

***T.R.***

***NİĞDE ÖMER HALİSDEMİR UNIVERSITY***

***ETHICS COMMITTEE APPLICATION FORM***



***Date***

***NİĞDE***

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**ETHICS COMMITTEE APPLICATION FORM**

The headings and required information that must be included in project/research proposals submitted to the Ethics Committee of Niğde Ömer Halisdemir University are provided below.

For the Ethics Committee to conduct a thorough evaluation, all the headings and required information listed below must be provided completely and accurately.

First, the "**Niğde Ömer Halisdemir University Ethics Committee Application Form**" must be filled out completely. Then, all the information and documents detailed below should be prepared and attached to the proposal form.

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| **PROJECT/RESEARCH TITLE IN TURKISH AND ENGLISH:** |
| **TURKISH :** |
| **ENGLISH :** |

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| **PRIMARY FIELD OF THE PROJECT/RESEARCH TOPIC:** |
| **( ) Social Sciences**  **( ) Natural Sciences**  **( ) Engineering Sciences**  **( ) Health Sciences**  **( ) Sports Sciences**  **( ) Educational Sciences**  **() Other (Please specify): ................................................................................................** |

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| **SUMMARY OF THE RESEARCH/PROJECT IN TURKISH** |
| **KEYWORDS:** |

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| **SUMMARY OF THE RESEARCH/PROJECT IN ENGLOSH** |
| **ABSTRACT:** |
| **KEY WORDS:** |
| **THE INSTITUTION OR ORGANIZATION TO WHICH THE PROJECT/RESEARCH PROPOSAL IS SUBMITTED:** |
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| **THE INSTITUTIONS OR ORGANIZATIONS SUPPORTING THE PROJECT/RESEARCH:***(If there are any other institutions or organizations supporting the research, the name of these institutions or organizations, the amount and nature of the contribution they will provide to the research, whether these institutions or organizations have any expectations from volunteers/research, if there are expectations, their nature, and the measures taken to ensure that volunteers adhere to the principles of rights, confidentiality, privacy, and non-harm should be specified..)* |

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| **PROJECT/RESEARCH TEAM MEMBERS**  **(Title, Name and Surname, Affiliated Unit):** | **SIGNATURE** |
| **(1)** |  |
| **(2)** |  |
| **(3)** |  |
| **(4)** |  |
| **(5)** |  |

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| **PROJECT/RESEARCH DURATION:** |
| **( )** |

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| **PROJECT/ RESEARCH START DATE / END DATE** |
| **( ) Start Date :**  **( ) End Date :** |

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| **PROJECT/RESEARCH:** |
| **Subject and Purpose:**  **(**The definition of the research problem, literature review, and objectives should be stated.) |
| **Originality:**  (The original value of the proposed study (scientific/technological) should be clearly stated (Contribution to the field such as a new technology, a new method, development of a new conceptual/theoretical framework, etc.). |
| **Wide Impact:**  **(**The potential impact of the project on the national and regional economy, contributions to scientific knowledge accumulation, and potential benefits should be discussed. It should be indicated how the expected results can be utilized.) |

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| **MATERIAL AND METHOD OF THE PROJECT /RESEARCH** |
| **Project/Research Type:**  (The type of research, whether descriptive, experimental, etc., should be indicated.) |
| **Population and Sample of the Project/Research**:  (The population of the research, the sampling method, and the characteristics of the selected volunteers should be described.) |
| **Data Collection Tools Used in the Project/Research:**  (The name of the data collection tools, the developer of the tools, if it is a scale; who conducted the validity-reliability, permission for use from the developer, suitability of the questions for the research and the volunteers involved in the research, etc., should be specified.) |
| **Hypotheses of the Project/Research:**  (The hypothesis/hypotheses on which the research is based should be clearly stated.) |
| **Methodology of the Project/Research**:  (Where the research will be conducted, whether the research environment is suitable and sufficient for the research, whether it is a suitable place for the comfort and privacy of the volunteers, whether necessary measures have been taken to keep the volunteers' information confidential, who will implement the data collection tools, who will intervene if any intervention is to be made, etc., should be specified.) |
| **Evaluation of Project/Research Data:**  (How the data will be evaluated, the research model, which statistical tests will be used, etc., should be specified.) |

