

Document type	SOP (Standard Operating Procedure)					
Intended for	Chair, Secretary and members of the Local Bioethics Committee of HemCenter LLP					
Nomenclature code	I-05	Number	Issl-3-5	Revision	001	
Title	EVALUATION OF A RESEARCH APPLICATION					
Developed by	Business Development Director		Volyanskaya N.V.		15 May 2023	
	Project Manager		Graf M.A.		15 May 2023	
Agreed by	Medical Director		Klodzinskiy A.A.		29 May 2023	
	Head of Patient Support and Internal Review Service		Demkina O.V.		29 May 2023	
Approved	By Order of the Director General of HemCenter LLP No. I-02-52 dated 2 June 2023					
Implemented						
Revision policy	Upon changes in regulatory legal acts and/or operational need					

Purpose

To establish the procedure for the consideration and evaluation of the study document package/ study protocol submitted to the Local Bioethics Committee of HemCenter LLP for initial evaluation and approval

Responsibilities

LEC members and independent consultants are responsible for completing the evaluation form, together with the decision and comments, after evaluating each study protocol

The Secretary of the Local Bioethics Committee of HemCenter LLP (LEC) is responsible for documenting the decisions, the relevant opinions and the reviews for each study document package/study protocol, including the reasons for such a decision.

The LEC Chair and Secretary must sign and date the approval of the decision.

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No. Terms and definitions

- a. **Biological equivalence** (hereinafter – bioequivalence) – the absence of significant differences in the rate and extent to which the active substance or active moiety of pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of its action when administered at the same molar dose under similar conditions in an appropriately designed study
- a. **Investigator's Brochure** - a compilation of the results of the clinical and preclinical (non-clinical) study of the investigational product that are relevant to its study in humans.
- b. **State expert organisation in the field of circulation of medicinal products and medical devices** (hereinafter – the expert organisation) – a state monopoly entity carrying out production and economic activities in the field of healthcare to en-
- c. **Study design** - the overall plan of the study, a description of the manner in which the study is conducted depending on the selection and formation of groups of study subjects and the blinding (masking) of data.

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- d. **Contract** - a dated and signed agreement between two or more parties that sets out arrangements concerning the allocation of the scope of work and responsibilities in the conduct of a study and, where necessary, financial matters. The study protocol should serve as the basis of the contract.
- e. **Case report form** - a document on paper, electronic or optical media designed to record all the information required by the protocol to be reported to the sponsor on each study subject.
- f. **Interventional study** – a study involving a human as a study subject, in which the investigator-physician, on the basis of an interventional clinical trial protocol that complies with the procedure for conducting clinical trials, assigns a specific intervention to the study subjects.
- g. **Informed consent** - a procedure by which a study subject or his or her legal representative voluntarily confirms consent to participate in a particular study after having been informed of all aspects of the study that are relevant to the decision. Written informed consent is documented using the form approved by the authorized body.
- h. **Bioequivalence study** – a comparative study of bioavailability aimed at establishing pharmacokinetic equivalence between the test product and the comparator product.
- i. **Investigator** - an individual responsible for the conduct of a clinical trial at the clinical sites of HemCenter LLP, a member of the research team.

Where a study is conducted at a clinical site by a group of investigators, a **Principal Investigator** - the head of the research team - is designated. The Principal Investigator is selected by the members of the Clinical Project Office and approved by the Director General of HemCenter LLP. The Order appointing the members of the research team (investigators) is approved by the directors of the branches and the division of HemCenter LLP

- j. **Investigational product** - a pharmaceutical form of an active substance or placebo being tested or used as a control in a clinical trial, including an authorised medicinal product where it is used in a way different from the approved one, or when used for a new indication or to gain further information about an approved indication
- k. **Ethics committee** - a consultative and advisory body established at the national level (the Central Bioethics Commission) and at the level of a medical organization, composed of specialists in healthcare and science and representatives of public organizations, which protects the rights, safety and well-being of study subjects and investigators and carries out the ethical and moral-legal assessment of clinical trial materials.

