**PLAN OF RESEARCH FOR DOCTORAL DISSERTATION**

*To be considered for enrollment into the TRIBE program, we kindly ask you to submit proposed protocol of at least two studies that you plan to conduct within your doctoral thesis, as well as a detailed suggested work plan with timeline (template for work plan is on the last page of this document). You can describe all your planned studies in this document, or you can submit each study protocol in a separate document based on this template. If there is anything unclear about our expectations, please feel free to email us:* [*ds@mefst.hr*](mailto:ds@mefst.hr) *or* [*livia@mefst.hr*](mailto:livia@mefst.hr)*.*

*Use textbook: Marušić M, editor. Principles of Research in Medicine. 1st. edition. Zagreb: Medicinska naklada; 2008. Use textbook’s Index to find explanations of the terms and concepts. Rely upon the Figure 6-1 from the textbook*

**Information about the candidate:**

**Name and surname:**

**Institution, Department:**

**E-mail address:**

**Work phone and cell phone:**

**Information about proposed mentor:**

**Name and surname:**

**Institution, Department:**

**E-mail address:**

**Work phone and cell phone:**

**Information about proposed supervisor\*:**

**Name and surname:**

**Institution, Department:**

**E-mail address:**

**Work phone and cell phone:**

*\*We would like prospective students to suggest an expert in addition to their mentor, who will oversee student’s progress (e.g. head of the department, external collaborator, senior co-author)*

Did mentor check and approve the last version of this document that you are submitting to the TRIBE directors? Yes/No

*Please, when you decide to send this document to TRIBE directors, put your mentor in the cc of an e-mail*

**1. Title of the research project**

Chose either indicative or informative; but mind that the title must be:

* clear,
* based on your hypothesis,
* indicate intervention, if any,
* indicate study design.

**2. Background (word limit: around 400 words in 3-4 paragraphs; please do not write less than350 words or more than 450 words. Cite relevant references, and provide list of the cited references at the end of the document, before the work plan)**

Clearly present the problem you plan to investigate. It is best to write two relatively short paragraphs: define the problem in the first and in the second clearly describe the aims of the planned research, ie, research question you are asking. The text should have:

• adequate length – be strictly related to the research theme (do not repeat textbook knowledge;

• ‘inverted triangle’ of problem presentation (from general to specific – to hypothesis);

• logic of presentation (sentences that logically follow each other);

• citations (each fact or opinion that you present and which is not yours – must be corroborated by a reference to the original publication). Search relevant databases and select articles with highest levels of evidence, such as the most recent systematic review or meta-analysis for a clinical question.

Do not leave any paragraph without reference(s).

**3. Hypothesis**

Hypothesis is the most important element of the research.

Write your hypothesis as a statement.

• the hypothesis should be simple and clear;

• the hypothesis determines the study design;

*•* the hypothesis determines main outcome measure;

• when you plan an intervention, it should be a part of the hypothesis.

(If you still have an irresistible desire to have more hypotheses, treat them as statistical hypotheses.)

**4. Design and description of the study**

Design of the study is determined by your hypothesis. Define and describe it, with respect to specificities of your planned research.

Use the following *subtitles* and explicitly define:

• description of study (short, clear, without unnecessary details);

• type of study;

• place of study;

• data sources (e.g., direct measurements, patient histories, etc.);

• ways of collection of data; indicate clearly how the data will be collected – via questionnaire, from patient records, direct measurement, etc.

Describe who will do measurements or collect data, when and how.

**5. Sample**

You cannot test the entire population at which your research aims. Thus you have to select *a sample* from that population. The sample must be representative of the entire population. (Think hard!)

Describe your study sample in detail, with concrete listing (subtitles) of:

• population represented by the sample;

• type of the sample;

• independent (entry) variables – most often they are basic data on subjects; list them explicitly, with respective measurement units*.*

**6. Subjects (Material) and Methods**

Describe in detail all methods that will be applied in the research. For common techniques just cite the source(s).

If you plan to work with patients, describe in detail (subtitles):

• inclusion criteria;

• exclusion criteria;

• composition of the experimental (intervention) group (relative to the hypothesis*);*

• composition of the control (non-intervention, gold standard intervention) group (relative to the hypothesis and experimental group*;*

• technique of randomization if you randomize the subjects;

• informed consent of the subjects (that you have obtained it, or plan obtain), written or oral*.*

If you plan to do a systematic review or meta-analysis, or include analysis of bibliographic data, the title of this part of the plan is **Data Sources**.

**7. Independent variables**

These are the data that subjects “carry” with themselves in the study – do not mix them up with dependent variables, which are the data that you will collect as outcome measures (primary and secondary).

