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

**1.1. Participants (applicants)**

Please provide the following information (if available):

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

1.1.2. a short curriculum vitae of the PI and the key members of the project team[[4]](#footnote-4) – working packages coordinators[[5]](#footnote-5), including:

* Relevant previous **experience in competitive public calls** **in previous 5 years** (include information about the funding source, implementation period, awarded grant amount, role in the project, project name, key results and key scientific publications);
* Relevant previous **experience** **related to the Project** (include a list of up to five publications[[6]](#footnote-6) relevant to the Project, up to five relevant previous projects or activities, and 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).

For some researchers, requested information in previous two aspects of the point 1.1.2. may overlap. In such cases, researchers are instructed not to repeat the same information, but to emphasize if some reference is related both to the previous experience from competitive public calls and the experience related to the project.

**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.[[7]](#footnote-7)**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **1. HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS** | | | | YES/NO | | |
| **Does your activity involve Human Embryonic Stem Cells (hESCs)?** | | | |  | |  |
| If **YES:** | | Will they be directly derived from embryos within this project? | |  | |  |
|  | | Are they previously established cells lines? | |  | |  |
|  | | Are the cell lines registered in the European registry for human embryonic stem cell lines? | |  | |  |
| **Does your activity involve the use of human embryos?** | | | |  | |  |
| If **YES:** | | Will the activity lead to their destruction? | |  | |  |
| **Does your activity involve the use of other human embryonic or foetal tissues / cells?** | | | |  | |  |
| **2. HUMANS** | | | | YES/NO | | |
| **Does your activity involve human participants?** | | | |  | |  |
| If  **YES:** | | Are they volunteers? | |  | |  |
|  | | Are they healthy volunteers for medical studies? | |  | |  |
|  | | Are they patients for medical studies? | |  | |  |
|  | | Are they potentially vulnerable individuals or groups? | |  | |  |
|  | | Are they children? | |  | |  |
|  | | Are there other persons unable to give informed consent? | |  | |  |
| **Does your activity involve interventions (physical also including imaging technology, behavioural treatments, tracking and tracing, etc.) on the study participants?** | | | |  | |  |
| If  **YES:** | | Does it involve invasive techniques *(e.g., collection of human cells or tissues, surgical or medical interventions, invasive studies on the brain, TMS etc.)*? | |  | |  |
| Does it involve collection of biological samples? | |  | |  |
| **Does your activity involve conducting a clinical study as defined by the Clinical Trial Regulation 536/2014 (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)?** | | | |  | |  |
| If  **YES:** | | Is it a clinical trial? | |  | |  |
|  | | 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? | |  | |  |
|  | | Is it a low-intervention clinical trial? | |  | |  |
| **3. HUMAN CELLS / TISSUES** | | | | YES/NO | | |
| **Does your activity involve the use of human cells or tissues** (other thanthose covered by [section 1](about:blank))**?** | | | |  | |  |
| If **YES:** | | Are they human embryonic or foetal cells or tissues? | |  | |  |
|  | | Are they available commercially? | |  | |  |
| Are they obtained within this project? | |  | |  |
| Are they obtained from another project, laboratory or institution? | |  | |  |
| Are they obtained from a biobank? | |  | |  |
| **4. PROTECTION OF PERSONAL DATA** | | | | YES/NO | | |
| **Does your activity involve processing of personal data?** | | | |  |  | |
| If **YES:** | | Does it involve the processing of specific categories of personal data *(e.g. sexual lifestyle, ethnicity, genetic, biometric and health data, political opinion, religious or philosophical beliefs)*? | |  |  | |
| If **YES:** | Does it involve processing of genetic, biometric or health data? |  |  | |
| Does it involve profiling, systematic monitoring of individuals, or processing of large scale of specific categories of data or intrusive methods of data processing *(such as, surveillance, geolocation tracking etc.)*? | |  |  | |
| **Does your activity involve further processing of previously collected personal data** *(including use of pre- existing data sets or sources, merging existing data sets)***?** | | | |  |  | |
| **Is it planned to export personal data (data transfer) from the EU to non-EU countries?**  *Specify the type of personal data and countries involved* | | | |  |  | |
| **Is it planned to import personal data (data transfer) from non-EU countries into the EU or from a non-EU country to another non-EU country?**  *Specify the type of personal data and countries involved* | | | |  |  | |
| **Does your activity involve the processing of personal data related to criminal convictions or offences?** | | | |  |  | |
| **5. ANIMALS** | | | | YES/NO | | |
| **Does your activity involve animals?** | | | |  | |  |
| If **YES:** | Are they vertebrates? | | |  | |  |
|  | Are they non-human primates (NHP) *(e.g. monkeys, chimpanzees, gorillas, etc.)*? | | |  | |  |
|  | Are they genetically modified? | | |  | |  |
|  | Are they cloned farm animals? | | |  | |  |
|  | Are they an endangered species? | | |  | |  |
| **6. ENVIRONMENT, HEALTH AND SAFETY** | | YES/NO | |
| **Does this activity involve the use of substances or processes (or technologies) that may cause harm to the environment, to animals or plants (during the implementation of the activity or further to the use of the results, as a possible impact)?**  *For activities involving animal experiments, see section 5.* | |  |  |
| **Does this activity deal with endangered fauna and/or flora/protected areas?** | |  |  |
| **Does this activity involve the use of substances or processes (or technologies) that may cause harm to humans, including those performing the activity (during the implementation of the activity or further to the use of the results, or the deployment of the technology as a possible impact)?**  *For activities involving human participants, see section 2.* | |  |  |
| **7. ARTIFICIAL INTELLIGENCE** | | YES/NO | |
| **Does this activity involve the development, deployment and/or use of Artificial Intelligence-based systems?** | |  |  |
| **Could the AI based system/technique potentially stigmatise or discriminate against people?** *(e.g. based on sex, race, ethnic or social origin, age, genetic features, disability, sexual orientation, language, religion or belief, membership to a political group, or membership to a national minority)*? | |  |  |
| **Does the AI system/technique interact, replace or influence human decision-making processes?** *(e.g. issues affecting human life, health, well-being or human rights, or economic, social or political decisions)*? | |  |  |
| **Does the AI system/technique have the potential to lead to negative social** *(e.g. on democracy, media, labour market, freedoms, educational choices, mass surveillance)* **and/or environmental impacts either through intended applications or plausible alternative uses?** | |  |  |
| **Does this activity involve the use of AI in a weapon system?** | |  |  |
| If **YES**: | Is it possible to establish which specific function/functions are automated/autonomous in the weapon system? |  |  |
| If the weapon system has AI-enabled functions, could these functions render the weapon system indiscriminate? |  |  |
| Does the design include the possibility of an autonomous mode for self- protection? If yes, can the system reliably distinguish between targets (threats) and non-targets? |  |  |
| **Does the AI to be developed/used in the project raise any other ethical issues not covered by the questions above** *(e.g., subliminal, covert or deceptive AI, AI that is used to stimulate addictive behaviours, life- like humanoid robots, etc.)*? | |  |  |
| **8. OTHER ETHICS ISSUES** | | YES/NO | |
| **Are there any other ethics 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 human participants or material. 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). Each SRO participating in the research must obtain Ethical approval issued by the Ethical Board of the corresponding SRO, if such approval is applicable to the proposed research. Ethical approval for the leading SRO must be issued and provided within the project proposal while other participating institutions must gain Ethical approvals before the start of the research/experiment on which the approval is applicable. 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. |