Local Bioethics Committee (LEC) of HemCenter LLP - an independent body that protects the rights, safety and well-being of patients, trial subjects, investigators and healthcare workers and carries out the ethical and moral-legal assessment of materials related to medical and scientific activities.

- l. **Clinical site** - a healthcare organization that conducts clinical trials.
- m. **Clinical trial** - a study involving a human as a subject, conducted to identify or confirm the safety and efficacy of means, methods and technologies for the prevention, diagnosis and treatment of diseases.
- n. **Contract research organization (CRO, Contract research organization)** — an individual/organization that, under a contract with the sponsor, performs one or more of the sponsor's functions related to the conduct of a clinical trial.
- o. **Confidentiality** - keeping information belonging to the sponsor, or information that makes it possible to identify a study subject, secret from unauthorized persons. Materials containing restricted information.
- p. **Medicinal product** – a product that is or contains a substance or combination of substances that comes into contact with the human body and is intended for the treatment or prevention of human diseases, or for restoring, correcting or modifying human physiological functions by exerting a pharmacological, immunological or metabolic action, or for the diagnosis of human diseases and conditions.
- q. **Study materials** – a set of documents submitted by the sponsor of clinical trials to the clinical site, which includes the authorization of the authorized body in the field of healthcare of the Republic of Kazakhstan to conduct the given clinical trial and to designate those responsible for its conduct in accordance with the procedure approved in the Republic of Kazakhstan; the clinical trial protocol; the Investigator's Brochure; explanatory documents on the specifics of the use of new medical technologies (where used) and other documents, as well as the draft clinical trial contract

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- r. **Medical record** — a medical document in which the attending physicians record the patient's medical history (inpatient or outpatient) and the treatment prescribed to the patient, in electronic or paper form.
- s. **Multicenter clinical trial** - a clinical trial conducted according to a single protocol at more than one study center and by more than one investigator.
- t. **Clinical trial monitor** – an individual appointed by the sponsor or contract research organization who works together with the coordinating investigator or coordinating committee and oversees the conduct of the clinical trial in accordance with the protocol, assesses the degree of its implementation, and assists the investigator in the analysis, interpretation and extrapolation of data.
- u. **Monitoring** - the procedure of overseeing the progress of a biomedical study and ensuring that it is conducted, the data are collected and the study results are reported in accordance with the protocol, plan, programme, standard operating procedures and Good Clinical Practice.
- v. **Good Clinical Practice (GCP)** - a standard for the design, organization, conduct, monitoring, auditing and recording of clinical trials, as well as for the analysis and reporting of their results, that provides assurance that the data obtained and the results reported are credible and accurate, and that the rights, health and confidentiality of study subjects are protected.
- w. **Adverse incident** – any malfunction and/or deterioration in the characteristics or performance of a medical device, or any inadequacy or inaccuracy in the accompanying information (documentation) for a medical device, or side effects or an adverse reaction not specified in the instructions for use or the operating manual, which directly or indirectly led, or might have led, to the death or serious deterioration in the state of health of users or third parties.
- x. **Adverse event** – any untoward change in the state of health of a patient or clinical trial (study) subject administered a medicinal (investigational) product, regardless of whether it has a causal relationship with its use.
- y. **Impartial witness** - an individual not involved in the conduct of the clinical trial, - who assists the study subject, including by reading out the written materials supplied to him or her.
- z. **Non-interventional clinical trial** – a study that is conducted after the state registration of a medicinal product or medical device and is prescribed within the framework of medical practice.
- aa. **Original medical records** – see the term "source documents".
- bb. **Essential documents** – documents which collectively or individually permit evaluation of the conduct of a study and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice (GCP) and with regulatory requirements.
- cc. **Clinical trial (study) report** - a document containing a description of a clinical trial of a therapeutic, prophylactic or diagnostic agent involving a human as a subject, which integrates the clinical and statistical descriptions, the presentation of data and their analysis; and long-term effects, including adverse reactions to the investigational medicinal product or medical device.
- dd. **Source documents** – all information contained in original medical records and certified copies thereof that describes the results of clinical observations, examinations and other activities and makes it possible to reconstruct and evaluate the course of the clinical trial. Source data are contained in source documents (originals or certified copies thereof).
- ee. **Comparator product** – an authorised medicinal product or placebo used as a control in a clinical trial.
- ff. **Clinical trial protocol** - a document that describes the objectives, design, methodology, statistical considerations and organization of a study.
- gg. **Serious adverse event and/or serious adverse reaction** - an adverse reaction that results in death, is life-threatening, requires hospitalization of the patient or prolongation of existing hospitalization, results in persistent or significant incapacity or disability, or in congenital anomalies or birth defects, or requires medical intervention to prevent the development of the listed conditions
- hh. **Protocol synopsis** - a brief summary of the clinical trial protocol.