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| **PROJECT/RESEARCH PLAN B:** |
| *In the event of unforeseen developments significantly hindering the implementation of the proposed research/project, a "Plan B" should be outlined, indicating the main strategies to be adopted.* |

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| **ETHICAL PRINCIPLES TO BE FOLLOWED DURING THE PROJECT/RESEARCH:** |
| **( ) RESEARCHERS' QUALIFICATIONS AND EXPERIENCES:**  *(The qualifications of the researchers regarding their ability to conduct the specified project/research should be emphasized. If they have previously participated in similar projects/research, it should be noted..)* |
| **( ) Informed Consent:** (*A form should be prepared containing the permissions obtained from volunteers both orally and in writing, including the purpose and duration of the research, who will conduct the research, how volunteers will be intervened during the research, any risks associated with the intervention, measures taken against the risks if any, situations where volunteers need to be insured, the amount and calculation method if insurance or compensation needs to be provided to volunteers, and it should be committed to obtaining the signatures of volunteers..*) |
| **( )** **Adherence to the principles of using research data and ensuring rights-privacy-confidentiality-non-harm.** *(The measures taken to protect the rights and privacy of volunteers, and where and for what purpose the data will be used, should be specified.* |
| **( ) Permissions obtained from the institution where the research will be conducted**  (The content of written and verbal permissions should be specified, and permission documents should be provided as attachments.*.)* |
| **THREE PRIMARY IMPORTANT RESOURCES TO BE USED IN THE PROJECT/RESEARCH:** |
| **(1)** |
| **(2)** |
| **(3)** |

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| **OTHER RESOURCES TO BE USED IN THE PROJECT/RESEARCH:** |
| **(1)** |
| **(2)** |
| **(3)** |
| **(4)** |
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| **(8)** |
| **(9)** |

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| **APPENDICES:** |
| **APPENDIX-1 :** *Sample Application Letter to the Ethics Committee.* |
| **APPENDIX-2 :** *Commitment Letter.* |
| **APPENDIX-3 :** *Commitment Statement Regarding the Reading of the Helsinki Declaration by Researchers.* |
| **APPENDIX-4 :** *Informed Consent Form* |
| **APPENDIX -5 :** *Informed Consent Form* |
| **APPENDIX -6 :** *Examples of Forms that Can be Used When Necessary* |
| **APPENDIX -7 :** *All Data Collection Tools to be Used in the Research* |
| **APPENDIX -8 :** *Permission Document Obtained from the Developer if a Scale is Used in the Research* |
| **APPENDIX -9 :** *CV (in the format of Niğde Ömer Halisdemir University CV Template)* |
| **APPENDIX -10:***One CD of the Application Form* |
| **APPENDIX -11:***Project/Research Final Report* |

**EXAMPLES OF FORMS THAT CAN BE USED IN NIĞDE ÖMER HALİSDEMİR UNIVERSITY ETHICS COMMITTEE APPLICATIONS**

***APPENDIX-1: Sample Application Letter to the Ethics Committee***

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| **daire, ekran görüntüsü, grafik, renklilik içeren bir resim  Açıklama otomatik olarak oluşturuldu**  **.../.../20..**  **TO NIĞDE ÖMER HALİSDEMİR UNIVERSITY**  **ETHICS COMMITTEE PRESIDENCY**  I respectfully request that our project/research named [project/research name] be evaluated by the Niğde Ömer Halisdemir University Ethics Committee.  ***Appendix :*** *1 Set of Application Files.*  **Name and Surname**    **Signature**    **ADDRESS : .....................**  **TELEPHONE :**  **(Office) :**  **(Mobile ) :**  **E-MAIL :** |

