impact of these interventions on health indicators;

10) non-interventional research is a research involving a person as a subject of research, which is carried out after approval for the use of the method and (or) means within the guaranteed volume of free medical care and (or) compulsory social health insurance and is assigned as part of medical practice in accordance with the instruction for medical use;

11) preclinical (nonclinical) research is a chemical, physical, biological, microbiological, pharmacological, toxicological and other experimental research or a series of researches to research the test method and (or) means by applying scientific assessment methods in order to research a specific action and (or) obtain evidence of safety for human health;

12) clinical research is a research involving a person as a subject, conducted to identify or confirm the safety and effectiveness of the means, methods and technologies for the prevention, diagnosis and treatment of diseases;

13) Clinical Research Report is a document containing a description of a clinical research of a test method and / or means involving a person as a subject, combining clinical and statistical descriptions, data presentation and analysis; long-term effects, including adverse reactions of the test method and / or means;

14) clinical research inspection is the procedure for the official verification of a clinical research of test methods and (or) means, documents related to a clinical research and clinical base (premises, equipment and equipment) by an authorized body with the involvement of specialists from an authorized organization with experience in conducting clinical researches to assess the quality of the research clinical research and findings;

15) life-science experiment is a research based on the reproduction (modeling) of the structural and functional complex of the studied condition or disease in a simplified form on laboratory animals to determine the causes, conditions and mechanisms of the occurrence of the condition or development of the disease, the development of treatment and prevention methods;

16) medical research is research, the purpose of which is to obtain scientific knowledge of new knowledge about human health, diseases, their diagnosis, treatment or prevention;

17) monitoring is the procedure for monitoring the implementation of preclinical (nonclinical) research and ensuring its implementation, data collection and presentation of research results in accordance with the protocol, plan, program, standard operating procedures and the Standard;

18) applicant is an individual or legal entity that has expressed a desire to make free voluntary transfer of biological material for storage in a biobank;

19) audit of a clinical research of tested methods and (or) means is a systematic, independent and documented verification of documentation and activities of parties involved in conducting a clinical research of tested methods and (or) means, which is carried out by experts independent of the clinical research and research center to confirm the fact of this activities, as well as to assess the compliance of procedures for the collection, processing and presentation of data with the requirements of the clinical research protocol, standard operation procedures, Good Clinical Practice and regulatory requirements;

20) standard operation procedures (hereinafter referred to as the SOP) are detailed written instructions designed to achieve uniformity in carrying out certain activities monitoring;

21) Good Clinical Practice is a standard for planning, organizing, conducting, monitoring, auditing, documenting clinical trials, and analyzing and presenting their results, which guarantees the reliability and accuracy of the data and presented results, as well as ensuring protection of rights, health and confidentiality of research subjects;

22) protocol synopsis is a summary of clinical research protocol;

Chapter 2. Procedure for conducting clinical research

Paragraph 1. Procedure of obtaining a permit for conducting medical research

3. Medical research shall include biomedical experiments, preclinical (nonclinical) research, clinical research and public health research.

4. To obtain a permit to conduct a medical research, Central and Local Commissions have been created.

The Central Commission is created by the authorized body in accordance with the order of the Minister of Health of the Republic of Kazakhstan dated April 5, 2019 no. ҚР ДСМ - 20 “On Approval of the Regulation on the Central Commission on Bioethics” (registered in the Register of State Registration of Normative Legal Acts under no. 18480).

Local commissions shall be created at medical organizations for an independent assessment of studies conducted on their basis.

5. Medical research shall be carried out with the following documents: 1) the positive conclusion of the Central (hereinafter referred to as the Central Commission) and local (hereinafter - the Local Commission) Bioethics Commission conducting a bioethical examination;

2) approval for a medical study by an advisory body authorized to consider issues of scientific and (or) scientific and technical activity (scientific, scientific, scientific, clinical, expert council) in a research center (hereinafter referred to as the Council).

6. To obtain conclusion on the bioethical examination of medical research materials, the research sponsor (hereinafter referred to as the sponsor) or the head of the research shall provide the medical research materials to the Central Commission or Local Commission.

When conducting medical research in the framework of the targeted program, documents for the study shall be submitted to the Central Commission, as part of grant projects, materials shall be submitted to the Local Commission.

