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| **Application No.** | **Received:** | **Approved:** |

**Ethical Committee of Administrative Research at Landspitali University Hospital**

# Application form

1. **RESEARCH TITLE.** The full research title is required, in English (and Icelandic language if applicable).

**2. PURPOSE OF RESEARCH AND A BRIEF DESCRIPTION.** The summary should include aims of the study, participants, methods, scientific value and anticipated gains. The text of the summary shall not exceed 300 words.

**3. Principal Investigator.** The PI will lead the scientific work, is professionally responsible and is the contact person for communications with the Ethical Committee of Administrative Research

**Name: ID No.: Position:**

**Place of work: Work tel.:** **Fax:**

**Address: Home tel.: E-mail:**

**4. OTHER APPLICANTS**. Names and places of work of all the other researchers.

**Name: Place of work: Position:**

**Name: Place of work: Position:**

**Name: Place of work: Position:**

**Name: Place of work: Position:**

**5. COLLABORATORS AND SUPPORTING PARTNERS.** Include other partners (companies) that finance or sponsor the research.

**Organization/Company: Address:**

**Organization/Company: Address:**

**6. DIVISION OF LABOUR.** Please indicate the division of labour between researchers. If researchers are recipients of grants or other funding, please inform of any relations between supporting bodies and researchers.

**7. PARTICIPANTS**. Specifythe number of participants, why and how they will be selected. Indicate criteria for inclusion and exclusion.

**8. BENEFITS/RISKS.** Specify the main possible benefits and risks for those participating in the study.

**9. INFORMED CONSENT.** Specify how and by whom informed consent will be obtained. Note that parental/custodial consent is required if participants are children, under 18 years of age. Copies of the information sheets and consent forms must be enclosed.

**10. RESEARCH DATA.** What type of data (personal information, biological samples, etc.) will be collected? Who will have access to the data? What protective measures will be taken to ensure integrity of participants and safe storage of the data? To whom will the data be entrusted when the study is completed? How will the confidentiality of the participants be preserved?

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**11. ETHICAL ISSUES.** Address the relevant ethical issues involved.

**12. SCIENTIFIC VALUE.** Account briefly for the assumed scientific benefits.

**13. THEORETICAL FOUNDATION OF RESEARCH.** Theoretic knowledge in the field of research shall be described, along with further background to the research project, including the main results of previous studies. Experience of relevant methods and/or treatment in previous research shall be mentioned in particular (max 3 pages).

**14. RESEARCH METHODS.** Account for the methodology of the research project. State if the intention is to obtain information from other sources than the participants themselves. If the intention is to use information from clinical records, public registries or samples from biological banks, copies of the relevant authorizations must accompany the application. Explain what participation entails, i.e. what type of research will be carried out on them, how often participants must attend for monitoring or evaluation purposes and what types of specimens will be aquired.

**15. DATA PROCESSING.** Specify what sort of processing (e.g. statistical) will be carried out and whether power analysis or other similar methods have been used during preparation of the research project.

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**16. RESEARCH SCHEDULE.** Specify scheduled start and end of the research project.

**17. RESEARCH RESULTS.** Account for the proposed utilization and/or publication/presentation of the results of the research project.

**18. TRANSFER OF DATA.** If the intention is to transfer data (e.g. biological specimens or personal information) from the research project from Iceland, state the purpose and how this will be done. Indicate to which institution and country the data will be moved. Also state the person who will be responsible for the data at the relevant institution.

###  Not applicable \_\_

**19. PROTECTIONS AND DESTRUCTION OF DATA.** Where and how will the research data be protected during the study; when and how will it be destroyed after concluding the study?

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**20. DATA SHARING.** Specify whether it is intended to share data from this study with other studies or use information and/or specimens from other research project. If so, indicate the relevant study.

 Not applicable \_\_

**21. MONITORING AND INSURANCE.** Who is in charge of monitoring the participants' health and well-being and how will the monitoring be carried out? On what terms and with who are the participants insured against possible injury?

### Not applicable

**22. PAYMENT FOR PARTICIPATION.** Specify whether participation in the study is reimbursed, and the nature and amount of the payments.

Not applicable

**23. OTHER AUTHORIZATIONS OR APPLICATIONS.** Copies of authorizations from the board of the biological specimen bank for the use of biological specimens; the application shall be accompanied by the authorization from the appropriate medical director for access to medical records and/or authorization from the institution involved in the execution of the research project.

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|  | Data Protection Authority, date |  | Medical Director |
|  | State Drug Inspectorate, date |  | Biological specimen bank, name |
|  | Radiation Safety Authority, date |  | Nursing Director |
|  |  |  | Chief Executive of Human Resources |

**24. SUPPLEMENTARY DOCUMENTS.** A CV/list of publications must always accompany applications to the Ethical Committee for the contact person (specifying peer-reviewed publications), together with information material and agreement forms for participants in the research project. All supplementary documents must be submitted in triplicate.

\_\_\_\_ Career summary of the contact person (CV) \_\_\_\_ Questionnaires (how many?)

\_\_\_\_ Information sheet/s \_\_\_\_ Consent form/s

\_\_\_\_ Copies of authorizations \_\_\_\_ Accompanying documents (please list)

**25. FURTHER COMMENTS.** **Further comments or details, which have not appeared elsewhere in the application, may be added here.**

**The Ethical Committee of Administrative Research at Landspitali University Hospital must be notified immediately by the contact person of any changes to the research program.**

**Place: Date: Signature of contact person:**

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**Please submit the application by an e-mail to the secretary of The Ethical Committee of Administrative Research; Helga Þórðardóttir, e-mail:** helthord@landspitali.is