**T.C.**

**SELÇUK UNIVERSITY**

**FACULTY OF HEALTH SCIENCES**

**NON-INTERVENTIONAL CLINICAL RESEARCH ETHICS COMMITTEE**

**APPLICATION CHECKLIST \***

|  |  |
| --- | --- |
| 1. Application Letter (signed) |  |
| 1. Good Clinical Practices Commitment (signed) |  |
| 1. Commitment That No Conflict of Interest (signed) |  |
| 1. Funding Commitment (signed) |  |
| 1. Approval Institutional Permission (An approval letter from the institution where the research will be conducted or a signed undertaking stating that the approval letter will be submitted within 6 months at the latest) |  |
| 1. Non-Interventional Clinical Research Ethics Committee Form (Completely completed)\*\* |  |
| 1. Informed Consent Form (If necessary-Must be specially prepared for the study-) |  |
| 1. Survey used, Forms etc. (All forms must be attached as an attachment) |  |
| 1. Three articles about study (Only the first pages of articles should be included) |  |
| 1. **Sending all documents as a digitally scanned pdf file to the ethics committee secretary (in a single file)** |  |
| 1. **Applied according to the current form on the Selçuk University Faculty of Health Sciences Ethics Committee website.** |  |

\* Applications are made via the specified e-mail address. **(etikkurulusbf@gmail.com)**

\* Mark the relevant boxes with a cross.

\* Applications with missing checklist will not be evaluated.

\* The Application Checklist should be placed on the first page and the forms should be added after it, taking into account the order in this list.

\*\*When filling out the form, spelling and referencing rules in the thesis writing guide which in Selçuk University Institute of Health Sciences is valid.

**I commitment that I have submitted all documents completely.**

**Project Coordinator:**

**Signature:**

|  |  |  |
| --- | --- | --- |
|  | **T.C.**  **SELCUK UNIVERSITY**  **FACULTY OF HEALTH SCIENCES**  **DEANERY** | http://www.selcuk.edu.tr/dosyalar/files/039/SAGB%c4%b0LFAK%20logo.jpg |

**THE NON-INTERVENTIONAL CLINICAL RESEARCH ETHICS COMMITTEE**

**TO THE PRESIDENCY**

**“…………………….………………………………………………………………………...……..…”** I submit the necessity for the evaluation of the research project titled.

**Date:** Tarih girmek için tıklayın veya dokunun.

**Project Coordinator**

**Name and Surname**

**Department**

**Signature**

**Attachments:**

1. Application Checklist
2. Petition for Application to Non-Interventional Clinical Research Ethics Committee
3. Letter of Undertaking Regarding Good Clinical Practices
4. Letter of Undertaking of No Relationship of Interest
5. Financial Commitment Letter
6. Letter of Approval from the Institution where the Research will be conducted or Letter of Undertaking to Obtain Approval from the Institution where the Research will be conducted
7. Non-Interventional Clinical Research Ethics Committee Form
8. Informed Consent Form (If necessary)
9. Survey used etc. Forms (All forms should be included)
10. At least three articles about study (Only the first pages of articles should be included)

**COMMITMENT TO GOOD CLINICAL PRACTICES**

**SELCUK UNIVERSITY**

**FACULTY OF HEALTH SCIENCES**

**THE NON-INTERVENTIONAL CLINICAL RESEARCH ETHICS COMMITTEE**

**TO THE PRESIDENCY**

During this research, we undertake to comply with the World Medical Association (WMA) Helsinki Declaration (and/or the World Psychiatric Association HAWAII Declaration) Good Clinical Practice boards, notify your ethics committee in writing immediately if there is an unexpected adverse effect or an event, if changes to the study protocol need to be made during the research, or if the research is stopped.