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- ii. **Clinical trial sponsor** – an individual or legal entity responsible for the initiation, organization and financing of a clinical trial.
- jj. **Standard operating procedures** – detailed written instructions designed to achieve uniformity in the performance of a specific activity.
- kk. **Study subject** - an individual who participates in a clinical trial either as part of the group receiving the investigational product or as part of the control group.
- ll. **Authorized body** in the field of healthcare – the Ministry of Health of the Republic of Kazakhstan.

mm Clinical trial phase:

the first phase of a clinical trial – the first testing of a medicinal product, conducted in healthy volunteers or, where the high toxicity of the investigational product makes it unethical to conduct the study in healthy volunteers, in patients suffering from the relevant disease, in order to establish tolerability, safety, the presence of a therapeutic effect, and pharmacokinetic and pharmacodynamic characteristics;

the second phase of a clinical trial – a study aimed at assessing the efficacy and short-term safety of the investigational medicinal product in patients with a specific disease, as well as demonstrating the clinical efficacy of the medicinal product and determining the therapeutic dose level when tested in a group of patients;

phase four of a clinical trial – a study of a medicinal product conducted after its registration and placing on the market in order to confirm its therapeutic efficacy and the strategy for its further use, as well as to obtain additional information on the range and frequency of adverse effects and on the interaction of the investigational medicinal product with other medicinal products;

phase three of a clinical trial – a study conducted in large groups of patients of various ages and with various concomitant conditions in order to examine all aspects of treatment, including assessment of the risk: benefit ratio.

No. Abbreviations

- a. **IB** – Investigator's Brochure
- b. **PI** – Principal Investigator
- c. **RT** – research team
- d. **MD** – medical device
- e. **IP** – investigational product
- f. **CRF** – case report form
- g. **IC** – informed consent
- h. **CT** – clinical trial
- i. **CTC** – clinical trial coordinator
- j. **LEC** – Local Bioethics Committee of HemCenter LLP
- k. **MoH RK** – Ministry of Health of the Republic of Kazakhstan
- l. **AE** – adverse event
- m. **ED** – essential documents
- n. **RK** – Republic of Kazakhstan
- o. **SAR** – serious adverse reaction
- p. **SAE** – serious adverse event
- q. **SOP** – standard operating procedure
- r. **LLP** – limited liability partnership
- s. **the Center** – HemCenter LLP
- t. **CBC** – Central Bioethics Commission of the Ministry of Health of the Republic of Kazakhstan
- u. **ҚР ДСМ** – abbreviation used when assigning numbers to regulatory legal acts of the RK (Kazakh)

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- v. **CRO** – contract research organization
- w. **GCP** – Good Clinical Practice
- x. **ICH-GCP** – International Conference on Harmonisation, the international conference on the harmonisation of GCP
- y. **CIOMS** – Council for International Organizations of Medical Sciences
- z. **EMA** – European Medicines Agency (EMA), the agency for the evaluation of medicinal products for compliance with the requirements set out in the European Pharmacopoeia
- aa. **FDA** – Food and Drug Administration of the USA (United States of America)
- bb. **UNESCO** – United Nations Educational, Scientific and Cultural Organization, a specialised agency of the United Nations for education, science and culture.
- cc. **WHO** – World Health Organization

No. Procedure

1. **Completing the assessment form** LEC members and independent consultants complete an assessment form for each study document package/study protocol in accordance with the approved LEC form (Appendix 1).
2. **Sections and criteria for assessing the study documentation package**
 - 2.1. The review of the study document package/study protocol must cover the following items:
 - the need for human participation in the study;
 - the objectives of the study;
 - the literature review;
 - the sample size;
 - the methodology and data management;
 - inclusion/exclusion criteria;
 - the control groups (placebo, if any);
 - the criteria for withdrawal from or discontinuation of participation in the study.

