GUIDELINES ON DOCTORAL DISSERTATION TOPIC PROPOSAL (MONOGRAPH)

1) THE CANDIDATE'S FIRST AND LAST NAME

2) DISSERTATION PROPOSAL DATE

3) DISSERTATION TOPIC TITLE

   When a revised version of the dissertation topic is submitted, the dissertation title should be followed by the version number, e.g. the 2nd revised and amended version.

4) SCIENTIFIC BRANCH OF RESEARCH

   Indicate the scientific branch of the planned research or, in case of multidisciplinary research, indicate the predominant scientific branch.

5) INTRODUCTION – Present the problem supported by the literature, i.e., what has been published on the problem and, especially, dilemmas and controversies. Avoid general aspects or aspects not specific to the topic. In the last section of the Introduction, describe the literature search strategy (see Addendum).

6) RESEARCH PROBLEM – On the basis of the Introduction, indicate clearly and unambiguously what is unknown and what you want to investigate (**up to 100 words**).

7) HYPOTHESIS – Clearly describe the expected findings (**up to 50 words**).

8) RESEARCH AIM – On the basis of presented problem, indicate clearly, succinctly, and unambiguously the specific research aim. If there are several aims, distinguish between the primary aim and the secondary aims (main outcome / secondary outcomes), in order to limit the reliability of conclusions on as few statistical tests as possible (**up to 200 words**).

9) RESEARCH DESIGN – Define the type of research design (descriptive study, case control study, cohort study, cross-sectional study, longitudinal study, experimental study). For experimental studies, indicate whether the inclusion was randomized or non-randomized. List the data sources (primary: data collected by yourself; secondary: you used the existing data from published articles or other publications) (**up to 100 words**)

   Whenever possible, the research process flowchart should be provided.

10) RESEARCH OUTCOME – On the basis of defined research aim (e.g. efficiency of anti-inflammatory therapy), and depending on the research design (e.g. clinical trial), define the research outcome (e.g. the difference in inflammatory marker concentrations between the study and control groups 1 month after therapy) and outcome measure, i.e. what type of variable will

be used: qualitative (e.g. inflammatory marker: yes/no), comparative (e.g. the level of expression of inflammatory marker: absent, weak, moderate, strong) or metric (e.g. inflammatory marker concentration in defined units).

For research designs where the outcome is reached indirectly, on the basis of individual data (variables) analysis or group parameters, indicate the input and output parameters (variables). E.g. if 5-year survival of patients with a disease X is the primary aim of the research, and it is determined from the Kaplan-Meier survival curve (i.e. indirectly), the 5-year survival is the (main) output parameter, whereas the patient follow-up time and patient outcomes at the end of the follow-up period are input variables (needed to calculate the outcome parameter). Measure/type of input and output parameters/variables (input/output measures) correspond to the measure of the research aim.

If, in addition to the primary aim, there are secondary aims, list the secondary aims, secondary outcome measures, and, if appropriate, secondary input and output parameters and their measures (**up to 100 words**).

11) RESEARCH METHODS (**describe in detail**)

a) Subjects (for human research) – Define in detail both the population and the sample, indicating the sample size and group size (number of subjects per group), sample type (e.g. random, convenience, follow-up), inclusion criteria, details of random allocation, failure of allocation, blinding.

For research using control/comparative groups, determine the optimum sample size. Analysis should be based on the main research outcome. The sample size should be large enough to ensure the statistical confirmation (e.g. at the cut-off p-value of 5%), with acceptably high chance (power of the study, e.g. 80%), of the smallest clinically/biologically important difference between the groups in the outcome-related parameter (e.g. 20%-difference between two types of diet in body weight reduction). Variability of parameters should be assessed from the literature or by a pilot study (better option). If the sample sizes are given, the power of the study should be determined from the sample sizes. If groups are not compared (e.g. in a clinical trial phase II, we test a new cytostatic agent and the main outcome is the 5-year survival of patients with colon cancer), the sample size must be large enough to assess the main outcome measure with the defined precision (e.g. we do not want the error of 5-year survival estimate to be more than 10%).

b) Research animals (for animal research) – Indicate the species and strain, strain origin, relatedness between animals, sex, food composition and maintenance, number of animals per group, and age and weight limits.

c) Methods – Describe the instruments or other equipment that will be used, as well as methods; well-known methods (procedures) should only be referenced.

d) Material – Describe the materials (origin, characteristics) whose quality is critical for the research (e.g. monoclonal antibodies). If a clinical trial is proposed, a sample of individual case report form should be provided.

e) Protocol – Describe the sequence and branching of the procedures per group and illustrate it as a flowchart (flow diagram), if appropriate.

f) Statistical analysis – Describe the planned data analyses after defining the research aim, design, and outcomes. For each variable and parameter, indicate the appropriate scale (qualitative, comparative or

quantitative) and units of measurement. It is not acceptable to indicate only descriptively, for example, that the association between the aggressive tendencies and serum cholesterol will be investigated, without indicating how the aggressiveness will be determined and whether the serum cholesterol will be presented as serum concentration or comparatively (low, normal, high). Only after these descriptors are provided, the adequacy of data collection, analysis methods, and presentation of results may be assessed. In the description of statistical methods, include the context of use for each statistical test rather than only listing the statistical tests according to the type of data. There should be no ambiguity as to which test will be used for obtaining *each* p-value, which will then be provided in the Results section. Therefore, it is necessary to predict all planned data analyses. This is especially important for *planned* vs. *unplanned (ad hoc) analyse*s. The latter have only minor, informative value and rarely are statistically tested (**up to 800 words, with an option of providing additional documents**).