***APPENDIX-2: Commitment letter.***

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| **daire, ekran görüntüsü, grafik, renklilik içeren bir resim  Açıklama otomatik olarak oluşturuldu**  **.../.../20..**      **TO NIĞDE ÖMER HALİSDEMİR UNIVERSITY**  **ETHICS COMMITTEE PRESIDENCY**  I hereby pledge to adhere to research ethics principles throughout the duration of this project/research, to inform the ethics committee of any unexpected adverse effects or incidents that may occur during the implementation of the research, to notify the committee in writing if any changes need to be made to the study protocol during the research, and to promptly inform the ethics committee if the research is halted.    **RESPONSIBLE RESEARCHER**  **Name and Surname**  **Signature** |
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***APPENDIX-3: Commitment Letter Stating That the Helsinki Declaration Has Been Read by Researchers***

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| **daire, ekran görüntüsü, grafik, renklilik içeren bir resim  Açıklama otomatik olarak oluşturuldu**  **.../.../20..**    **TO NIĞDE ÖMER HALİSDEMİR UNIVERSITY**  **ETHICS COMMITTEE PRESIDENCY**  As the researchers signed below, we hereby declare and commit that we have read the latest version of the Helsinki Declaration for the clinical project/research named……………………………………..   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Name and Surname** | **Title** | **Date** | **Address** | **Signature** | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |

***APPENDIX-4: Informed Consent Form***

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| ***daire, ekran görüntüsü, grafik, renklilik içeren bir resim  Açıklama otomatik olarak oluşturuldu* .../.../20..**    **INFORMED CONSENT FORM**  (This form should be prepared by the researchers. The permissions obtained verbally and in writing from the volunteers, the purpose of the research, its duration, who will conduct the research, the type of interventions that will be made to the volunteers during the research, the risks of the intervention if any, the precautions taken against the risk if there is a risk, situations requiring the insurance of the volunteers if any, the amount and calculation method of any compensation or insurance payments to be provided to the volunteers should be included in this form and volunteers should be committed to signing it.) |

**Appendix 5. INFORMED CONSENT FORM**

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| **../.../20..**  ***This form should clearly explain the following information and the headings in the second part of the form should be completed and signed by the volunteer.***   * *Participants agreed that the study is research,* * *Purpose of the research,* * *Treatments to be applied in the research,* * *Methods to be applied during the research, including invasive procedures,* * *Responsibilities of the volunteer,* * *Experimental parts of the research,* * *Possible risks or discomfort for the volunteer,* * *Expected benefits (If there is no intended clinical benefit for the volunteer, the volunteer is also informed about this.),* * *Alternative procedures or treatments that can be applied to the volunteer, their possible benefits and risks,* * *In case of any harm or injury caused by the research, the volunteer must be informed about how they will be compensated and how treatment will be provided,* * *Payment to be made to volunteers for their participation in the research, if foreseen,* * *Expenses to be covered for volunteers due to their participation in the research,* * *The volunteer's participation in the research is voluntary, he/she can refuse to take part in the research or leave the research at any stage, and this will not lead to a penalty or hinder the volunteer's benefits,* * *It should be noted that observers, auditors, ethics committees, and official authorities may have access to the volunteer's medical information. However, this information will be kept confidential, and the volunteer or their legal representative consents to this by signing the informed consent form,* * *Records that reveal the identity of the volunteer will be kept confidential,* * *If there is information that emerges during the research that may concern the volunteers, it will be immediately notified to the volunteer or his/her legal representative,* * *People from whom additional information can be obtained about the research, the rights of the volunteers, and people to contact in case of harm due to the research,* * *Situations in which the volunteer will be excluded from the research against his/her wishes,* * *The period during which the volunteer is expected to take part in the research,* * *Number of volunteers who will take part in the research* |

1. I, the undersigned, agree to participate in the study entitled "...............................................................".
2. The study conductor, ..........................................., has provided me with detailed verbal and written information regarding the structure, purpose, and probable duration of the study, what is expected of me, and what actions to take if I experience any side effects.
3. I had the opportunity to ask .............................................. any questions I had regarding the study. I have understood the answers and the information provided to me.
4. I agree to adhere to all rules throughout the study, to work in full cooperation with Dr. ..............................., and to contact them immediately if I encounter any health issues.
5. I understand that I will not restrict the use of the study results and accept that these results may be published in the literature.
6. I understand that I am free to withdraw from the study at any time.

