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| **Protocol No:**  | **Date:** |

*Sekreterya tarafından doldurulacaktır.*

**Request for Approval (Human Subjects Research)**

*In all cases, research must not proceed until approved by CHR. The total review process for non-exempt protocols which require full committee review can take up to 8 weeks. Exempt protocols, which are reviewed in the Office, can take from 2 to 4 weeks. Please leave adequate time for the revision cycle.*

**ADMINISTRATIVE INFORMATION**

**Application type**: [ ]  Initial [ ]  Renewal [ ]  Revision

**Review type**: [ ]  Exempt [ ] Expedited Review [ ]  Full Review

*(You read the explanation in Section 9)*

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Is this Project part of an undergrad/grad course? | [ ]  | [ ]  |
| Will the output of this project be published in scientific journals? | [ ]  | [ ]  |
| Is this application initiated to fulfil a legal requirement | [ ]  | [ ]  |

|  |  |  |
| --- | --- | --- |
| **Clinical trial test** | Yes | No |
| 1. Does the study involve human participants research?
 | [ ]  | [ ]  |
| 1. Are the participants prospectively assigned to an intervention?
 | [ ]  | [ ]  |
| 1. Is the study designed to evaluate the effect of the intervention on the participants?
 | [ ]  | [ ]  |
| 1. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?
 | [ ]  | [ ]  |

*İf all the answers to the 4 questions above are “yes”, you need to submit your project to the ethics Committee for Clinical Trials (IRB I)*

**1.1. Project title:**

**1.2. Investigator in charge:**

|  |  |
| --- | --- |
| Name |       |
| College/Division: |       |
| Department/Unit: |       |
| Work Phone: |       | Mobile: |       |
| E-mail Address: |       |
| Status: | [ ]  Undergraduate student\*[ ]  Graduate student\*[ ]  Post-doctoral fellow\* | [ ]  Faculty[ ]  Staff[ ]  Other (Specify):       |
| \* Faculty member supervising the project: |       |
| E-mail address: |       |
| Phone: |       |

**1.3. Co-PIs and members of the Research team:**

| Title, Name, Surname | College/Division: | Institution/Country: | E-mail: |
| --- | --- | --- | --- |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |

(*Add rows if necessary.)*

**1.4. Funding information**

Is this research being funded by an External Funding Agency?

[ ]  No

[ ]  Yes (Specify)

Funding agency:

Grant no and amount:

[ ]  This study will be submitted to TUBITAK for funding

**2. STUDY DESIGN, METHODS AND PROCEDURES**

**2.1. Type of project/study:**

Please select ALL of the categories of work that apply to this proposed project.

[ ]  Active collection of data (no human biological materials or biomedical data\*\*)

[ ]  Active collection of human biological materials or biomedical data

[ ]  Use of existing data (not human biological materials)

[ ]  Use of existing human biological materials

\*\*includes biological, clinical, medical data or anthropomorphic data

**2.2. Please provide a lay summary of the study, including the purpose, research questions and hypotheses in non-technical language. Provide supporting background information from prior studies.**

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**2.3. Please describe briefly of how this study will contribute to existing knowledge in the field.**

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**3. PARTICIPANTS, RECRUITMENT**

**3.1. Does your study involve interaction with or observation of human participants (e.g., interviews, surveys, Focus groups, shadowing, etc.)?**

[ ]  No [ ]  Yes

Sample population:       Sample size:

Explain how sample size is determined:

**3.2. Please select all the categories of participants that will be included in your study.**

|  |  |
| --- | --- |
| [ ]  Healthy adult volunteers | [ ]  Children under 18 |
| [ ]  Employees of the investigating group | [ ]  KU students |
| [ ]  KU employees | [ ]  Cognitively impaired persons |
| [ ]  Physically disabled persons | [ ]  Pregnant or nursing women |
| [ ]  Prisoners or individuals under detention or on probation | [ ]  People in foreign countries |
| [ ]  People with specific health conditions  | [ ]  People with limited literacy |
| [ ]  People unable to read, speak or understand Turkish | [ ]  Other vulnerable populations not listed above:       |

**3.3. Special Protections**

Vulnerable populations require special protections. Explain the measures that you will take to obtain informed consent protect confidentiality and prevent undue coercion in all of the above populations that you have selected.

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**3.4. Recruitment**

**3.4.1. How are subjects recruited? What inducement is offered? Will participants be compensated for their participation? (Append copy of letter, advertisement, poster, or recruitment text for online posting, if any)**

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**3.4.2. Describe the inclusion or exclusion criteria for participants as applicable in this study.**

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**3.4.3. Please describe the tasks that the participants will be asked to perform for each phase of the study.**

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**3.5. Location**

*State the actual location of the research. For observational studies be as specific as possible e.g. Main Library, etc.*

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**3.6. Transfer of biological materials**

Will collected human biological materials be transferred to another center or country?

