1. **RESEARCH**

|  |  |  |
| --- | --- | --- |
| **A.1.** | **The exact name of the research:** | |
|  | | |
| **A.2.1** | **First application?** Yes No If no, write down the number of applications and add the ethics committee decision to the file: | |
| **A.2.2** | **Has an application been made to a different ethics committee?** Yes No If yes, add the ethics committee decision to the file: | |
|  | | |
| **A.3.** | **Status of the research** ( *tick the appropriate box below* ) | |
| **A.3.1.** | master's thesis |  |
| **A.3.2.** | doctoral thesis |  |
| **A.3.3.** | Master thesis |  |
| **A.3.4.** | Individual research project |  |
| **A.3.5.** | If other, please specify: | |

1. **NATURE OF THE RESEARCH**

|  |  |  |
| --- | --- | --- |
| **B.1.** | survey studies |  |
| **B.2.** | Retrospective archive scanning using file and image records , etc. observational study |  |
| **B.3.** | Research to be carried out with biochemistry, microbiology, pathology and radiology collection materials such as blood, urine, tissue and images |  |
| **B.4.** | Research to be conducted with materials obtained during routine examination and treatment procedures and/or from healthy volunteers |  |
| **B.5.** | Cell or tissue culture study |  |
| **B.6.** | Research to be carried out with genetic material for identification purposes, other than gene therapy clinical research |  |
| **B.7.** | Research to be conducted within the boundaries of nursing activities |  |
| **B.8.** | Research on body physiology, such as exercise |  |
| **B.9.** | Study based on anthropometric measurements |  |
| **B.10.** | Research on the evaluation of living habits |  |
| **B.11.** | Other ( …………….. ) |  |

1. **SUPPORTING AND RESEARCH BUDGET**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **C.1.** | **Is there a sponsor of the research?** | | Yes | No | |
| **C.1.1.** | If your answer to C.1 is yes, please tick the appropriate box below. | | | | |
| **C.1.1.1.** | University | | | |  |
| **C.1.1.2.** | training and research Hospital | | | |  |
| **C.1.1.3.** | TÜBİTAK ( *Turkish Scientific and Technological Research Council* ) | | | |  |
| **C.1.1.4.** | If international, please specify: | | | | |
| **C.1.1.5.** | If other, please specify: | | | | |
|  |  | | | | |
| **C.2.** | **Research budget** | **…………….. TL** | | | |
| **C.2.1.** | If there are examinations to be performed on healthy volunteers within the scope of the research, a detailed budget breakdown | | | | |

1. **GENERAL INFORMATION ABOUT THE RESEARCH**

*This section should be used to provide information regarding the purpose, scope, design and outcome of the study.*

|  |  |
| --- | --- |
| **D.1.** | **Purpose of the research:** |

|  |  |
| --- | --- |
| **D.2.** | **Literature information explaining the study :**  *(Do not exceed 2 pages)* **:** |
|  | |
| **D.3.** | **Please specify the approach and methods (Material Method ) to be applied in the research** *(specify as free text)* **:** |
|  | |
| **D.4.** | **any tests/ laboratory examinations and interventions to be performed during the research, please specify** *(specify as free text)* **:** |
|  | |
| **D.5.** | **If there are any security precautions that need to be taken during the application, please specify** *(specify in free text)* **:** |
|  | |
| **D.6.** | **Criteria for including volunteers in the study** *(please list them in items)* :  *(Leave blank for retrospective studies)* |
|  | |
| **D.7.** | **Criteria for not including volunteers in the study** *(please list them in items)* :  *(Leave blank for retrospective studies)* |
|  | |
| **D.8.** | **Statistical Analysis Method:** |
|  | |
| **D.9.** | **Research period** |
| **D.9.1.** | Approximately how long the research will take ( *in days, months and years* ): |
| **D.9.2.** | Recommended date to start recruiting volunteers for the study ( *in day, month and year* ):  *(Leave blank for retrospective studies)* |

|  |  |
| --- | --- |
| **D.10.** | **Place(s) where the research will be conducted :** |

|  |  |
| --- | --- |
| **D.11.** | **Source List** *(At least three of them will be added in full text)* **:** |

