# Project Description − Part B[[1]](#footnote-2)

**1.1. Participants (applicants)**

Please provide the following information (if available):

 a short[[2]](#footnote-3) description of each Science and Research Organization (SRO) and its main tasks, with an explanation of how its profile matches the tasks in the proposal;

 a short curriculum vitae of the PI and the key members of the project team – working packages coordinators[[3]](#footnote-4), including:

* a list of up to five publications[[4]](#footnote-5) relevant to the Project for the PI and each key member of the project team;
* a list of up to five relevant previous projects or activities, connected to the subject of this proposal for the PI and each key member of the project team;
* if applicable, a list of up to five products, services, and/or other achievements relevant to the Project for the PI and each key member of the project team.

**1.2. Ethics and Security**

**1.2.1. Ethics**

* Fill-out the Ethics issues table (Table 1.2.1).

**Table 1.2.1 Ethics issues table.**

|  |  |
| --- | --- |
| **1. HUMAN EMBRYOS/FOETUSES** | YES/NO/N/A |
| Does the proposed research involve human Embryonic Stem Cells (hESCs)? |  |
| Does your research involve the use of human embryos? |  |
| Does your research involve the use of human fetal tissues /cells? |  |
| **2. HUMANS** | YES/NO/N/A |
| Does your research involve human participants? |  |
| Does your research involve vulnerable persons or groups? |  |
| Does your research involve persons unable to give informed consent (including children/minors)? |  |
| Does your research involve physical interventions on the study participants? |  |
| Does your research involve a clinical trial? |  |
| If yes, please confirm that approval from Ethics Board of Serbia (EOS) and Medicines and Medical Devices Agency of Serbia (ALIMS) will be obtained prior to study commencement? |  |
| Will the clinical trial be registered in a publicly registry? |  |
| **3. HUMAN CELLS / TISSUES** | YES/NON/A |
| Does your research involve human cells or tissues (other than from Human Embryos/Fetuses)? |  |
| **4. PERSONAL DATA** | YES/NO/N/A |
| Does your research involve personal data collection and/or processing? |  |
| Does your research involve further processing of previously collected personal data (secondary use)? |  |
| If any potentially commercially exploitable results may be based upon tissues or samples derived from human participants, will appropriate informed consent be sought? |  |
| **5. ANIMALS** | YES/NO/N/A |
| Does your research involve animals? |  |
| **6. ENVIRONMENT & HEALTH and SAFETY** | YES/NO/N/A |
| Does your research involve the use of elements that may cause harm to the environment, to animals or plants? |  |
| Does your research deal with endangered fauna and/or flora and/or protected areas? |  |
| Does your research involve the use of elements that may cause harm to humans, including research staff? |  |
| **7. DUAL USE** | YES/NO/N/A |
| Does your research involve items that are normally used for civilian purposes, but may have military applications or may contribute to the proliferation of weapons of mass destruction, or involve other items for which an authorization is required? |  |
| **8. EXCLUSIVE FOCUS ON CIVIL APPLICATIONS** | YES/NO/N/A |
| Could your research raise concerns regarding the exclusive focus on civil applications? |  |
| **9. MISUSE** | YES/NO/N/A |
| Does your research have the potential for misuse of research results? |  |
| **10. OTHER ETHICS ISSUES** | YES/NO/N/A |
| Are there any other ethical issues that should be taken into consideration? Please specify! |  |

In addition to 1.2.1 Ethics issues table, if your answer was YES to any of questions, you must fill out and submit information in Table 1.2.1.a and/or Table 1.2.1.b, required by the Science Fund of the Republic of Serbia depending on whether your research involve use of animals and/or human participants or material. If your answers to all questions from Table 1.2.1 were NO, you can delete Table 1.2.1.a and Table 1.2.1.b and proceed to Section 1.2.2 Security.