If the Local Commission is absent in the research center, the sponsor or the head of the study will contact the Local Commission of another organization. When choosing a Local Commission, the experience of the Commission considering materials of the corresponding type of research shall be taken into account.

7. The Central Commission shall conduct a bioethical examination of the materials of an interventional clinical research in case of:

1) conducting an interventional clinical research of the test method and (or) means in two or more research centers (according to a uniform research protocol);

2) conducting an interventional clinical research of the test method and / or means produced outside the Republic of Kazakhstan.

8. The Central Commission shall conduct a bioethical examination of the materials of a non-interventional clinical research in the case of conducting a research in two or more research centers (according to a single research protocol).

9. The local commission shall carry out a bioethical examination of materials of all types of medical research, with the exception of clinical researches specified in clauses 6 and 7 of these Rules.

10. To conduct a biomedical experiment, a preclinical (nonclinical) research, the sponsor or the head of the study shall submit the following documents to the Local Commission:

1) application for bioethical examination with a cover letter prepared in any form;

2) protocol of a biomedical experiment, preclinical (nonclinical) research with justification for the use of laboratory animals;

3) information about the research center for the biomedical experiment, preclinical (non-clinical) research;

4) information about laboratory animals, conditions of their housing;

5) curriculum vitae of the researcher in the form according to the appendix to these Rules, as well as for preclinical (nonclinical) researches - a certificate of completion of courses in Good Laboratory Practice.

11. To conduct a bioethical examination of the materials of an interventional clinical research, the sponsor or head of the research shall submit the following documents to the Central or Local Commission:

- 1) application for a clinical research with a cover letter prepared in any form;
- 2) clinical research protocol (original or copy) signed by the sponsor or head of the research;
- 3) synopsis of the clinical research protocol for international researches in Kazakh and Russian;
- 4) Investigator's brochure;
- 5) instructions (or project) for the medical use of the test method and (or) means;
- 6) information for the research subject or his legal representative on the clinical research in Kazakh and Russian;
- 7) a Sample Informed Consent of the research subjects in Kazakh and Russian;
- 8) curriculum vitae of the researcher, confirming his qualification and certificate of completion of courses of good clinical practice (GCP);
- 9) information about clinical bases;
- 10) power of attorney issued by the sponsor or head of the research with clearly defined delegated authority if the clinical research applicant is not the sponsor (or head of the research);
- 11) information regarding events for the recruitment of research subjects (information and advertising materials that will be used to attract research subjects to clinical research (if any) in Kazakh and Russian);
- 12) copy (or draft) of the civil liability insurance contract of the sponsor or the head of the research for causing harm to health and life of the subjects of the research;
- 13) a document defining the conditions for the payment of remuneration or compensation to subjects of research for participation in a clinical research (if this is provided for by the protocol of the clinical research). Information regarding the terms of payment or compensation to the research subjects for participation in the clinical research shall be provided in a cover letter with reference to the relevant document providing it.

12. To obtain a conclusion on the bioethical examination of materials from a non-interventional clinical research, the sponsor or the head of the research shall submit the following documents to the Local Commission:

- 1) application for a clinical research with a cover letter prepared in any form;
- 2) curriculum vitae of the researcher, confirming his qualification and certificate of completion of courses in Good Clinical Practice;
- 3) copy of registration certificate for the method and (or) means;
- 4) copy of instructions for medical use (approved version);
- 5) clinical research protocol signed by the sponsor or the head of the research;

6) information for research subjects or their legal representatives about the clinical research in Kazakh and Russian languages (if required by the protocol);

7) a Sample Informed Consent of the research subject in Kazakh and Russian languages (if required by the protocol);

8) a sample of an individual registration card on paper (if required by the protocol);

9) additional documents (if required by the protocol).

13. To conduct a public health research, the sponsor or the head of the research shall submit the following documents to the Local Commission:

1) request for a public health research with a cover letter prepared in any form;

2) curriculum vitae of the researcher in the form according to the annex to these Rules;

3) Research protocol signed by the researcher;

4) information for research subjects or their legal representatives about research in Kazakh and Russian languages (if required by protocol);

5) a Sample Informed Consent of the research subject in Kazakh and Russian languages (if required by the protocol);

6) a sample data collection form on paper (if required by protocol);

7) additional documents (if required by the protocol).

14. The term of bioethical examination of medical research materials and the issuance of a conclusion shall not exceed fourteen working days from the date of payment for expert work and the submission of a complete list of documents.