1. **VOLUNTEER POPULATION IN THE RESEARCH**

*(Leave blank for retrospective studies)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **E.1.** | **Age range** *(Indicate the estimated number of volunteers planned in each age range for the entire research)* : | | | | |
| **E.1.1.** | under 18 years old | | Yes | No | |
| **E.1.1.1.** | If your answer to E.1.1 is yes, please specify the age range and number of volunteers: | | | | |
| **E.1.2.** | over 18 years | | Yes | No | |
| **E.1.2.1.** | If your answer to E.1.2 is yes, please specify the age range and number of volunteers: | | | | |
|  | | | | | |
| **E.2.** | **Gender** | | | | |
| **E.2.1.** | Woman | | | |  |
| **E.2.2.** | Male | | | |  |
|  | | | | |  |
| **E.3.** | **Volunteer group in the study** | | | | |
| **E.3.1.** | healthy volunteers | Yes | | No | |
| **E.3.2.** | patients | Yes | | No | |
| **E.3.3.** | **special populations** | Yes | | No | |
| **E.3.3.1.** | pregnant women | Yes | | No | |
| **E.3.3.2.** | breastfeeding women | Yes | | No | |
| **E.3.3.3.** | emergency cases | Yes | | No | |
| **E.3.3.4.** | If other, please specify: | | | | |

1. **RESEARCH CENTERS/RESEARCHERS INCLUDED IN THE APPLICATION**

|  |  |
| --- | --- |
| **F.1.** | **Coordinator** *(For multicenter studies)* |
| **F.1.1.** | Name and surname: |
| **F.1.2.** | Title: |
| **F.1.3.** | Profession: |
| **F.1.4.** | Institution: |
| **F.1.5.** | Phone number: |
| **F.1.6.** | E-mail address: |

|  |  |
| --- | --- |
| **F.2.** | **Responsible investigator** *(Please repeat this section when necessary for multi-center studies)* |
| **F.2.1.** | Name and surname: |
| **F.2.2.** | Title: |
| **F.2.3.** | Profession: |
| **F.2.4.** | Institution: |
| **F.2.5.** | Phone number: |
| **F.2.6.** | E-mail address: |
|  | |
| **F.3.** | **Assistant researcher** *(Please repeat this section when necessary)* |
| **F.3.1.** | Name and surname: |
| **F.3.2.** | Title: |
| **F.3.3.** | Profession: |
| **F.3.4.** | Institution: |
| **F.3.5.** | Phone number |
| **F.3.6.** | E-mail address |

1. **RELATED DOCUMENTS**

*The documents specified in this section must be added to the application file respectively.*

|  |  |
| --- | --- |
| **H.1.** | **If available, the original or a certified copy of the previously rejected ethics committee decision must be submitted.** |
| **H.2.** | **Informed Volunteer Consent Form (BGOF)\***  \* BGOF It must be prepared in accordance with the minimum informed consent form sample available at [http://etik.selcuk.edu.tr and added to the application file. For](http://etik.selcuk.edu.tr) BGOFs in languages other than English, the original and a translation approved by a sworn translator must be attached. |
| **H.3.** | **Survey if any** |
| **H. 4.** | **Supporting documents / literature regarding the research** |

**I. SIGNATURE OF THE COORDINATOR/RESPONSIBLE INVESTIGATOR**

|  |
| --- |
| **With this application form** |
| * The information provided in the application is correct, * The research will be carried out in accordance with the protocol, relevant legislation, the current Declaration of Helsinki and the principles of good clinical practice, * I informed the research team (including the laboratory team, research nurse, etc.) about the research, * I declare that I take full responsibility for the research in accordance with the provisions of the relevant directive. |

**COORDINATOR/RESPONSIBLE INVESTIGATOR**

Name and surname in handwriting:

Date (in day/month/year):

Signature: