**Research protocol**

**Doctoral dissertation**

The completion of the " Doctoral Dissertation Research protocol" is done exclusively through this electronic form, which is available:

• by the Doctoral Dissertation Secretariat

(e-mail: [grammedphd@auth.gr](mailto:grammedphd@auth.gr))

* by the Medical School website

(<https://www.med.auth.gr/content/didaktorikes-diatrives>)

**Section 1: Study identitication**

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|  | | *Completed by the reviewer* |
| **1.1 Τitle** | | *Satisfactory;* |
| **1.1.1 Τitle**  *To be consistent with the main research question. Avoid abbreviations and unnecessary punctuation.*  *Maximum number of words:* ***35*** | |  |
|  | | *yes*  *no* |
| **1.1.2 Title (in Greek)**  *To be consistent with the main research question. Avoid abbreviations and unnecessary punctuation.*  *Maximum number of words:* ***35*** | |  |
|  | | *yes*  *no* |
| **1.2. Identity of the candidate and advisory committee** | | *Satisfactory composition?* |
| **1.2.1 Candidate: full name, post and signature** | |  |
|  |  | *yes*  *no* |
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| **1.2.2 Supervisor: full name, post and signature** | |
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| **1.2.3 Advisory committee member: full name, post and signature** | |
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| **1.2.4 Αdvisory committee member: full name, post and signature** | |
|  | **Εικόνα που περιέχει κείμενο, γράμμα  Περιγραφή που δημιουργήθηκε αυτόματα** |
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**Section 2: Abstract**

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|  | ***Completed by the reviewer*** |
| **2.1 Abstract**  *Sections: Background, Aim, Study type, Materials, Protocol, Intervention (if applicable), Outcomes, Sample size.*  *Maximum number of words:* ***500*** | *Satisfactory formulated?* |
|  | *yes*  *no* |
| **2.2 Abstract (in Greek)**  *Ενότητες: Επιστημονική βάση, Σκοπός, Είδος μελέτης, Υλικό, Πρωτόκολο, Παρέμβαση (εφόσον προβλέπεται), Αποτελέσματα έκβασης, Μέγεθος δείγματος.*  *Μέγιστος αριθμός λέξεων:* ***500*** | Satisfactory formulated? |
|  | yes  *no* |

**Section 3: Research hypothesis and scientific basis**

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|  | ***Completed by the reviewer*** |
| **3.1 Hypothesis(es) to be tested:** *Clear formulation of the research hypothesis, which the dissertation is called to answer [preferably in the form of null (H0) and alternative (H1) hypothesis]. Number the primary and secondary research hypotheses. The hypothesis formulation should be such that it can be answered as "accepted" or "rejected".* | *Clearly formulated?* |
|  | *yes*  *no* |
| **3.2 Scientific basis of the proposed dissertation** |  |
| **3.2.1 Analysis of concepts associated with the hypothesis to be tested:** *The description must be made to such an extent that it can be understood by scientists and researchers who know the scientific field, but it is not considered necessary that they are experts in the particular subject of the proposed research project.*  *To be mentioned what is already known ("state of the art" knowledge with the corresponding bibliographic evidence).*  *Word count range:* ***500 - 1000*** | *Adequate and documented analysis?* |
|  | *yes*  *no* |
| **3.2.2 Necessity / Originality**  *Why is it necessary to prepare the dissertation? Which is its originality? Which knowledge gap is it trying to fill? Is this the first study done on this topic? If not, how do the researchers plan to differentiate its design and/or methodology from pre-existing studies?*  *Word count range:* ***100*** *-* ***250*** | *Sufficient necessity - originality?* |
|  | *yes*  *no* |
| **3.2.3 Importance / Clinical relevance**  *What is the significance of rejecting or accepting the research hypothesis (bibliography, if required)? How does the knowledge gained from the completion of the dissertation promote existing knowledge and future research in the specific area?*  *Word count range:* ***100*** *-* ***250*** | *Sufficient importance?* |
|  | *yes*  *no* |

**Section 4: Methodology**

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|  | ***Completed by the reviewer*** |
| **4.1 Study type**  *(e.g., observational, intervention, case-control). See:* [*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2689572/*](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2689572/)*.*  *A different type of study may be required for each research question. If necessary, match the research hypotheses with the types of studies that will be applied to investigate them.* | *Correct study type?* |
|  | *yes*  *no* |
| **4.2 Selection criteria of the study population**  *Definition of study groups (e.g., cases, controls). Detailed and precise inclusion and exclusion criteria for each of the study groups. Corresponding list of inclusion criteria if animal, cell line, or meta-research studies.* | *Suitable population?* |
|  | *yes*  *no* |
| * 1. **Research protocol (flow chart)**   *Brief description of the stages of the research protocol. In addition to the description, the presentation of the research protocol with a diagram is desirable.* | *Correct research design?* |
|  | *yes*  *no* |
| * 1. **Description of the intervention**   *(Only applicable to interventional studies).*  *A clear description of the nature of the intervention and its characteristics [e.g., blinding, randomization, intention-to-treat and/or per protocol analysis, control groups].* | *Suitable intervention?* |
|  | *Yes*  *no* |
| * 1. **Description of the measured variables**   *List of variables to be recorded according to the research protocol. It is desirable to attach the data entry form.* | *Suitable parameters?* |
|  | *Yes*  *no* |
| * 1. **Description of the measurement methods / assays**   *Reference only to specialized techniques/methods (those beyond the level of the average reader/judge of the research protocol).*  *Word count range:* ***50 –******500*** | *Correct and adequate description?* |
|  | *yes*  *no* |
| * 1. **Outcomes**   *List of variables set as primary and secondary endpoints. Match them with the research hypotheses. If there is more than one, number them. Why were they chosen?* | *Right choice?* |
|  | *yes*  *no* |
| * 1. **Planned subgroup analysis**   *It has been decided from the beginning of the study that some of the groups (e.g., cases group) will be divided based on some specific characteristic (e.g., age, sex).* | *Right choice?* |
|  | *Yes*  *no* |
| * 1. **Description of the statistical methods that will be applied to assess the primary and secondary outcomes**   *Reference to basic and more extensive analysis of specific statistical tests (e.g., bioinformatics, cost-benefit analyses, model building). Matching them to the main outcome results. The statistical methodology to be applied in basic research protocols should be adequately described.*  *Word count range:* ***250 –******500*** | *Sufficient description?* |
|  | *yes*  *no* |
| **4.10 Sample size calculation**  *Why were the study groups chosen to be of this size? The calculation must have been made based on the primary research hypothesis and the corresponding primary outcome(s). How is the expected difference between groups documented (bibliography)? In case of the non-existence of data, these should be drawn from relative fields. In the few cases where there is a complete lack of data, a pilot study is required first (*[*https://s4be.cochrane.org/blog/2017/07/31/pilot-studies/*](https://s4be.cochrane.org/blog/2017/07/31/pilot-studies/)*). What method and software were used? Attaching an image (print screen) with the sample size calculation from the program used is desirable. Have drop-outs and subgroup analysis been taken into account?* | *Correct calculation?* |
|  | *yes*  *no* |
| **4.11 Place of study**  *Is the study site appropriate (e.g., existing equipment, patient recruitment, expertise available)? Will part of the study be required to be conducted in additional settings (clinics, laboratories, private or public settings)? Confirmation of the receipt of the relevant licenses and the signing of the cooperation agreements.* | *Suitable place of study?* |
|  | *yes*  *no* |
| **4.12 Additional investigators**  *Will the collaboration of other investigators be required besides the PhD candidate and the three-member advisory committee? Justify their participation.* | *Indicated study group?* |
|  | *yes*  *no* |
| **4.13 What will be the contribution of the candidate to the research?**  *Describe exactly what the PhD candidate will do and what the other researchers will do. The PhD candidate should be actively involved in the study intervention and not just in data collection. The possibility of active participation should be documented.* | *Sufficient contribution?* |
|  | *yes*  *no* |
| **4.14 How will the data be recorded?**  *To describe the way of recording the data by the PhD candidate.* | *Significant contribution?* |
|  | *yes*  *no* |
| **4.15 Ethics**  *Apart from the Bioethics Committee (whose approval is required for all types of studies except meta-research), are additional permissions required (e.g., Hospital Scientific Council, Veterinary Service, National Organization for Medicines, National Authority for Medically Assisted Reproduction)?*  *How the personal data of participating groups will be secured (General Data Protection Regulation (EU) 2016/679 (GDPR);*  *Who will have access to the database and for how long? How will confidentiality be ensured?*  *The "Informed Consent Form" should be submitted as a supplementary document to this "Research Protocol".* | *Are the bioethical conditions met?* |
|  | *yes* *no* |

**Section 5: Processing capabilities**

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|  | ***Completed by the reviewer*** |
| **5.1 Estimated time of completion based on the cases availability**  *Time required from initiation to completion of recruitment of study subjects. Documentation with relevant data.* | *Applicable planning?* |
|  | *yes*  *no* |
| **5.2 Detailed timetable for completing the dissertation**  *A Gannt diagram is proposed (*[*https://www.gantt.com*](https://www.gantt.com) *and* [*https://support.microsoft.com/el-gr/topic/παρουσίαση-δεδομένων-σε-γράφημα-gantt-στο-excel-f8910ab4-ceda-4521-8207-f0fb34d9e2b6*](https://support.microsoft.com/el-gr/topic/παρουσίαση-δεδομένων-σε-γράφημα-gantt-στο-excel-f8910ab4-ceda-4521-8207-f0fb34d9e2b6)*).* | *Proper planning?* |
|  | *yes*  *no* |
| **5.3 Budget and funding sources**  *Submit a brief budget plan regarding the costs required (indicative: devices required to be purchased, consumables, software, sample shipping costs, publication fees). How are costs expected to be covered?* | *Sufficient sources?* |
|  | *yes*  *no* |

**Section 6: Publication strategy and bibliography**

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|  | ***Completed by the reviewer*** |
| **6.1 Publications that will result from the research project**  *In which journals will the publications be submitted?*  *What is the publication strategy (Will review publications come from the general part of the dissertation? Will primary publications come from the special part? Will there be publications about the development of techniques?).*  *What are the priorities (where and when will the publications resulting from the research work be submitted)?* | *Proper planning?* |
|  | *yes*  *no* |
| **6.2 References**  *Formatting as suggested by the “New England Journal of Medicine”:*  *(*[*https://paperpile.com/s/the-new-england-journal-of-medicine-citation-style/*](https://paperpile.com/s/the-new-england-journal-of-medicine-citation-style/)*).*  *Focus on recent and important publications.*  *References should refer to specific points within the text.*  *Number of bibliographic references:* ***20 - 40*** | *Correct formatting;* |
|  | *yes*  *no* |

**Comments by the reviewer**

***It is completed by the reviewer.***

*For any module, the reviewer formulates comments, performs a "double click", in the selection box, which allows him/her to select it* () or deselect it ()*.*

*A comment is required for each selected "no" in the right column.*

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| **Section** | **Comment** |
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**Comments by the PhD Committee**

***It is completed by the PhD Committee secretariat.***

*Additional comments arose during the discussion of the "Research protocol" in the plenary session of the Doctoral Dissertation Committee.*

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| **Section** | **Comment** |
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