15. If an incomplete set of documents is provided, the Local Commission shall return the documents to the sponsor (or the head of the research) within three working days from the date of official acceptance of documents.

16. The Local Commission shall carry out bioethical expertise of materials of medical research according to the procedures approved by the research center. The Central Commission shall carry out bioethical expertise of materials of medical research according to the procedures approved by the Central Commission.

17. When necessary the Central Commission or the Local Commission shall request additional explanations on submitted documents from the sponsor or the head of the research. The time required for the sponsor or the head of the research to submit additional data requested by the Central Commission or the Local Commission shall not be included in the bioethical examination and shall not exceed sixty calendar days.

18. Based on the results of a bioethical examination of a medical research, the Central or Local Commission shall make one of the following decisions:

1) on the approval of a medical research in any form;

2) on the need to improve the materials of the application for a medical research;

3) on the denial of medical research.

19. The reason for the refusal to conduct a research shall be:

- 1) lack of scientific justification in the research;
- 2) the unacceptability of the research from a bioethical point of view;
- 3) violation of the basic principles of conducting studies with humans and animals, reflected in the Standards for Good Laboratory Practice (for preclinical (non-clinical) studies, if applicable) and Good Clinical Practice (for clinical studies, if applicable), approved by the order of the Minister of Health and Social Development of the Republic of Kazakhstan dated May 27, 2015 no. 392 "On approval of Good Pharmaceutical Practice" (registered with the Register of State Registration of Regulatory Legal Acts under no. 11506) (hereinafter referred to as the Order No. 392).

20. The decision of the Central or Local Commission on the results of bioethical examination shall be drawn up in the form of a conclusion. The report shall be sent to the sponsor or the head of the research.

In the event of a disagreement between the head of the research and the results of the examination, the Central or Local Commission will re-examine the medical research materials with the participation of the sponsor (head of the research) and independent experts.

21. Based on the positive conclusion of the Central or Local Commission, researchers shall submit an application for a medical research to the Council of the Research Center. An application for a medical research shall include a package of documents referred to in clauses 10-13 of these Rules and a positive conclusion of the Central or Local Commission.

22. An application for a medical research shall be considered at a meeting of the Council, which takes one of the following decisions:

- 1) on the approval of a medical research;
- 2) on the appropriateness of improving the materials of the application for a medical research;
- 3) on the inappropriateness of conducting a medical research.

The period of consideration of an application for a medical research from the date of receipt by the Secretariat of the Council of the Research Center depends on the frequency of meetings of the Council, but shall not exceed 30 calendar days.

23. The decision on approval of conducting a medical research shall be made if the research center has the conditions specified in clauses 36 and 37 of these Rules, as well as if the application materials comply with the requirements of the Republic of Kazakhstan legislation in the field of health and science, international and national bioethical standards and good practice of medical research.

The decision on the appropriateness of finalizing the materials of the application for a medical research shall be made in the presence of removable comments on the design and content of the application.

The decision on the inappropriateness of conducting a medical research shall be made if there are no conditions in the research center specified in clauses 36 and 37 of these Rules, as well as if the application materials do not comply with the requirements of the Republic of Kazakhstan legislation in the field of health and science, international and national bioethical standards and good practice of medical research.

24. Protocol decision of the Council indicated in sub-clause 1) of clause 22 of these Rules, shall be the grounds for conducting medical research.

**Paragraph 2. Procedure for conducting medical research
(general requirements)**

25. Medical research shall be conducted subject to the existence of the following documents:

- 1) positive conclusion of the Central or Local Commission;
- 2) Protocol decisions of the Council, indicating the approved topic, plan and design of the research, the composition of the research group, the process of tracking and monitoring the performance of the research.

26. A medical research shall be conducted under the guidance of a sponsor or a head of the research according to an approved research plan with a study protocol and a report containing the results of the research. Monitoring the implementation of the plan shall be entrusted to the head of the study.

27. Medical research shall be conducted on the basis of a research center that has the necessary material and technical base and qualified specialists in the relevant field of research.

28. Documents drawn up during medical research in accordance with these Rules shall be subject to accounting in electronic and (or) paper form by the organization that issued them, in the record book(s).