When assessing the qualifications of the investigator and of the study site, it is necessary to consider whether the investigator's experience and training are appropriate to the study he or she is conducting, and also to verify the disclosure or declaration of a potential conflict of interest and whether the equipment and infrastructure of the study site are adequate

The lead investigator, if he or she has no medical education, must obtain advice from a physician where necessary.
 - 2.2. Participation in the study must be voluntary and free from coercion. The following information and documents must be available:
 - the procedure for obtaining informed consent (IC);
 - the patient data information sheet;
 - provision of a translation of the IC document into the local language;
 - indication of contact persons with their address and telephone numbers;
 - coverage of confidentiality and privacy;
 - risks – physical, mental, social;
 - benefits – to participants and to other interested parties;
 - indication of compensation – justified/unjustified;
 - involvement of vulnerable groups;
 - provision of medical/psychosocial support;
 - provision of medical care in the event of injury;
 - use of biological materials.

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2.3. Involvement of the study population in the research process and impact consultations with the group of study subjects;

involvement of local investigators and institutions in the design of the study plan and in the analysis and publication of the results ;

contribution to the development of science and medicine locally;

benefit to the local population;

availability of the study results.

3 **Preparation of the assessment report** In the course of decision-making, it is necessary to complete the assessment report form (Appendix 2) and to mark the decision in the appropriate place:

approved;

approved with recommendations;

re-review;

not approved.

In the event of refusal, it is necessary to state the rationale, provide comments and suggestions, sign the document and send the form to the LEC Secretary.

4 **Preparation of the decision** The LEC Secretary collects the assessment form and the assessment results from each reviewer, then summarises the comments, suggestions and opinions on each study on the meeting agenda.

When drawing up the LEC decision, the decision form (Appendix 3) must be at hand. The LEC Secretary supplements the information. The members who took part and their votes must be listed. The instructions, advice and decisions reached by the LEC members must be summarised.

The LEC Chair or Secretary signs the final decision. The original of the document is placed in the "LEC Decisions" file.

Appendix 1

Study assessment form

Protocol No.:	Date (D/M/Y)
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Title

Lead investigators:	tel.
Study site:	tel.
Co-investigator(s):	tel.
Total number of investigators:	Number of participating sites:

Funding organisation:

Duration of the study	Status:	☐ new ☐ resubmission
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☐ supplementary

Reviewer's full name:	tel.
Type of study	☐ Interventional ☐ Epidemiological ☐ Observational ☐ Records ☐ Clinical ☐ Genetic ☐ Sociological survey ☐ Other (specify)
Assessment status:	☐ Regular ☐ Expedited ☐ Urgent

Briefly describe the study:

Tick the relevant items:

☐ Randomised ☐ Stratified random. ☐ Open-label ☐ Double-blind ☐ Placebo-contr. ☐ With treatment ☐ Crossover
☐ Parallel ☐ Interim analysis ☐ Tissue ☐ Blood ☐ Genetics

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☐ Multicentre ☐ Screening ☐ Descriptive

Brief study plan and statistical methods:

the objectives of the study;

Tick the relevant items:

1 Objectives	What needs to be improved?
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☐ clear ☐ unclear

2 Human participation is needed	Comments
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☐ Yes ☐ No

3 Methodology	What needs to be improved?
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☐ clear ☐ unclear

4 Background information and data Comments

☐ sufficient

☐ insufficient

5 Risk-benefit assessment	Comments
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☐ acceptable

☐ unacceptable

6 Inclusion criteria	Comments
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☐ appropriate

☐ inappropriate

7 Exclusion criteria	Comments
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☐ appropriate

☐ inappropriate

8 Discontinuation criteria	Comments
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☐ appropriate

☐ inappropriate

9 Participation of vulnerable groups	Comments
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☐ Yes ☐ No

10 Voluntariness of participation

☐ Yes ☐ No

11 Adequacy of the number of participants

☐ Yes ☐ No

12 Control groups (placebo)	Comments
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☐ yes ☐ no 13 Adequacy of the qualifications of the lead investigator

