**Application for ethics assessment of research study**

**submitted to the University of Ljubljana Human Research Ethics Committee**

Title of proposed study

**Checklist**

Before submitting your application, check the elements listed below and tick all the items that are appropriately presented in the application. Also tick those items that are not relevant to the study, if this is adequately clear from the application.

**Basic information**

[ ]  The full and abbreviated titles of the proposed study are provided

[ ]  The name of the primary investigator is provided

[ ]  The names of the other researchers and possible external contractors are provided

[ ]  The research field is described

[ ]  The proposed type of ethical treatment with explanation is provided

[ ]  A brief description of the research is provided

[ ]  The type of the study is described and basic information is provided

**Introduction**

[ ]  The theoretical bases of the study are described

[ ]  The research question is presented in an understandable way

[ ]  It is clear what the contribution of the study will be

**Participants**

[ ]  The size of the sample of participants is described and substantiated

[ ]  There is a clear description of the target participants and the inclusion and exclusion criteria

[ ]  It is clear how participants will be recruited, including the mechanisms for ensuring voluntary participation and relevant representation of diverse social groups

[ ]  It is clear what kind of compensation there will be for participation

**Research plan**

[ ]  The research plan is clearly described

[ ]  The data analysis procedure is clear

**Procedure**

[ ]  The planned instruments and research tools are listed and presented

[ ]  The research tasks and procedures are clearly described

[ ]  The instructions that will be given to participants are presented

[ ]  The scope and duration of participation are described

**Consent to participation**

[ ]  It is clearly presented how participants will receive information about the research

[ ]  The procedure for giving informed consent is described

**Protection and confidentiality of data**

[ ]  The procedure for (pseudo)anonymisation is described

[ ]  The means of ensuring security and confidentiality of the data during data acquisition are described

[ ]  The means of ensuring security and confidentiality of the data during data acquisition period are described

[ ]  When and how data will be fully anonymised are described

[ ]  The manner and duration of data storage after study completion are described

[ ]  Whether and how data will be shared with third persons or accessible for renewed processing are described

**Assessment of possible risks and benefits of participation**

[ ]  The benefits for participants and how they will be presented are clearly described

[ ]  The risks for participants and how they will be presented are clearly described

[ ]  The protocols in the event of emergencies are clearly described

**Annexes**

[ ]  The Informed Consent form is attached

[ ]  An example of the invitation to participate in the research is attached

[ ]  Presentations of the instruments and questionnaires are attached, except in the case of standard, previously tested and validated instruments

[ ]  An information sheet is attached