29. Persons responsible for medical research shall:

- 1) amend the research plan with permission of the Council;
- 2) ensure timely collection of the findings, registration of deviations from the research plan, indicating the reasons and assessing the impact of the changes made on the results obtained, and also, if necessary, take measures to eliminate the revealed deviations;
- 3) provide interpretation and analysis of the results, preparation of a report on the results of a medical research, confidentiality of the results.

30. The quality of medical research shall be ensured by:

- 1) material and technical equipment for medical research provided by the head of the research center;
- 2) the presence of management (adherence to a medical research protocol at all stages of a medical research; compliance with SOP (for clinical research));

- 3) planning of the parameters of medical research;
- 4) system of drawing up the documentation (working journals with primary data, final report, archives);
- 5) quality assurance system to ensure the reliability of the research and the validity of the results.

The equipment on which the medical research is conducted shall have an appropriate quality certificate, indicating the period of warranty service, and a schedule for checking the operation of the equipment shall be attached.

31. Quality control shall be carried out at all stages of work in order to ensure the reliability of medical research data and the correctness of their processing.

32. The head of the research center, shall ensure the compliance with the requirements established by the research plan, objectivity and independence of the study and be responsible for the reliability of the results.

33. The audit of the study shall be carried out according to the protocol decision of the Council by competent specialists from among the employees of the research center, it shall be allowed to engage experts from other relevant organizations to conduct an audit.

34. Documents drawn up during medical research in accordance with these Rules, or their copies shall be subject to storage according to established requirements by the head.

35. Documents drawn up by the research center during medical research in accordance with these Rules, or copies thereof must be stored in third-party organizations (if involved) for three years. The need for further storage in third parties of the specified documents or their copies shall be determined by the contract concluded by the developer and the third party.

Chapter 3. Requirements to research centers

36. The requirement for research centers on the basis of which clinical trials are conducted shall be:

- 1) availability of a license for conducting medical activities;
- 2) availability of the SOP for conducting clinical research;
- 3) availability of staff with a medical education and a document on training in good clinical practice;
- 4) availability of conditions for intensive care and resuscitation (if required by the protocol).

37. For research centers having biobanks, on the basis of which clinical trials are conducted, the following requirements shall be imposed:

- 1) availability of a license for conducting medical activities;

2) availability of the SOP for conducting clinical research and for work with biobanks;

3) the presence of personnel with a medical education and a document on training in good clinical practice;

4) availability of conditions for intensive care and resuscitation (if required by the protocol).

5) availability of a positive conclusion of the Central Commission.

38. To obtain a conclusion from the Central Commission, the research center shall send a statement on the creation of a biobank to the Central Commission and shall attach the following documents:

1) an application indicating the name of a biobank;

2) legal and financial details of the owner of the biobank;

3) information about the location and methods of storage and coding of biological samples, as well as data associated with these samples, and conditions for managing these data;

4) a description of the area (s) of biobank activity, principles and conditions that apply when collecting and storing biological samples and data; providing access to them for research and other use of biological samples, information and restrictions regarding the use of biological samples;

5) approved samples of informed consent;

6) information about procedures for recording, destruction of biological samples and personal data.

39. The Central Commission shall issue an opinion on the creation of a biobank within 30 days after receiving a request.

40. Based on the positive conclusion of the Central Commission, the head of the research center shall issue an order to create a biobank.

To ensure the activities of a biobank at the level of a research center, the following shall be approved:

1) regulations on activities of a biobank;

2) guidance on quality management system;

3) guidance on risk management;

4) organizational structure, number of staff, their qualifications and responsibilities;

5) registration procedure for the description of personal data registers supported by biobank on physical media;

6) list of instructions regarding biobank activities.

41. The activities of the biobank shall be subject to internal and external monitoring . The research center, which creates the biobank, shall provide an internal monitoring procedure. Internal monitoring shall be carried out annually. External monitoring shall be carried out by the Central Commission once every 5 years. Monitoring shall be

subject to procedures for the collection, storage and use of biological samples, collection, registration, storage, protection and transfer of personal data.

42. If the research center decides to close the biobank or destroy biological samples, personal data stored in the biobank, the research center shall notify the Central Commission and shall ensure the destruction of biological samples, personal data and the transfer of biological samples, personal data on physical media to another biobank.

43. The Local Commission shall review and approve all researches with biological samples, identifiable or non-identifiable, or grants exemption from bioethical examination before starting the research.

44. The protection of privacy and respect for the confidentiality of donors of biological materials and their personal information, including information received from donors regarding other persons, shall be ensured.