☐ yes ☐ no 14 Disclosure or declaration of a conflict of interest

☐ yes ☐ no 15 Equipment of the infrastructure of the study site

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☐ appropriate

☐ inappropriate

16 Consultations with the community

☐ yes ☐ no 17 Involvement of local investigators in planning, analysis and publications ☐ yes ☐ no 18 Contribution to the development of local science and medical care

☐ yes ☐ no 19 Benefit to the local population

☐ yes ☐ no 20 Are there similar studies/results

☐ yes ☐ no 21 Shipment of tissue/blood abroad

☐ yes ☐ no 22 Are the procedures for obtaining IC acceptable?

☐ yes ☐ no 23 Content of the IC document

☐ clear ☐ unclear 24 Style of wording of the IC

☐ clear ☐ unclear 25 Contact persons for participants

☐ yes ☐ no 26 Privacy/ Confidentiality

☐ yes ☐ no 27 Coercion to participate

☐ No ☐ True 28 Provision of medical/psychological care

☐ appropriate

☐ inappropriate

29 Medical care in the event of injury ☐ appropriate

☐ inappropriate

30 Provision of compensation

☐ appropriate

☐ inappropriate

Appendix 2

Assessment report

Date (D/M/Y): _____ Protocol No. _____

Title

Assessment items	☐ attached ☐ not attached
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Assessment of a resubmitted application Date of re-review

☐ Yes ☐ No

Decision	☐ Approve ☐ Approve with comments ☐ Resubmit ☐ Do not approve
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Comments:

Signature _____ Date _____

Appendix 3

LEC decision

Meeting No. _____ Date (D/M/Y): _____

Protocol No. _____ Assigned number _____

protocol title;

Lead investigator: _____

Study site:

Items reviewed:	☐ attached ☐ not attached
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Re-review				Date of previous review			

☐ Yes ☐ No

Decision:	☐ Approved ☐ Approved with recommendations ☐ Resubmission ☐ Not approved		
No. Voting of LEC members	Decision		
A	AR	RS	NA

Note: A – approved; AR – approved with recommendations; RS – resubmission; NA – not approved