[ ]  No [ ]  Yes

*\*If you answered yes, you must attach “Biological Material Transfer Form” to this application.*

**3.7. Study procedures**

*In the box below provide a detailed description of the study including all the procedures to be performed (preferably in sequential order). Be sure to specify which procedures are experimental (i.e. testing a new intervention for psychiatric illness) versus which procedures are standard of care. Be sure to include the following information:*

* *Methods of data collection*
* *Details regarding experimental interventions*
* *Number, frequency and duration and types of subject contacts (visits, phone calls, internet surveys, mailings, etc.)*
* *Duration of participation for single subject*
* *Anticipated duration of the entire study (up to and including data analysis)*

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*\*\* Note, for complex studies it may be useful to attach visit calendars and charts that indicate which interventions will occur for which group at which time.*

*\*\*\* You must attach to this application all surveys, interviews, questionnaires, focus group outline, etc. that will be used in this study. The CHR must review these materials as part of its review.*

**4. RISKS AND BENEFITS**

**4.1. From the list below, please select ALL of the potential risks that are involved in your study.**

|  |  |
| --- | --- |
| [ ]  Use of deceptive techniques | [ ]  Use of private records (such as educational or medical records) |
| [ ]  Manipulation of psychological or social state such as sensory deprivation, social isolation, psychological stress | [ ]  Probing for personal or sensitive information in surveys or interviews (e.g.: private behaviors, employer assessments) |
| [ ]  Presentation of materials which some participants may consider sensitive, offensive, threatening or degrading | [ ]  Possible invasion of privacy of subject or subject’s family social or economic risk (reputational, cultural, employability etc) |
| [ ]  Identification of child, spousal, or elder abuse | [ ]  Identification of illegal activity |
| [ ]  Risk of injury or bodily harm | [ ]  Other risks (please specify):       |

[ ]  There are no risks of any kind to any participants enrolled in this study. *This option is valid only if none of the risks above are selected*.

**4.2. Describe the nature and degree of the risks or harms selected above. All of the risks harms must be disclosed in the consent form.**

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**4.3. Explain what steps will be taken to minimize risks or harms and to protect subjects’ welfare. If the study will include protected populations, please identify each group and provide an explanatory paragraph for each group.**

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**4.4. Describe any benefits that individuals may reasonably expect from participation. If there are none, state "None".**

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**5. PRIVACY AND CONFIDENTIALITY**

**5.1. Will you or any member of your research team collect or have access to any of the personal identifiers listed below? Select ALL that apply.**

|  |  |
| --- | --- |
| [ ]  Name | [ ]  Date of birth |
| [ ]  Mailing or email address | [ ]  Phone or fax numbers |
| [ ]  Citizenship / Social Security number | [ ]  Medical records |
| [ ]  License, certificate or Vehicle ID | [ ]  IP address |
| [ ]  Signatures, handwriting samples  | [ ]  Photos/images/audio recording |
| [ ]  Biometric identifiers (Biometric Identifiers are observable biological characteristics which could be used to identify an individual, e.g., fingerprints, iris/retina patterns, and facial patterns.) | [ ]  Any unique identifier not mentioned above:       |

[ ]  No member of the research team will have access to any personal identifiers. This option is valid only if none of the other options in this question are selected.

**5.2. Describe why each identifier is required.**

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**5.3. Describe how will the information be stored and secured, including the types of devices used to store the information. Check all that apply.**

**5.3.1. How will research data be recorded?**

[ ] Data Entry Sheet

[ ] Computer

[ ] Database

[ ] Other (specify):

**5.3.2. How will data be stored?**

[ ]  Computer

[ ]  Locked File Cabinet

[ ]  Locked Office

[ ]  Other (specify):

**5.3.3. How will patient confidentiality be protected?**

[ ]  Coding System

[ ]  Limiting access to data/specimens

[ ]  Password protected

[ ]  Other (specify):

**5.4. Who will have access to the identifiers? Please describe how you have ensured that non-authorized personnel do not have access to the identifier data.**

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**5.5. What will be done with the identifiers after the study is completed? If the data will be destroyed, please describe when and how.**

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**5.6. Will names or other identifiers be used in publications?**

[ ] No

[ ] Yes

Which identifiers and why? (Specify):

**6. CONSENT PROCEDURES**

*The Committee on Human Research requires written evidence of informed consent whenever the research may involve a risk of harm to subjects; in addition, we ordinarily require written parental consent for studies of infants or minors.*