45. Donors of biological materials shall not receive financial remuneration for the donation, with the exception of a reasonable reimbursement of expenses directly related to the implementation of the donation.

46. Researchers and biobank managers shall respect the religious and cultural beliefs and traditions of people or groups of people / communities regarding human tissues and organs.

47. Informed consent shall be obtained prior to the collection of biological material for research purposes for storage of research use indicating these objectives.

48. Consent is general or special. General consent is a consent that does not limit the use of biological material to the scope of a specific research project. The general consent means consent to the storage and use of biological material or personal information obtained in a study with biological materials, without the need for a second consent. The donor limits general consent to the use of biological material and any related information. Special consent shall be the consent for a specific research project.

49. Donors of biological material shall receive complete information in an accessible form necessary for a voluntary decision on consent (if necessary),

50. This information shall include:

- 1) research goals, risks and benefits for donors;
- 2) type and quantity of biological materials; safety and risks associated with the procedures for obtaining them;
- 3) intended use of biological materials, including any commercial use;
- 4) measures used to protect confidentiality and minimize risks for participants;
- 5) storage of biological material, the probability of use for any future research, the duration of storage of biological materials, the procedure for their storage, storage location (for example, in Kazakhstan, outside Kazakhstan), and the disposal process, if applicable;

6) any alleged association of biological materials with participant information; the likelihood of repeated contact in future studies, or for reporting clinically relevant data and random findings;

7) the possibility of withdrawal of consent, procedures and consequences of such withdrawal.

51. The repeated consent shall be required:

1) when the planned study was not provided for in the initial consent when collecting biological material (except in cases where the consent is canceled by the Local Commission);

2) when the selection of biological material was made from a minor who did not personally give his consent to the donation; after reaching adulthood, he must again obtain consent for research with previously obtained biological samples or related information. A person who has reached the age of majority must be informed of his right to withdraw / destroy his biological materials from research or storage for the purpose of research. In some cases, the Local Commission may waive these requirements in accordance with the criteria for revoking the consent;

3) in researches related to sensitive, for example, with human reproductive cells, embryos, or combinations with animal-sourced materials.

52. Researchers who are entitled to reuse identifiable human biological materials may use the materials if approved by the Local Commission, subject to the following conditions:

1) identifiable human biological materials are needed for research;

2) the use of identifiable biological human materials without the consent of the participant will not adversely affect the well-being of the participants from whom the materials were collected;

3) Researchers observe measures to protect the privacy of individuals and to protect these biological materials in accordance with the legislation of the Republic of Kazakhstan;

4) Researchers comply with recommendations previously submitted by experts, experts on any use of these biological materials;

5) it is impossible or impracticable to obtain consent from the persons from whom the materials were collected;

6) researchers have obtained the necessary permission for the reuse of human biological materials for research purposes.

53. Researchers shall demand an approval from the Local Commission, but do not request participant's consent for studies that are based solely on the secondary use of unidentifiable human biological materials.

54. If the reuse of human identifiable biological materials without the requirement of obtaining consent is approved in accordance with sub-clause 5) of clause 52 of these

Rules, the researcher shall contact the Local Commission for approval of the consent plan for the reuse of human biological material.

55. If clinically relevant information is found during research with biological materials, researchers will inform the donor if this desire has been reflected in informed consent.

56. The Local Commission shall review and approve all agreements for access to data and / or biological samples in order to ensure the best ethical use of biological samples and data from donors in accordance with their consent.

57. When publishing research results using data and biological samples provided by biobanks, it is necessary to indicate the intellectual contribution determined on the basis of copyright and intellectual property rights.

Annex
to the Rules for
conducting medical research and
requirements to research centers
Form

Curriculum Vitae of the Researcher

Surname, name, patronymic if any (in full)
Date of birth
Education (indicating the educational institution)
Specialty
Post-diploma degree
Academic degree and title (if available)
Place of employment and position
Work experience in the specialty
Scientific works, publications (indicate the number and titles of articles, monographs related to the research problem, year of publication and publishing house)
Experience in conducting research (area of study)
Availability of certificates of training in courses on Good Clinical Practice / Good Laboratory Practice, other certificates of ethics and (or) research methodology
Organization address, contact phone, fax, e-mail
Signature of the Principal Investigator (Researcher)
Signature of the head, officially certified (HR Department)
Date