Signature: _____

_____ Chair Secretary

Date _____

Governing documents

1. Code of the Republic of Kazakhstan "On Public Health and the Healthcare System" No. 360-VI ZRK dated 7 July 2020. [Link](#)
2. Order of the Minister of Health of the Republic of Kazakhstan No. ҚР ДСМ- 248/2020 dated 11 December 2020 "On approval of the rules for conducting clinical trials of medicinal products and medical devices, clinical laboratory testing of medical devices for diagnostics outside a living organism (in vitro), and the requirements for clinical sites, and for the provision of the public service Issuance of authorisation to conduct a clinical trial and (or) testing of pharmacological and medicinal products and medical devices". [Link](#)
3. Order of the Minister of Health of the Republic of Kazakhstan No. ҚР ДСМ- 35 dated 4 April 2022, registered with the Ministry of Justice of the Republic of Kazakhstan on 12 April 2022 under No. 27526, on amendments and additions to Order of the Minister of Health of the Republic of Kazakhstan No. ҚР ДСМ- 248/2020 dated 11 December 2020 "On approval of the rules for conducting clinical trials of medicinal products and medical devices, clinical laboratory testing of medical devices for diagnostics outside a living organism (in vitro), and the requirements for clinical sites, and for the provision of the public service Issuance of authorisation to conduct a clinical trial and (or) testing of pharmacological and medicinal products and medical devices". [Link](#)
4. Order of the Minister of Health of the Republic of Kazakhstan No. ҚР ДСМ- 310/2020 dated 21 December 2020 "On approval of the rules for conducting biomedical research and the requirements for research centres". [Link](#)
5. Order of the Minister of Health of the Republic of Kazakhstan No. ҚР ДСМ- 181/2020 dated 4 November 2020 "On approval of the rules for assessing, within the framework of pharmaceutical inspection, the materials of preclinical (non-clinical) studies and the compliance of the conditions for conducting them with the requirements of Good Laboratory Practice (GLP) of the Republic of Kazakhstan and (or) the Eurasian Economic Union". [Link](#)
6. Order of the Minister of Health of the Republic of Kazakhstan No. ҚР ДСМ- 151/2020 dated 23 October 2020 "On approval of the Regulation on the Central Bioethics Commission". [Link](#)
7. Order of the Acting Minister of Health of the Republic of Kazakhstan No. ҚР ДСМ- 130 dated 20 December 2021 "On approval of the standard for the organisation of haematological care for the adult population of the Republic of Kazakhstan". [Link](#)
8. Order of the Acting Minister of Health of the Republic of Kazakhstan dated 4 February 2021 No. ҚР ДСМ-
15. Registered with the Ministry of Justice of the Republic of Kazakhstan on 9 February 2021 under No. 2216, "On approval of good pharmaceutical practices". [Link](#)
9. Order of the Minister of Health of the Republic of Kazakhstan No. ҚР ДСМ- 304/2020 dated 21 December 2020. Registered with the Ministry of Justice of the Republic of Kazakhstan on 22 December 2020 under No. 21848, "On approval of the regulations on the clinical site, the clinic of a healthcare education

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organisation, the university hospital, the residency site and the integrated academic medical centre, and the requirements for them". [Link](#)

10. Order of the Minister of Health of the Republic of Kazakhstan No. ҚР ДСМ- 299/2020 dated 21 December 2020 "On approval of the rules for accreditation in the field of healthcare". [Link](#)
11. Standard ISO14155:2014№ "Clinical investigations. Good Clinical Practice". [Link](#)
12. Recommendation of the Board of the Eurasian Economic Commission No. 11 dated 17 July 2018 "On the Guideline on general issues of clinical trials". [Link](#)
13. Decision of the Council of the Eurasian Economic Commission No. 79 dated 3 November 2016 "On approval of the Rules of Good Clinical Practice of the Eurasian Economic Union". [Link](#)
14. Recommendation of the Board of the Eurasian Economic Commission No. 19 dated 3 November 2020 "On the Guideline on the application of biostatistics principles in clinical trials of medicinal products". [Link](#)
15. Recommendation of the Board of the Eurasian Economic Commission No. 18 dated 27 October 2020 "On the Guideline on safety pharmacology studies of medicinal products for human use".
16. Decision of the Council of the Eurasian Economic Commission No. 85 dated 3 November 2016 "On approval of the Rules for conducting bioequivalence studies of medicinal products within the Eurasian Economic Union". [Link](#)
17. Declaration of Helsinki of the World Medical Association, June 1964 (latest revision of 9 July 2018). [Link](#)
18. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, World Health Organization (2011); and other international declarations and guidelines in the field of research ethics (WHO, ICH-GCP, UNESCO, CIOMS, CE).
19. Regulation on the Local Bioethics Committee (hereinafter- the LEC or the Committee) of HemCenter LLP, approved by Order No. I-02-44 dated 31 June 2023
20. Rules for conducting clinical trials and scientific research at HemCenter LLP, approved by Order No. I-02-47 dated 31 June 2023
21. Job descriptions of the Local Bioethics Committee of HemCenter LLP dated 31 June 2023.
22. Other regulatory legal acts of the Republic of Kazakhstan governing clinical trials.

Related documents

No.	type	title
Issl-3-20	SOP	Maintaining the confidentiality of LEC documentation

List of changes

Rev. No. Date	Order No. List of changes Change of the SOP form, corrections to terminology based on amendments/additions to the regulatory legal acts of the RK, corrections throughout the text

Document acknowledgement list

No.	Full name	Position	Date	Signature
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