**Date:** Tarih girmek için tıklayın veya dokunun.

|  |  |
| --- | --- |
| **Project Coordinator** *Name and Surname* | Signature |
|  |  |
| **Research Partıcıpants (Other)** *Name and Surname* | Signature |
| 1. |  |
| 2. |  |
| 3. |  |
| 4. |  |
| 5. |  |

**THAT THERE IS NO CONFLICT OF INTEREST COMMITMENT**

**SELCUK UNIVERSITY**

**FACULTY OF HEALTH SCIENCES**

**THE NON-INTERVENTIONAL CLINICAL RESEARCH ETHICS COMMITTEE**

**TO THE PRESIDENCY**

I declare that I have no connections with the organizations that provided funding during the planning, implementation, evaluation and publication of this research, and the place and people where I will conduct the research, that could harm the scientific or ethical aspects of the research for commercial, political or personal reasons.

**Date:** Tarih girmek için tıklayın veya dokunun.

|  |  |
| --- | --- |
| **Project Coordinator** *Name and Surname* | Signature |
|  |  |
| **Research Partıcıpants (Other)** *Name and Surname* | Signature |
| 1. |  |
| 2. |  |
| 3. |  |
| 4. |  |
| 5. |  |

**FINANCIAL COMMITMENT**

**SELCUK UNIVERSITY**

**FACULTY OF HEALTH SCIENCES**

**THE NON-INTERVENTIONAL CLINICAL RESEARCH ETHICS COMMITTEE**

**TO THE PRESIDENCY**

**“……………………………………...……………........………………………….………..........……….”** the study titled, we undertake that all non-routine tests and similar expenses will be covered by us, and social security institutions and revolving funds **will not be used** as a financial source.

**Date:** Tarih girmek için tıklayın veya dokunun.

|  |  |
| --- | --- |
| **Project Coordinator** *Name and Surname* | Signature |
|  |  |
| **Research Partıcıpants (Other)** *Name and Surname* | Signature |
| 1. |  |
| 2. |  |
| 3. |  |
| 4. |  |
| 5. |  |

**A COMMITMENT THAT APPROVAL WILL BE OBTAINED FROM THE INSTITUTION WHERE THE RESEARCH WILL BE CONDUCTED**

**SELCUK UNIVERSITY**

**FACULTY OF HEALTH SCIENCES**

**THE NON-INTERVENTIONAL CLINICAL RESEARCH ETHICS COMMITTEE**

**TO THE PRESIDENCY**

To your ethics committee **"…………………….........……………………………..…….."** We have made our application with the study titled. If our research requires institutional permission, I hereby declare that we will obtain the institutional permission within six months and declare it to your board, that we assume all legal responsibility in this regard, and I respectfully request for your information that our ethics committee application should be evaluated by your board without including the institution permission information.

**Date:** Tarih girmek için tıklayın veya dokunun.

|  |  |
| --- | --- |
| **Project Coordinator** *Name and Surname* | Signature |
|  |  |
| **Research Partıcıpants (Other)** *Name and Surname* | Signature |
| 1. |  |
| 2. |  |
| 3. |  |
| 4. |  |
| 5. |  |