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

* + an Ethical Board 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 Board or authority concerned). There is no need for the official translation of these documents*.

*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 and to provide statement of the Ethical Board that such an approval is not necessary for the proposed research.*

*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 Science Fund if approval for extension of the License is submitted to the Ethical Board.*

* + 1. **Security[[8]](#footnote-8)**

**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.*

**1.3. Science Fund mission and policy**

Summaries (MAX. 500 words) how the project proposal addresses mission and policy of the Science Fund of the Republic of Serbia, with regard to:

* ensuring competitiveness, quality, practical value, transparency, and the functionality of the results;
* supporting the professional development of researchers, integration into the international research projects and scientific ecosystem, and cooperation with the scientific diaspora and industry;
* advancing a knowledge-based society and achieving the strategic objectives of scientific and technological development of the Republic of Serbia.

1. All information in Part B is mandatory (including the filled-out forms). Inaccurate and/or incomplete information will result in disqualification. [↑](#footnote-ref-1)
2. Provide key information about the SRO(s) participating on the project; use up to 1,000 characters per each SRO. [↑](#footnote-ref-2)
3. Do not include information of SRO where External Collaborator is employed. [↑](#footnote-ref-3)
4. CVs of working package coordinators should only be included. External Collaborator cannot be the coordinator of the working package. [↑](#footnote-ref-4)
5. 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/.](http://fondzanauku.gov.rs/poziv/2020/03/ideje/) 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 in project description where applicable. [↑](#footnote-ref-5)
6. Please provide a list of up to 5 selected publications relevant to the Project. **Do not attach or list a full bibliography.**

   [↑](#footnote-ref-6)
7. Baseline for preparation of this document was the Horizon Europe procedure for ethics self-assessment. While filling out the Ethics issue table, please take in consideration the information provided in the document *How to complete your ethnics self-assessment*:<https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf>. [↑](#footnote-ref-7)
8. For more information on the classification of information, please refer to the following: <https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/classification-of-information-in-he-projects_he_en.pdf>. [↑](#footnote-ref-8)