**6.1. Check ALL that apply.**

[ ]  Signed consent will be obtained from subjects and/or parents (if subjects are minors),

[ ]  Verbal consent\*\*\*\* will be obtained from subjects, using an information sheet (attach) or Script (attach)

*\*\*\*\* Only certain types of studies qualify for using oral consent procedures. The CHR can approve oral consent procedures when the research poses no risk and is conducted under circumstances where a written consent procedure is not normally required, or when the only risk to the participants is a breach of confidentiality resulting from the documentation of identity on the consent document.*

**6.2. Describe in detail in the box below your plans for obtaining informed consent from subjects. Be sure to include the following information;**

*Who (specifically) will obtain informed consent (these persons must be listed in Part 1.3 as investigators). How long will subjects have to consider whether or not they wish to participate in the study? When and how will consent be obtained (in person, by telephone, by mail, by internet, etc.)*

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*Please attach a copy of the consent form to be used.*

**7. CONFLICT OF INTEREST**

**Do you and/or any other investigators associated with the project described in this application have, or appear to have, any actual or potential conflict of interest with respect to this research?**

[ ]  No [ ]  Yes

If yes, explain:

**8. PATIENT AUTHORIZATION**

Check all that apply:

Are study data:

[ ]  Derived from a medical record?

[ ]  Added to the hospital or clinical medical record?

[ ]  Created or collected as part of health care?

[ ]  Used to make health care decisions?

*If you answered “yes” to any of the above questions, Patient authorization form is required.*

[ ]  None of the above (specify):

*Please attach a copy of the Patient authorization form to be used.*

**9. Levels of CHR review**

There are three levels of CHR review:

**Exempt Status (Level I review)**

*Research is reviewed for exempt status by an IRB committee member if it involves minimal or no risk. In general, research which does not propose to disrupt or manipulate the normal life experiences of subjects, incorporate any form of intrusive procedures, or involve deception will be exempt from expedited or full committee review. Projects that involve more than absolutely minimal risk and those that include any degree of deception do not qualify for exempt status.*

*Please note that all of the rights and protection afforded to human subjects in research are required in exempt status cases. Researchers engaged in human subjects research that qualifies for exempt status must still complete a full application form and prepare an informed consent statement. Researchers must engage in practices that minimize risk, maximize benefit and ensure privacy. In short, research with exempt status is exempt only from full committee review.*

**Expedited Review (Level II review)**

*Expedited review is a procedure through which certain kinds of research may be reviewed and approved without convening a meeting of the entire IRB. The term "expedited" can be misleading: Reviews of this type are not "quicker" or conducted with less rigor, but fewer reviewers are required for approval.*

**Full Review (Level III)**

*All research not qualifying for Exempt status or Expedited review and most research involving protected classes of subjects requires Full (Level III) review. In general research requiring Full review places the subject at greater than minimal risk. Full review means that the research protocol is read, discussed and voted upon by the full IRB committee.*

**Signature(s)**

*This page is to be signed by the investigator(s). If the investigator is an undergraduate, graduate student, or doctoral student, the faculty supervisor must also sign in the lower box.*

**Investigator**

I certify that the information I provide in this application is correct and complete. I also pledge that I will not change any of the procedures, forms, or protocols used in this study without the approval of the Ethics Committee.

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| --- | --- |
| Name, Surname: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |

**Faculty Supervisor**

*"I have examined this completed form, and I am convinced with the adequacy of the proposed research design and the measures taken to preserve the justice, autonomy, and beneficence of the human participants. I declare to take responsibility for providing supervision to the investigator/student throughout the study. I will keep him/her informed on the safeguarding of the raw data (e.g., surveys, questionnaires, interview notes, video/audio recordings, test protocols, laboratory books, etc.), as well as signed consent forms in a University office or a secure computer. I will also oversee the compliance with the IRB's policies and procedures."*

|  |  |
| --- | --- |
| Name, Surname: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |

**IMPORTANT NOTICE**

Your application MUST be accompanied by the supporting documents (including signed and dated CVs of all research team) at the time of SUBMISSION. Missing documents and information may result in delaying of the Committee decision.

Submit an electronic copy of all the required documents to chr@ku.edu.tr

All documents and application form must be submitted to the CHR Office.

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|  |  |
| --- | --- |
| Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Protocol no: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_MUST be reviewed by: [ ]  IRB1[ ]  IRB2[ ]  IRB3 | Type of Review Recommended [ ]  Full IRB Review [ ]  Expedited Review [ ]  Exemption \*\*\* |
| Utilizing expedited review procedures, I have reviewed the Human Subjects Protocol Application attached and all appended documentation and have determined that this research protocol is exempt from full CHR Review. Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_IRB Chair |