**Table 1.2.1.а – Information required for research involving the use of animals**

|  |  |
| --- | --- |
| **Information** | **Fill-out the information required if your research involves the use of animals. Replace the instructions in the table with your answers. The table headings on the left should be kept throughout the document. The instructions on the right side should be removed and replaced with text.** |
| Ethical Statement | Indicate the nature of the ethical review permissions, relevant licenses and national or institutional guidelines for the care and use of animals that cover the research. SF will require evidence that relevant ethical and regulatory approval has been granted prior to the award commencing. |
| Study Design | For each experiment, give brief details of the study design including: a) The number of experimental and control groups.  b) Any steps taken to minimize the effects of subjective bias when allocating animals to treatment (e.g. randomization procedure) and when assessing results (e.g. blinding).  c) The experimental unit (e.g. a single animal, group or cage of animals.  d) The number of times each animal will be measured. |
| Experimental animals | a) Provide details of the animals used, including species, strain, sex, developmental stage and weight. Include a sound scientific reason for these choices.  b) Provide further relevant information such as the source of animals, international strain nomenclature, genetic modification status (e.g. knock-out or transgenic), genotype, health/immune status, drug or test naïve, previous procedures, etc. |
| Sample Size | a) Specify the total number of animals used in each experiment, and the number of animals in each experimental group.  b) Explain how the number of animals was calculated. Provide details of any calculation used for sample size.  c) Indicate the number of independent replications of each experiment, if relevant. |
| Experimental Outcomes | Details regarding the experimental outcomes to be assessed. |
| Planned statistical analysis | An explanation of how the number of animals was calculated, including power calculations, if appropriate, or other supporting information to demonstrate that the findings will be robust.  A brief overview of the planned statistical analyses in relation to the choice of sample size, along with details of any statistical advice available. |

**Table 1.2.1.b – Information required for research involving the use of human participants or material**

|  |  |
| --- | --- |
| **Information** | **Fill-out the information required if your research involves the use of animals. Replace the instructions in the table with your answers. The table headings on the left should be kept throughout the document. The instructions on the right side should be removed and replaced with text.** |
| Ethical Approval | Ethical approval is required for all research work funded by SF that involves human participants or human material (including tissue). Please state by whom and when the research program will be reviewed and specify any other regulatory approvals that have been obtained or will be sought. Applicants should allow sufficient time to obtain Ethical approval. SF will require evidence that relevant ethical and regulatory approval has been granted prior to the award commencing. |
| Study Recruitment | Please provide specific details on study recruitment procedures including inclusion and exclusion criteria and informed consent procedures. These should include relevant, additional details for specific groups including children/minors, patients and vulnerable groups. |
| Clinical Research Infrastructure | Please provide specific details where you have access to, or plan to access, the support/services of a Clinical Research Facility/Centre (CRF/C) at study design and/or implementation phase. The following information must be provided:  • Name and address of the CRF/C  • Information on the nature and stage/s of the input/advice/collaboration/service  • Rationale for the choice of facility/centre  Information on the costs of providing the service/input, setting out where this is provided in-kind, from additional funding or requested from the project budget. Evidence of this support/service must be provided to SF in the form of a letter from the Director of the facility at the time of application for funding. |
| Clinical Trials | SF will only support trials that are fully approved by the Medicines and Medical Devices Agency of Serbia (ALIMS). Applicants are responsible for ensuring that all necessary approvals are in place and provided to SF prior to study initiation.  • **Sponsor**: Plans for appropriate sponsorship arrangements must be included in the application i.e. Letters of Support must be provided from sponsors or potential sponsors. Please note that SF cannot act as sponsor.  • **Study Registration**: Please outline plans for the registration of their trial or investigation on a publicly available, free to access, searchable clinical trial or investigation registry such as the Register for Clinical Trials in the Republic of Serbia (ALIMS) or International Standard Randomized Controlled Trial Register (ISRCTN) or ClinicalTrials.gov. |
| Human Cells/Tissues | Please provide details on the cells or tissues types, including the source of the material. |
| Biobanking | Please describe how you will comply with international best practice for biobanking components in this research, with particular regard to quality of sample collection, processing, annotation and storage, and describing data protection measures where appropriate. Please also reference relevant guidelines/standards you will use. |
| Protection of Personal Data | Compliance with national legislation and EU rules on data protection is required. Please provide that appropriate safeguards will be put in place and provide examples e.g. details of the procedures for data collection, storage, protection, retention, transfer, destruction or re-use (including, collection methodology (digital recording, picture, etc.), methods of storage and exchange. |