**READ AND APPROVED.**

Volunteer’s Name, Surname, Address:

Signature, Date:

Researcher's Name, Surname, Address:

Signature, Date:

Witness’s Name, Surname, Address:

Signature, Date:

\*A copy of this document will be provided to both the volunteer and the researcher.

***APPENDIX-6: Form Examples That Can Be Used When Necessary***

***Commitment Letter Confirming that the Good Clinical Practice Guidelines Have Been Read by the Researchers***

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| ***A blue circle with white text and numbers  Description automatically generated***  **../.../20..**  **ÖMER HALİSDEMİR UNIVERSITY**  **TO THE ETHICS COMMITTEE CHAIRMAN**  **(Please fill out if necessary.)**  We, the undersigned researchers, hereby declare and commit that we have read the "Good Clinical Practice Guidelines" published by the Ministry of Health of the Republic of Turkey on December 29, 1995, under number 51738, for the clinical project/research titled “.........................................................................................................................”.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Name and Surname** | **Title** | **Date** | **Address** | **Signature** | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |

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| **A blue circle with white text and numbers  Description automatically generated .../.../20..**  **PATIENT FOLLOW-UP (CASE REPORT) FORM**  **(Please fill out if necessary.)** |

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| **A blue circle with white text and numbers  Description automatically generated**  **.../.../20..**  **ADVERSE EFFECT MONITORING FORM**  **(Please fill out if necessary.)** |

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| **.../.../20..**  **COMMITMENT TO COLLECT AND DELIVER REMAINING MEDICATIONS TO THE MINISTRY IF THE PROJECT/RESEARCH IS TERMINATED**  **(Please fill out if necessary.)** |

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| **A blue circle with white text and numbers  Description automatically generated** **.../.../20..**  **COMMITMENT ON SHARING OF RESPONSIBILITIES BETWEEN THE SPONSORING ORGANIZATION AND THE PRINCIPAL INVESTIGATOR**  **(Please fill out if necessary.)** |

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| **.../.../20..**  **PACKAGE INSERT AND LABEL CONTENTS FOR THE DRUGS TO BE USED IN THE STUDY**  **(Please fill out if necessary.)** |

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| **.../.../20..**    **INSURANCE UNDERTAKING STATEMENT FOR COMPENSATING THE FINANCIAL LOSS ARISING FROM POSSIBLE SIDE EFFECTS/UNDISIRABLE SITUATIONS DURING THE COURSE OF THE PROJECT/RESEARCH**  **(Insurance Policy Attached)**  ***(Please fill out if necessary.)***  To the relevant authority,  In the context of the project/research titled "............................................................................", it is hereby committed that, provided that both the researcher and the volunteers fully adhere to the protocol, in the event of any medical harm (including death) occurring in volunteers due to the research drug or other interventions conducted within the scope of the research, regardless of whether the volunteers are covered by public or private health insurance, we undertake to bear all medical treatment and care expenses, as well as other financial and legal responsibilities..  ***Attachment-1:*** *Sample Insurance Policy.*  **RESPONSIBLE RESEARCHER ASSISTANT RESEARCHER**  **Name and Surname Name and Surname**  **Signature Signature** |
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***APPENDIX-11: Project/Research Final Report***

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| **.../.../20..**  **TO THE ETHICS COMMITTEE CHAIRMANSHIP OF NİĞDE ÖMER HALİSDEMİR UNIVERSITY**  Our project/research titled "............................................................." has been completed, and the final report is attached herewith.  Yours sincerely.  ***Attachment:*** *1 Copy of the Final Report.*    **Name and Surname**  **Signature**  **Address: .....................**  **Phone:**  **(Work):**  **(Mobile):**  **E-mail:** |
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