ETHICAL PROTOCOL

If some of the foreseen subheadings do not correspond to the nature of your research, state „not applicable“. Avoid technical notions that are incomprehensible outside your scientific field.

*Purpose, aims and hypothesis of your research*

* State the purpose, aim/aims and hypothesis of your research.

*Research methodology*

* Describe how you will conduct the research. Provide a description of procedures that you are going to apply in the research (interview, survey questionnaire, blood tests, etc.). State precisely the expected duration, number and frequency of certain procedures.
* If the research includes a survey questionnaire, enclose a copy of the instrument.
* If the research includes collecting data (e.g. from the documents or data basis), describe how you are going to use these data and state the sources.
* Describe how you are going to analyze the data.
* Explain the proposed sample size.
* Explain the (possible) use of placebo.
* Outline any research interventions you plan to undertake.
* Briefly describe the direct implications and application of the research.

*Participants/subjects of the research (respondents)*

* State who the subjects of the research are and why exactly they have been chosen.
* Provide a sample size proposal.
* State relevant criteria of inclusion/exclusion of the subjects (especially with regard to possible benefits or harms). State all the specifics related to the proposed subjects (e.g. current or permanent incapacity, minors, etc.).

*Selection of the subjects*

* Describe who and how is going to choose the subjects. Enclose copies of materials prepared for this purpose (letters, information, invitations in the media, leaflets etc.). Specify where the subjects will be chosen from (hospitals, hospital departments, institutes, clinics, schools etc.).
* Be specific about your relationship with the subjects, independent of the research (e.g. their physician).

*Risks and benefits*

* List all the risks and benefits that may be expected for the subjects of your research. Describe how you are going to balance risks and benefits and explain the strategy that you will apply in order to minimize possible risks, i.e. how to control any risk.

-2-

*Privacy and confidentiality*

* Describe how you are going to protect privacy and confidentiality. Include description of data storage, disclosure of information, access to information, use of names or coding, data destruction upon research completion; include information about the use of audio and visual records.

*Compensation*

* State whether certain costs will be compensated to the subjects, whether they will get any financial or other compensation for their participation in the research and under what conditions.

*Conflict of interest*

* State relevant information for the existing or possible conflict of interest (this is necessary so that the Ethical Committee can assess whether this information should be included in the informed consent, i.e. presented to the subjects).

*Procedure for obtaining informed consent*

* State description of all procedures that are going to be used to obtain the informed consent.
* Enclose a copy of Information for the subjects and the Informed Consent form. If you do not collect the informed consent, specify in detail why. In case when subjects are minors or incompetent, enclose a copy of consent signed by their representative or guardian.

*Use of biological samples and dental/medical documentation (diagnostic, anamnestic and therapy data collected during clinical work in healthcare institutions)*

* The above stated can be used for the research without informed consent of the patient/subject only in case when Ethical committee determines: (1) that the research may cause minimum risk, (2) that the rights or interests of the patient/subject will not be harmed, (3) that privacy and confidentiality or anonymity will be ensured, (4) that research design indicates that the research will answer important scientific questions and that (5) obtaining of the informed consent would be exceptionally impractical.
* Patients have right to know that their medical data or biological samples will be used for the research and reject it.

*Secondary use of biological samples and dental/medical documentation*

• If informed consent was obtained for the original collection or use of such data, secondary use is generally limited by the specific terms of the original consent. That is why researchers, when seeking informed consent during the original data collection, should also anticipate their secondary use.

-3-

*Additional ethical assessments*

* When the research is conducted in institutions that are under the authority of other ethical committees, a copy of the decision of those authorities must be enclosed.

*Clinical research*

For all clinical researches it is necessary to include:

* a copy of the clinical research plan (clinical protocol) with all amendments;
* a copy of brochure for researchers;
* a test lists;
* a copy of the information for the subjects;
* a copy of the informed consent;
* a copy of the budget;
* an insurance statement;
* documentation on the researcher's qualification for conducting the research (C.V. or certificate from the head of the department).