Describe and explain in detail how you intend to address the issues in the previous tables, in particular as regards:

* + - research objectives
    - research methodology

Provide documents that you need under the national law (if you already have them), e.g.:

* + an ethics committee opinion;
  + document notifying activities raising ethical issues or authorizing such activities.

*If these documents are not in English, you must also submit an English summary of the documents (containing, if available, the conclusions of the committee or authority concerned).*

*If you plan to request these documents for the project you are proposing, your request must contain an explicit reference to the project title.*

*If you have initiated a request for these documents, which are pending at the time of submission of your proposal, please make a reference to the authority concerned and the expected decision date. Please bear in mind that approval from the Ethical Board must be obtained and submitted in a timely manner, with project proposal documentation. Exceptions from this rule must be approved by the Science Fund and ethical approval must be submitted before the experiment begins.*

*If you have obtained/prepared any of the above documents, you should attach them as an additional documentation.*

*The Science Found requires evidence that relevant ethical and regulatory approval has been granted for studies involving human or animal subjects as well as human cells/tissues prior to research commencing.*

*The PI is obliged to contact the Ethical Board and obtain guidance for applicants on ethical and scientific issues. If ethical approval is not required, the PI must state in the application that the proposed study does not require approval of the Ethical Board.*

*Should any serious and/or unexpected adverse events occur during the project implementation, the PI is obliged to inform the Science Fund in written form and/or if relevant submit a copy of the written report to the responsible ethical board and/or attach a copy of the report of the competent ethical board.*

*The approved experiment must be completed within the stipulated term of the License. PI is obliged to inform SF if approval for extension of the License is submitted to the Ethical Board.*

* + 1. **Security[[5]](#footnote-6)**

**Please indicate if your project will involve activities or results raising security issues.**

This may include technologies that gather or use information for surveillance, technologies, ideas, products or other outputs intended for military use, other issues pertaining to security. (YES/NO)

*If you have answered yes, please elaborate.*

1. All information in Part B is mandatory (including the filled out form). Inaccurate and/or incomplete information will result in disqualification. [↑](#footnote-ref-2)
2. Provide key information about the SRO(s) participating on the project; use up to 1,000 characters per each SRO. [↑](#footnote-ref-3)
3. The short curriculum vitae should contain information about education, employment, research or academic title, research field/area, number of citations (excluding self-citations) and Hirsch index from SCOPUS or WoS citation databases. Research or academic title should correspond to the List of Research and Academic Titles in Higher Education available at [http://fondzanauku.gov.rs/](https://eur03.safelinks.protection.outlook.com/?url=http%3A%2F%2Ffondzanauku.gov.rs%2F%3Fpost_type%3Dakona-portfolio%26p%3D6231%26preview%3Dtrue&data=01%7C01%7Cmara.zivkov%40fondzanauku.gov.rs%7C27e89f67790348bf704808d77269bf5c%7Ce9869d9e5f16415689b0d51630ff7000%7C1&sdata=qBXrDftcNsVRr9F0GxbMAkAg82PTfyvltUMVB9mtKNs%3D&reserved=0). Awards, prizes, skills and other information relevant to the Project, not included into other parts of Section 1.1 of this document, could be entered where applicable. [↑](#footnote-ref-4)
4. Please provide a list of up to 5 selected publications relevant to the Project. **Do not attach or list a full bibliography.** [↑](#footnote-ref-5)
5. For more information on the classification of information, please refer to the Horizon 2020 guidance: <https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/secur/h2020-hi-guide-classif_en.pdf>. [↑](#footnote-ref-6)