**Note**: Those who apply to the ethics committee with an institutional research permit will not fill out this commitment. They will deliver the institution approval letter.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | **T.C.**  **SELCUK UNIVERSITY**  **FACULTY OF HEALTH SCIENCES**  **THE NON-INTERVENTIONAL CLINICAL RESEARCH**  **ETHICS COMMITTEE FORM** | | | | | | | | http://www.selcuk.edu.tr/dosyalar/files/039/SAGB%c4%b0LFAK%20logo.jpg | |
| **Date:** Tarih girmek için tıklayın veya dokunun. | | | | | | | | | | | | | |
| **1) RESEARCH**  **TITLE** | | |  | | | | | | | | | | |
| **2) ENGLISH**  **TITLE** | | |  | | | | | | | | | | |
| **3) RESPONSIBLE RESEARCHER** *(Project Coordinator, Advisor for postgraduate theses)* | | | | | | | | | | | | | |
| **Name / Surname** | |  | | | | | | | | | | | |
| **Title / Duty** | |  | | | | | | | | | | | |
| **Institution / Department / Division of Work** | |  | | | | | | | | | | | |
| **Phone ( )** | | | | | | **Faks ( )** | | | | **GSM ( )** | | | |
| **Communication**  **address** | |  | | | | | | | | | | | |
| **E-posta** | |  | | | | | | **Signature** |  | | | | |
| **4) OTHER RESEARCHERS** | | | | | | | | | | | | | |
| **Name, Surname** | | | | | **Degree** | | **Institution Department/Division** | | | | **Phone** | | **Signature** |
|  | | | | |  | |  | | | |  | |  |
|  | | | | |  | |  | | | |  | |  |
|  | | | | |  | |  | | | |  | |  |
|  | | | | |  | |  | | | |  | |  |
|  | | | | |  | |  | | | |  | |  |
| **5) QUALİTY OF RESEARCH (Depending on the nature of the study, more than one box can be checked)**   |  |  |  |  | | --- | --- | --- | --- | | Survey study | |  | | | Retrospective archive scanning using files and image records, etc. observational study  *(Permission must be obtained before retrospective studies.)* | |  | | | Biochemistry, microbiology, pathology and radiology collection materials such as blood, urine, tissue, images or materials  obtained during routine examination and treatment procedures. | |  | | | Cell or tissue culture study | |  | | | Randomized controlled study | |  | | | Qualitative research | |  | | | Quasi experimental study | |  | | | Mixed Methods Research | |  | | | Research on body physiology such as exercise | |  | | | Study based on anthropometric measurements | |  | | | Research on the evaluation of living habits | |  | | | Other (Please explain).......................................................................................................................... | |  | | | **6) INSTITUTION/ORGANIZATION/CENTER TO WHERE THE RESEARCH WILL BE APPLIED** |  | |  | | | Research will not be conducted ın any ınstıtutıon/organızatıon/center. | | |  | | | | | | | | | | | | | | | |
| **7) INTRODUCTION OF THE RESEARCH** | | | | | | | | | | | | | |
| **A. Aim of the Study** | | | | | | | | | | | | | |
| * *The aim statement should include what is desired to be achieved by the research, clear, measurable and achievable, and include the study location, participants and the variables of the research (dependent, independent).* * *If the research purpose statement is not clear enough, research questions should be added.* | | | | | | | | | | | | | |
| **B. Type of Study** | | | | | | | | | | | | | |
|  | **b1. Research The Project** | | | | | | | | | | | | |
|  | **b2. Doctoral Thesis** | | | | | | | | | | | | |
|  | **b3. Master's thesis** | | | | | | | | | | | | |
| **C. The Rationale of the Study And Literature İnformation Explaining This Rationale** | | | | | | | | | | | | | |
| * *The necessity of conducting the research and whether the application has been done before in our country or in other countries should be explained. If so, the additional data and expected benefits expected from this study should be discussed within the framework of scientific data.* | | | | | | | | | | | | | |
| **D. Approaches and Methods To Be Used** | | | | | | | | | | | | | |
| **D1. Estimated Working Time/Schedule** | | | | | | | | | | | | | |
| * *The starting and finishing schedule for data collection. (Should be detailed at each stage of the study.)* * *The data collection process should be planned at least one month after the ethics committee meeting date.* | | | | | | | | | | | | | |
| **D2. Materials and Methods** | | | | | | | | | | | | | |
| * *The type/pattern/design/model of the research should be clearly stated. If there are variables to be examined in the research (dependent or independent), they should be clearly stated.* | | | | | | | | | | | | | |
| **D3. Number and Qualification of Participants** | | | | | | | | | | | | | |
| * *It should include information about the population and sample of the research (sample size-sample selection method).* | | | | | | | | | | | | | |
| **D4. Inclusion or Exclusion Criteria and Exclusion Criteria After the Start of The Research** | | | | | | | | | | | | | |
| * *Acceptance/exclusion criteria to be taken into account, apart from the characteristics of the research's designated study group, should be mentioned.* ***(Write in detail.)*** | | | | | | | | | | | | | |
| **D5. Data Collection Tools** *(Scales, Diagnostic Tests, Parameters)* | | | | | | | | | | | | | |
| * *Introduction of data collection tools* * *Validity-reliability information of the scales used should be given with appropriate reference* * *An explanation regarding the usage permission status of the scales to be used should be included.*   *(The scale use permission certificate will be given in the attachment.)*   * *The data collection method should be mentioned.* * *The data collection tools used should be given in the appendix.* * *Names of data collection tools (scales, etc.) added to the appendices section, must be written above it as a title, scale and survey questions should not start directly.* | | | | | | | | | | | | | |
| **D6. Precautions To Be Taken** | | | | | | | | | | | | | |
| * *Precautions to protect the health of participants and unexpected situations in the study should be stated.* * *Precautions to be taken in terms of research ethics should be written.* | | | | | | | | | | | | | |
| **D7. Evaluation of Data** | | | | | | | | | | | | | |
| * *It should be explained how quantitative or qualitative data will be evaluated.* | | | | | | | | | | | | | |
| **E. Reference List** | | | | | | | | | | | | | |
| * *Write according to Selçuk University Institute of Health Sciences Thesis Writing Guide.* * *Add only the first pages of at least 3 articles.*     **ADDS** | | | | | | | | | | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **(DO NOT LEAVE THIS SECTION BLANK)** | | | |
| **8) RESEARCH BUDGET** | **Estimated Budget:** | | **………..…..TL** |
| **Is there a sponsor of the research? Yes  No** | | | |
|  | **If yes, please tick the appropriate box below:** | | |
|  | **BAP Coordination Office Research Project** | | |
|  | **BAP Coordination Publication and Citation Incentive** | | |
|  | **TÜBİTAK** | | |
|  | **If other, please specify and document: ………………** | | |
| **(DO NOT FILL THIS SECTION)** | | | |
| **DATE OF DECISION: …../ …../ 202…**  **DECISION NO: …….** | | **NOTES** | |
| **APPROPRIATE** | |  | |
| **CONDITIONALLY SUITABLE** | |  | |
| **TO BE EVALUATED BY CORRECTION** | |  | |
| **NOT APPROPRIATE** | |  | |