12) RESEARCH ORGANIZATION – Indicate whether or not the research is part of a scientific research project; if it is, provide the title of the research project, the name of the project leader and institution, specify where the research will be conducted (clinical departments, laboratories, public health institutions, outpatient offices), who will participate in the research and the research coordinator (**up to 100 words**).

13) THE CANDIDATE'S ROLE IN THE RESEARCH – Specify the intellectual contribution and procedures preformed by the candidate personally and describe the candidate's entire contribution to the research (**up to 100 words**).

14) EXPECTED SCIENTIFIC CONTRIBUTION – Describe the scientific contribution your research is expected to provide (**up to 200 words**).

15) DIFFERENCES BETWEEN THE DISSERTATION-BASED PAPER AND DISSERTATION – Describe the differences in the content (introduction, methods, results, discussion, references) between the published paper and the dissertation. If the dissertation contains more results and has greater scientific contribution than the published paper, it should be especially highlighted (**up to 200 words**).

16) ETHICAL PRINCIPLES – The Ethics Committee approval of the proposed research (and whether the approval is sought by: the candidate, the Dissertation Proposal Committee or Doctoral Committee). In principle, the consent consists of the written informed consent of the patients, approval from the Ethics Committee and sample size calculation.

17) REFERENCES – References should follow the Vancouver style (instructions available at http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=citmed) and be written in Croatian language, according to the guidelines in *Liječnički vjesnik*. Use the most recent references and provide only the relevant literature data; use Medline and ensure that you obtain the full-text articles, because the abstracts are not a reliable and sufficient data source; do not cite the congress presentations or non-indexed articles (except in cases of a completely new and original research) (**list up to 25 references, the rest include in the annex to literature review**).

The proposals that are not written within the given framework, containing incorrect bibliographic data and grammatical, orthographic, and typing errors will not be considered.

Addendum to Guidelines on Doctoral Dissertation Topic Proposal

Literature search strategy

Presentation of the search structure

Search date

- the source of medical information (database)
- limits
- description of the search strategy
- excluded references
- search outcome

Describe in detail the database search strategy that enabled the candidate to identify and review all the literature relevant for the research topic and the criteria for selection of the references included in the reference list. It is not necessary to justify the choice of standard textbooks or monographs. However, it is not enough only to list the key words. A all searched databases should be listed, as well as search dates, search algorithms (descriptively, without the use of syntax of individual search engines), and search outcomes.

For example, if the topic is "A new method of radiotherapy for diffuse toxic goiter", the following description is acceptable:

"I searched the PubMed and EMBASE last time on 23 September 2016. I did not use the limits for publication type or language. I searched for the publications that contain, anywhere in the text, any of the following terms/concepts (or their MeSH equivalents): "diffuse toxic goiter', 'Graves disease', 'Basedow disease', 'Graves-Basedow disease', 'hyperthyroid disease', 'hyperthyroidism', in combination with any of the following: 'radioiodine therapy', '131-I therapy', 'I-131 therapy', 'radiotherapy', 'radionuclide therapy', 'radioiodine treatment', '131-I treatment', 'I-131 treatment', 'radiotreatment', 'radionuclide treatment'. This approach was shown to be non-specific and yielded 3452 references in PubMed only. Therefore, I decided to limit the search algorithm to the title, abstract, and subheadings, and the search yielded 253 references from PubMed and 192 from EMBASE. By combining the searches, I obtained 271 references. After reading carefully the titles or abstracts, I excluded 112 references that did not relate to my topic, 12 congress abstracts, and 4 repeated reports. After further reading, I excluded 51 articles due to small samples (N=31), too short follow-up (N=3) or unsatisfactory evaluation (N=17). However, majority of these articles was critically cited in 3 review articles, which I cite (references No. 12, 27, and 28). The remaining 92 original articles, with 3 review articles, and 7 textbook or monography chapters, are cited in appropriate context."

DISSERTATION FORMATTING GUIDELINES

1) Dissertations should be in A4 format (21 × 29.7 cm)

2) Full-cloth binding
   a. On covers:
   - University of Split
   - School of Medicine
   - First and last name of the author
   - Title
   - Dissertation
   - Place
   - Year

   b. On spine:
   - First and last name of the author
   - The word "DISSERTATION"
   - The year of dissertation defense
   - Rectangular box 1 × 4 cm (a place for library label)

   This information is printed from left to right.

3) The second page contains the same text as that on the covers.

4) The next page contains the following text:
   - The name of the institution (institute, or alike) where the work was done
   - Mentor's name
   - Optionally: purpose, dedication or acknowledgment

5) The dissertation should have the following elements:
   a. Table of contents
   b. List of symbols and abbreviations
   c. Introduction, Aim, and Problem
   d. Material and Methods (subjects – sample)
   e. Results
   f. Discussion
   g. Conclusion
   h. Abstract in Croatian language
   i. Abstract and title (of the dissertation) in English language (up to 500 words)
   j. List of references according to the Vancouver style
   k. Biographical note.

6) Pages should be numbered.

7) Figures, graphs, and tables should be numbered and given a title.

8) The dissertation text should conform to Croatian grammar and spelling rules.

9) A CD (dissertation in electronic format) should be enclosed.