Independent variables sometimes form the study groups or subgroups: age, sex, stage of disease, social status, educational status, questionnaires at the start of the study, etc.

**8. Treatment/intervention**

* List and describe all interventions/treatments and procedures which you plan to use.
* Describe how, when and how long the subjects were exposed to the intervention.

This part is not necessary if the research does not include intervention – it is indispensable for description of randomized controlled trials, cross-over studies and before-and-after studies.

**9. Main outcome measure(s)**

These parameter(s) are tools that serve to quantify changes in subjects during time. They are closely related to a) hypothesis of the study, b) design of the study.

• Chose outcome(s) important for the patients, for example morbidity, incidence, odds ratio, pain, quality of life …

• For each outcome give its concrete measuring unit (g/L, yes/no, percentage, etc.).

• Pay attention to your measurement scales, ie, the sort and accuracy of data.

**10. Secondary outcome measure(s)**

• Distinguish them clearly from main outcome measures, taking into account the hypothesis, type of the study and study plan.

• Define data collection and presentation the same way as for main outcome measure.

• Pay attention to your measurement scales, ie, the sort and accuracy of data.

**11. Calculation of the minimal sample size**

Sample size is calculated on the basis of the main outcome measure.

Use statistical software or free internet program(s) to calculate [sample size](http://www.stat.ubc.ca/~rollin/stats/ssize/). Explain in detail:

• the calculation of the sample size;

• all data included in the equation (average values, measure of variability and other required parameters);

• sources of data for the equation (your preliminary data, literature data, your learned, objective guess);

• type of the statistical test that was used;

• calculated number of subjects per group.

**12. Statistical tests**

• Provide the name of statistical program that you will use for analysis (e.g., MedCalc).

• State that first you will do analysis of normality of data distribution using appropriate test (e.g., Kolmogorov Smirnov).

• List statistical tests which you judge will be used for data analysis, and list for which purposes (comparison, correlation... of which outcome measures) they will be used;

• State how you will present the variability of your data (for clinical research we suggest to use 95% confidence interval).

• List carefully the *measures of effect* that must be used for data presentation as required for the given type of the study (e.g., NNT for RCT, OR for case-control study, sensitivity and specificity for diagnostic studies, etc.).

**13. Possible biases and confounding variables**

• List biases and confounding variables in your study.

• For each describe why (it is a bias or a confounder) and how you will minimize/prevent its influence on the results of the study.

**14. Validity of the study**

Describe and assess (subtitles):

• Internal validity (relevance of chosen outcome measures for proper testing of the hypothesis);

• External validity (generalizability of your findings).

**15. Ethical approval**

Consult the rules of the School of Medicine in Split for details on what types of studies need approval of the Ethics Committee.

When research engages more than one institution, each of them must provide ethical approval.

**16. Financing**

If your thesis is a part of a research grant, provide the name of the principal investigator, institution which has approved the grant, and title and number of the project/grant.

**17. Conflict of interest**

If there is a potential conflict of interest in relation to your research, it should be declared.

**18. Literature (references)**

List at up to 20 relevant articles, and cite them according to the Vancouver system of [writing references](http://www.mefst.hr/default.aspx?id=2248) (check [Medline](http://www.ncbi.nlm.nih.gov/pubmed)). Take care that:

• referencing is accurate (Vancouver system);

• all references are written in the same style;

• you select the most important and the newest literature sources (systematic reviews whenever available for clinical research).

**19. Publication plan**

*•* Clearly describe the publishing plan for your research results:

• Identify the most appropriate journal(s) for your article, and delineate its appropriatness.

• Find journals’ Guidelines for Authors (give here the web-site).

**20. Authorship**

• List the names of all researchers who will participate in the study.

• Describe their planned contributions; take care to assign for each author those contributions which will qualify her or him to fulfill all four ICMJE authorship criteria.

In principle, the first author of the publication of research results of the study that constituted the thesis the doctoral fellow should be the first, and the mentor the last author in the byline.

**21. Reporting guidance**

Find reporting standard [HERE](https://www.equator-network.org/) (e.g. for randomised trials look for CONSORT checklist)

**WORK PLAN**

**Describe in the work plan all activities, from the start to the defense of doctoral thesis (protocol development, enrollment into TRIBE, data collection, data analysis, manuscript 1 writing and publishing, manuscript 2 writing and publishing, submitting thesis protocol, thesis defense)**

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| --- | --- | --- | --- | --- |
| **Objectives** | **Activities** | **Outputs – Milestones (M) and/or Deliverables (D)** | **Team members** | **Expected duration of activity (month/year)** |
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