|  |
| --- |
| **INFORMED CONSENT FORM**  We invite you to the research entitled **“.............................................................................................”** conducted by **.........................,** **...............................** and **.........................** Before deciding whether to participate in this research, you need to know why and how the research will be conducted. It is therefore very important that you read and understand this form. If there is anything that is not clear to you or if you would like more information, please ask us.  Participation in this study is entirely voluntary. You have the right not to participate in the study or to withdraw from the study at any time after participation. Your response to the study will be interpreted as your consent to participate in the study.  **Information about the study:**  **Aim of the Study:** This study was planned for the purpose of **…………………………….**  **Type of Study: ………………………………**  **Foreseen Duration of the Study:** The study will be conducted between .**..................** - **....................**  **Number of Participants/Volunteers Expected to Participate in the study: ………………**  **Place where the study will be conducted: ……………………………………**  **Consent to Participate in the Research:**  I have read the information above that should be given to the participant/volunteer before the research and I understand the purpose and scope of the research in which I was asked to participate voluntarily and the responsibilities I have as a voluntary participant. The written and verbal explanation I needed about the research was given by the researchers named above. I understood that I could participate in this study whenever I wanted and that I would not encounter any negativity.  **Under these conditions, I agree to participate in this study voluntarily and without any pressure or coercion. Participant (in his/her own handwriting)**  **Name-Surname: …………………………………**  **Signature:**  **Note: This form must be specially prepared for the study and must be filled out if necessary.** |